CÔNG TY TNHH ASIA ACTUAL VIETNAM
MST: 0316765196

TÀI LIỆU ĐƯỢC KÝ BẰNG CHỮ KÝ SỐ

Người đại diện hợp pháp của cơ sở
Giám đốc
Võ Trung Việt
(đã ký)

Người đại diện hợp pháp của cơ sở
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Digitally signed by CÔNG TY TNHH ASIA ACTUAL VIETNAM
Location: TP.HCM

noul
Beyond Diagnostics

CE IVD

miLab™ Platform

DMLA

Instructions for Use

Preface

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One or more patents in Korea, the US, Europe, Japan, and China cover this product.

Table of Contents

1. Before Reading Document

This Instruction for Use provides a detailed description and understanding of the miLab™ Platform and its features. All users **MUST** be fully aware of the proper method of operation, safety information, and precautions in this document before using the miLab™ Platform.

Always use the miLab™ Platform in the safest manner possible. Using the miLab™ Platform without being suitably qualified or in ways not specified by this document may damage or deteriorate the product, cause misleading results, or even lead to personal injury.

1.1. Safety Alerts

The following safety alert symbols are used throughout this document. Carefully study the meaning of the following signs before reading this document. Make sure to understand and follow any information or instructions following these signs.

Signs	Explanation
Warning!	May cause personal injury.
Caution!	May cause damage to the system.
Important!	May cause misleading results.

1.2. Support

To contact product-related support, collect the following information:

- Product serial number
- Error code and error message (if any)
- Lot number of cartridges and the slide ID
- Software(SW), Firmware(FW or Shark), and Microscope (MS or Hawk) version

If the packaging is damaged or an item is missing or damaged, immediately contact Noul service representatives. Retain the shipping container and packaging materials if the analyzer needs to be returned to Noul for service.

1.2.1. Corporate Headquarters

Manufacturer	Noul Co., Ltd. (Hereafter, it is indicated as Noul in this IFU.)
Address	B-6F, 10F, 338, Gwanggyojungang-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16942, Republic of Korea
Telephone	+82 (0) 31 308 6310

Fax	+82 (0) 31 893 6672
Email	cs@noul.com
Website	www.noul.com

1.2.2. European Authorized Representative

Authorized representative	Medical Technology Promedt Consulting GmbH
Email	ear@mt-procons.com vigilance@mt-procons.com (for vigilance cases)
Website	www.mt-procons.com
Address	Ernst-Heckel-Straße 7, 66386 St. Ingbert Germany

1.2.3. Switzerland Authorized Representative

Authorized representative	Decomplix AG
Website	www.decomplix.com
Address	Freiburgstrasse 3, 3010 Bern, Switzerland

2. Introduction

For *In Vitro Diagnostic Use Only*

2.1. Device Overview

The miLab™ Platform, which is the decentralized diagnostic device applicable to various tests and contains a microscopic lens for digital imaging, works along with the cartridge, SafeFix, and SafeFix CER. Each test requires specific components from the cartridges.

The miLab™ Platform is a highly advanced digital imaging system designed for specific clinical applications following the purpose of separate tests. It features a motorized stage for automated sample preparation, a digital microscope for high-speed and clear imaging, and an embedded graphics processing unit (GPU) for deep learning-based image analysis.

The system is intended for use by qualified personnel who have received training in operating the device by personnel from Noul or the entitled distributors. It must be used along with miLab™ Cartridges, which enable the platform to perform cartridge-specific hematological or cytological sample preparation. After the slide preparation, the system takes microscopy images and analyzes them from the miLab-prepared slides, and displays the analyzed results on the

screen. It can save and export the results with/without the images, making it an ideal solution for hematological and cytological analysis in a clinical diagnosis environment.

2.1.1. Reference Number

The miLab™ Platform is available in the following variants, depending on the lens type and magnification.

Product Name	Model Name	Reference Number
miLab Platform	DMLA	DMLA-AP50
		DMLA-AC50
		DMLA-SA20

2.1.2. Other products that are intended to be used in combination with the device

The miLab™ Platform can be used with the following:

No.	Product Name	Model Name	Remark
1	miLab™ Cartridge MAL	CMAA	Cartridge & AI Analysis SW
2	miLab™ Cartridge BCM	CBCA	Cartridge & AI Analysis SW
3	miLab™ Cartridge CER	CCEA	Cartridge & AI Analysis SW
4	miLab™ Cartridge FNA	CFNA	Cartridge & AI Analysis SW

The intended use of other products used in combination with this device can be found in each product's Instructions for Use (IFU)

2.1.3. Optional Products

The following products are sold separately for optional use with the miLab Platform (DMLA-AP50, DMLA-AC50). Each miLab™ Slide Case and miLab™ Slide Microscope Adapter is provided free of charge with the equipment.

- miLab™ Slide Case (Model Name: ASCA) for miLab slide storage.
- miLab™ Slide Microscope Adapter (Model Name: ASAA) for mounting miLab slides on microscope stages.
- Thermal printer(SLK-TL100, SEWOO, BOM no.: 613-0001)

2.1.4. Equipment and materials required but not provided

- Adjustable calibrated pipettes to cover a range of volumes from 4µl. (Model Name: DMLA-AP50, DMLA-AC50)
- Pipette tips capable of delivering volumes of 1 ~10µL, 2-20µL.(Model Name: DMLA-AP50, DMLA-AC50)

- Liquid-based cytology (LBC) system LBC sample collection tool kit. (Model Name: DMLA-SA20)

2.2. Intended Purpose

The miLab™ Platform operates with miLab™ Cartridges and accessories reagent, performing cartridge-specific automated sample preparation, including smear, fixation, and staining to generate digital slide images. After acquiring digital slide images, the AI SW installed on the device analyzes and exports the images for diagnosis. The miLab™ Platform is intended to be used by professional users.

2.2.1. Sample Preparation Reagents

The device can be used with reagents for sample preparation, such as fixation, decolorization, and staining, and AI-based analysis software can be installed on it. Please refer to Section 2.1.2 for a detailed list.

Please note that Sample preparation Reagents are not included with the miLab™ Platform and must be purchased separately as an accessory.

2.3. Principle of miLab™ Platform

The miLab™ Platform (Model Name. DMLA) automates slide preparation and digital imaging. This method is the automated light microscope principle. The device operates through the following steps.

1) Sample preparation (smear, fixation, staining)

The sample preparation process is tailored to the specific type of cartridge being used. When a cartridge loaded with a specimen (cell or tissue) is inserted into the device and a command is given, the stage and press within the device are activated to perform the sample preparation process. The specimen(cell), smeared by the movement of the cartridge's top and bottom assembly, is used on the slide with SafeFix™ (fixative), SafeFix™ CER(dehydration and decolorization) and then stained through contact with the staining reagent contained in the cartridge. (For detailed information, refer to the *Instructions for Use for miLab™ Cartridge MAL, miLab™ Cartridge BCM, and miLab™ Cartridge CER)*

2) Digital imaging

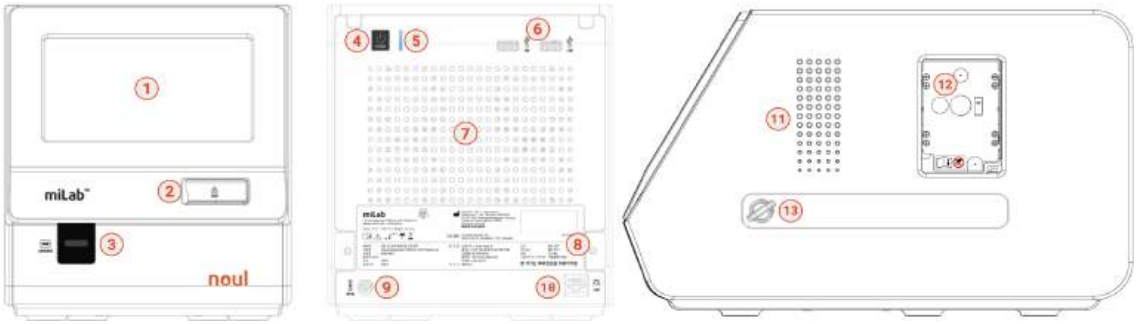
Once the sample preparation process is completed, the cartridge is moved to a position for imaging acquisition by driving the stage. The miLab™ platform is equipped with an optical microscope system that allows magnification of the specimen, and through this, an image of the stained specimen on a slide glass is captured by a camera at high magnification.

3) View image results

Through the display of the miLab platform, users can check, enlarge, reduce, view, and save images of cells or tissues and information that identifies specific cells or tissues set by the reader. When the AI software is installed, the analysis results are displayed on the screen.

2.4. Parts Names and Functions

Front View **Back View** **Right View**



- **Front View**
  - ① **LCD touch screen**
    A display interface for device operation
  - ② **Cartridge inlet & Inlet hatch**
    Covered opening for miLab cartridge insertion and ejection
  - ③ **Barcode scanner**
    For patient ID input and SafeFix™ barcode

- **Back View**
  - ④ **Main power button**
    On/Off switch for the device
  - ⑤ **Power indicator**
    Light indicator for the device power status

LED Status	AC/DC Adaptor	Battery Status
Light OFF	Not Connected	Not Applicable
Light ON	Connected	Battery charging / Fully charged

  - ⑥ **USB ports**

    Applicable models:
    - DMLA-AP50 / DMLA-AC50 - USB 2.0 ports are for system updates and thermal printers.
    - DMLA-SA20 - USB 3.0 ports are for system updates.

> ⚠ **Caution!**
> - The USB ports MUST ONLY be used for system updates and a thermal printer.

- Any other use of the USB ports may damage the device and will void the warranty.
- The authorized personnel can only provide the system update.

⑦ **Output vent**

Ventilation holes for internal temperature control

⑧ **miLab product label**

A product label containing miLab information

⑨ **DC power connector**

For AC/DC adapter.

- **AC/DC Adapter Connection Instruction (Model Name: DMLA-SA20)**
  1. Hold the connector end of the cable with one hand and support the device body with the other.
  2. **To connect**, press the end of the cable and insert it into the DC port until a click is heard.
  3. **To disconnect**, press the end of the cable again and gently pull it out while holding the device body to avoid strain on the port.

⑩ **Ethernet port**

Ethernet port for network connection

- **Right View**

⑪ **Intake vent**

Ventilation holes for internal temperature control

⑫ **SafeFix variants compartment**

Compartment for SafeFix variants installation

Warning!

- The SafeFix variants compartment contains SHARP needles. DO NOT put your hand inside the compartment.

⑬ **Maintenance door (Accessible with a provided key)**

Maintenance door for internal access by authorized service representatives

Warning!

- DO NOT open the maintenance door without supervision from a Noul service representative or authorized personnel.
- The maintenance door allows access to the internal moving parts of miLab and may cause personal injury if accessed during device operation. Ensure the device power is off and no parts are moving before opening the maintenance door.

- **AC/DC adaptor**

Caution!

- ONLY use the AC/DC adaptor provided by the manufacturer.

- **Battery**
  - DMLA-AP50 / DMLA-AC50 - 3,000mAh rechargeable Li-ion battery
  - DMLA-SA20 - 3,600mAh rechargeable Li-ion battery

Caution

- ONLY use the battery provided by the manufacturer.
- Battery replacement MUST ONLY be performed by qualified personnel. DO NOT remove or tamper with the battery. Consult customer service for battery replacement.
- Batteries MUST be replaced with the same type and number of batteries.

Caution!

- Bring all cartridges and specimens to operating temperature before use.
- DO NOT press the reagents area and film part on the cartridge.
- Make sure not to contaminate the cartridge with dust.

2.5. SafeFix Variants Overview

2.5.1. Reference Number

No.	Product Name	Model Name	Remark
1	SafeFix™	CSFA	Accessory
2	SafeFix™ CER	CSCA	Accessory

2.5.2. Parts Names and Functions

SafeFix variants may differ in labeling depending on the device model.

or

Frontside

Backside

- **Frontside**
  - ① **label**
    A product label containing information

- **Backside**
  - ② **Vent silicone cap**
    Silicone cap for miLab vent needle insertion
  - ③ **Inlet silicone cap**
    Silicone cap for miLab inlet needle insertion
  - ④ **Locking magnet**
    Magnet to lock the container to the miLab

2.5.3. Warnings and Precautions

⚠ **Warning!**

- SafeFix variants are highly flammable and MUST be stored with EXTREME CAUTION, accordingly.

⚠ **Caution!**

- The reliability of the analysis results cannot be guaranteed if SafeFix variants are

used beyond the scope of the intended use or not by the provided directions for use.

- Do not tamper with or forcibly open the SafeFix variants. Doing so may compromise their integrity and lead to contamination of the solution, which can result in low sample quality.
- If the SafeFix variants are stored outside the recommended temperature range, the analysis results cannot be guaranteed.
- DO NOT expose SafeFix to direct sunlight. (Model Name: CSFA)
- DO NOT use expired SafeFix. The analysis results cannot be guaranteed when expired SafeFix is used.
- MUST USE ONLY SafeFix produced by the manufacturer.

⚠ Warning!
H225: Highly flammable liquid and vapor.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H336: May cause drowsiness or dizziness.
H350: May cause cancer.
H372: Causes damage to organs through prolonged or repeated exposure.
P201: Obtain special instructions before use.
P202: DO NOT handle until all safety precautions have been read and understood.
P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233: Keep container tightly closed.
P240: Ground/bond container and receiving equipment.
P241: Use explosion-proof electrical/ventilating/lighting equipment.
P242: Use only non-sparking tools.
P243: Take precautionary measures against static discharge.
P260: DO NOT breathe fume/gas/mist/vapors/spray
P264: Wash exposed skin thoroughly after handling.
P270: DO NOT eat, drink or smoke when using this product.
P271: Use only outdoors or in a well-ventilated area.
P280: Wear protective gloves/clothing/eye protection/face protection.
P312: Call a POISON CENTER/doctor/physician/EMERGENCY NUMBER if you feel unwell.
P314: Get medical advice/attention if you feel unwell.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313: IF exposed or concerned: Get medical advice/attention.
P337+P313: If eye irritation persists: Get medical advice/attention
P370+P378: In case of fire: Use carbon dioxide (CO_2), powder, alcohol-resistant foam

to extinguish.
P405: Store locked up.
P403+P233: Store in a well-ventilated place. Keep the container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P501: Dispose of contents/container to comply with local, state, and federal regulations.

Noul products are labeled with Hazard Symbols and Risk and Safety Phrases in compliance with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

2.5.4. Transportation condition

For transportation, the following conditions must be met.

- Temperature range : 21 ~ 40 (°C)
- Humidity : 35 ~ 90 (% Relative Humidity)

⚠ **Caution!**

- SafeFix variants contain flammable liquid. Exercise extreme caution when transporting SafeFix variants.
- DO NOT drop or apply excessive pressure to SafeFix variants, as this may compromise the integrity of the container and cause leakage.
- DO NOT relocate the miLab device while a SafeFix variant is installed. If relocation is unavoidable, DO NOT tilt the device. Liquid may leak from the vent on the SafeFix container, resulting in permanent damage to the device.
- Always follow all necessary safety precautions when handling and transporting SafeFix variants.

2.5.5. Disposal Procedures

Disposal procedures should meet the requirements of applicable local regulations. Read the GHS Hazard and Precautionary Statements mentioned in *2.5.3. Warnings and Precautions (for in vitro diagnostic use only).*

3. Installation Procedures

3.1. miLab™ Platform Package Contents

The miLab™ Platform package contains the following.

- miLab™ Platform Device (1 ea)
- SafeFix Variants (Model Name: CSFA/CSCA) (1 ea)

- miLab™ Slide Case (Model Name: CMAA/CBCA)(1 ea)
- miLab™ Slide Microscope Adapter for (Model Name: CMAA/CBCA)(1 ea)
- AC/DC Adaptor (1 ea)
- Power Cord (1 ea)
- miLab™ Platform Instructions for Use (1 ea)

3.2. Required Items Needed to Operate the miLab™ Platform

The following items are required for use with the miLab™ platform but are sold separately and not included in the package.

- Accessory: SafeFix Variants (Model Name: CSFA and CSCA)

The cartridge types used with the miLab™ platform are as follows.

- Malaria application-specific miLab™ Cartridge MAL (Model Name: CMAA)
- BCM application-specific miLab™ Cartridge BCM (Model Name: CBCA)
- CER application-specific miLab™ Cartridge CER (Model Name: CCEA)
- FNA application-specific miLab™ Cartridge FNA (Model Name: CFNA)

3.3. miLab™ Platform Installation

3.3.1. Before Installation

miLab™ should be installed by authorized service distributors or Noul.

The following is a list of necessary actions before installation.

- Secure sample, vibration-free, and flat surface for installation.
- The usage environment should be dust-free and well-ventilated.
- Make sure to have enough space clearance around the system.
- When using an AC/DC adaptor, ensure there is a reliable source of electricity.
- If electricity is unreliable, ensure the battery is fully charged before operating the miLab.

3.3.2. Installation

The following is a list of necessary actions for installation.

- Set the device on the prepared workspace.
- Ensure the AC/DC adaptor is securely connected to the power source.
- Insert the SafeFix variants.

> ⚠ **Caution! Safefix Variants**
>
> - The device may produce inaccurate results in the following cases:
> - When the SafeFix variants are improperly inserted into the device.
> - When the SafeFix variants are depleted.

- When the SafeFix variants are denatured by exposing them to direct sunlight.

- A warning message will appear when SafeFix variants are improperly inserted. Unlock and re-insert SafeFix variants.
- A warning message will appear when there are less than 10% of SafeFix variants remaining. Replace SafeFix variants before they run low.
- DO NOT remove SafeFix variants from miLab except when replacing SafeFix variants and relocating the device.

3.3.3. Powering on

1. **Make sure the device has sufficient power.**

⚠ Caution!

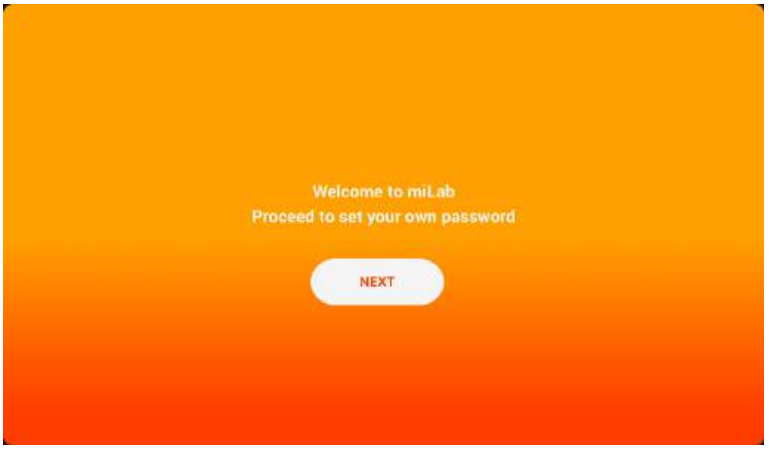
- When using battery power, check if the remaining battery level is sufficient. When it's charged less than 70% of battery, the test is not available.
- When using the AC/DC adaptor, ensure the power cords are securely connected.
- **Ensure that you press the end of the cable and support the device body when connecting or disconnecting the power cable (Model: DMLA-SA20) to avoid strain on the DC port.**

2. **Press the main power button on the back of the device for 3 seconds.**
   a. When the power is on, the device makes a sound of audible tones (Refer to *2.4. Parts Names and Functions* for power status).

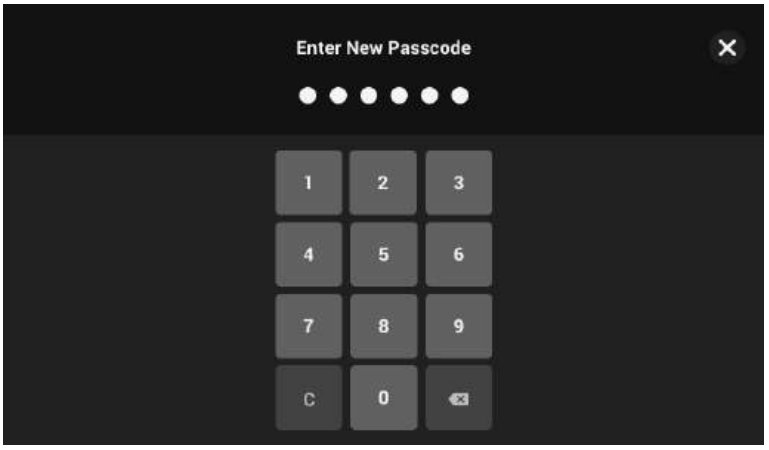
   b. Once the device is on and booting, a Noul logo screen will briefly appear on the LCD screen. Wait for the system to complete booting.

3.3.4. Initial Setup

1. **When the device is on, a welcome screen will appear. Then touch the [NEXT] button.**



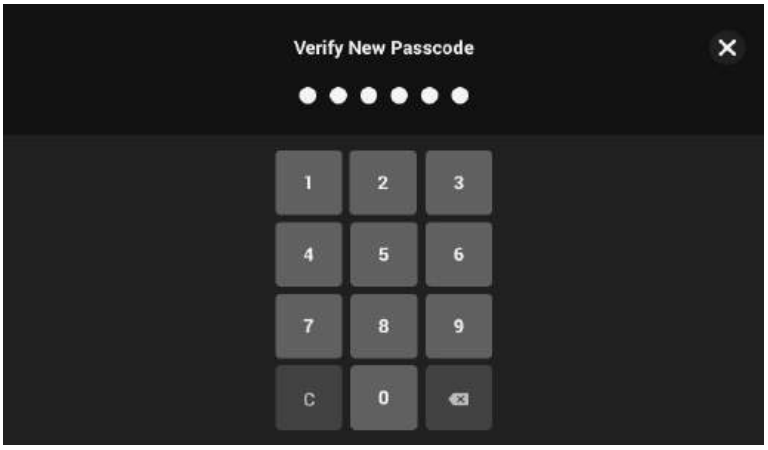
2. **Enter a new passcode.**
    a. This passcode will be saved and used whenever the device is locked.



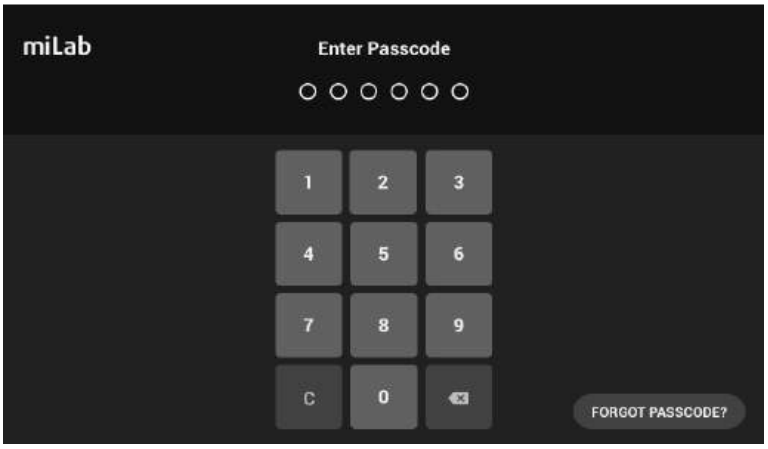
Caution!

- If passwords are not properly secured, unauthorized users can change or delete data or change settings, resulting in errors in the diagnostic examination, resulting in re-examination, and incorrect results.

3. **Then, re-enter the new passcode to confirm.**



4. **Lastly, enter the passcode again to activate the device.**

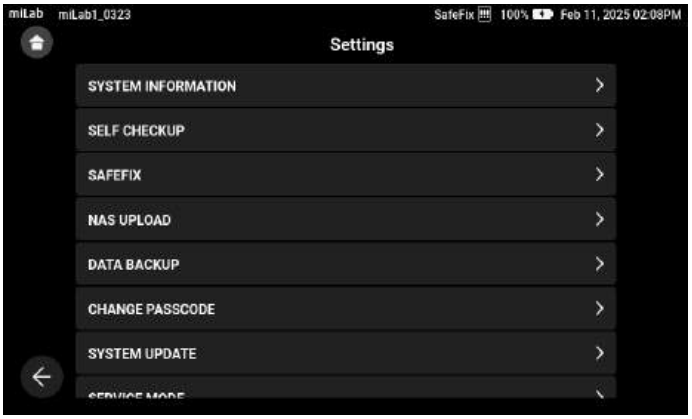


3.3.5. SafeFix Variants: Installation, Removal, and Replacement

SafeFix variants may differ in **color**, **labeling**, and **the names of on-screen menu** options depending on the device model, but the installation procedure remains the same.

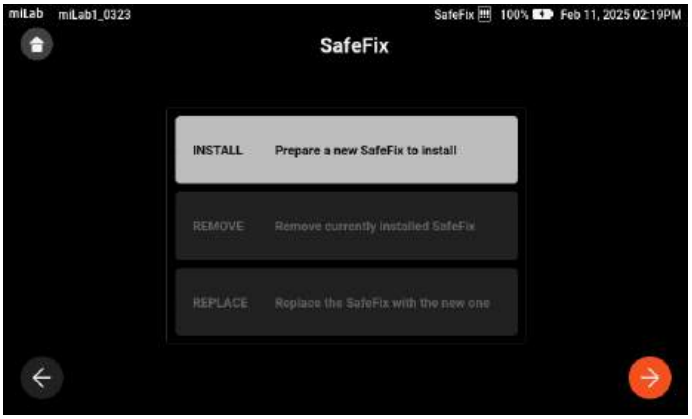
3.3.6. SafeFix Variants: Installation

1. Touch the settings button on the bottom left corner of the home screen and then choose the [SAFEFIX] or [SAFEFIX CER]

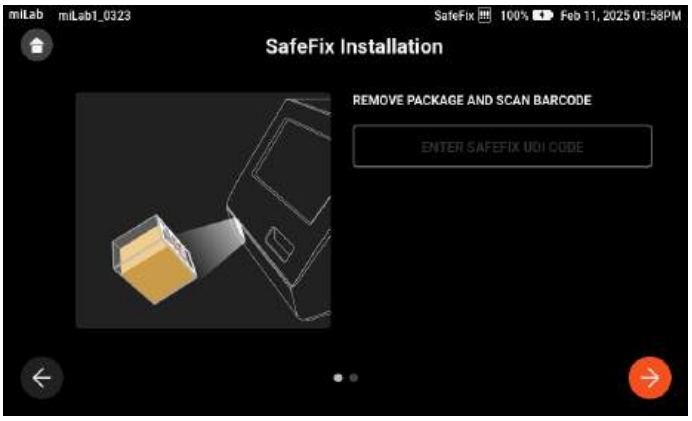


2. Confirm the status of the SafeFix variant, then touch the [→] button.

3. Choose [Install], then touch the [→] button.

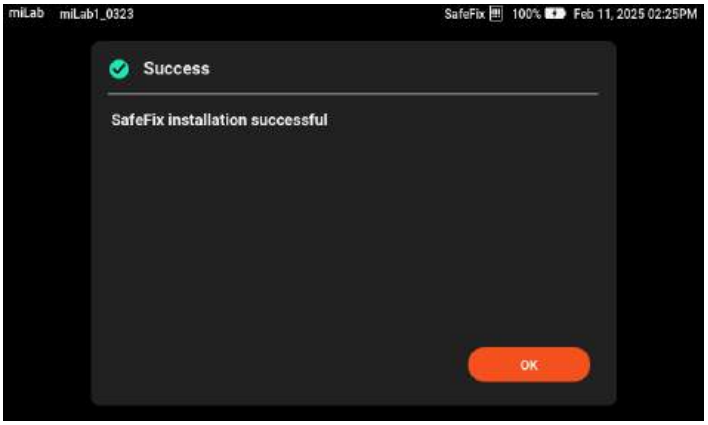


4. Scan the barcode on the product label of a new SafeFix variant, then touch the [→] button.



5. Insert the new SafeFix variant gently into the SafeFix compartment of the miLab™ device. Then, press the [→] button to continue.

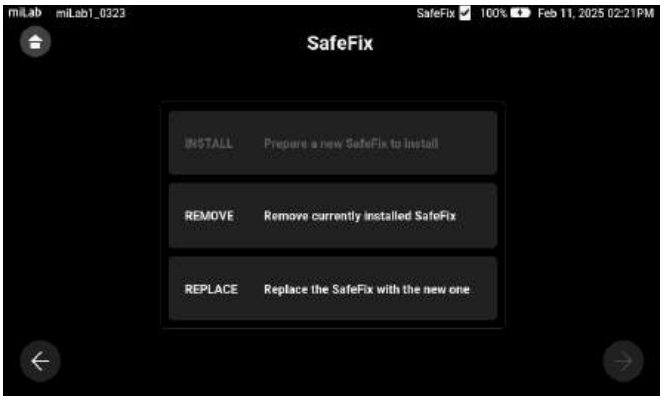
6. If the SafeFix variant is installed successfully, a success message will appear.



3.3.7. SafeFix Variants: Removal and Replacement

1. Review the information regarding the currently installed SafeFix variant, then touch the [→] button.

2. Select [Remove] or [Replace], then touch the [→] button.

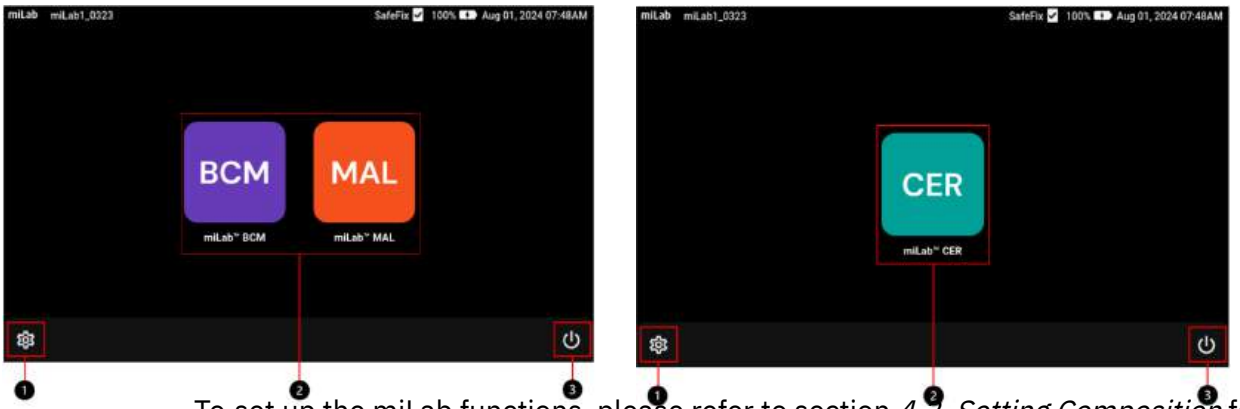


3. The currently installed SafeFix variant will be ejected from the miLab™ Device automatically. Gently pull out the SafeFix, then touch the [→] button.

4. Refer to 3.3.5.1 SafeFix Variants: Installation and install the new SafeFix variant.

4. Operation Instructions

4.1. Home Screen



To set up the miLab functions, please refer to section *4.2. Setting Composition* for detailed information.

② **Application**

- **BCM:** For blood count & morphology analysis.
- **MAL:** For a routine Malaria test with the analysis of a pre-set number of RBCs.
- **CER:** For cervical cell morphology analysis (While BCM and MAL tests can be conducted on a single device, CER requires a separate device for testing.)

③ **Power off**

To shut down or lock the device

4.1.1. Status Bar

① **Device ID**

A unique device ID.

② **Status of Safefix Variant**

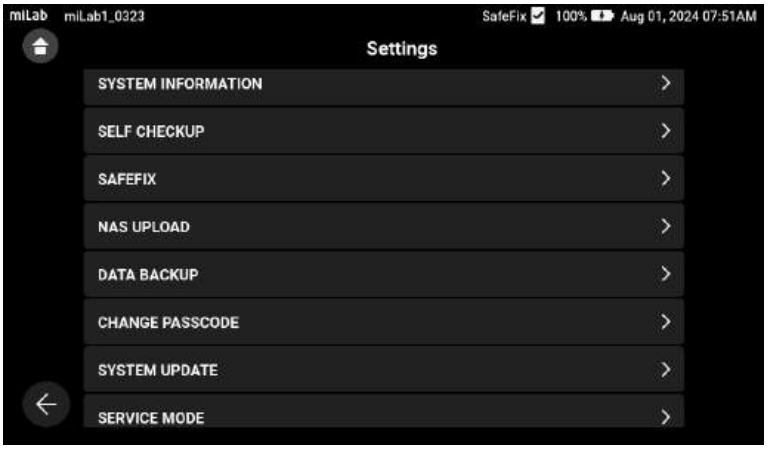
☑	The SafeFix variant is installed and sufficient.
!	The SafeFix variant is running low.
▯	The SafeFix variant is either not installed or is empty.

③ **Battery status**

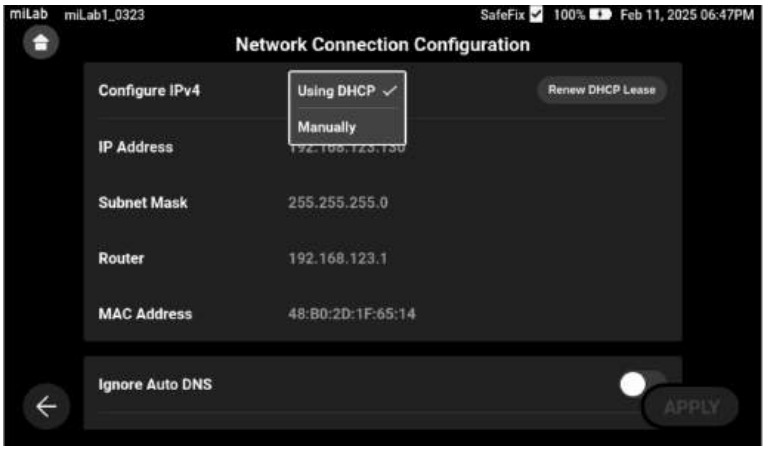
③ **Date & time**

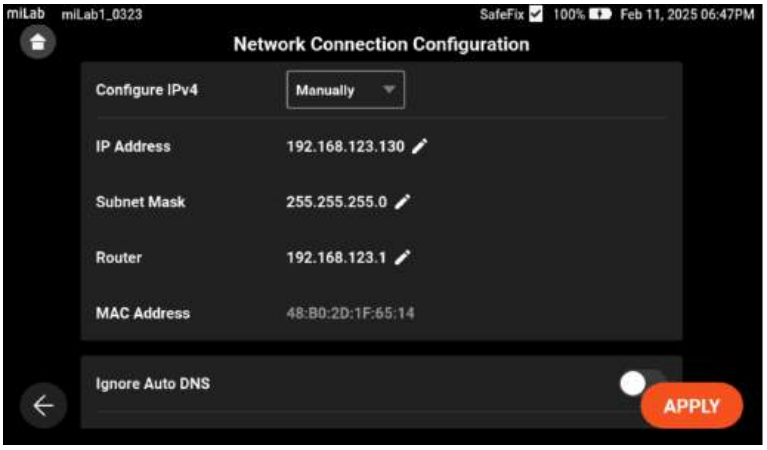
4.2. Setting Composition

The settings page includes the following information and functions.(The menu name may vary as 'SAFEFIX' or 'SAFEFIX CER' depending on the device model.)



- **SYSTEM INFORMATION**
  This menu provides access to various system-related information below.
  - Product Name
  - Model Name
  - Serial Number
  - Device ID
  - Manufacturer
  - Software Version
  - Firmware Version
  - Rootfs Version
  - Test Count
  - Network





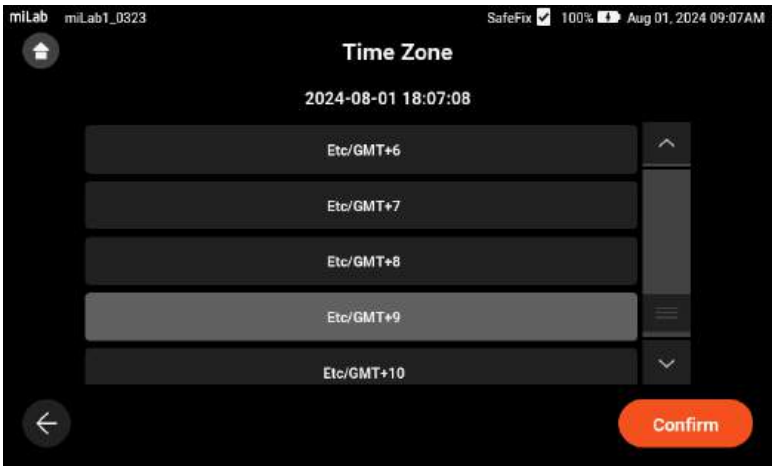
- Allows users to manually configure the IP settings as required.

- Network (VPN)
- Storage
  - It shows the capacity of saved results out of the total storage available.
  - Delete Data: In the Delete Data section, users can selectively delete data after directly reviewing it.
  - Auto-delete functionality can be configured for each app in use. If the total remaining storage is less than 15GB, testing cannot proceed, and a prompt will appear advising the user to free up space. If it's turned on, data will be deleted automatically to free up space when miLab is low on space. It is recommended to keep a written record of the data in advance.

Caution!

- If 'Auto-delete' is off, further tests won't be available when the remaining storage is less than 15 GB. Please manually remove the test results from the history page.

- Time Zone: The time zone can be set based on regional criteria or using the international standard time zone format defined by IANA.



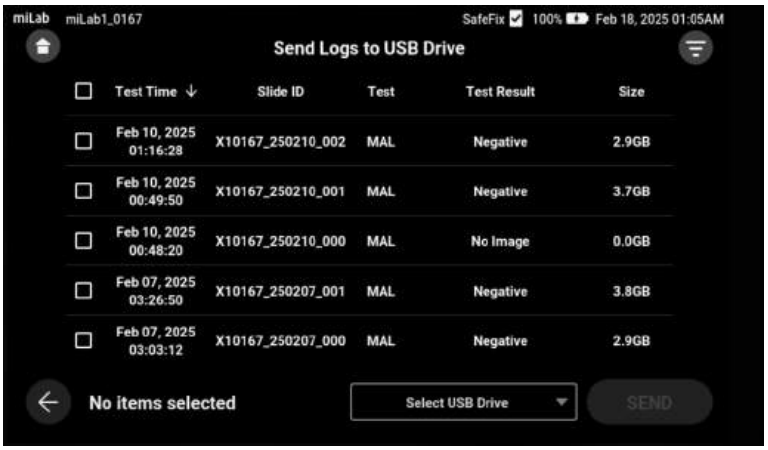
- Time Setup

> **Caution!**
>
> - If the time is not appropriately set up, it will affect the installation of SafeFix variants and the test time displayed on the history page.

- Site ID
  - When the users enter the information, it will appear on the 'Status Bar'.
- Remote Support Connection
  - It will be used to provide the service from Noul, such as in case of customer service.
  - The personnel from Noul or authorized distributors must support the Internet connection to users and press 'CONNECTION REQUEST' after informing Noul Customer Service for remote assistance.

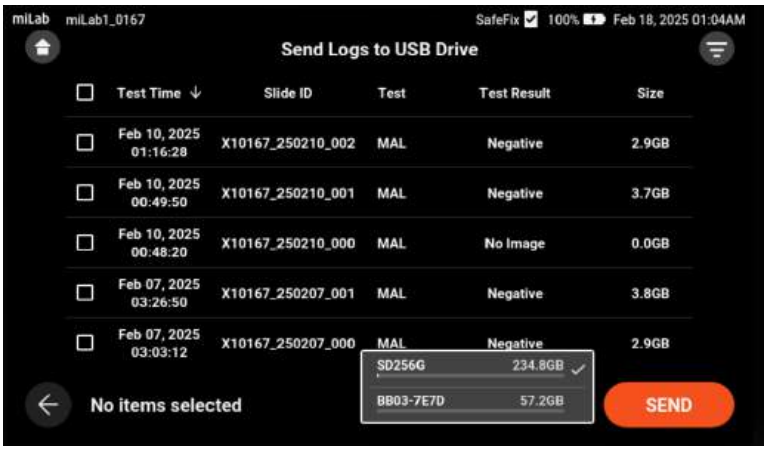
> **Caution!**
>
> - ONLY the authorized personnel can provide this service to the users.
> - Remote Support Connection MUST be scheduled with Noul Customer Service before pressing the 'CONNECTION REQUEST'.

- Send Logs to USB Drive
  - This feature is used to collect test logs for troubleshooting when an issue occurs.
  - The [Send] button remains disabled until a USB drive is inserted, as shown in the image below.



  - When only one USB drive is connected, the system automatically selects it. In this case, simply press [Send] to continue.

- When **two USB drives** are connected, use [**Select USB Drive**] to choose the desired USB drive, then press **[Send]** to continue.

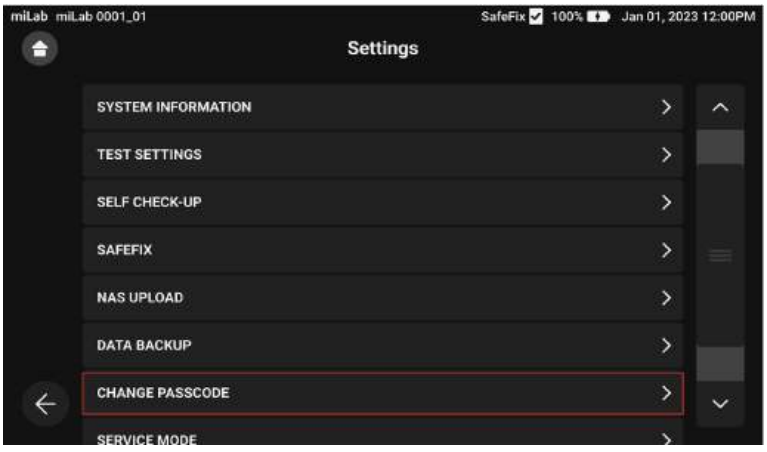


  - If the **checkbox located on the left side** is selected, **miLab platform**, **application logs**, and **logs of selected test results** are saved to the USB drive.
  - If the **checkbox located on the left side** is not selected, **miLab platform** and **application logs** are saved to the USB drive.
- **SELF CHECK-UP**: Using this function, the user may regularly run a self-check to ensure that the device's mechanical components are operating correctly.
- **SAFEFIX**: For SafeFix variants installation, removal, and replacement.
- **NAS UPLOAD:** If the device is connected to a Network Attached Storage (NAS), the test result data may be uploaded to the NAS.
- **CHANGE PASSCODE**: The user may change the passcode using this function.
- **SERVICE MODE**: Service mode may only be accessed by an authorized service representative.

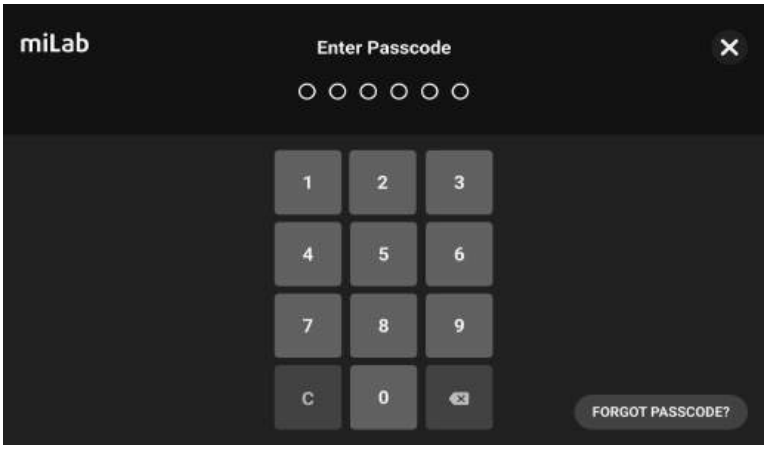
4.3. Change Passcode

1. To change the passcode, touch the settings button on the bottom left corner of the home screen.

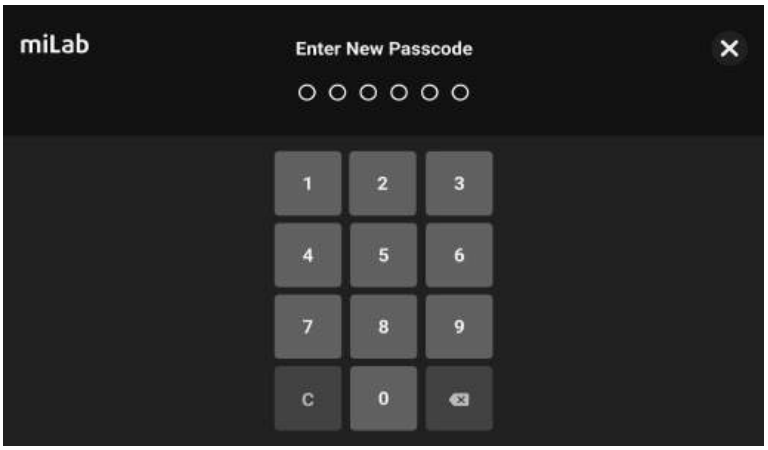
2. Touch the [CHANGE PASSCODE] button.



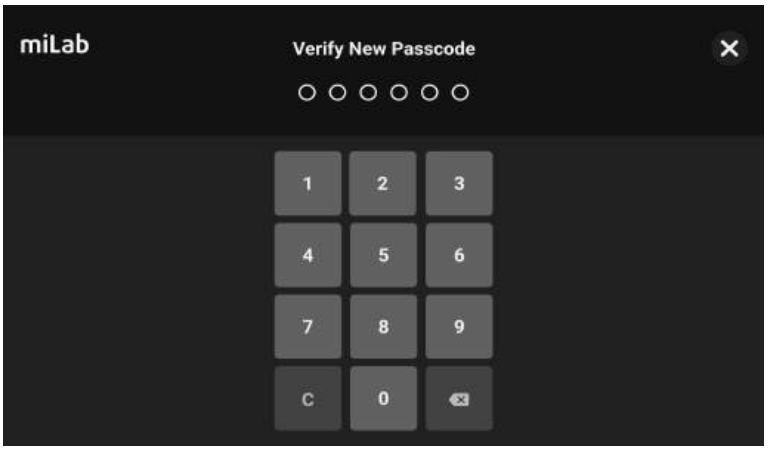
3. Enter your current device passcode.



4. Then, enter a new passcode.



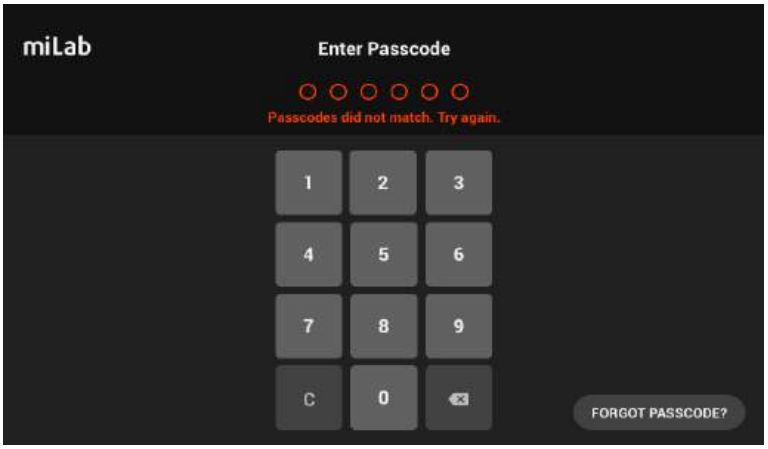
5. Lastly, verify the new passcode to confirm it.



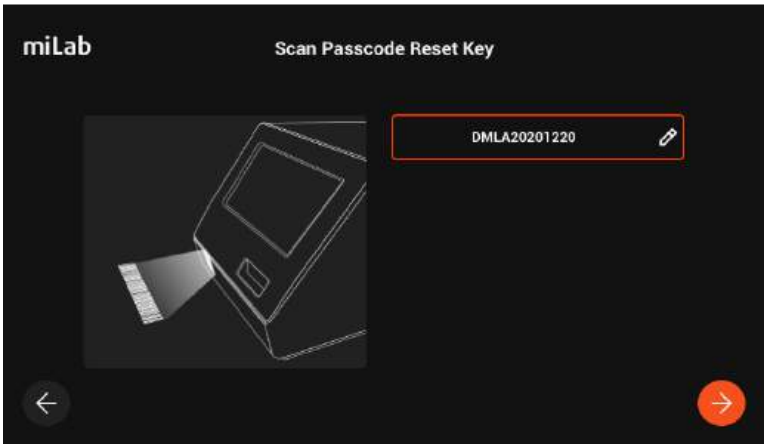
4.4. Forgot Passcode

If you forget the passcode for the miLab™ Platform, follow the steps below to reset the passcode.

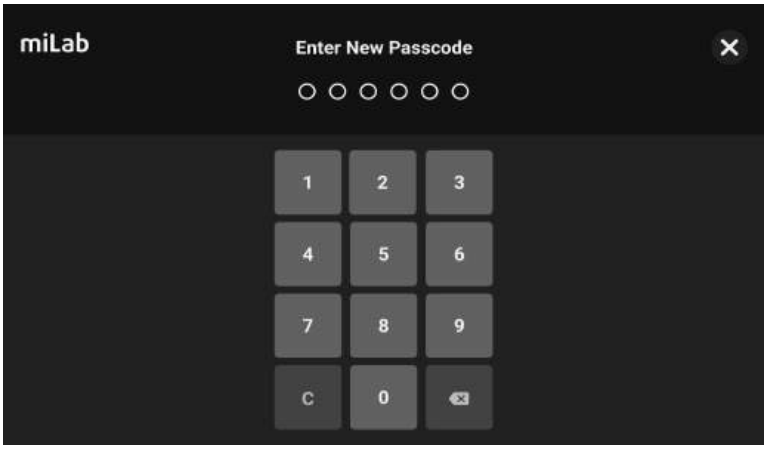
1. Touch the [FORGOT PASSCODE] button.

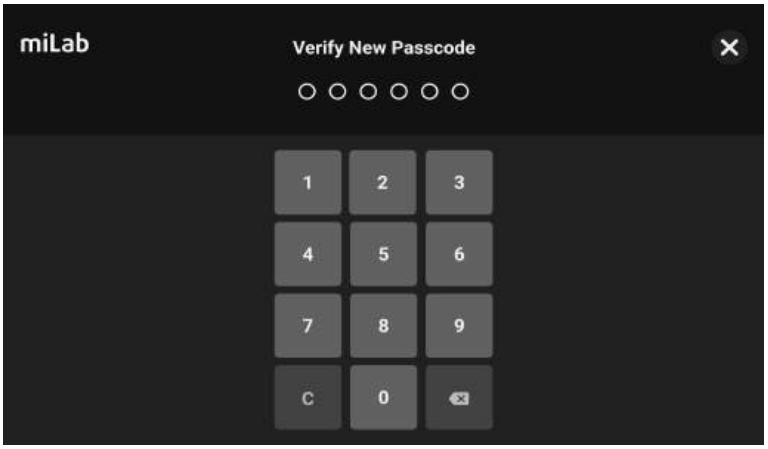


2. Scan the passcode reset key provided by Noul.

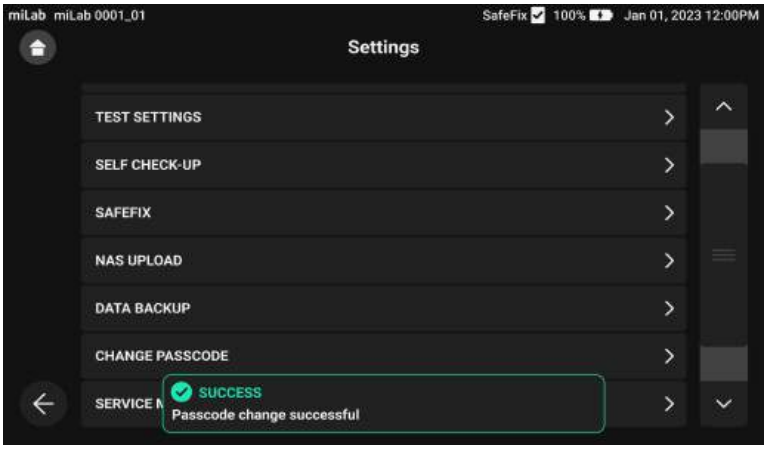


3. When a new passcode screen appears, enter a new passcode. Then, re-entered the new passcode to confirm it.





4. Apply a new passcode, and then you can access miLab.



5. miLab Viewer™

Before Starting

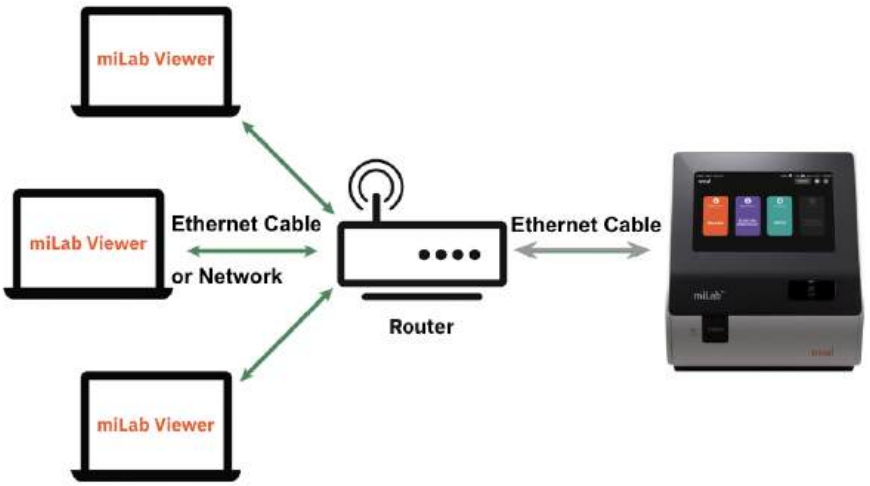
[Notice] *Some of the cell images in the document are dummy images included to help understand UI functions, so please understand that they may not match the actual cell type.*

Before starting, make sure to check the following.

5.1. System Configuration

- **Materials**
  - miLab™ Device (Model Name: DMLA)
  - Mac or Windows Computer
  - Router and Ethernet Cables

    (Recommended) Each port supports 1Gbps (Gigabits / sec).
- **miLab™ - miLab Viewer™**



To access miLab data stored in locally-connected miLabs, users must connect their PCs to the same local network as the miLabs. In order to establish the network connection, users should prepare their own network switch (or use the existing router if enough ports are available) and Ethernet cables. Once the network connection is established, users can connect to miLab by accessing the pre-designated unique IP addresses assigned to each miLab.

Users should ensure that the miLab device is connected properly and that both the miLab device and miLab Viewer are connected to the same local network.
Please note that the system configuration may vary depending on the local network configuration and security.

If accessing the miLab device using miLab Viewer with the existing network configuration is difficult or if you need detailed consultation, please contact the Noul Customer Center at cs@noul.com.

5.2. PC Technical Requirements

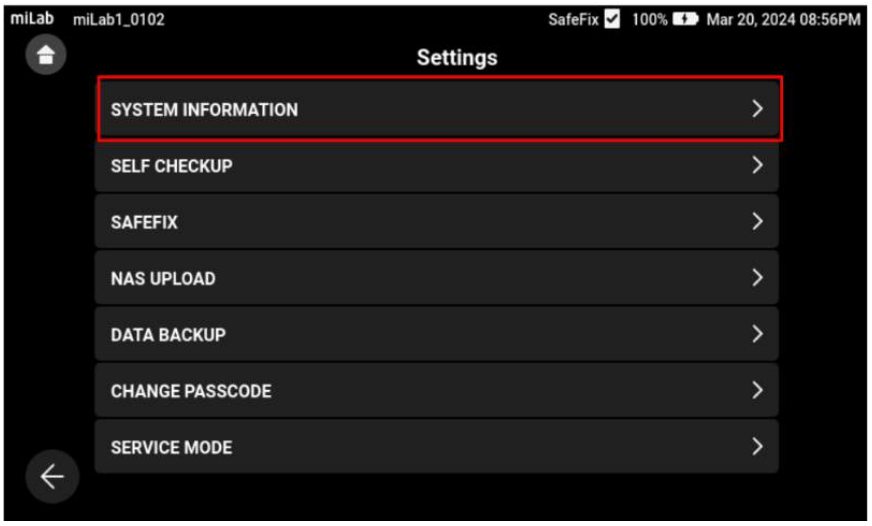
The PC being used should meet the minimum requirements before using miLab Viewer.

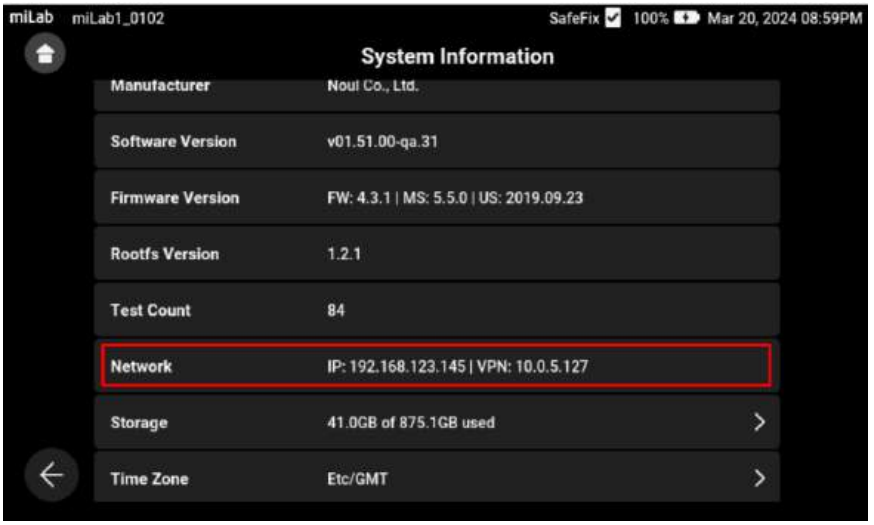
- Operating system
  - macOS: OS X El Capitan (10.11+), including macOS Monterey.
  - Windows: Windows 7 and later are supported. Older operating systems are not supported (and do not work).
- miLab SW version
  - Recommended to use miLab SW 01.44.00 or higher.
- Monitor resolution
  - Minimum 1280 x 720
  - (Recommended) 1920 x 1024 or higher
- Peripheral
  - Local network connection (for miLab Device)
  - A compatible keyboard and a pointing device (e.g. a mouse)
  -

5.3 Find IP Address

Each miLab device will obtain its unique IP address (e.g. 192.168.128.246) when the device is connected to the router with an ethernet cable.

The unique IP address(LAN) can be found in **System Information → Network** in the settings of the miLab device. (For more details, refer to *miLab™ Platform DMLA Instructions for Use, Setting Composition.*)





5.4. Using miLab Viewer™

5.4.1. Accessing Network

Ensure that the PC being used is connected to the same network as the miLab you are trying to access. The PC must be connected to the network in one of the three configurations shown in *5.1. System Configuration*.

5.4.2 miLab Viewer™ Application

5.4.2.1. Installing Application

1. **Click the link provided by Noul Customer Service (CS) to install the miLab Viewer application.**
2. **When you click the link, the following screen will appear.**

a. Please click the appropriate button based on your computer specifications (Mac or Windows) to proceed with the setup file download.

3. **When you click on the setup file, the following screen will appear.**
   a. Click the [Agree] button to complete the installation, and the Viewer App button will be created on your desktop.

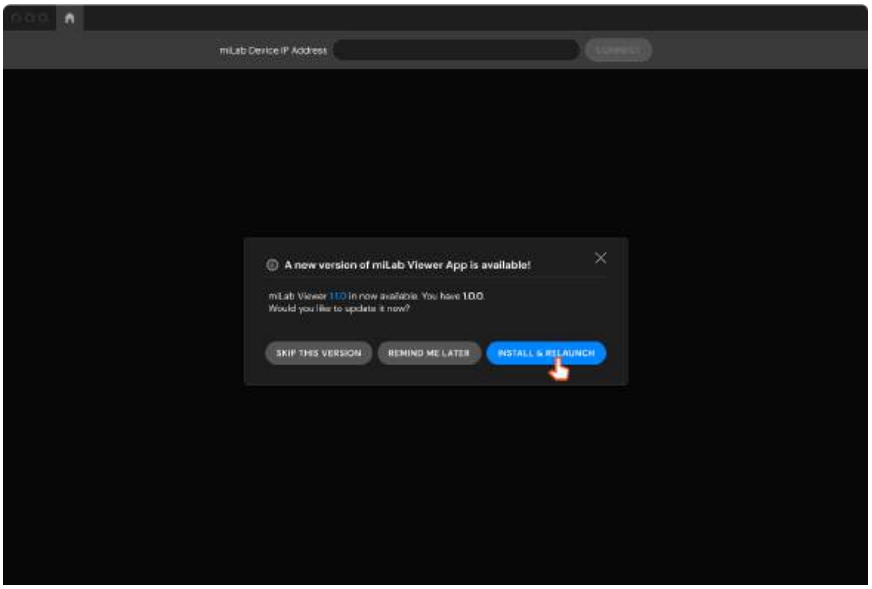
5.4.2.2. Opening Application

1. **When you click on the app to access it, the home screen appears, and the network scanning feature automatically displays miLab equipment on the same network environment. Clicking on the equipment will switch to the Login tab.**
   a. If no miLab device is found after network scanning, a message such as ‘No miLab device found can be connected. Please check the device and local network.’ will be displayed.
   b. If you are connected to the same network but Local Network Devices scanning is not working, please check your SW version (Available from miLab SW 01.43.00 or higher).

2. **You can connect to it by directly entering the IP address at the top of the page if the desired device is not on the list. For more detailed information about IP Address, refer to *5.3. Find IP Address*.**
    a. The format of the IP address should be four, numbering up to three digits separated by periods (“.”). (e.g., **192.168.128.165**)
3. **If there are previously connected devices, they can be viewed on the ‘Recently Used Devices’ screen.**
    a. Each device is listed with its IP address and sorted by the most recent connection.
    b. When hovering over the miLab image, a delete button (-) will appear in the upper right corner, allowing the device to be removed if desired.
    c. The home screen continues to scan the network, and available and unavailable devices may be updated.

5.4.2.3. Updating Application

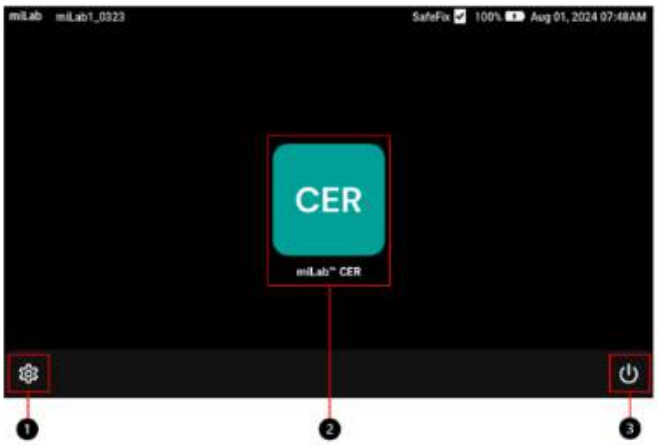
1. **When accessing miLab Viewer, a pop-up window will automatically appear to guide you through the latest version installation process if a new software version is released.**
    a. Clicking [SKIP THIS VERSION] will prevent the update notification from popping up until the next version is updated.
    b. Clicking [REMIND ME LATER] will prevent the update notification from popping up for two weeks.



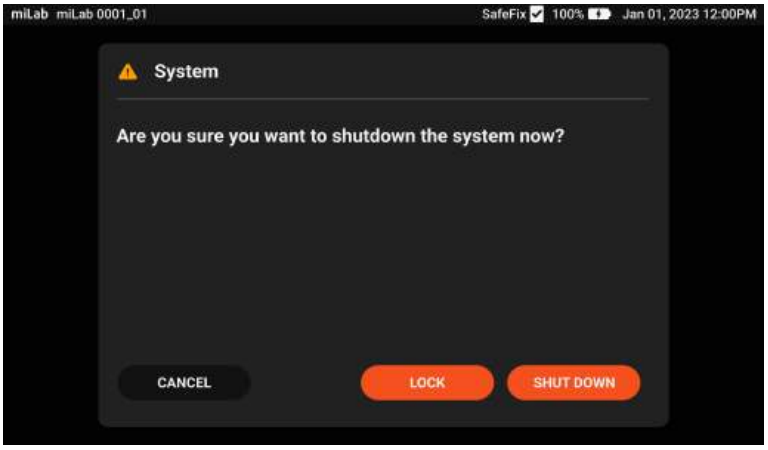
2. **If you don't update from the pop-up page, you can manually proceed with the update through the app's menu (miLab Viewer - Check for Updates).**

5.5. Shutting Off

1. On the home screen, tap the Shut button at the bottom right corner.



2. Touch the [SHUT DOWN] button.



Caution!

- Ensure no tests are running on the device.
- Shutting off the device while a test is in progress might result in device damage or failure.
- Only use the main power button to shut off when the exit button is unresponsive or not accessible.

6. MAL Instruction details

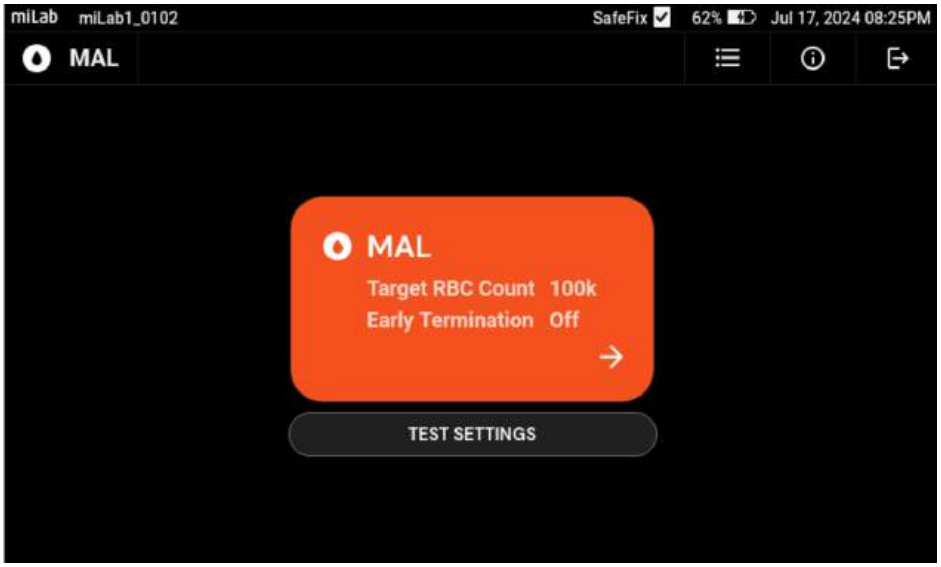
6.1. Test Procedures

6.1.1. Operation Instructions for the miLab Device

Before Start the Test: Test Setting

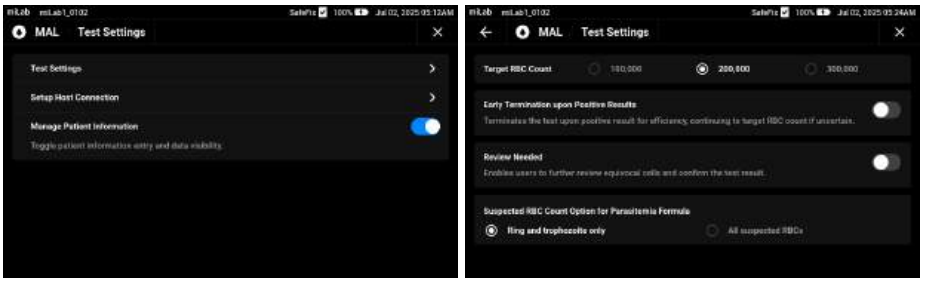
1. Before initiating the test, double-check that SafeFix™ is properly installed.
2. **[Settings]**

- Before initiating the test, click the [TEST SETTINGS] on the home screen.



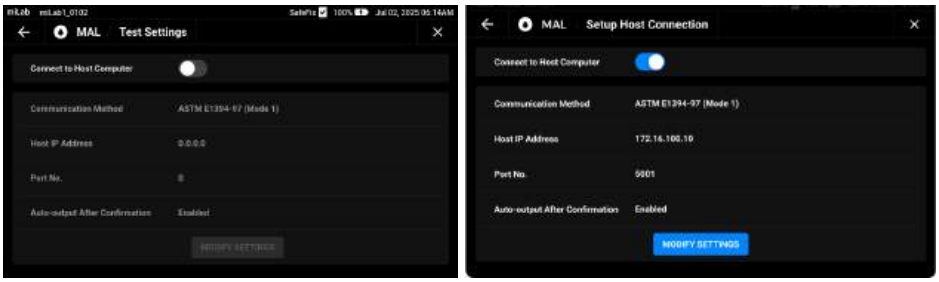
(This page is the page you can see after pressing MAL application on the very first page.)

- **[Test settings]** Select the [Test Settings] again.



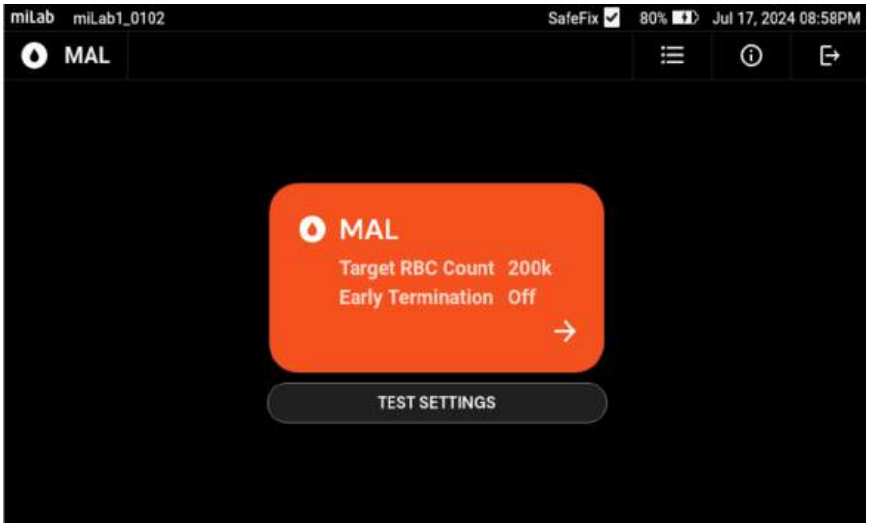
- Configure the following options on the Test Setting page; **Target RBC Count, Early termination upon Positive Results, Review Needed, Parasitemia formula**
- **[Target RBC Count]** Set the total RBC count to 100K, 200K, or 300K. 100K, 200K, or 300K means the maximum number of red blood cell tests.
    - Selecting the 100K option reduces test time but may cause different performance results.
- **[Early Termination upon Positive Results]** Ends the test upon detecting sufficient suspected RBCs to derive a test result
    - 'On': The test finishes upon detecting at least 20 suspected RBCs, with the possibility of falling short of the user-specified total RBC count.
    - 'Off': The test finishes upon detecting the user-specified total RBC count.
- **[Review Needed]** When 'Review Needed' is enabled, it allows users to further review equivocal cells and confirm the test result.
- **[Suspected RBC Count Option for Parasitemia Formula]** The calculation of parasitemia level (%, parasites/μL) can be performed by choosing whether to include only Ring and Trophozoite as suspected RBCs or all infected cells up to and including Gametocytes.
  For detailed instructions, refer to the parasitemia formula described in '*8.3. Calculations*'

- **[Setup Host Connection]** This page is intended for LIS (Laboratory Information System) integration. Use only after completing the data interface test between the site's LIS and miLab. When set to [On], miLab data can be transmitted to the LIS.
  All results will be transmitted after the user's confirmation is completed, and the transmitted information will be as follows:
  - Positive / Negative
  - Species name (Plasmodium falciparum or Plasmodium vivax, if species is identified)
  - P. level (%)

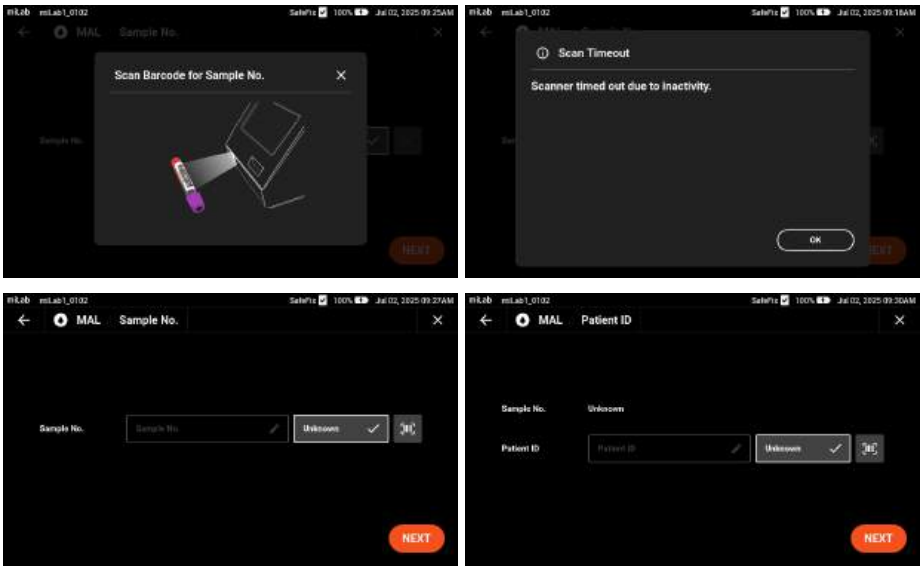


- **[Manage Patient Information]** Allow checking whether the patient information screen is displayed or bypassed.
  - 'On': Patient information, including Date of Birth, Sex, Pregnancy, RBC Count, Patient Visit Count, etc. will be displayed as described in '5. [Patient Information]' at next page.
  - 'Off': Patient information step will be passed over without display(In this case, RBC count will follow the default value, 5.00 million cells/μl).

3. **The Target RBC count and Early Termination on/off status, configured in the Test Setting values, can be verified once again in the Test Start tab.**
4. **[QC]** QC mode is to perform internal quality control to verify the performance of the miLab device and software. For more information, Please refer to **[Appendix B]**
5. **To start the test, click the**  **button on the screen.**



6. **Scan the Barcode for Sample No. and Patient ID.**
    - The code scanner automatically deactivates after 10 seconds. After clicking 'OK' on the 'Scan Timeout' message window, you can either manually enter the information or reactivate the barcode scanner by clicking the b de icon .

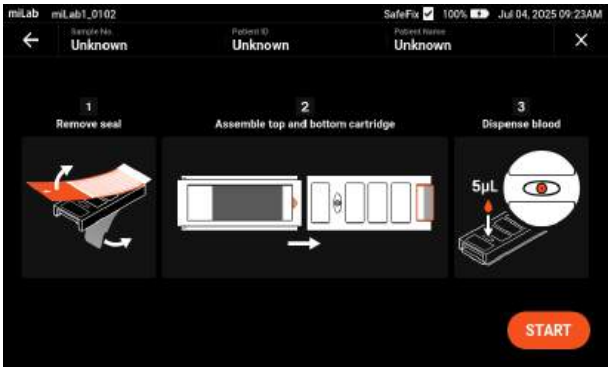


7. **[Patient Information]** ***(Only when it is 'On' in the 'TEST SETTINGS')***

    Enter the Date of Birth, Sex, Pregnancy, RBC Count, and Patient Visit Count information on the Patient Information page.

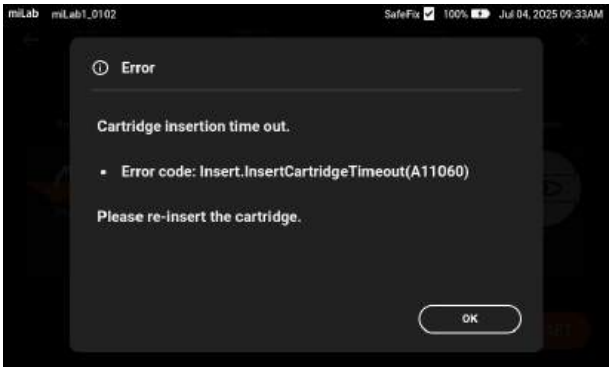
    - Press the [NEXT] button to skip.
    - Enter the patient body temperature, symptoms, and medication interval
    - Click the [NEXT] button to skip.
    - [Patient Information] pages are displayed only when the user sets the Patient information to 'on' in the [TEST SETTINGS]. The following is the flow according to this setting.

8. **[Cartridge Preparation] The following screen will be displayed when ready to start the test.**
    - DO NOT Touch the [START] button until the cartridge is ready to be inserted.



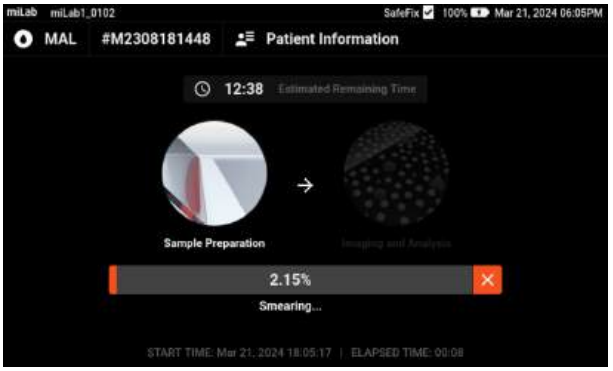
9. **Click the [START] button, then insert the prepared cartridge into the device cartridge inlet for 5 seconds (spreader film side first) until a whirring sound can be heard.**
    - A correctly inserted cartridge will be automatically pulled in.
    - When correctly inserted, the internal barcode scanner will automatically read the barcode on the cartridge bottom assembly.

    - If the cartridge is not inserted properly, an error message will appear. Press [OK] and try again.



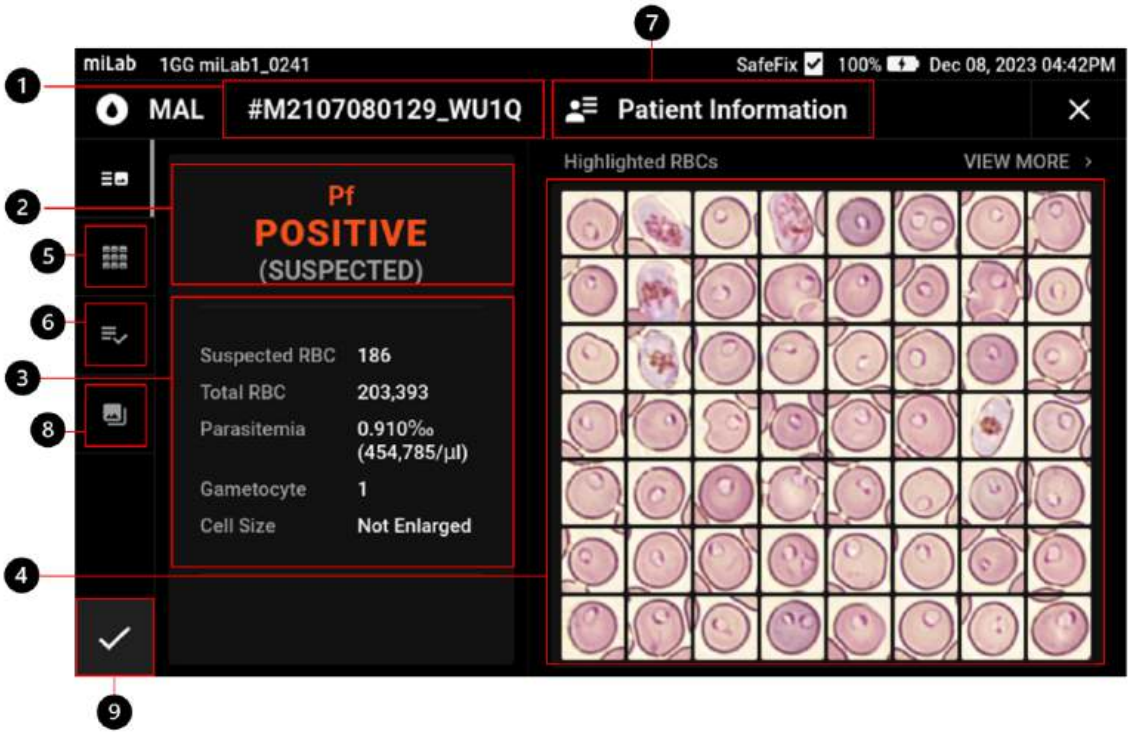
(An error popup is displayed 5 seconds after clicking the Start button if no cartridge is mounted.)

10. **Once the cartridge is inserted, the device will automatically begin the test.**



6.1.2. Result Page Overview

The main result page will be initially displayed on the device when the miLab completes the analysis or when the results are accessed from the history page.



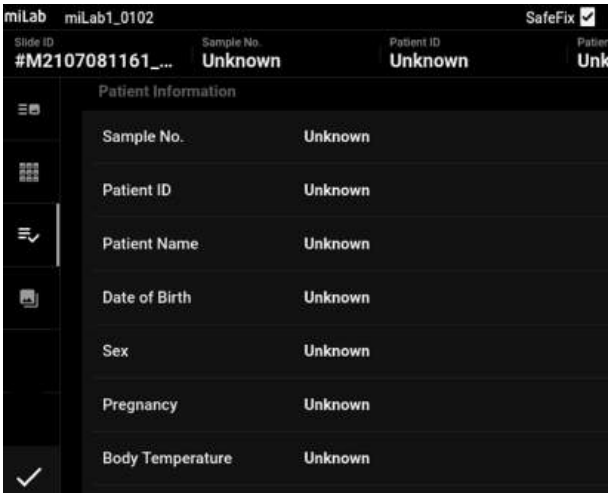
The main result page contains the following information:

① **Slide ID**

A unique serial number associated with the cartridge is used. The test date and time can be viewed by clicking on the Slide ID.

② **Patient Information (Sample No. Patient ID, Patient Name)**

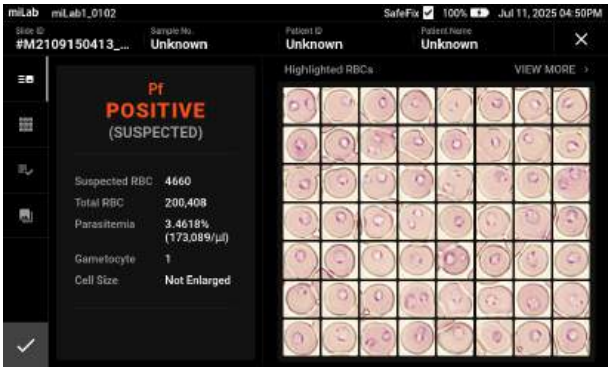
Clicking on Patient Information at the top of the screen or clicking the detail tab  icon allows for the review of previously entered patient information.

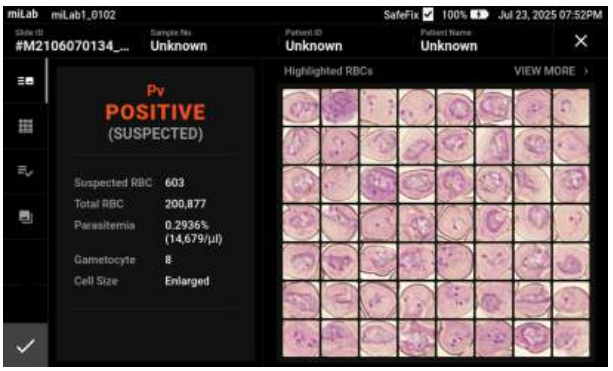


③ **Test result**

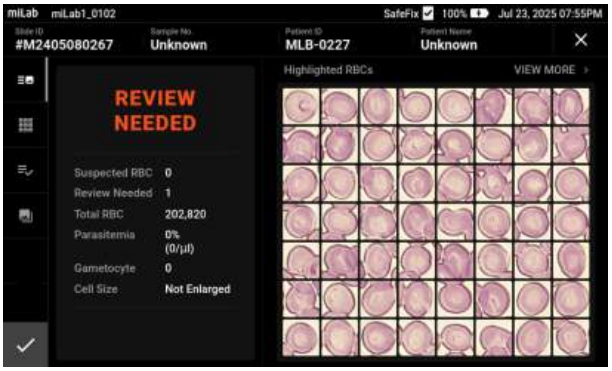
The malaria test result (by AI) is displayed as Negative, Negative Suspected, Positive Suspected, Review Needed (Optional), or No Image. Even if there is insufficient RBC count, the test results screen will display normally if a minimum single RBC is obtained. In the case of insufficient RBC count, a 'Insufficient RBC count due to oo~' note will appear at the results screen.

- **[NEGATIVE]** appears when a clear positive cell is not detected.
- **[NEGATIVE SUSPECTED]** appears no clear positive cells are detected, but there is an insufficient RBC count.
- **[POSITIVE SUSPECTED]** appears when clear positive cells are detected. AI may suggest *P. falciparum(Pf)* or *P. vivax(Pv)* as the suspected parasite type. Or AI just shows Positive(suspected) without species suggestion, which is the case when it is not possible to choose a species because of some reason, such as insufficient counted RBC.

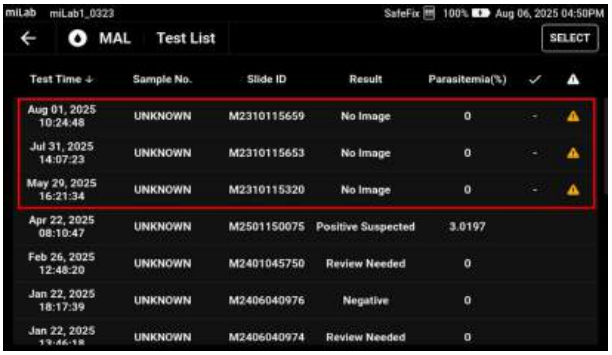




- **[REVIEW NEEDED]** appears when results show equivocal cells and a clear positive cell is not detected. After reviewing the 'Review needed' results, the user can select one of the options by clicking the confirm( ) button located at the bottom left.



- **[No Image]** If no image is available due to reasons such as device error, user abort, or early termination, the result will be displayed as 'No Image' and a [⚠] icon will appear.

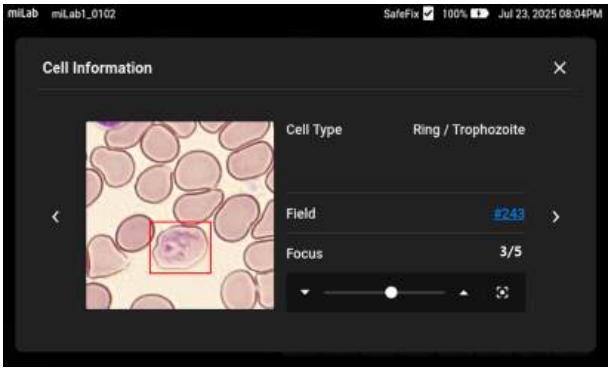


④ **Test Result in Detail: Suspected RBC, Total RBC, Parasitemia, Gametocyte, Cell Size**

- **Suspected RBC:** The number of red blood cells with suspected infection
- **Total RBC**: The total number of analyzed red blood cells.
- **Parasitemia level**: Parasitemia level is calculated in the units of % and parasites per microliter. Parasites per microliter calculated from user-entered RBC count (RBCs/µl). If the user does not enter the RBC count, the value is automatically estimated as 5 million RBCs per microliter.
- **Gametocyte**: If gametocytes are detected, their number will be displayed.
- **Cell size:** Based on the analysis results, it is indicated as either Not Enlarged or Enlarged. *6.1.3 Result Details*.

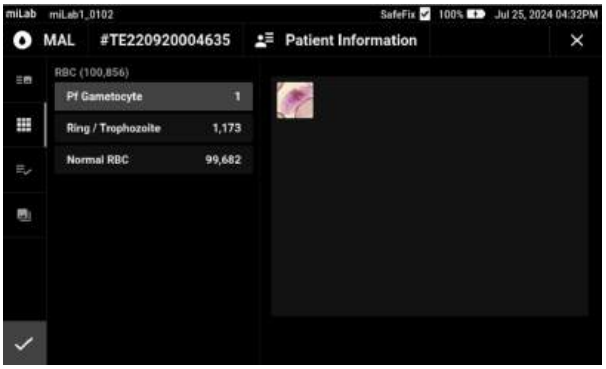
⑤ **RBC images**

Highlighted RBC images can be viewed. Click on a cropped cell image to show the cell information.



⑥ Cell Information( )

- The number of Normal RBCs can be seen, and if there are suspected cells, the number of suspected cells at each stage can be checked.
- All single-cell images can be viewed on the Cell Information page by flipping through the cell pages.

An example case of *P. falciparum(Pf)*	*An example case of P. vivax(Pv)*
 [Example of Pf Gametocyte]	 [Example of Pv Gametocyte]
 [Example of Pf Ring / Trophozoite]	 [Example of Pv Schizont]

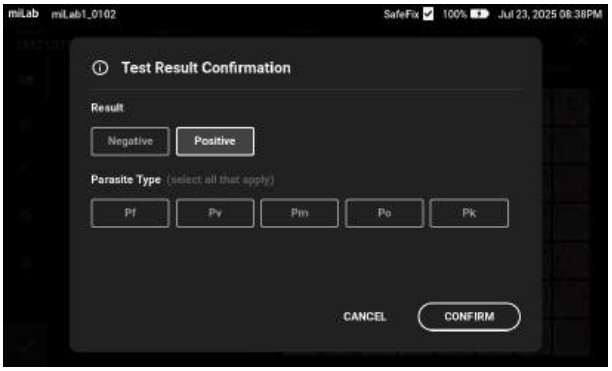
[Note] *If the specific stage cell is not found, the stage will not be displayed. This applies to both Pf and Pv.*	 [Example of Pv Ring / Trophozoite]

⑦ **Result Details**
View detailed analysis results. For further information, refer to *6.1.3 Result Details*.

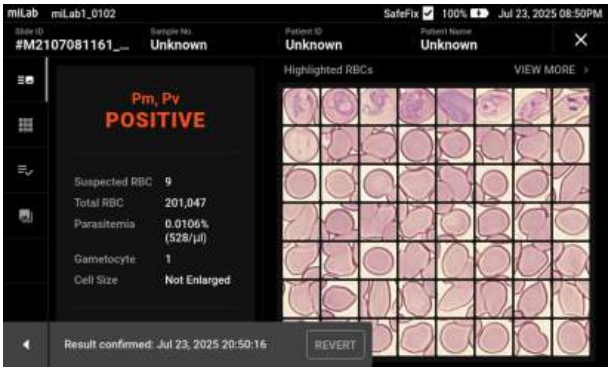
⑧ **Field Images**
View raw field images acquired by miLab. *6.1.4 Field Image Screen*.

⑨ **Test Result Selection and Confirmation**
After reviewing the image based on the AI-suggested result (positive/negative and species), click the confirm button (icon) to finalize the test result.

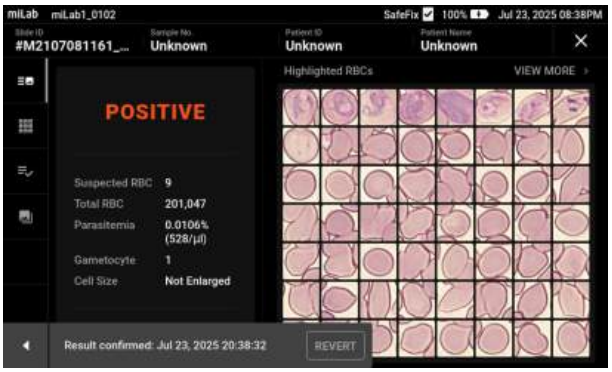
- If species differentiation is difficult, selecting only the 'Result' without a 'Parasite Type' will display the outcome as [POSITIVE].



- Save the test result as you confirmed by clicking [CONFIRM]
- Based on the user's review result, more than one species can be selected and the result page is shown like below.



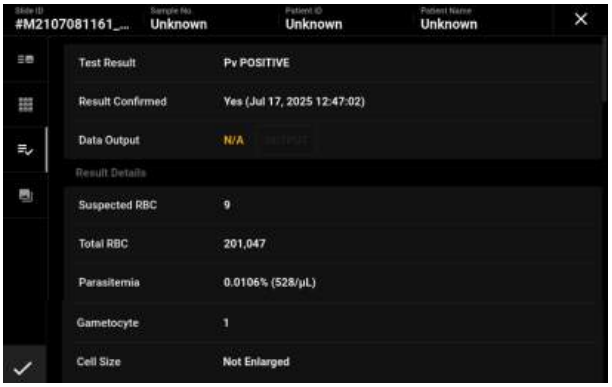
- In case a result revision is required after confirming the test result, click the [REVERT] button to re-confirm the result.

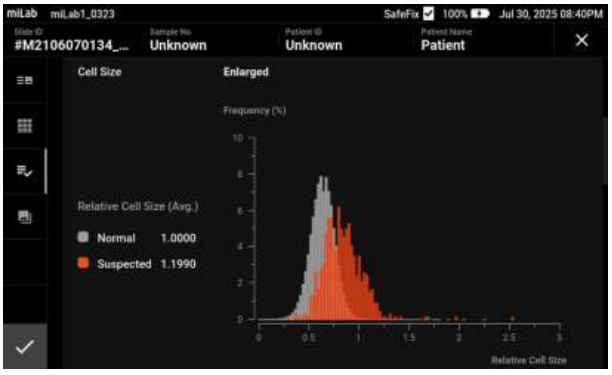


6.1.3. Result Details

detail tab(icon) from the result page. For a precise diagnosis, it's recommended to check the result details page.

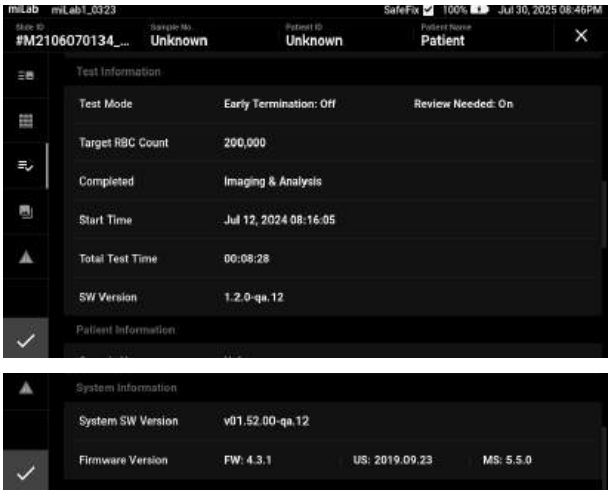
- Clicking the detail tab(icon) enables a comprehensive view of the **Result details**, including Test results, parasite type, suspected RBC number, Total RBC count, Parasitemia level, Gametocyte count, and cell size.
    - **Cell Size:** Based on the normal cell size, the degree of enlargement of infected cells is shown as a histogram.
        - Not Enlarged: The cell size is within the normal range.
        - Enlarged: The cell size is larger than the normal value.





- **Result Confirmed**: If users confirm the result, it shows ‘Yes’, otherwise it shows ‘No’

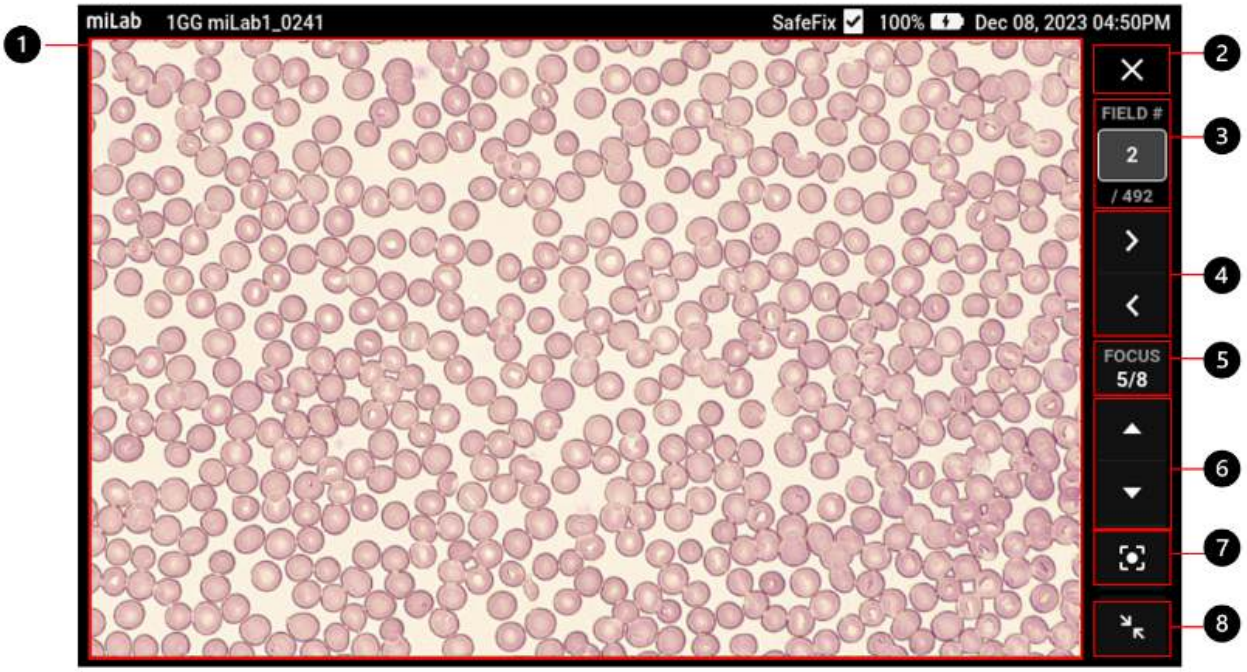
- Additionally, **Test Information,** including Test mode, Target RBC count, Completed, Start time, Total test time, and SW version, indicates the settings used and processes performed from Smear, Stain, Fix, and Imaging to analysis. **System Information** and **Patient Information (refer to 6.1.2. Result Page Overview -②)** can also be accessed.



- Only when the test is interrupted due to any issues Support Code will be displayed with the issue description and aborted status. Otherwise, this information will not be displayed.

6.1.4. Field Image Screen

By clicking the field tab(icon), the screen is shifted to the field images.



① **Main image window**
Displays the field-of-view image.

Function	Gesture
Zoom in/out	Pinch with two fingers
Move	Drag with one finger

② **Close**
Exit the field screen and return to the result page.

③ **Field image number**
Jump to a particular field-of-view image.

④ **Previous/Next image**
Move to the previous or the next field-of-view image.

⑤ **Focus level**
Displays the focus level of the particular field-of-view image.

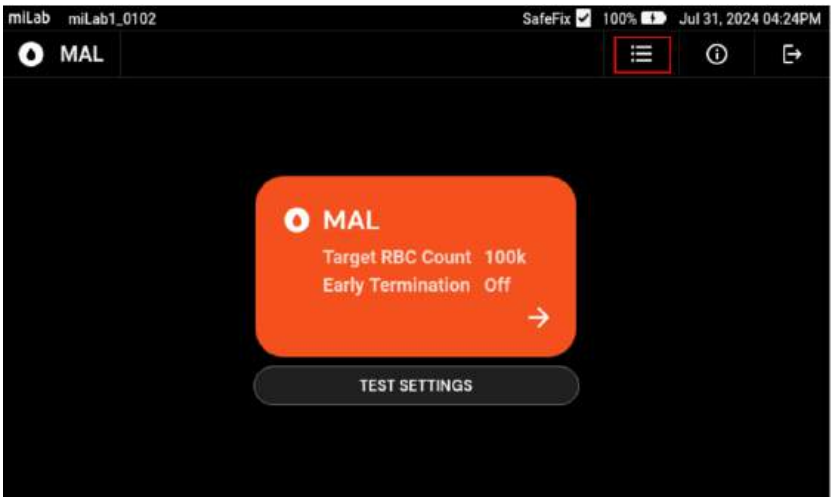
⑥ **Previous/Next focus level**
Move to the previous or the next focus level of the field-of-view image.

⑦ **Best focus**
Jump to the focus level with the best focus.

⑧ **Zoom to fit**
Zoom out to fill the entire window.

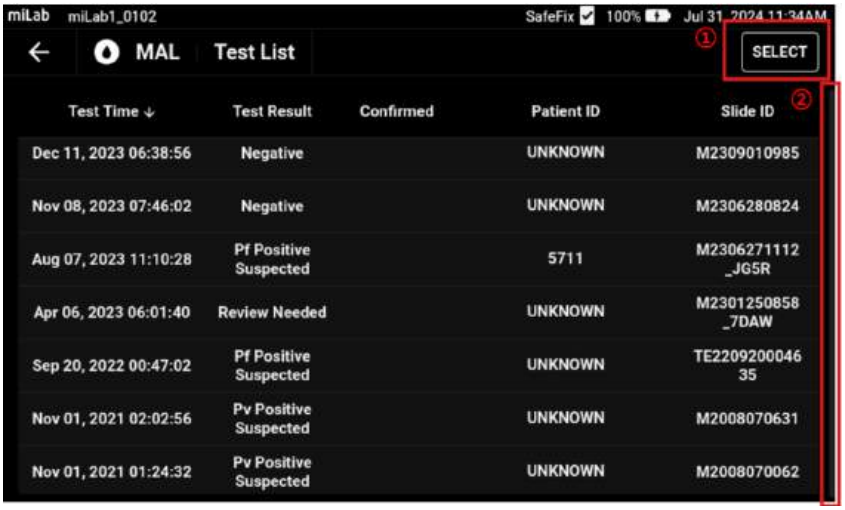
6.1.5. Result History

- To review the complete test history, users should press the button, which will display the subsequent screen.



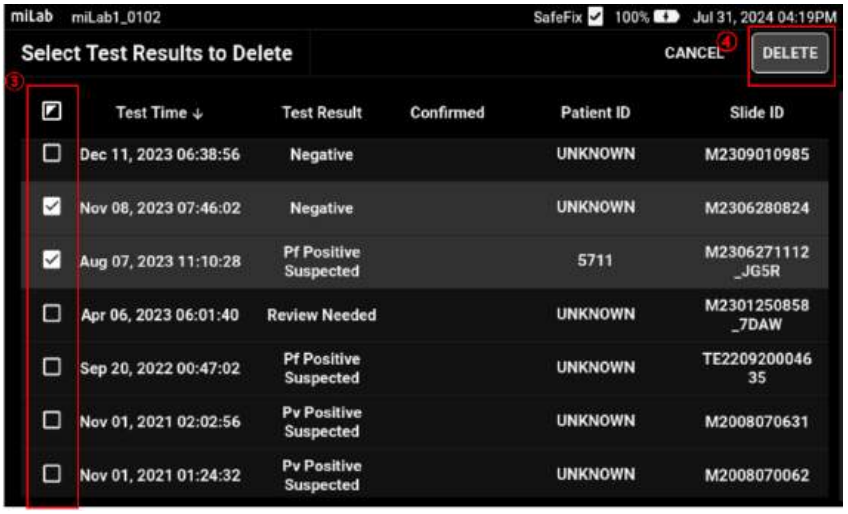
- Test time, Test result, Confirmed, Patient ID, and Slide ID can be checked in this history.

① SELECT: This button is used to choose a specific test to delete from the device.
② Scroll Bar: To navigate the list, a thin scroll bar is located on the right side of the screen.



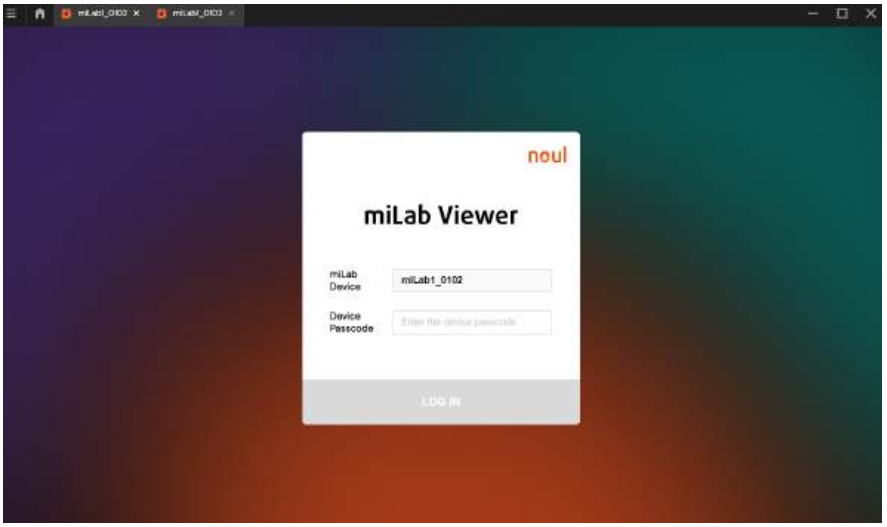
- After pressing the ‘SELECT’ button, check boxes will appear on the left side of the list, allowing specific tests to be selected for deletion.

③ Check box ( ): Specific tests can be chosen.
④ DELETE: After checking checkboxes, pressing the ‘DELETE’ button will remove the chosen tests from the device.



6.2. miLab Viewer login

1. **When a device is selected on the Viewer home screen, it switches to the login screen. The device number is automatically put in when you open the viewer by clicking.**
    a. When connecting via IP, you will be connected to the device with the specified IP address.
2. **Enter the device passcode, then click [LOG IN] and the  icon.**
    a. If the password is entered incorrectly more than five times, access to login from that IP address will be restricted. In such cases, please either reboot the device or wait for five minutes and try again.

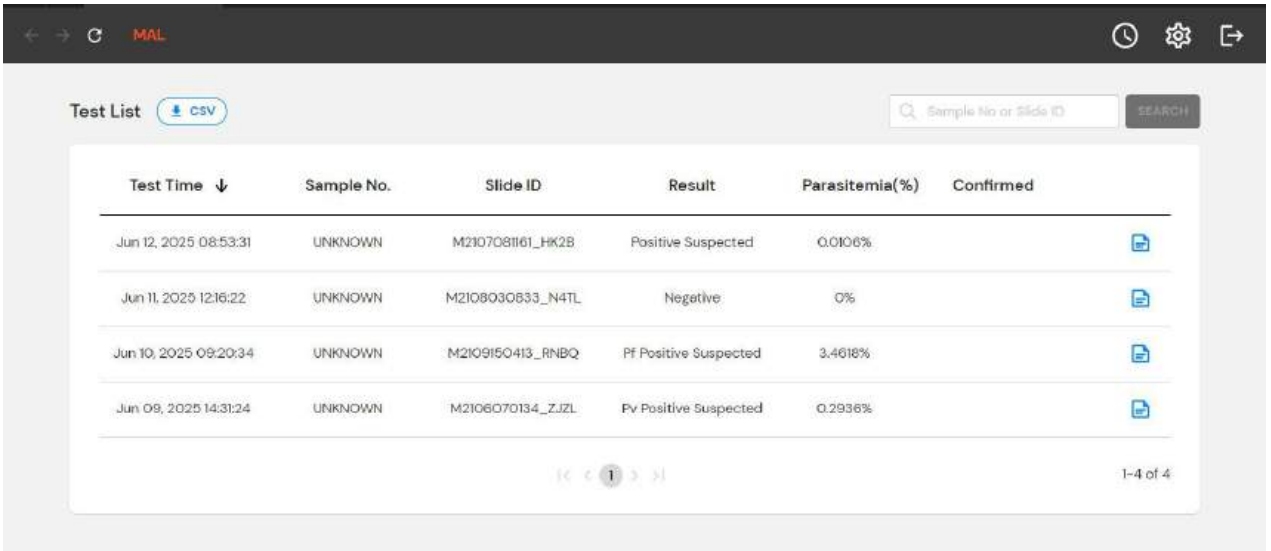


> ⚠ **Caution!**
>
> - If the access rights are not properly controlled, there is a risk of degrading system performance, and diagnostic examination may fail due to simultaneous access.

6.3. Test Result Data Review

6.3.1. Test List

Once logged into miLab Viewer, the main page titled [MAL] will display all previous tests.



The [MAL] page includes all test result data saved on the miLab device. Tests are added to the viewer list screen when they are completed or interrupted. For more detailed information, please refer to the documentation provided below.

1. **The [MAL] page displays the same information saved on the miLab.**
   - ① **Test Time**

Date and time of the test.

② **Sample No.**
The user may enter a sample No. during the test. If not entered, it will display as 'Unknown'.

③ **Slide ID**
The unique slide ID of the cartridge used for the selected test.

④ **Result**
Test results will be displayed. If the user confirmed the result differently, the confirmed result by the user will be displayed(When the test result is confirmed as Positive, the result will be displayed in orange color in the Result Tab. For more detailed information, refer to *6.3.2. Result Tab*).

⑤ **Parasitemia(%)**
The calculated percent parasitemia of the selected test.

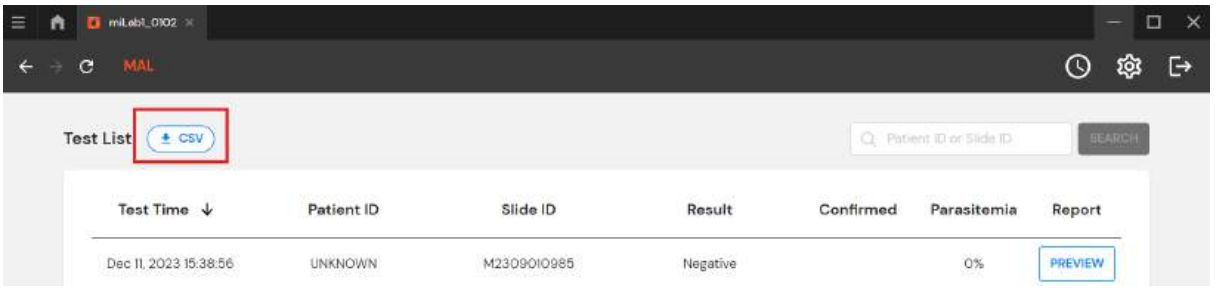
⑥ **Confirmed**
Confirm the status of the test result confirmation.
a. Checkmark (✔): Completed result confirm
b. Blank: Pending result confirm
c. Hyphen (-): Not available for result confirmation

⑦ **Report**
The summary of diagnostic results is accessible via the Report tab. Clicking the 'View Report' [ ] icon in the test list page will redirect users to the report preview page. For more detailed information, users may opt to save the report as either a Print or PDF document using the [EXPORT] button on the page. For more detailed information, refer to *6.3.4. Report Tab*.

2. Search for the test that you are looking for.

a. When you input numbers or letters in the search bar, the tests corresponding to the search criteria, such as Patient ID or Slide ID, will be displayed. If there are no matching results, "No search results" will be shown.

3. Download of test results



a. When more than one data result is available, the CSV icon becomes active.
b. Clicking the button at the top of the page allows you to bulk download the test results. After filtering data in the search box, clicking [CSV] will download only the results for the filtered test data.
c. The result items that can be checked in the CSV file are as shown in the image below.

Institution Name	Test Type	Patient ID	Slide ID	Test Time	Confirmed Time	Test Result	Presence of Gametocyte	Parasitemia (%)	Parasitemia (/μL)	Suspected RBC	Total RBC	Target RBC Count	Early Termination
CMC (Centre Medical Croze)	miLab Digital Microscopy	900215090012	#AYYMMDDNNN	Mmm DD, YYYY HH:MM:SS	Mmm DD, YYYY HH:MM:SS	Pf Positive Suspected	Yes	0.1	5,000	200	201,988	200,000	Off
CMC (Centre Medical Croze)	miLab Digital Microscopy	900215090012	#AYYMMDDNNN	Mmm DD, YYYY HH:MM:SS	Mmm DD, YYYY HH:MM:SS	Pf, Pv Positive	No	0.1	5,000	200	202,000	200,000	On

4. Click the test bar (e.g., Slide ID) to review test results in detail. For more information, refer to *6.3.2. Result Tab*.

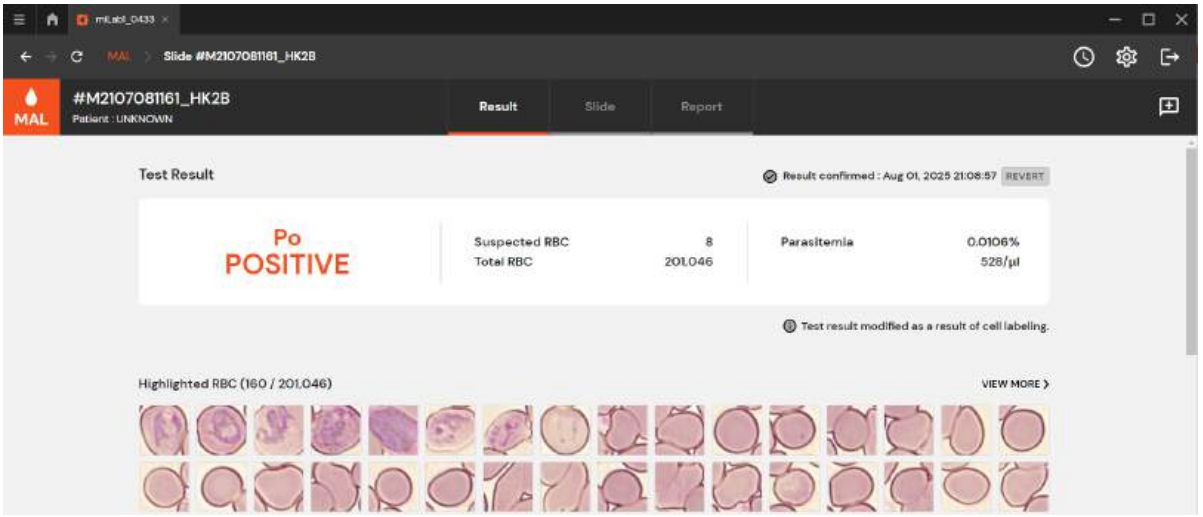
**When a test is in progress on the miLab device, a toast popup appears at the bottom right of the page. The popup automatically disappears when the test is finished.*
***If the test result has already been deleted in the miLab, you can't also review it on the miLab viewer.*

6.3.2. Result Tab

miLab utilizes AI to predict the class of the cells. The AI results can be Positive Suspected (Species Recommendation: *P.f* / *P.v*), Negative, Negative Suspected, Review Needed (Optional), or No Image.

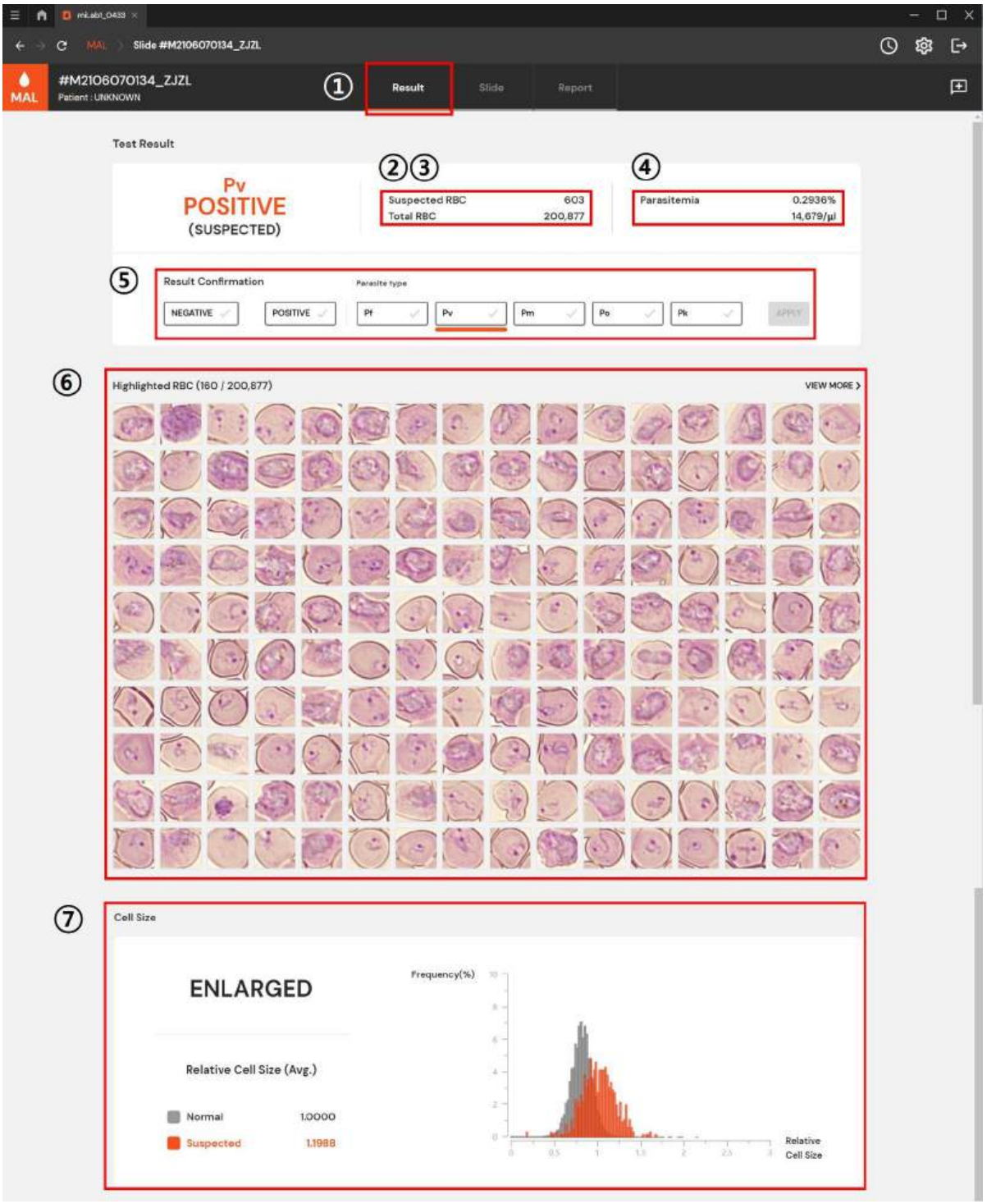
6.3.2.1. Result Confirmed in miLab

If the test result is already confirmed in the miLab device, it is shown below in the viewer. If you want to modify the test, click the [REVERT] button to revert it to the state before the confirmation.


Slide #M2107081161_HK2B
MAL
#M2107081161_HK2B
Patient : UNKNOWN
Result
Slide
Report
Test Result
Result confirmed : Aug 01, 2025 21:08:57
REVERT
Po
POSITIVE
Suspected RBC
8
Total RBC
201,046
Parasitemia
0.0106%
528/μl
Test result modified as a result of cell labeling.
Highlighted RBC (160 / 201,046)
VIEW MORE

6.3.2.2. (Pv or Pf) Positive Suspected

The following test result indicates a suspicion of *P.vivax* infection. As an example, we will provide detailed explanations of the results in this case. *(*Species Recommendation: P.f / P.v)*



1. **If the test result by AI is *P.vivax* Positive Suspected, the information is displayed as shown below.**

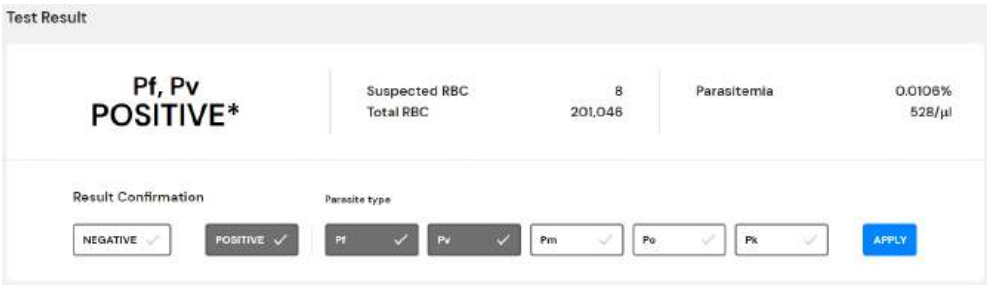
① **Result**
AI result is *P.v* Positive SUSPECTED.
If the AI results indicate *P.f* or *P.v*, an orange bar will be displayed below the species button.

② **Suspected RBC**
The number of infection-suspected RBCs for the selected test.

③ **Total RBC**
The total number of RBCs analyzed for the selected test.

④ **Parasitemia**
The calculated percent and per microliter parasitemia of the selected test.

⑤ **Result Confirmation**
You may choose as many malaria species(*P.f, P.v, P.m, P.o, P.k*) as possible (For the case of mixed infections). The button turns gray to confirm the selection.



To finalize the result, click the [APPLY] button.
**Cell labeling is not allowed after applying the result.*

a. After confirming the result, the date and time are displayed.
b. When you want to change the result, click the [REVERT] button. The test results will show the previous AI results and display the screen that was confirmed upon completion of the test.

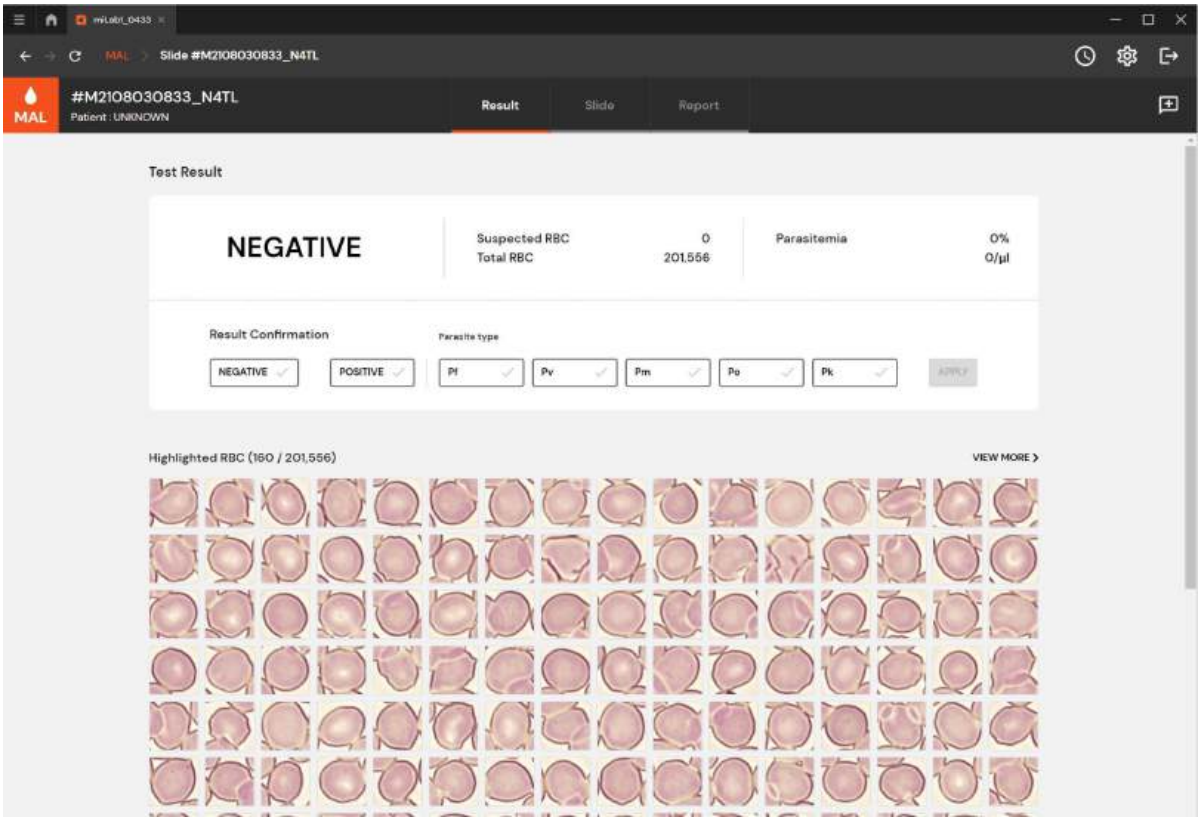
⑥ **Highlighted RBC**

To facilitate rapid review by users, the result tab allows for the display of up to 160 cells. If users wish to examine more cells, they can navigate to the cell tab to view the complete set of cells.

⑦ **Cell Size Histogram**
The cell size histogram will be displayed. The trend of cell size is expressed as ‘ENLARGED’ or ‘NOT ENLARGED,’ and both the numerical value and the graph can be confirmed simultaneously.

2.Click [VIEW MORE] or click the [Slide] Tab to check those cells in detail, and clicking a cell will take you to that cell in the [Slide] tab. For detailed information related to cell information, refer to *6.3.2.8 Slide Tab*

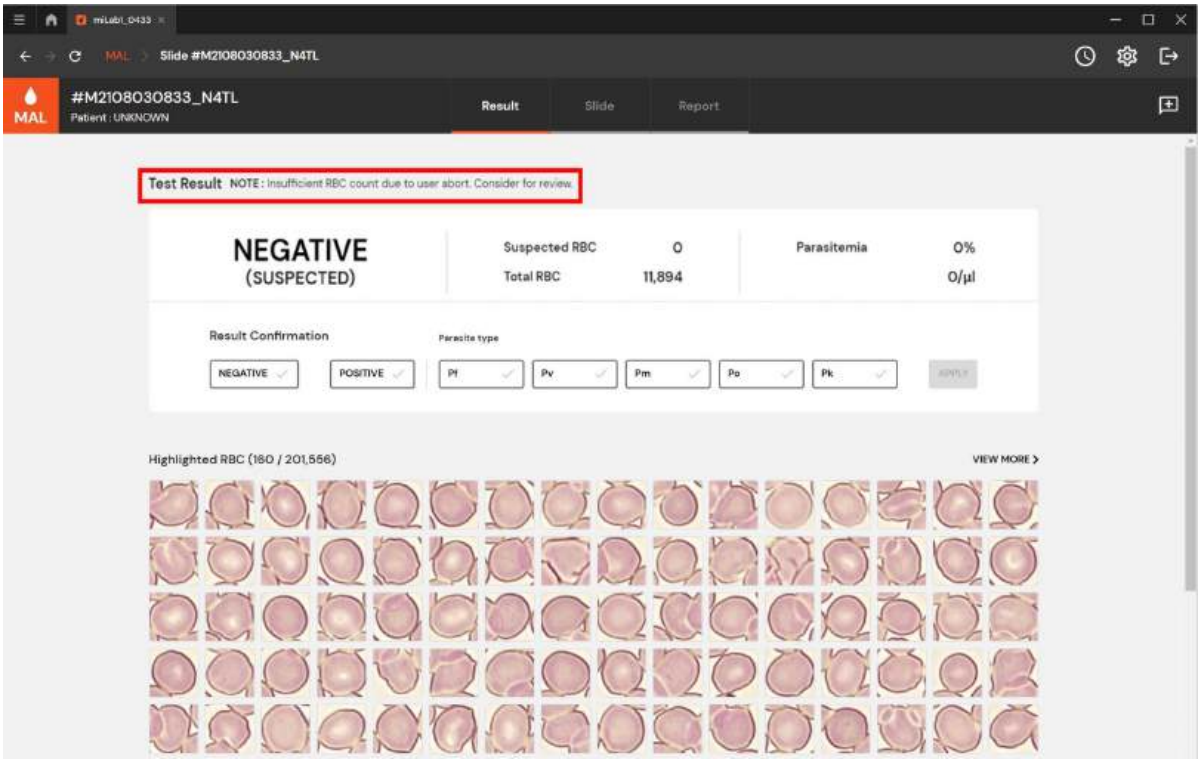
6.3.2.3. Negative



1. **If the test result by AI is Negative, the information is displayed as shown below.**
   - ① **Result**
     The AI Result is Negative.
   - ② **Total RBC**
     The total number of RBCs analyzed for the selected test.
   - ③ **Suspected RBC & Parasitemia are shown as 0**
   - ④ **Result Confirmation**
     This function is also available when the AI result is Negative.
   - ⑤ **Highlighted RBC**
     To facilitate rapid review by users, the result tab allows for the display of up to 160 cells. If users wish to examine more cells, they can navigate to the cell tab to view the complete set of cells.
2. **Click [VIEW MORE] or click the [Cell] Tab to check those cells in detail. For detailed information related to cell information, refer to *6.3.2.8 Slide Tab***

6.3.2.4. Negative Suspected

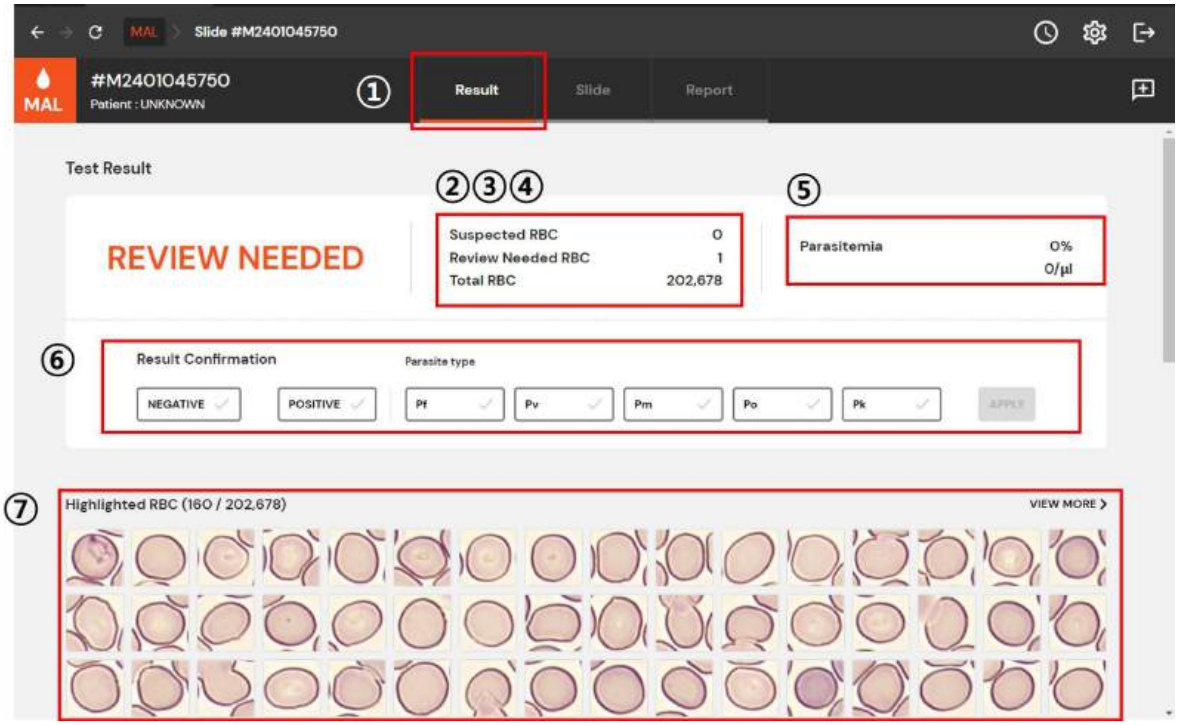
When the test result by AI is Negative, but the target RBC count set by the user is not achieved, it will be displayed as 'Negative (Suspected)'. The displayed information remains the same as when the result is 'Negative'.



6.3.2.5. Review Needed (Optional)

[REVIEW NEEDED] result is an optional function that can be turned on/off by the user. This setting is available in miLab. For detailed information related to the Review Needed, refer to 4.1.4. Result Page Overview.

If the result is Review Needed, it is recommended that you go to the [Slide] tab and check the cells classified as the [Review Needed] category. After reviewing and labeling, return to [Test Result] for result confirmation.



2. If the test result by AI is Review Needed, the information is displayed as shown below.

① **Result**
AI Result is REVIEW NEEDED.
**[REVIEW NEEDED] results appear in a situation where a clear positive cell is not detected and equivocal cells are found.*

② **Suspected RBC**
The number of suspected RBCs is displayed as 0 by default. It will be updated if the user performs reclassification. For more information about cell labeling, refer to *6.3.3. Cell Labeling*.

③ **Review Needed RBC**
Review-needed RBC represents the number of RBCs that require human inspections.
Any cells manually labeled as infected (e.g., *P.f* Ring) during the [Review Needed] session will be counted towards the suspected RBC.

④ **Total RBC**
The total number of RBCs analyzed for the selected test.

⑤ **Parasitemia**
Indicated as 0% in [REVIEW NEEDED].
**Parasitemia values will not be updated when cell labeling is checked.*

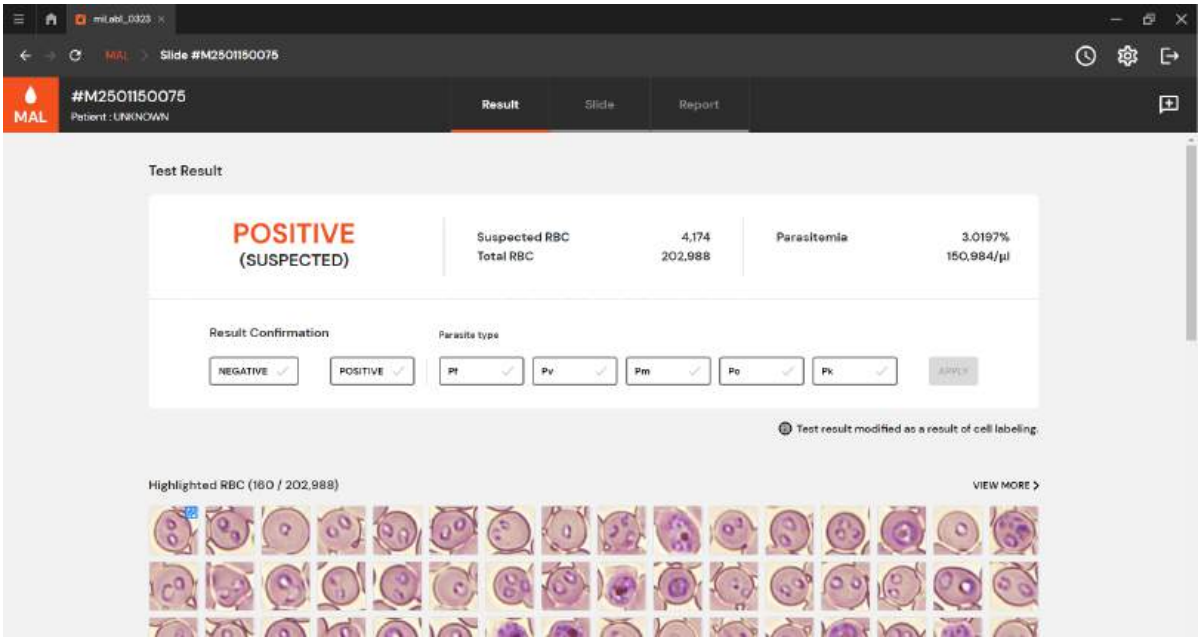
⑥ **Result Confirmation**
After confirming the result, the date and time are displayed.
**Cell labeling and Comment correction are not allowed after result confirmation.*

⑦ **Highlighted RBC**
To facilitate rapid review by users, the result tab allows for the display of up to 160 cells. If users wish to examine more cells, they can navigate to the cell tab to view the complete set of cells.

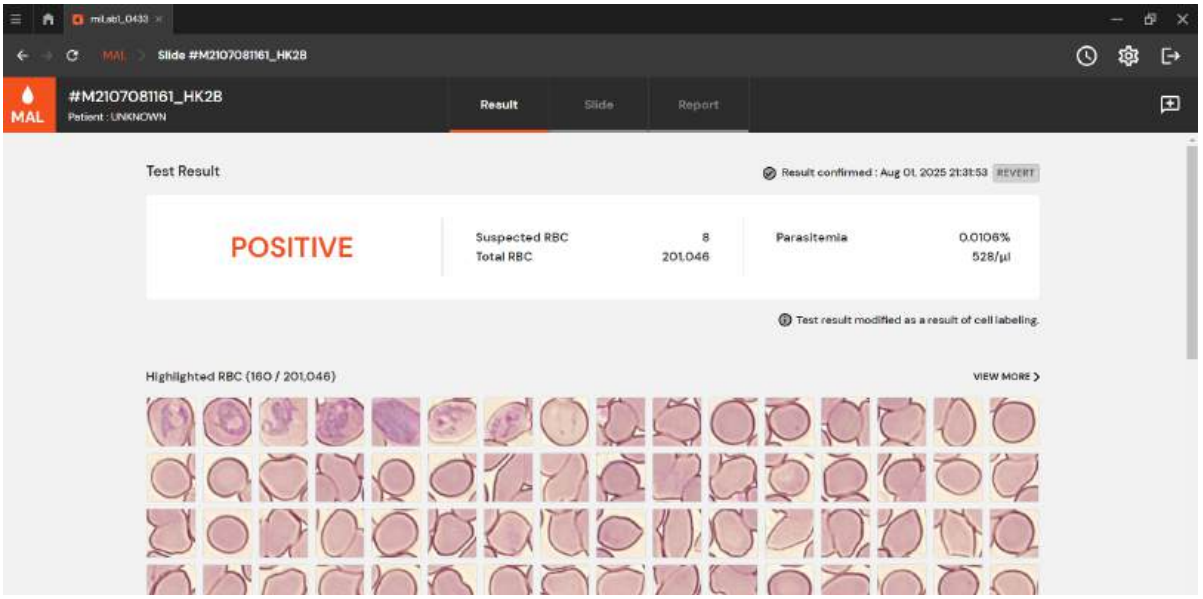
2. **Click [VIEW MORE] or click the [Cell] Tab to check those cells in detail. For detailed information related to cell information, refer to *6.3.2.8 Slide Tab***

6.3.2.6. Positive suspected

1. **If the AI detects infected cells but cannot specify the species, it is labeled as 'Positive (suspected)'.**



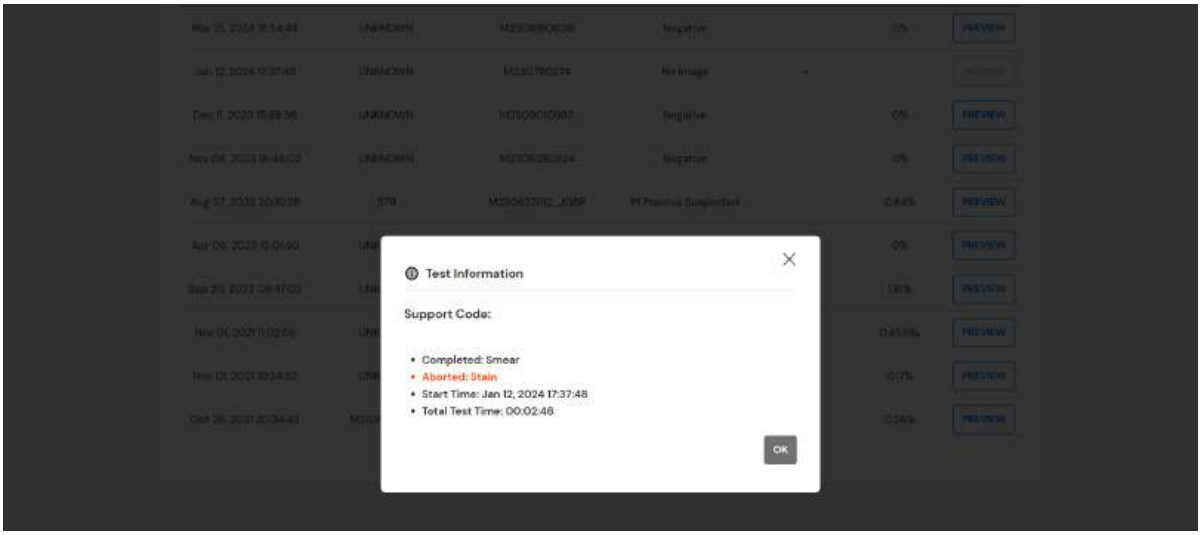
2. **When a user selects [Positive] on the test results page in miLab without specifying a species, the information is displayed as shown below.**
    a. If species differentiation is desired at a later stage, click the [REVERT] button at the top right corner, and the user can select the parasite type again.



6.3.2.7. No Image

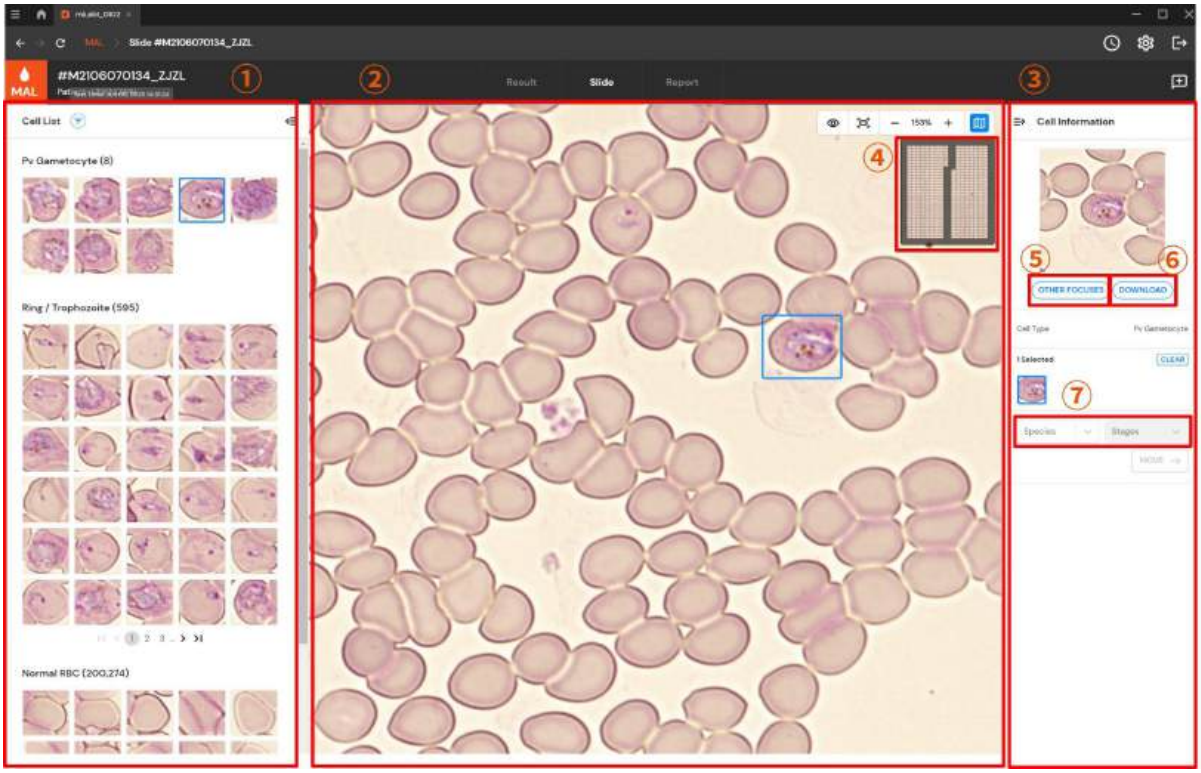
1. **If the number of RBCs counted by miLab is 0, the Viewer will display as below.**

2. **If click 'No Image' or any areas in the line, the message will be displayed as below.**



6.3.2.8. Slide Tab

In the slide tab, you can check the detailed cell information. In the [Slide] tab, the first cell of the first category is automatically selected and highlighted in the Field View.



1. **The [Slide] page displays the information as shown below.**

① **Cell List**

a. Cells detected by AI are categorized on the cell list panel on the left side of the screen.

b. Click the [FILTER] button, you can choose the cells' categories that you want to check.

② **Field View**

a. When you click a desired cell, you can see its field image.

b. On the field view, you can change the focus, zoom in/out, and turn the bounding box on/off.

c. Here, the stained and imaged area in the slide can be viewed at 1% scale to see the entire slide, and it can also be zoomed in up to 250%.

③ **Cell Information**

a. Cell information is displayed on the right side of the screen.

b. The user can check the cell type and the number of selected cells.
**If multiple cells are selected, the field view and cell information of the last cell selected will be displayed.*

④ **Mini Map**

The actual field image of the slide glass can be viewed on the minimap. When a cell in the [Cell List] is clicked, its location is also highlighted on the minimap.

⑤ **Focus bar and Other Focuses**

Click the [OTHER FOCUSES] button in the Cell information, and you can check the different focuses of the cell. And in the **Focus Bar**, you can see the FoV of different focuses. Clicking on [ ] will display the best focus.

⑤ **Download**
Click the [DOWNLOAD] button in the Cell information to download the picture displayed there.

⑥ **Cell Labeling**
There is a cell labeling function in the [Cell information] panel, so the selected cell can be classified into the desired species and stage. For more details, refer to *6.3.3. Cell Labeling.*

2. **After reviewing the cells, click the [Result] tab or Slide # to return to the [Result] page and confirm the test results. For detailed information, refer to *6.3.2 Result Tab.***

6.3.3. Cell Labeling

The [Cell Information] panel has a cell labeling function. Below is the step-by-step procedure to label the cells.

**If the test result is already confirmed, the [Cell Labeling] function will be disabled. Click the [REVERT] button in the Result tab to activate the cell labeling function.*

Step 1. Select a cell for labeling

The selected cell's information is displayed under [Cell Information].

Step 2. Select [Species] and [Stages]

Step 3. Click [MOVE]

The labeled cell is marked with a blue icon at the top right of the cell image, and a new [Modified Cell Type] is created in [Cell Information] in a separate column.

1. Original Cell Type: classified by AI
2. Modified Cell Type: saved as the latest modified type

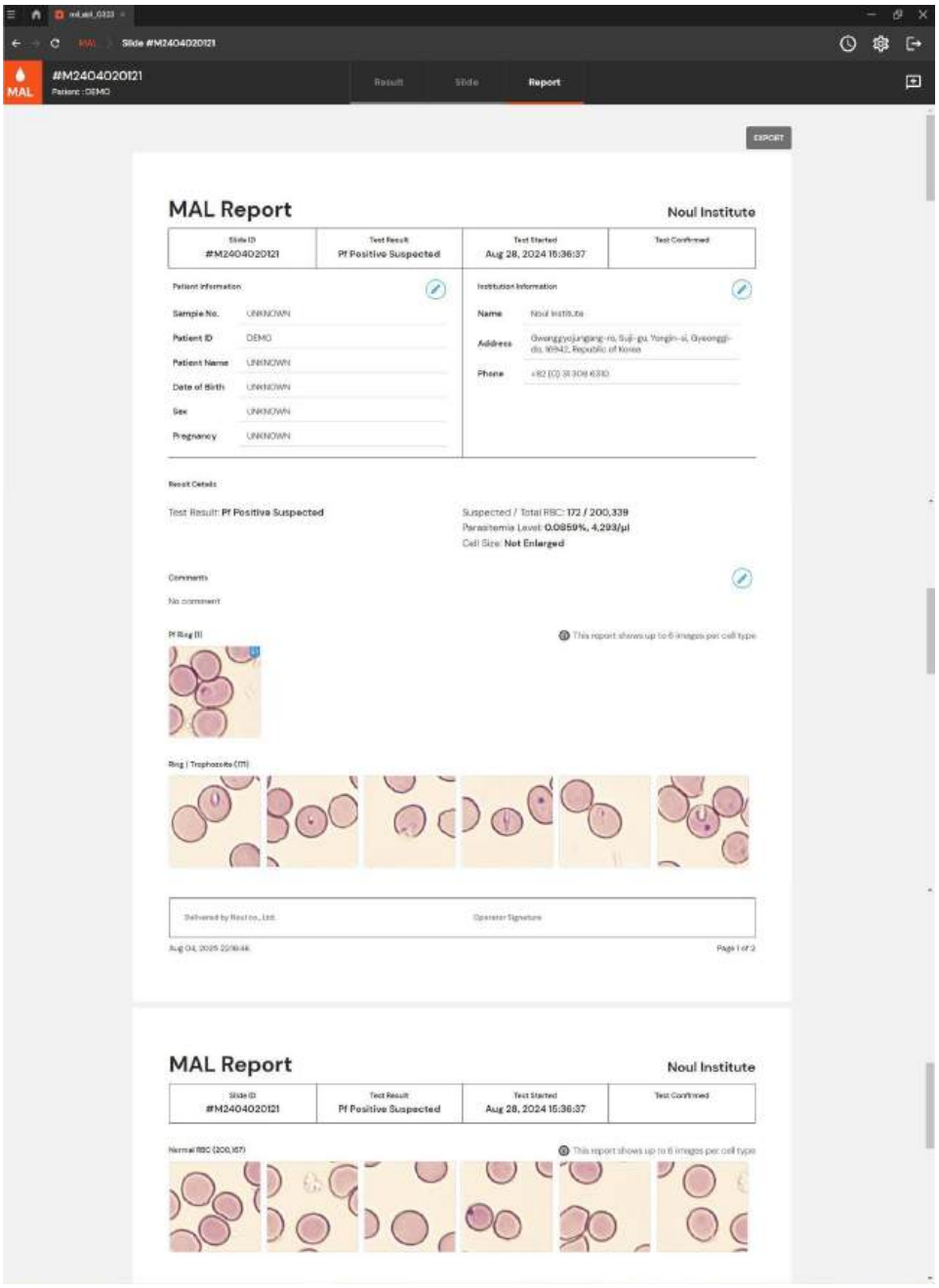
***Tips. Cell Multi-select**

Multi-select is possible by clicking the cells while holding down the Ctrl Key (Windows) or the Command key(Mac) for the labeling of multiple cells at once.

6.3.4. Report Tab

You can switch to the report page by clicking the [Report] tab or the report [PREVIEW] button in the test list. On this page, you can edit some of the Patient Information, Institution Information, and Comments in the Report tab.

You can also [EXPORT] the summary of malaria test results as a PDF file.

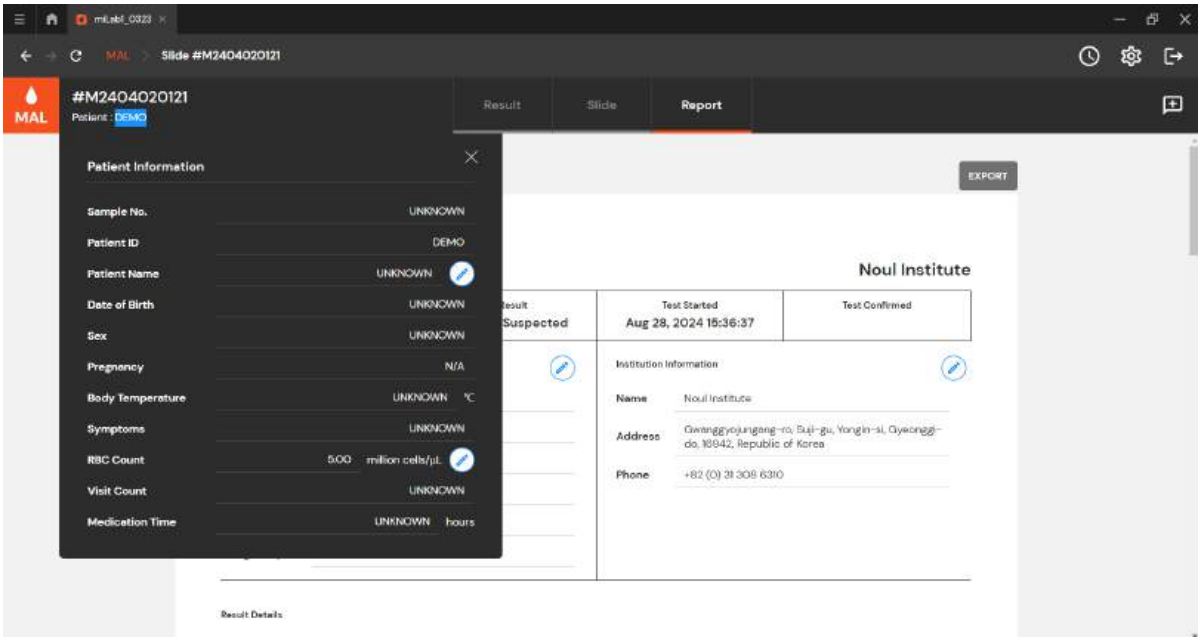


6.4. Detailed Functions

You can enter the patient name, institution name, and institution address that will be included in the report. The patient name is entered in the patient information for each test, and the institution name and address are entered for each device. This information can only be entered in the Viewer.

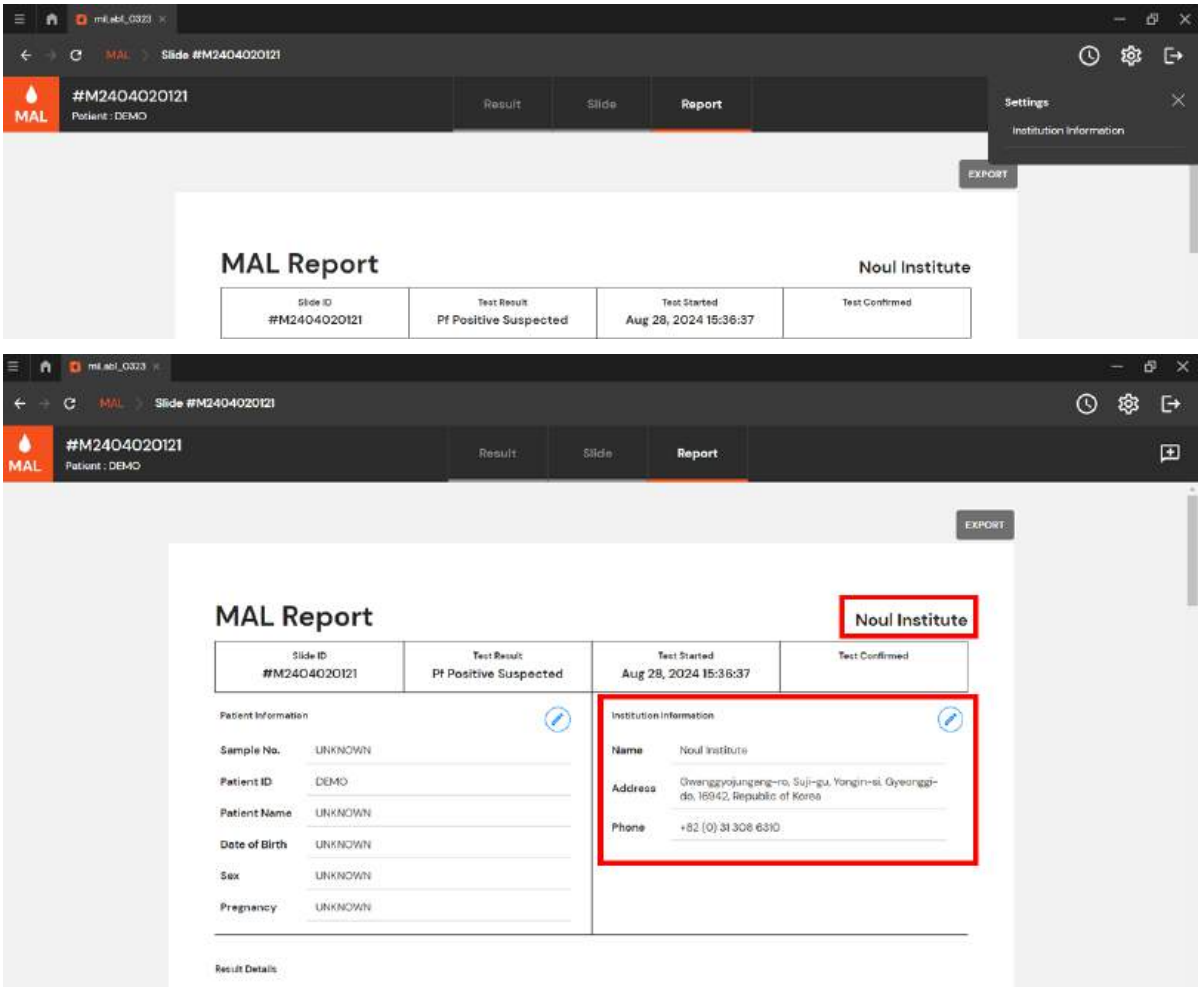
6.4.1. Patient Information

Click on the patient ID (e.g., UNKNOWN OR ID written by a user) to check the patient information.
**Patient Information is linked with information entered in miLab Device, and only 'Patient Name' and 'RBC Count' can be modified.*



6.4.2. Institution Information

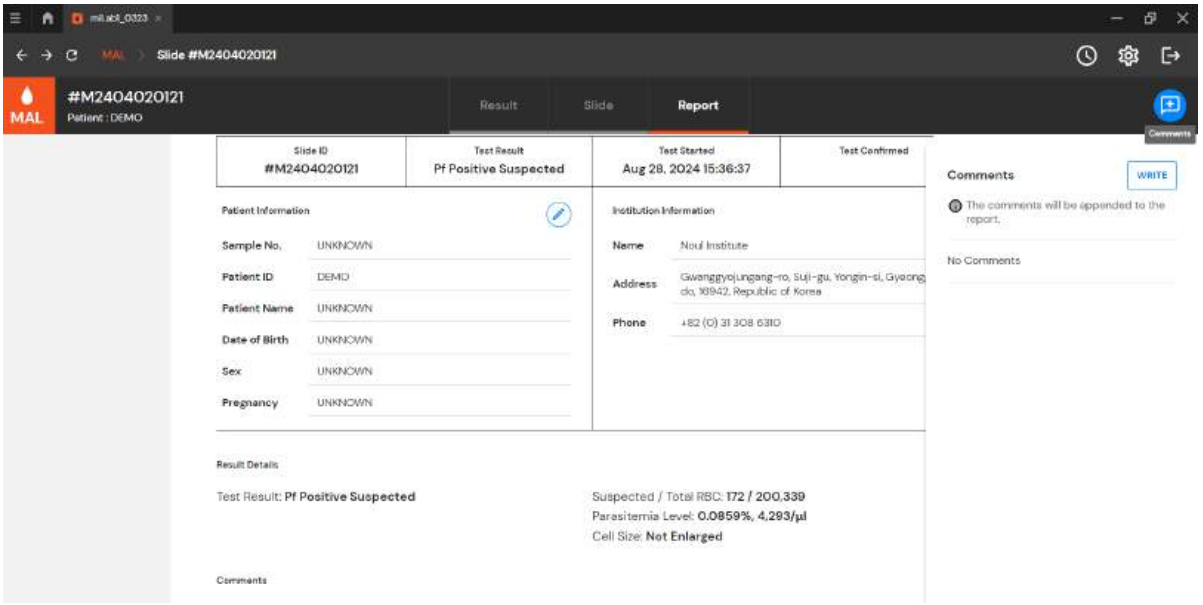
If you click the setting icon on the top of the screen, the [Institution Information] menu will be displayed. You can enter and edit institution information by clicking [Institution Information]. Written institution information will be included in the miLab Report like below in red (Refer to *6.3.4. Report tab*).



6.4.3. Comment

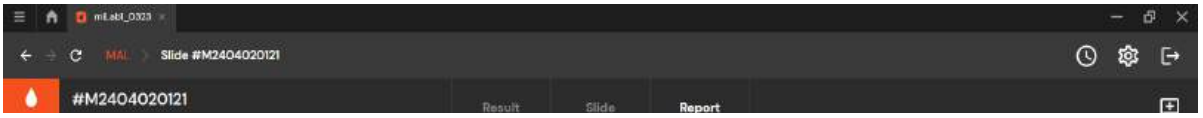
You can write by clicking on the comment icon(⊞). If there is a written comment, [DELETE] and [EDIT] buttons are created for its changes. Saved comments show the latest date and time modified.

**You cannot write comments if the test is confirmed. So, [REVERT] first to write comments.*



6.4.4. Back to List

Upon clicking the MAL button, you will move to the [Test List] page.



7. Specifications and Performance

Category	Specifications
Analytical Performance[1)]	- Precision(Reproducibility): 100 %(*N = 3) - Precision(Repeatability): 100 % (*N = 3) - Cut-off: 25.1 parasitemia/μL(N=120)
Clinical Performance[2)] N=341	Sensitivity: 90.51% (85.94% - 95.08%) Specificity: 98.36% (96.52% - 100.00 %) PPV: 97.95% (95.65% - 100.00 %) NPV: 92.31% (88.57% - 96.05%) Accuracy: 94.72% (92.35% - 97.09%)

N = Patient Number

1) Agreement of Decision = Decision Agreed Number/ Test Numbers*100%
2) Clinical sensitivity: TP/(TP+FN)*100, Clinical specificity: TN/(FP+TN)*100, PPV: TP/(TP+FP)*100, NPV: TN/(FN+TN)*100, Accuracy: (TP+TN)/(TP+FP+TN+FN)*100
   (TP: True Positive, FN: False Negative, FP: False Positive, TN: True Negative)

8. Parameters and Calculations

8.1. Parameters

The system provides an array of useful parameters, which are calculated from the measurement values of each sample.

Parameter	Unit 1(Default)
Malaria	%

8.2. Range

Parameter	Range
Malaria	100K : 0 ~ 101,000 RBCs/μl 200K : 0 ~ 201,000 RBCs/μl 300K : 0 ~ 301,000 RBCs/μl

8.3. Calculations

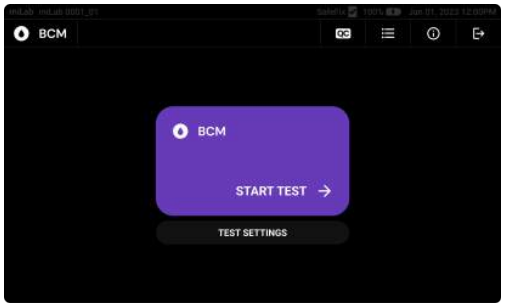
Parameter	Equation
Parasitemia (%, /μl)	1) Parasitemia (%) = ● The median value of suspected parasite counts on the thin film according to WHO Malaria Parasite Counting (MM-SOP-09) ● 20 FoVs surrounding the FoV where AI detected a positive cell 2) Parasitemia (/μl) = $\frac{\text{Parasitemia (\%)}}{100}$ x # of RBCs per μL of blood **The default value for red blood cell count is 5 million red blood cells per microliter.** Users can set the reference range for the number of red blood cells before starting the test. Refer to the patient symptoms image (#6) in 6.1.1. Operation Instructions for the miLab Device section.00

9. BCM Instruction details

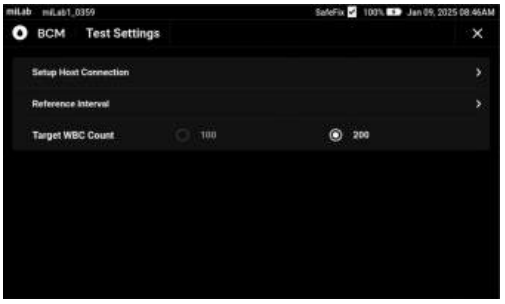
9.1. Test Procedures

Before Start the Test: Test Setting

- In the Test Settings menu, users can choose to 1) Setup Host Connection, 2) Set the reference interval range for the parameters tested, and 3) Set the target WBC Count for analysis.

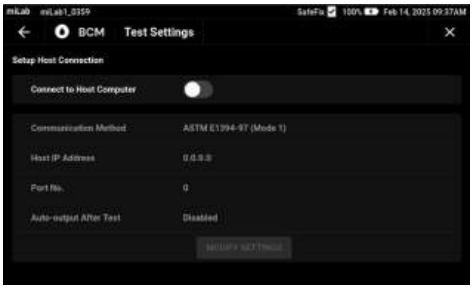


[BCM Screen]



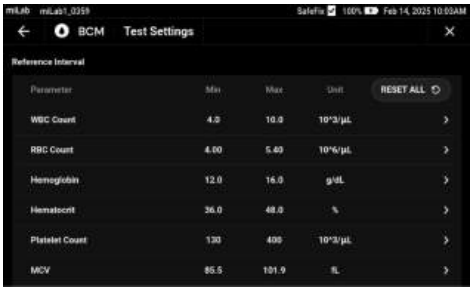
[Test Settings]

- For setting up the host connection, click on the 'Setup Host Connection' button and the screen will appear as below. ASTM E1394-97 protocol is supported. The connection to host computer can be turned on by touching the  button. It will turn blue when turned on. When the connection is on, the 'Modify Settings' button will turn blue as well so that the Host IP Address, Port No., and Auto-output after test can be set.



[Setup Host Connection]

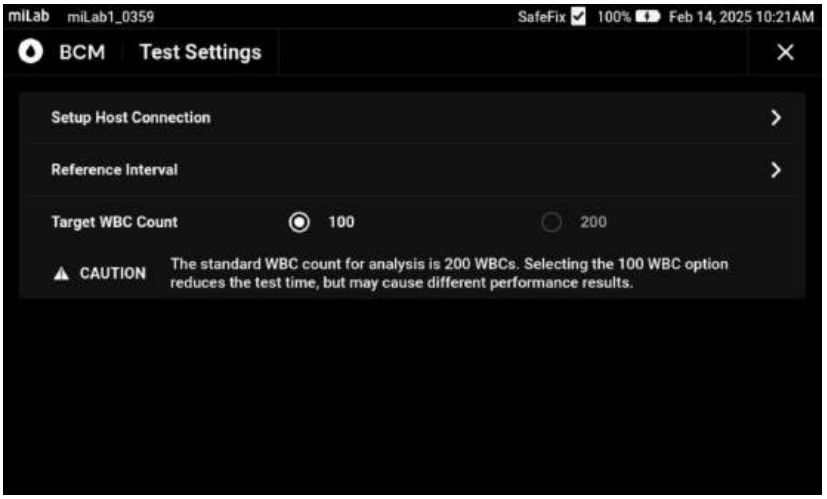
- Users can change the reference interval for the parameters whether the result values are within the normal range to adjust the normal and abnormal result displays of the Result page. To set up the reference interval, click on the 'Reference Interval' button and the screen will appear as below. Click on the parameter and a new screen will appear to adjust the values. Change the reference value and press the 'Apply' button to change the reference interval.



[Reference Interval]

[Change Value]

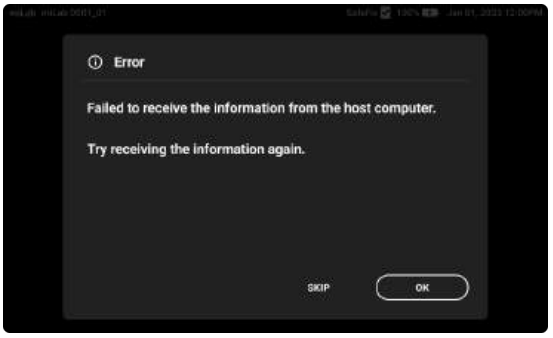
- Users can change target WBC count. The default target WBC count is set as 200 which is the standard. Changing the target WBC count to 100 will reduce the testing time however it may cause different performance results. The results from testing in 100 WBC count mode cannot be guaranteed.



[Target WBC Count]

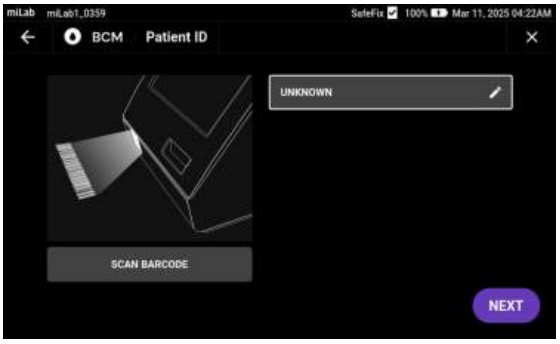
- To proceed to the Cartridge Preparation stage, enter or scan the sample number from the EDTA tube. The sample number can bring the information from your Laboratory Information System (LIS). The screen will display “Receiving Patient Information..” if it has successfully transitioned. Error message can appear if 1) LIS connection has not been setup, 2) Network has been disconnected, 3) There is no registered information in the LIS, 4) If there is no patient information. However, you can proceed to the Cartridge Preparation stage without entering a Sample Number, and the Sample Number will be automatically recorded as 'UNKNOWN'.

[Sample No.]

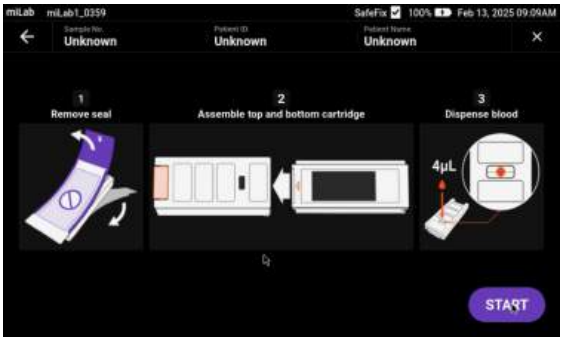


[LIS Error]

- Enter or scan the Patient ID. However, you can proceed to the Cartridge Preparation stage without entering a Patient ID, and the Patient ID will be automatically recorded as 'UNKNOWN'.
- If patient information from the host computer is successfully received in the [Sample Number] stage, [Patient ID] stage will be skipped and the screen will directly go to display the [Cartridge Preparation] stage.



[Patient ID]



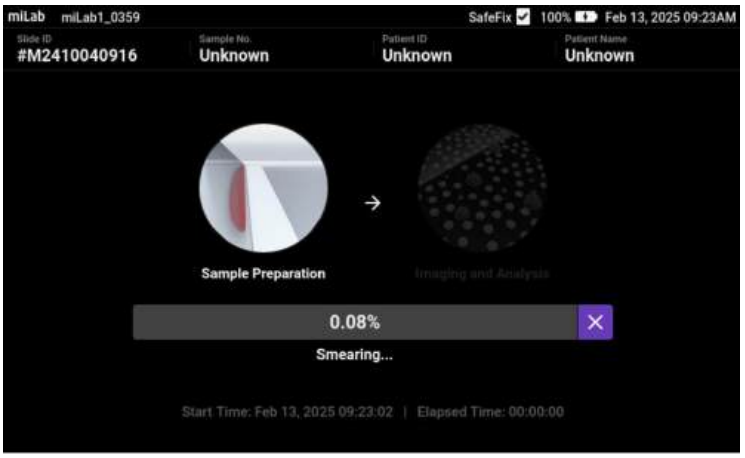
[Cartridge preparation page]

- After dispensing blood, **insert the prepared cartridge (Spreader film side first) immediately** into the device cartridge inlet until a whirring sound can be heard.
  a. A correctly inserted cartridge will be automatically pulled in.
  b. The internal barcode scanner will automatically read the barcode on the cartridge bottom assembly when correctly inserted.

> ⚠ Caution
> - A cartridge inserted in the wrong direction might result in a test or device failure.

[Insert cartridge page]

- Once the cartridge is inserted, the device will automatically begin the test. The status screen displays the elapsed time and current phase of the test with the Slide ID, Sample No., Patient ID, Patient Name information. If there is no information retrieved from the host computer, or the input phase was skipped, each of the patient information will be marked as Unknown.

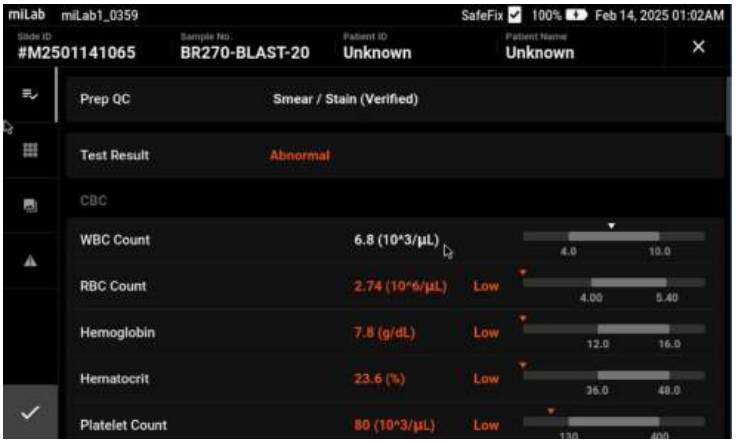


9.2. Result Details

1. Once the test is complete, the cartridge will automatically be ejected.
    a. Carefully remove the cartridge from the cartridge inlet.

2. The result page will be displayed.
    a. The results of CBC, WBC differential count(%, #, including Immature Granulocyte/Blast/Reactive Lymphocyte), nRBC(#), PLT Clumping(#), Smudge(#) and Artifact are shown on the screen as well as patient information, test information, system information and data output status to the host computer. The main result page contains the following information.
        ① Prep QC : The validity of smear and stain prep QC is shown.
        A. The Smear Prep QC may appear as “Needs Verification” if the adequate number of images are not acquired during the test process.
        B. The Stain Prep QC may appear as “Needs Verification” if 1) the stain color is different from the normal staining color.

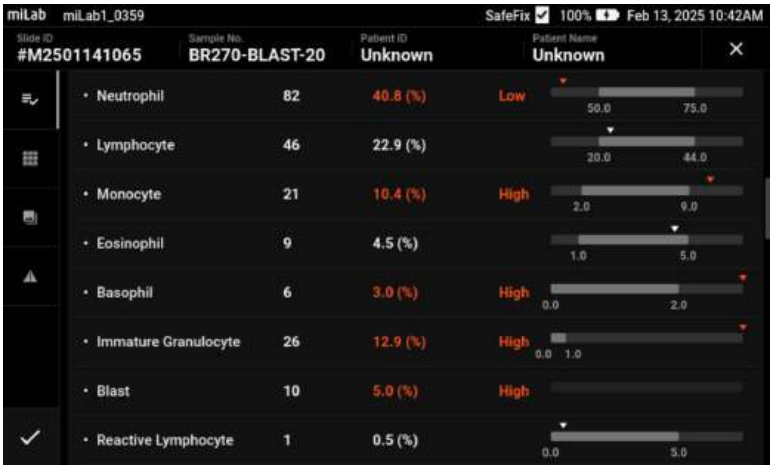
② Test Result : If the result is out of range from the reference range, it is shown as 'Abnormal'.(Tests results that are in range is shown as 'Normal')



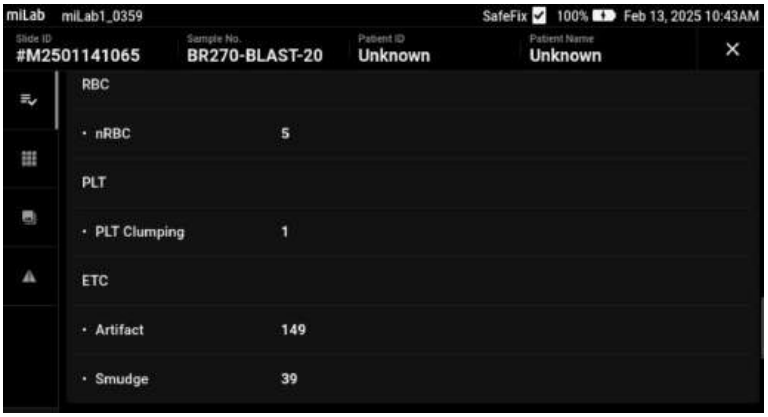
③ CBC: WBC Count, RBC Count, Hemoglobin, Hematocrit, Platelet Count, MCV, MCH, MCHC and RDW-CV are shown with numbers and indication of the result compared to the reference range with analyzed position information such as 'Low', or 'High'' in orange colored letters.

④ Differential count: WBC differential(Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophil, Immature granulocyte, Blast, Reactive Lymphocyte) count, %, and absolute values are shown with results numbers and indication of the result, compared to normal range bar with analyzed position information such as 'Low', or 'High' in orange colored letter.

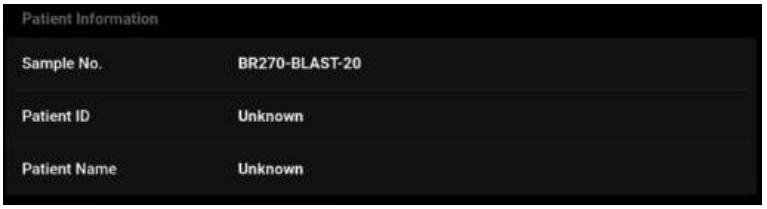
** Even if the test counts the total WBC as less than 200 and ends, it provides information to allow users to directly assess the WBC 5-differential results, displaying as (!) N/200.*



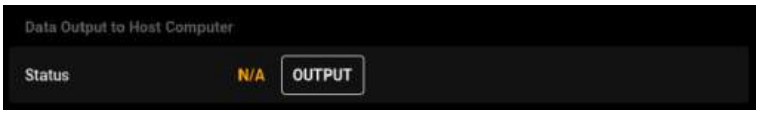
⑤ nRBC, PLT Clumping, Etc.: The counted number of nRBC, PLT clumping, Smudge and Artifact are shown below. In this result, only the counts are shown.



⑥ Patient Information: The patient information received from the host computer or the information manually entered on the device are shown on this tab.

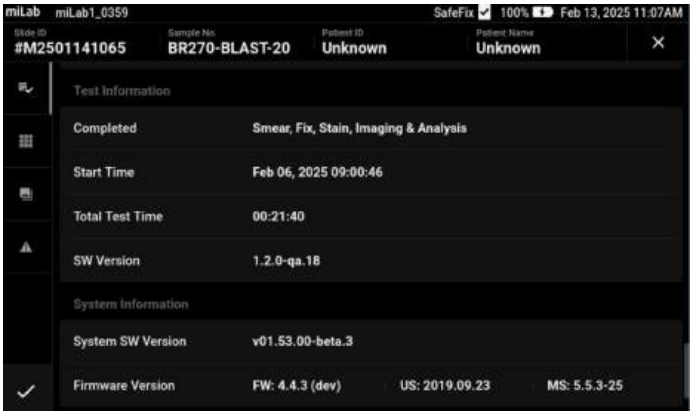


⑦ Data output to host computer: If the test result has been successfully sent to the host computer, it will display as ‘Completed’. If it was not successful, it will display as “Failed”. If the LIS connection was not made at all, it will display as “N/A”. If the host connection is turned on, [OUTPUT] button will be activated. Pressing the button will send the data to the host computer.



⑧ Test Information: The information of test stages done successfully, test start time, total test time and software version are shown. If the test was aborted or not properly completed due to some reason, this tab will also provide the information on what was the issue to test abortion, at which phase the test was aborted, and the error codes will be displayed.

⑨ System information: System software version and firmware version are shown.



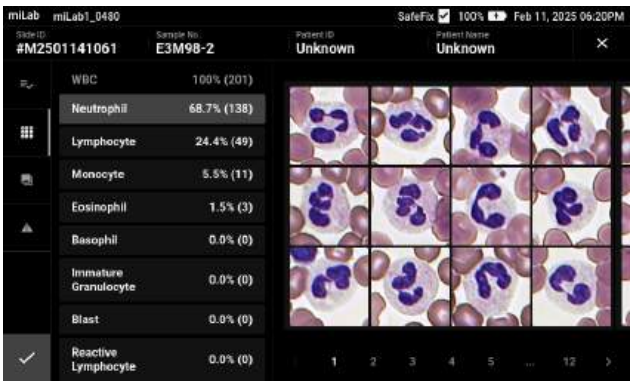
b. The image results of WBC (WBC 5-part differential, Immature Granulocyte, Blast, Reactive Lymphocyte), including nRBC, PLT clumping, smudge, and artifact, are shown if you go to this tab  at the left side bar. This result page contains the following information:

① WBC Differential: Displays the ratio of each of the WBC 5-differential, abnormal WBCs including IG, Blast, Reactive Lymphocyte, and any custom/default cell type that may be created under the WBC tab(from miLab Viewer), out of a total of 200.
** The Neutrophil count combines band and segmented neutrophils.*
*** Due to rounding reasons, the total may not add up to exactly 100%.*

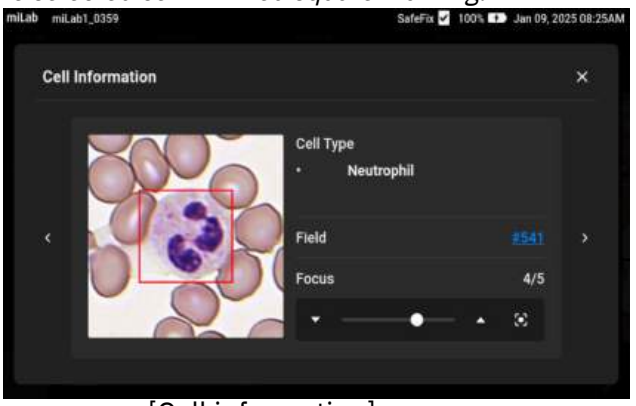
② WBC Count: Displays the count of each of the WBC 5-differential, IG, Blast, Reactive lymphocyte, and any custom/default cell type that may be created under the WBC tab (from miLab Viewer).

③ Cell Morphology: Shows images of all images acquired as listed above.

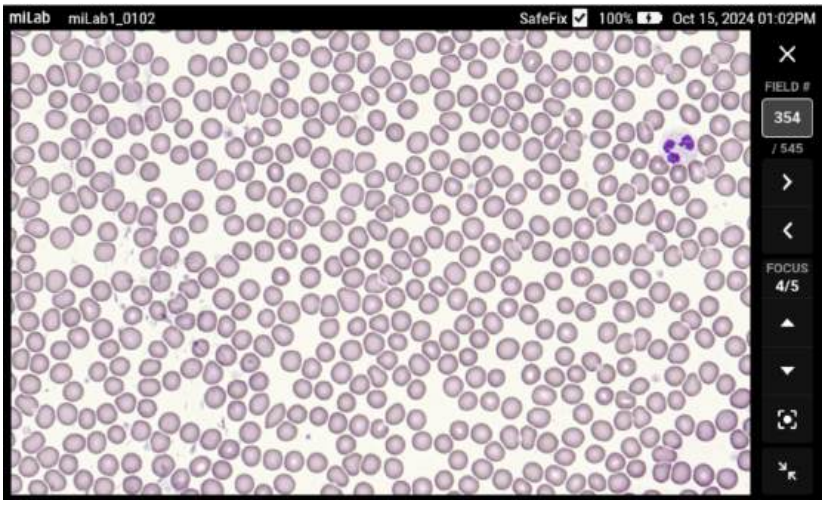
④ Cell information and Field Images: If you select one of acquired cell images, you can check basic cell information such as cell type, field number and focus with the selected cell. And if you select the field number, then the field view is shown up.
**In the field view, the SW marks the selected cell with red square marking.*



[Image results]

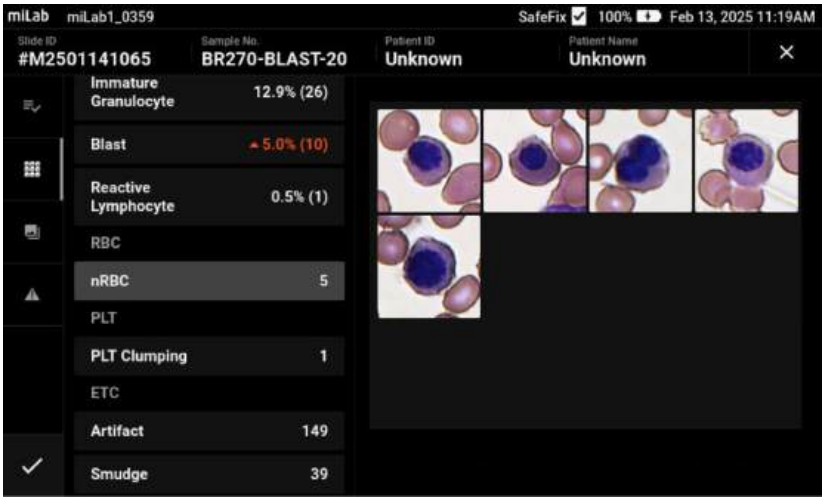


[Cell information]



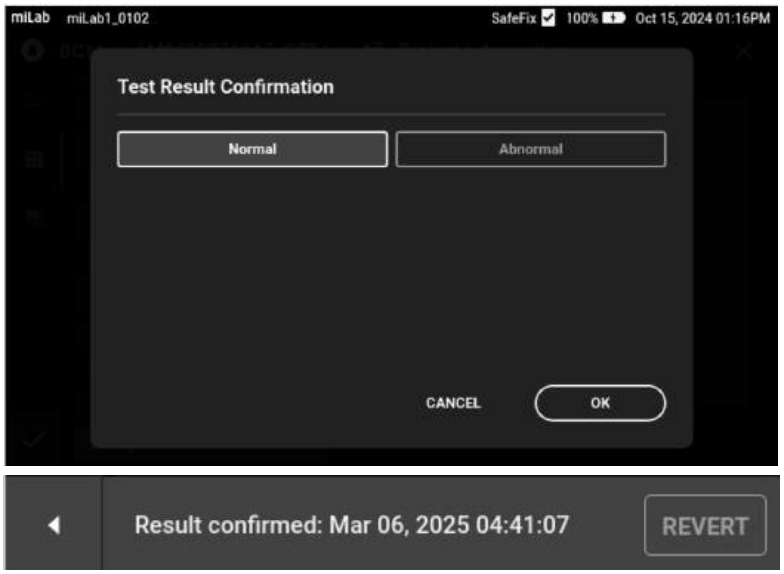
[example of field view]

⑤ The acquired Images of nRBC, PLT clumping, smudge and artifact are shown with the count of each image.



⑥ Confirm: Confirm the result (available on both device and viewer). The confirm button is on the bottom of the left sidebar as check mark ✓.

Users can confirm the test result by selecting the result as “Normal” or "Abnormal" and then clicking the 'OK'' button located in the top right corner of the summary tab. Users can make the test confirmation or reopen it by folding or unfolding it. If you want to modify the test, click the [REVERT] button to unconfirm the test result.

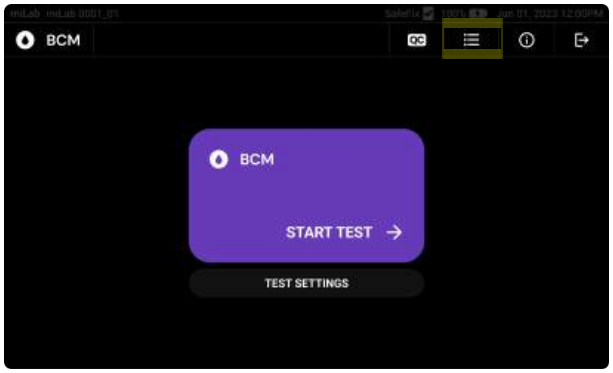


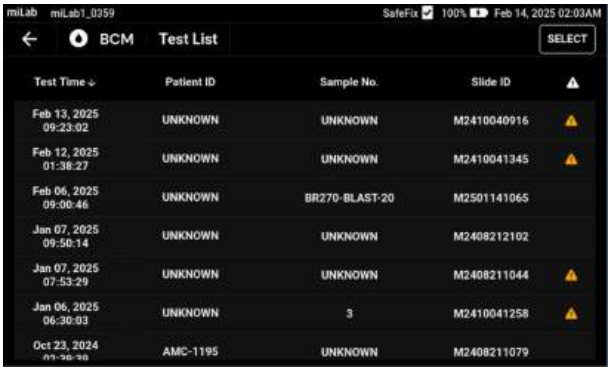
** The confirmation status of the results within the miLab device affects the functionality of 'Cell labeling' and 'Custom cell type' within the miLab Viewer.*

c. The results for each CBC, WBC differential count will be interpreted as normal, low, or high based on the **Reference Interval** set in the device. The default setting may be modified. For more details on modifying the reference interval, please refer to *9.1. Test Procedures*

9.2.1. Result History (Test List)

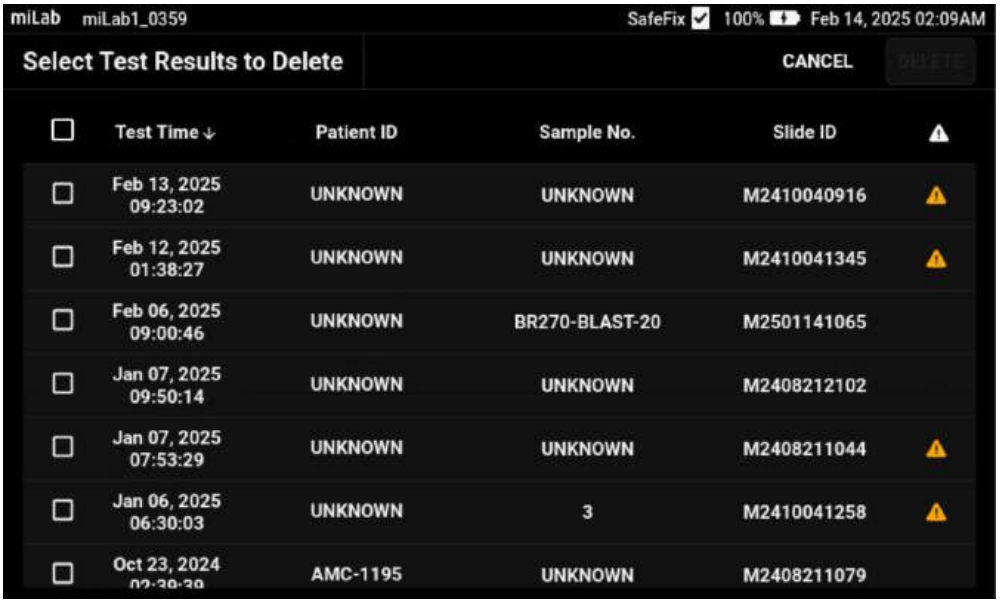
- To review the complete test history, users should press the  button, which will display the subsequent screen.





- Test time, Patient ID, Sample No., Slide ID and Warning sign is displayed.
- Clicking a specific test will move the screen to the detailed test results of the relevant test.
- Warning signs appear when 1) No image was acquired, 2) Prep QC needs verification, 3) If test result output to the host computer failed.
- To delete a specific test, the following steps can be performed :

  ① SELECT: This button is used to choose a specific test to delete from the device. You may scroll the test results upward or downward by touching the screen to scroll through the test results.



- After pressing the ‘SELECT’ button, check boxes will appear on the left side of the list, allowing specific tests to be selected for deletion.

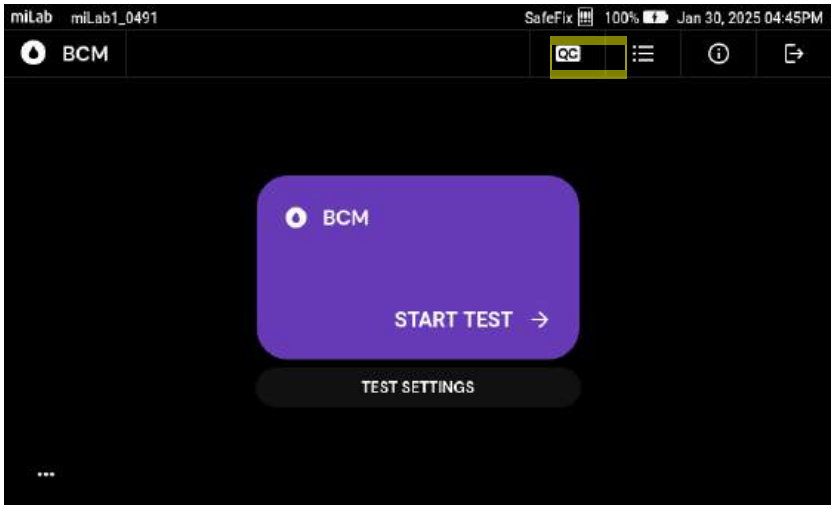
  ② Check box (): Specific tests can be chosen.

③ DELETE: After checking checkboxes, pressing the ‘DELETE’ button will remove the chosen tests from the device.

9.3. QC Mode Activation

Step 1: QC Mode Activation

1. Enter **BCM test mode**.
2. Select the **QC mode** by clicking the QC icon.



Step 2: Register the QC Slide

1. Press the **Register Slide** button.
2. Scan the **Material QR Code** on the Assay Sheet.
3. Verify that the slide ID, type, expiration date, and material level are correctly registered.

noul

miLab™ BCM QC Assay Sheet

Material
miLab™ BCM Control Level 1

Expire Date
2025. 12. 31

Lot No.
50125020700002

Parameter	Mean	Limit	Upper Limit	Lower Limit
Total WBC count	1.7	0.6	2.4	1.1
Total RBC count	4.62	0.19	4.81	4.43
Hemoglobin	10.0	1.2	11.2	8.8
Hematocrit	34.3	2.2	36.5	32.1
Platelet count	92	16	108.0	76
MCV	74	5	79	69
MCH	21.5	2.8	24.3	18.8
MCHC	29.1	2.3	31.3	26.8
Neutrophil (%)	39.4	19.1	58.5	20.3
Lymphocyte (%)	56.7	18.3	75.0	38.4
Monocyte (%)	1.6	1.6	3.1	0.0
Eosinophil (%)	1.1	1.1	2.1	0.0
Basophil (%)	1.0	1.0	2.0	0.0

Material QR Code

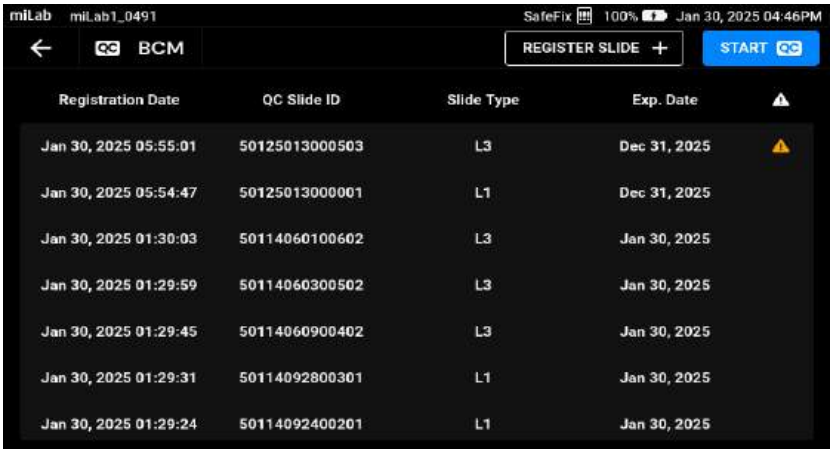
Disclaimer for QC Demo & Prototype Data Sheet:

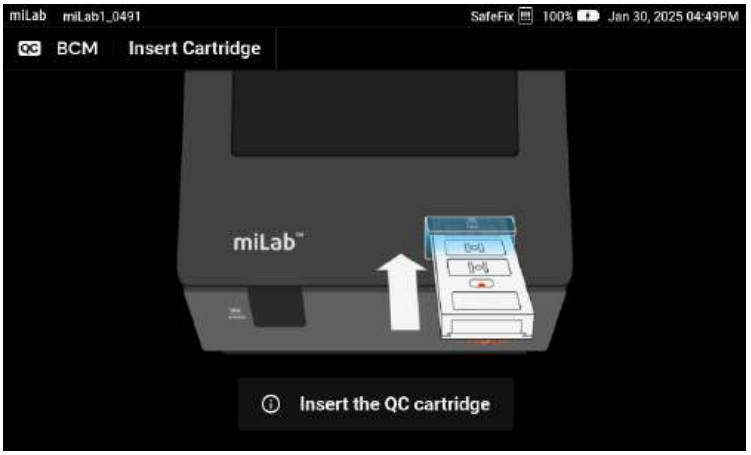
This QC material is intended for demonstration purposes with a prototype device.
The data presented in this sheet may differ from that of the final commercial product.
This information is provided for reference only and should not be used for diagnostic or clinical decision-making.

Distributed by: Noul Co., Ltd.
Issued: February 7, 2025

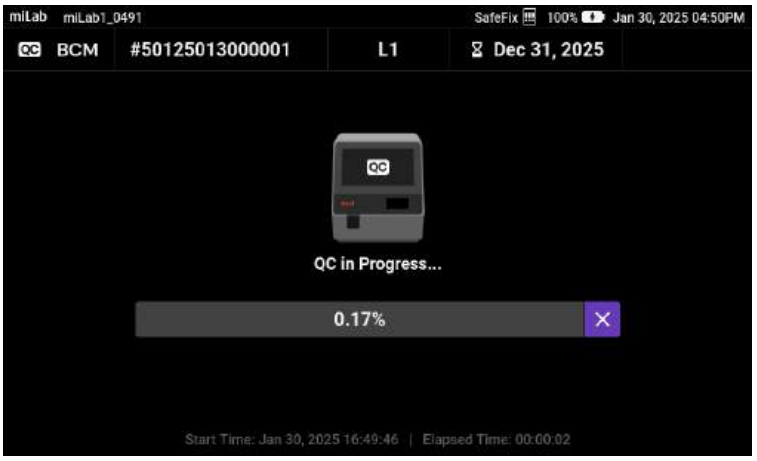
Step 3: Performing the QC Test

1. Assemble the **top cartridge with the bottom cartridge** to ensure proper alignment.
2. Press **Start QC** to begin the test. The screen will transition to the one shown below.

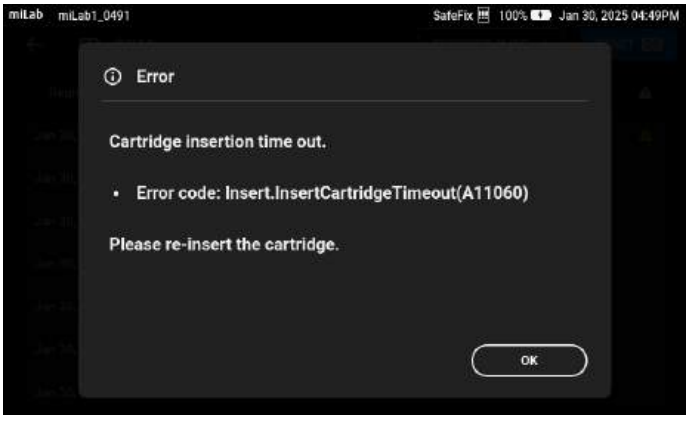




3. Insert the assembled cartridge to the device cartridge inlet.
4. The system will automatically draw the cartridge if it is properly assembled and will scan the barcode for recognition.
5. If the slide is **not recognized**, manually select the slide ID from the system.

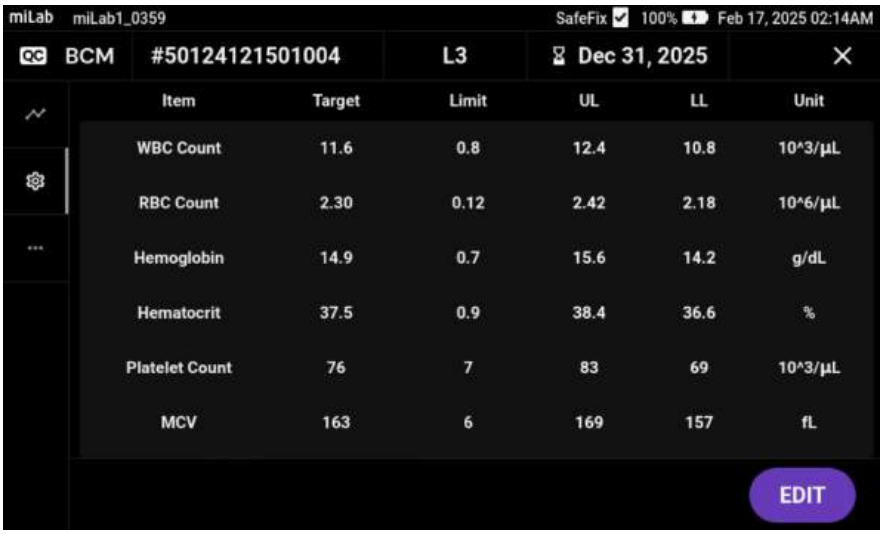


6. Ensure the slide is inserted within the required timeframe to prevent automatic test cancellation. If the slide is not inserted on time, an error screen like below will be displayed.

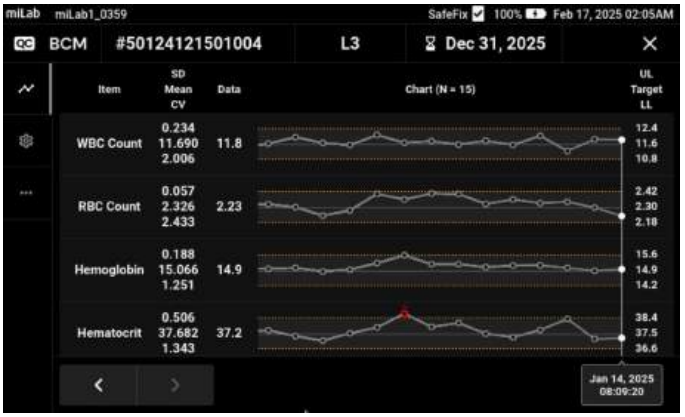


Step 4: Reviewing QC Results

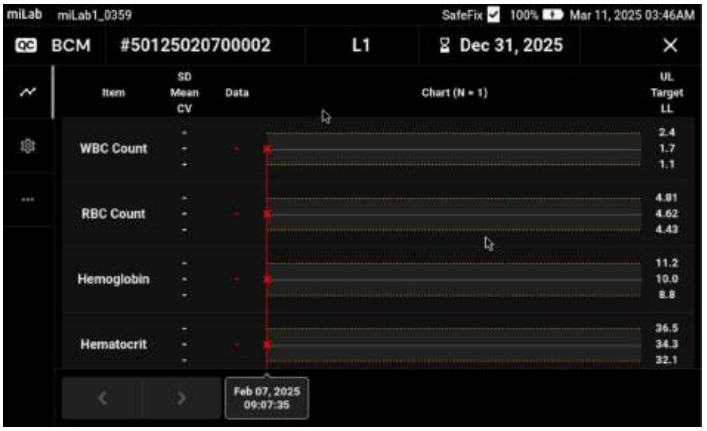
- When the QC test is successfully completed, the data is automatically accumulated and recorded. The results can be reviewed using charts, which also allow access to previous QC results. The analyzer will display the test results, including:
  - **Standard Deviation (SD)**
  - **Mean**
  - **Coefficient of Variation (CV)**
  - **Upper, lower limits**
  - **Target value**
- The QC range may be edited on the  button. When the **'Edit'** button is pressed, the screen will change so that it will allow direct modification of the input fields. Additionally, by pressing the  button, you can rescan the QR barcode to update all information at once.



- A **red circle icon** will appear, indicating:
  - The result is outside the acceptable range.



- A **X mark icon** will appear, indicating:
  - The test operation failed (e.g. test aborted, imaging failed)

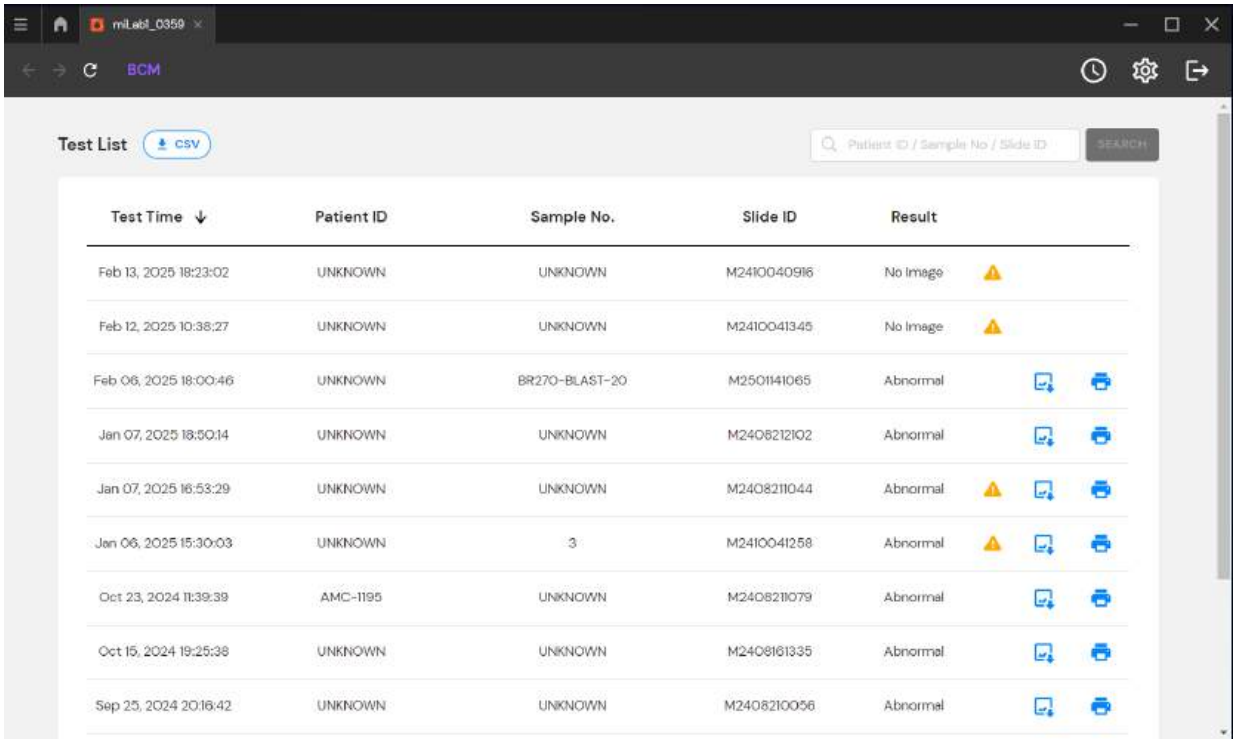


- If necessary, delete previous QC data. Press the ··· button and the '**Delete slide data button'** will appear to the right. However, please note that all QC tests performed from the slide will be deleted.

10. miLab Viewer™

10.1. Test List

Once logged into miLab Viewer, the main page titled [Test List] will display all performed tests.

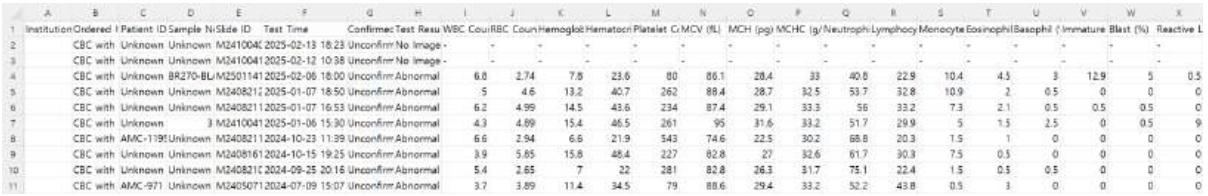


The [Test List] page includes all finished test result data stored in the miLab device. Tests are added to the viewer list screen when the inspection is completed, stopped, or when there is no further progress for that test on the miLab device.

1. The [Test List] page displays the same information saved on the miLab.
   - ① Test Time: Date and time of the test.
   - ② Patient ID: Patient ID is received from the host computer or entered manually. If not entered, it will display as ‘Unknown’.
   - ③ Sample No.: Sample No. is received from the host computer or entered manually. If not entered, it will display as ‘Unknown’.
   - ④ Slide ID: The unique slide ID of the cartridge used for the selected test.
   - ⑤ Result: The result will display as Normal, Abnormal and No Image. ⚠ symbol will be displayed for results for the following 3 reasons : 1) No image was acquired, 2) Prep QC needs verification, 3) If test result output to host computer failed.
   - ⑥ Download Image : Users may opt to download the WBC images acquired from the test using the button. It will download all individual WBC images in a zip file that consists of folders for each relevant parameter..

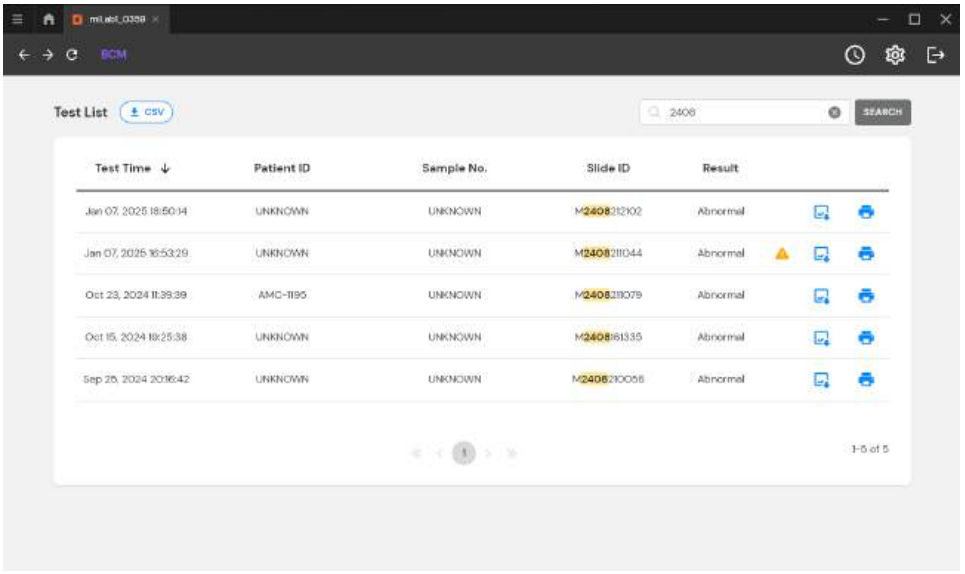
⑦ Download/Print Report : Users may opt to download or print the report as either a Print or PDF document using the button. Clicking this button will redirect the user to the Report Tab menu of the test result. Users can print the report or download it as a pdf file. For more detailed information, refer to *10.6. Report Tab.*

2. Pressing the CSV button at the top of the page allows for the bulk download of test results. The result items that can be verified within the CSV file are as shown in the image below.



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X
1	Institution	Ordered I	Patient ID	Sample N	Slide ID	Test Time	Confirmec	Test Resu	WBC Cou	RBC Coun	Hemoglol	Hematocri	Platelet Cı	MCV (fL)	MCH (pg)	MCHC (g/	Neutrophi	Lymphocy	Monocyte	Eosinophi	Basophil (	Immature	Blast (%)	Reactive L
2		CBC with	Unknown	Unknown	M2410041	2025-02-13 18:23	Unconfirm	No Image	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3		CBC with	Unknown	Unknown	M2410041	2025-02-12 10:38	Unconfirm	No Image	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4		CBC with	Unknown	BR270-BL	M2501141	2025-02-06 18:00	Unconfirm	Abnormal	6.8	2.74	7.8	23.6	80	86.1	28.4	33	40.8	22.9	10.4	4.5	3	12.9	5	0.5
5		CBC with	Unknown	Unknown	M2408212	2025-01-07 18:50	Unconfirm	Abnormal	5	4.6	13.2	40.7	262	88.4	28.7	32.5	53.7	32.8	10.9	2	0.5	0	0	0
6		CBC with	Unknown	Unknown	M2408211	2025-01-07 16:53	Unconfirm	Abnormal	6.2	4.99	14.5	43.6	234	87.4	29.1	33.3	56	33.2	7.3	2.1	0.5	0.5	0.5	0
7		CBC with	Unknown	3	M2410041	2025-01-06 15:30	Unconfirm	Abnormal	4.3	4.89	15.4	46.5	261	95	31.6	33.2	51.7	29.9	5	1.5	2.5	0	0.5	9
8		CBC with	AMC-1195	Unknown	M2408211	2024-10-23 11:39	Unconfirm	Abnormal	6.6	2.94	6.6	21.9	543	74.6	22.5	30.2	68.8	20.3	1.5	1	0	0	0	0
9		CBC with	Unknown	Unknown	M2408161	2024-10-15 19:25	Unconfirm	Abnormal	3.9	5.85	15.8	48.4	227	82.8	27	32.6	61.7	30.3	7.5	0.5	0	0	0	0
10		CBC with	Unknown	Unknown	M2408210	2024-09-25 20:16	Unconfirm	Abnormal	5.4	2.65	7	22	281	82.8	26.3	31.7	75.1	22.4	1.5	0.5	0.5	0	0	0
11		CBC with	AMC-971	Unknown	M2405071	2024-07-09 15:07	Unconfirm	Abnormal	3.7	3.89	11.4	34.5	79	88.6	29.4	33.2	52.2	43.8	0.5	3	0	0	0	0

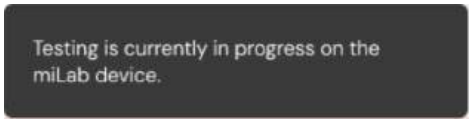
3. Search for the test that you are looking for.
   a. When you input numbers or letters in the search bar, the tests corresponding to the search criteria, such as Patient ID, Slide ID, or Sample No., will be displayed. If there are no matching results, "No search results" will be shown.



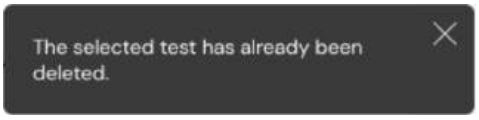
[Search bar]

4. Click the test bar to review the test results in detail.

*** When a test is in progress on the miLab device, a toast popup is displayed at the bottom right as below. The popup will automatically disappear when the test is finished.*



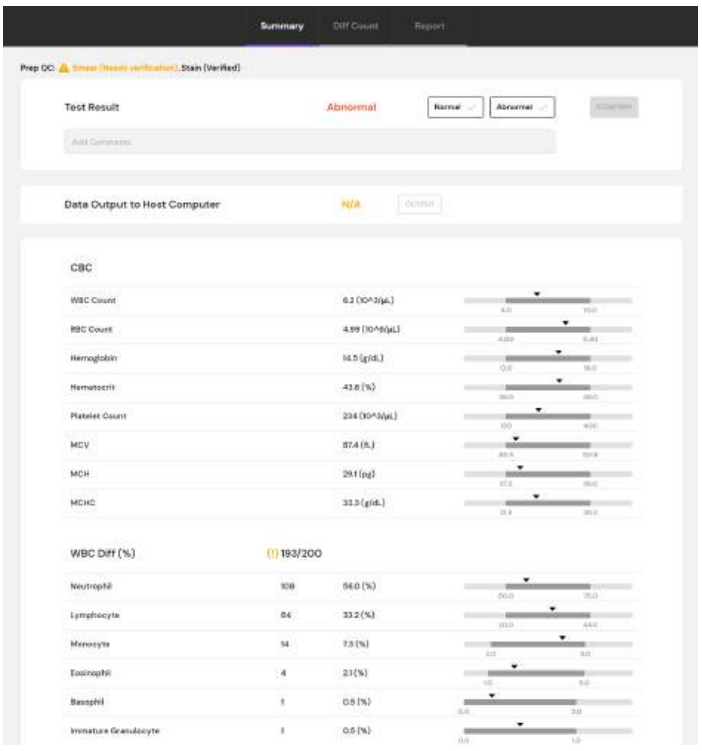
*** If a test result has been deleted in the miLab device, a toast popup is displayed at the bottom right as below and you cannot view the results on the miLab viewer.*



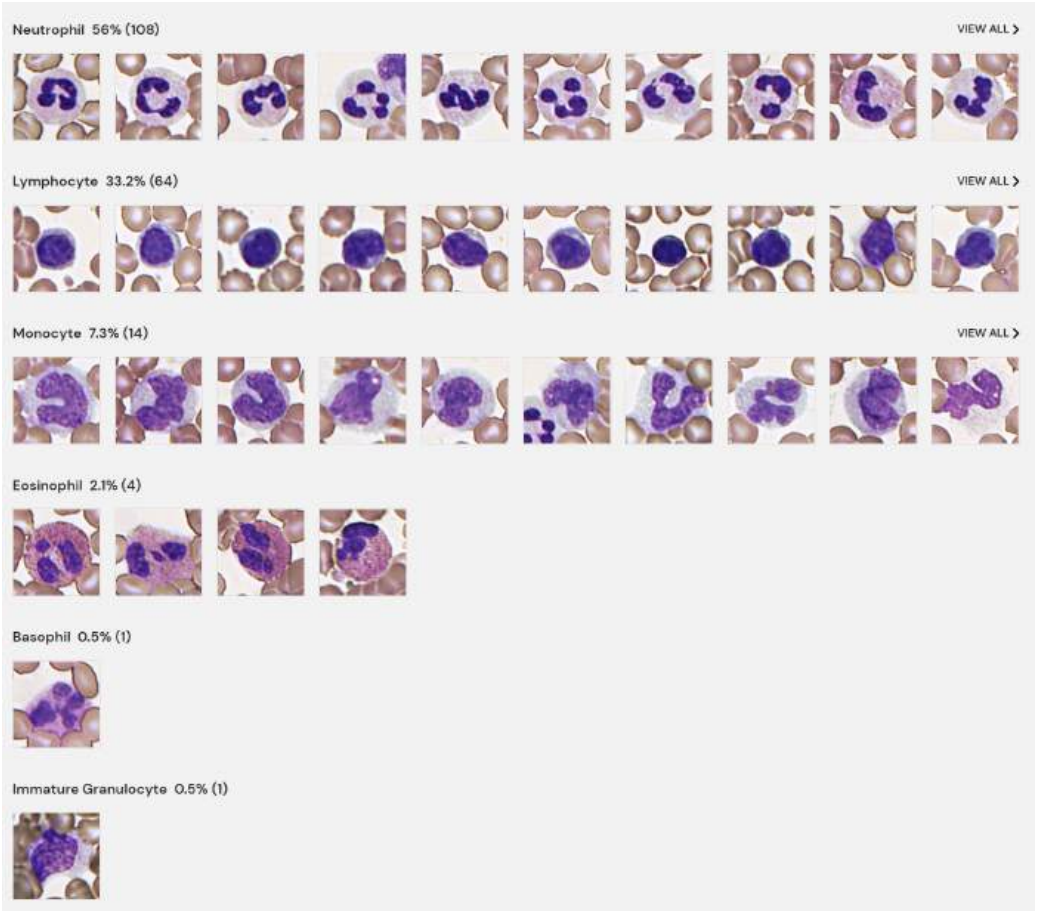
10.2. Summary Tab

The summary tab will be shown when clicking the test on the [Test List] page.

- This is the first screen that displays detailed information about the BCM test.
- At the top, it shows 1) The validity of Prep QC (please refer to *10.6 Report Tab* for more details on the validity of Prep QC), 2) the test result, and the option to confirm the test result, and 3) the status of the test results output to host computer is displayed. If the test result has been successfully sent to the host computer, it will display as 'Completed'. If it was not successful, it will display as "Failed". If the LIS connection was not made at all, it will display as "N/A". If the host connection is turned on from the device, [OUTPUT] button will be activated. Clicking the button will send the data to the host computer.
- Just below the above information, the summary of the test result is shown. The CBC results, #/%/Absolute values of the WBCs, as well as whether they fall within the normal range or not.
- At the bottom, it displays up to 10 cell images for each WBC type. You can click on a cell image to navigate to its detailed information, and clicking on "VIEW ALL" will take you to a list of cells for that specific cell type.

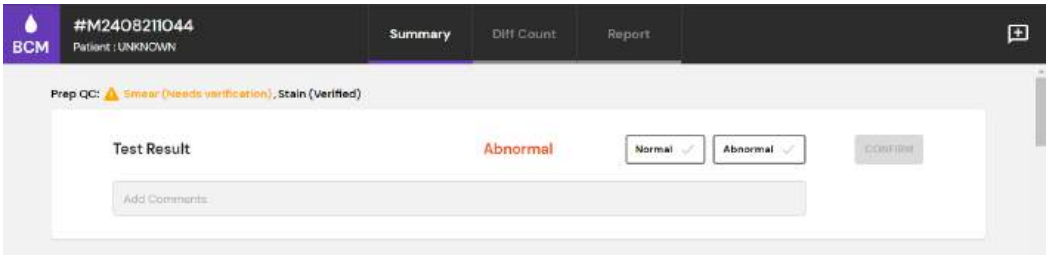


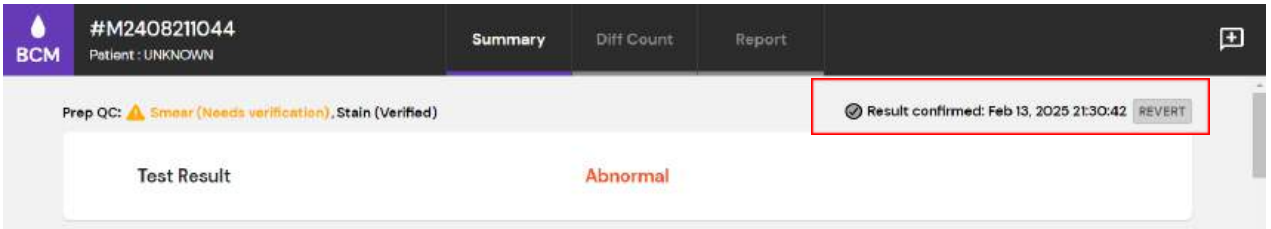
[Summary tab: Result Information]



[Summary tab: Images]

- Users can confirm the test result by selecting the result as “Normal” or "Abnormal" and then clicking the 'Confirm' button located in the top right corner of the summary tab. If you want to modify the test, click the [REVERT] button to unconfirm the test result.

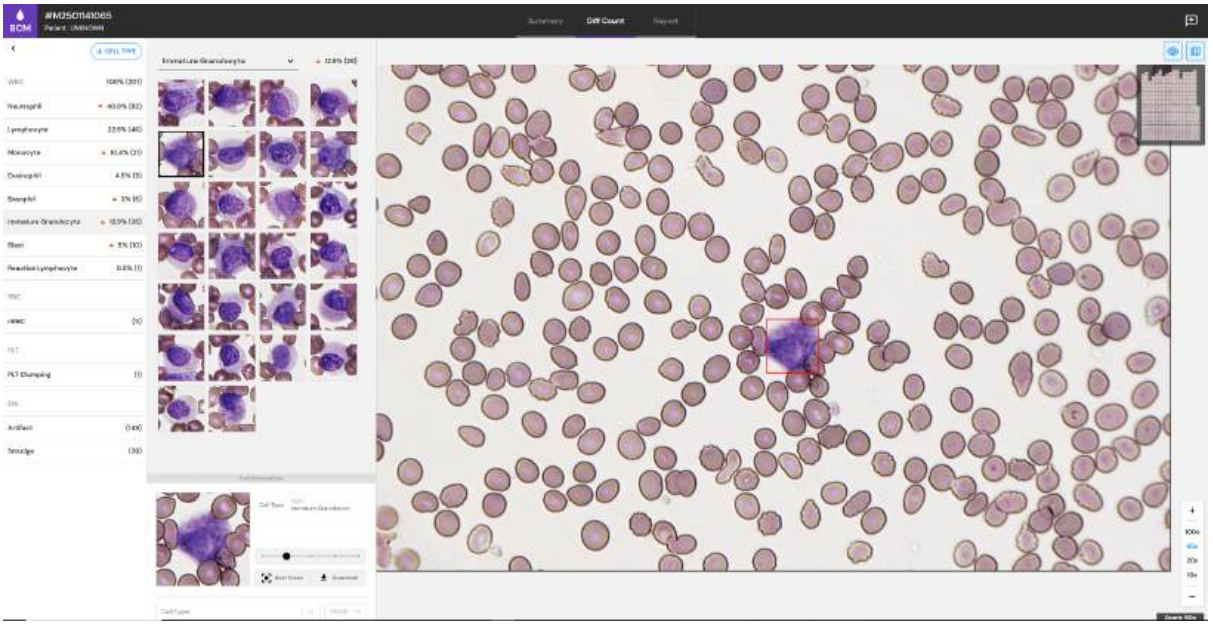




[Result Confirmation]

10.3. Diff Count

- In the Diff Count tab, the user can check the detailed cell information and utilize cell labeling functionality. Users can click on the Diff Count tab at the top or enter by clicking on the cell image or [VIEW ALL] button on the Summary screen.



[Diff Count tab]

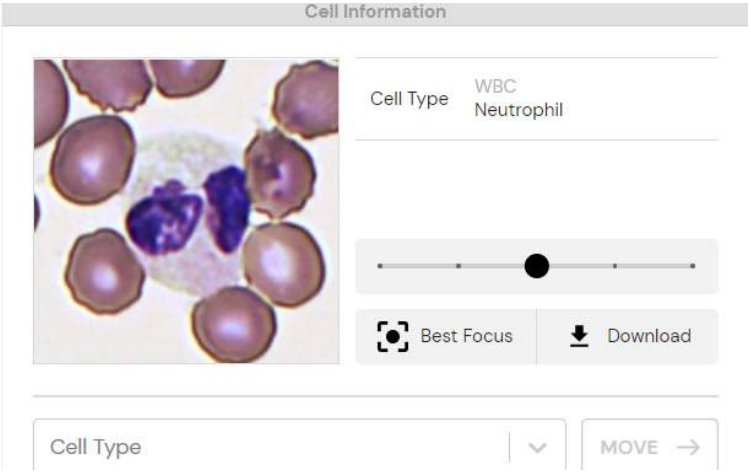
1. The [Diff Count] page displays the information as shown below.
   - ① Cell type list (on the left side of the screen)
     a. Cells detected by AI are categorized on the cell list panel.
     b. At the top of the cell type list, + CELL TYPE can be clicked to create custom cell types. Upon clicking this button, a pop up will appear as below where you can create new cell types for each different categories.This new cell type will only apply to the current test result. Refer to *10.5. Custom Cell Type* for more detailed information.
   - ② Cell image list
     a. All cell images corresponding to the selected cell type in the cell type list will be displayed.
   - ③ Field view
     a. The field view of the selected cell from the cell image list is displayed.
     b. On the field view, the user can change the focus, and zoom in/out.
   - ④ Cell Information (below Cell image list)
     a. Detailed information about the selected cell from the cell image list is displayed.
   - ⑤ Other Focuses (in the Cell information)
     a. By adjusting the focus bar, the focus of the selected image can be changed. Clicking the 'Best Focus' will adjust the focus bar to the most optimized focus.
   - ⑥ Download (in Cell Information)
     a. Users can download the image of the selected cell in the Cell tab by clicking the 'Download' button in Cell Information.
   - ⑦ Cell Labeling (in Cell Information)

There is a cell labeling function below the cell images. The selected cell can be re-classified. Refer to *10.4. Cell Labeling* for more detailed information.

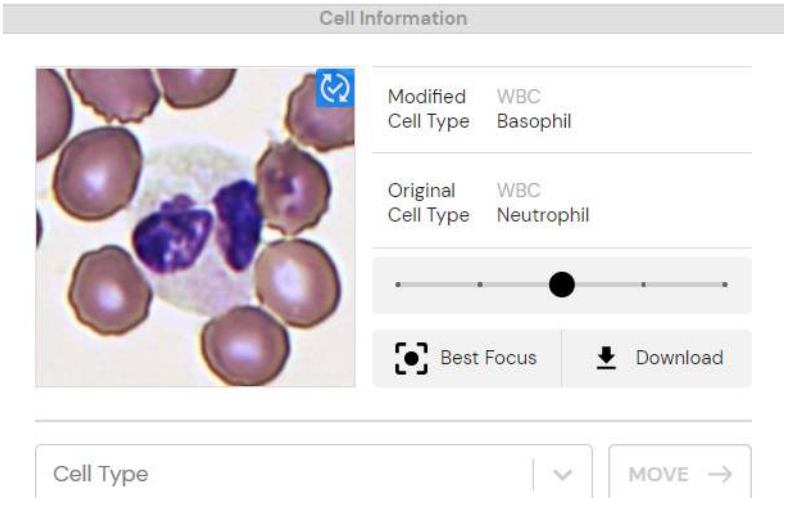
10.4. Cell Labeling

- Cell labeling function can be done as follows :

1. **Cell Information**: The [Cell Information] panel has a cell labeling function. Below is the step-by-step procedure to label the cells.
   **If the test result is already confirmed, the [Cell Labeling] function will be disabled. To activate the cell labeling function, click the [REVERT] button in the Summary tab on the top right corner.*



Step 1. Select a cell for labeling: The selected cell's information is displayed under [Cell Information].
Step 2. Select the cell type that you wish to move the clicked cell to.
Step 3. Click [MOVE]: The labeled cell is marked with a blue icon at the top right of the cell image, and a new [Modified Cell Type] is created in [Cell Information] in a separate column.
- Modified Cell Type: saved as the latest modified type
- Original Cell Type: classified by AI

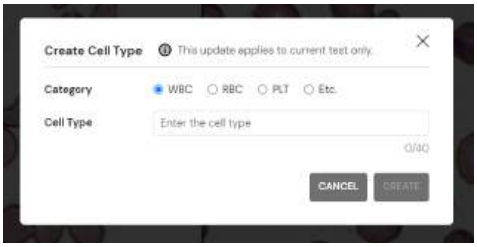


*Tips. Cell Multi-select
: Multi-select is possible by clicking the cells while holding down the Ctrl key(Windows) or the Command key(Mac) to label multiple cells at once.*

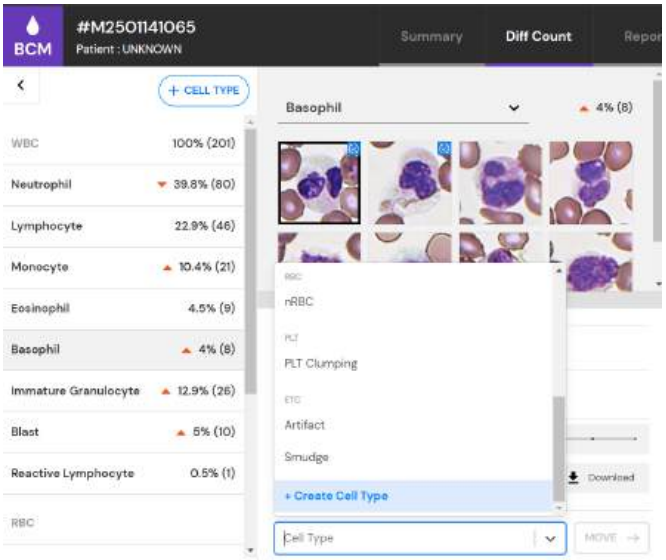
2. After finishing the review of the cells, go back to the [Summary] page for confirmation of the test results.

10.5. Custom Cell Type

- Click the [+ CELL TYPE] button (on the top right of the cell type list menu) or [+ Create Cell Type] (on the last column of the Cell Type tab in Cell Information) to allow users to create additional cell types. These cell types created by the user are referred to as custom cell types. This custom cell type only applies to the current test result.

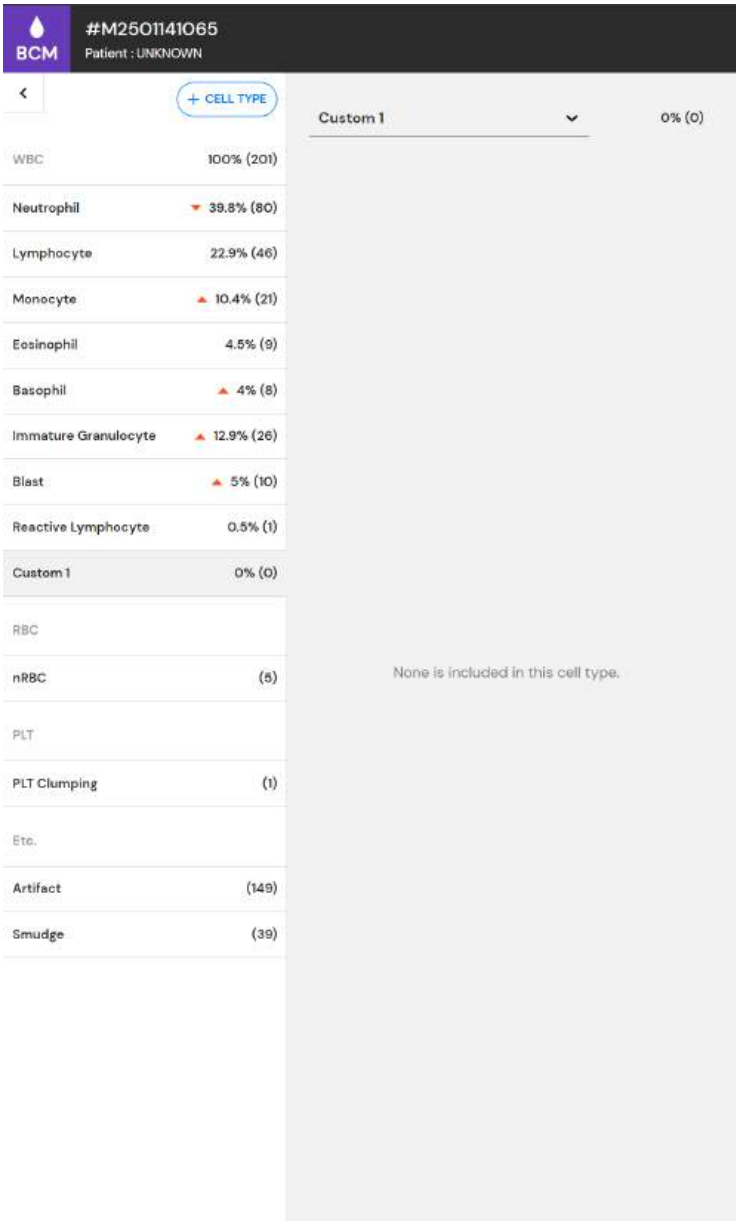


[Cell Tab - Create Cell Type]



[Cell Tab - Cell Information - Create Cell Type]

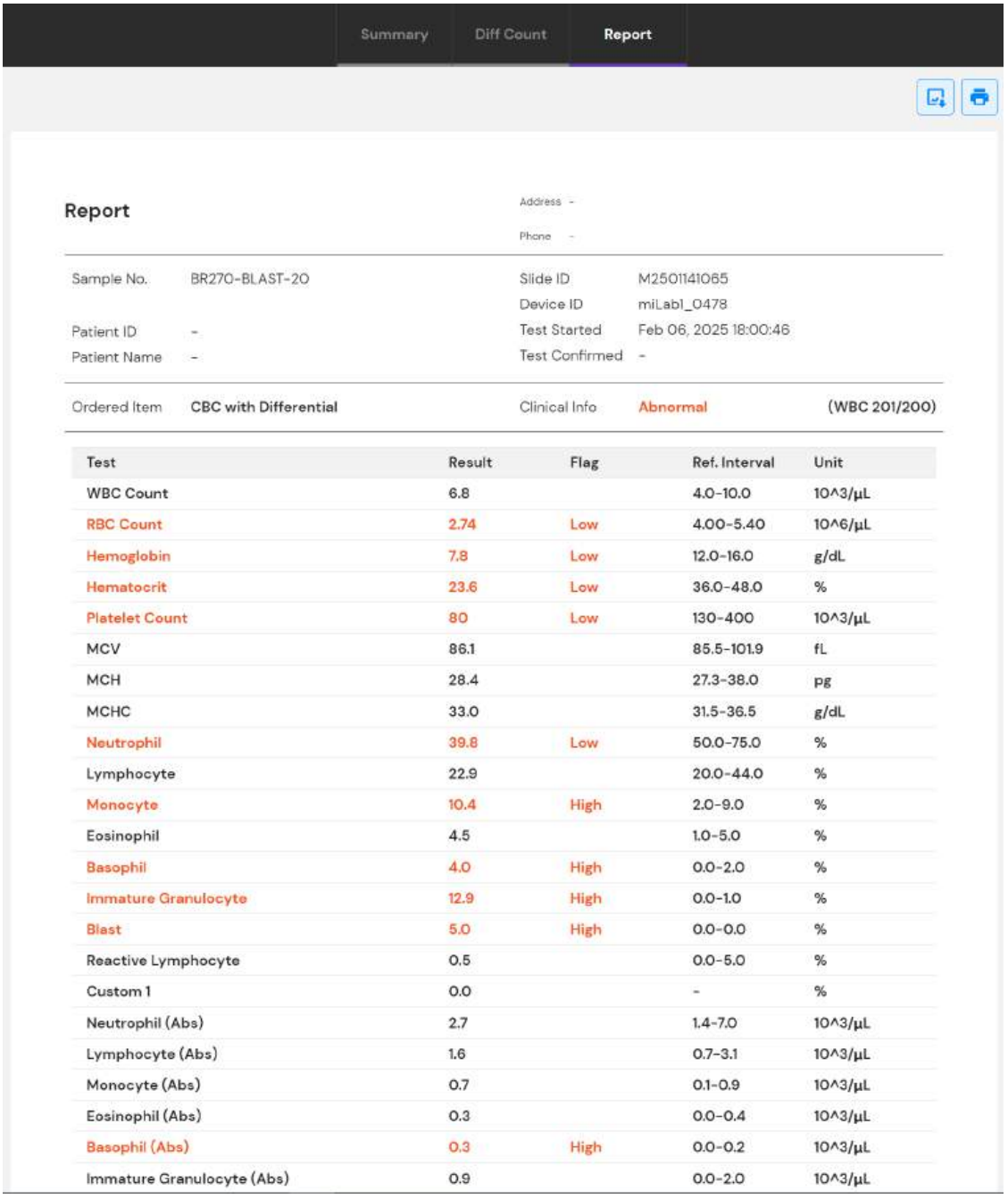
- With these custom cell types, it is possible to move existing cells and modify/delete the created custom cell types.
  * *Deletion is only possible when there are no cells belonging to the 'Custom Cell Type'.*



10.6. Report Tab

- By clicking the [Report] tab or the report [Print Report] button in the test list, you can switch to the report page.
- The report includes the following information: Institution Information, Sample Number, Patient ID, Patient Name, Slide ID, Device ID, Test Start Time, Test Confirmation, Ordered Item, Clinical Info, Test Details (count and percentage of cells by cell type, normal range), and Signature. On the report page, you can edit some of the Patient Information, Institution Information, and Comments in the Report tab.
- Images can be downloaded all at once. By clicking the button, it will allow the user to download all individual WBC images per classification in a zip file that consists of folders for each relevant parameter.

- The report can be printed or downloaded. By clicking the button, it will allow the user to print or download the report as “PDF” to generate the report as a PDF file.



Summary | Diff Count | Report

Report

Address -
Phone -

Sample No.	BR270-BLAST-20	Slide ID	M2501141065
		Device ID	miLab1_0478
Patient ID	-	Test Started	Feb 06, 2025 18:00:46
Patient Name	-	Test Confirmed	-

Ordered Item: CBC with Differential | Clinical Info: Abnormal (WBC 201/200)

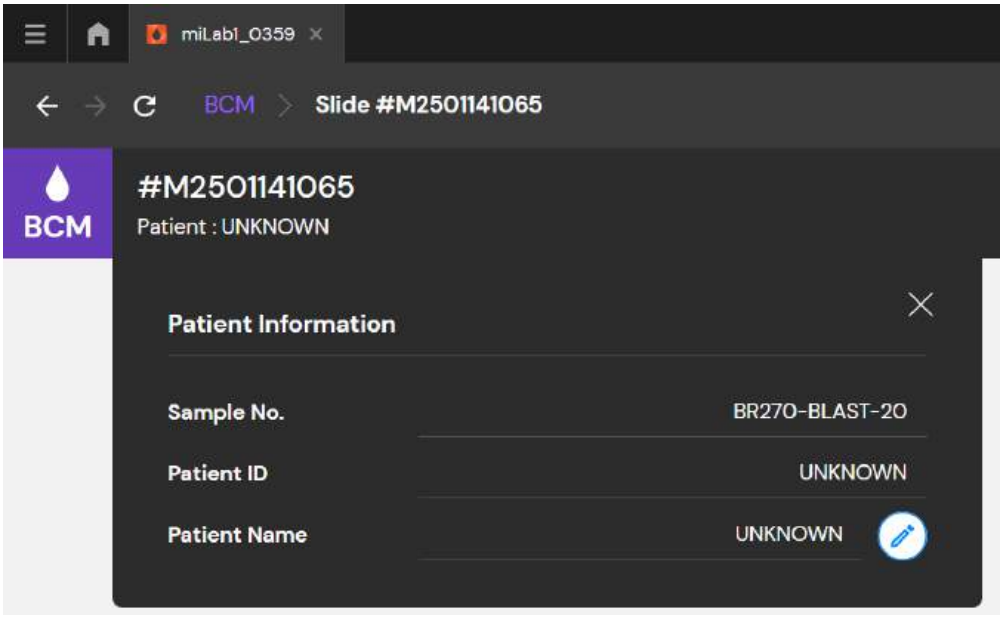
Test	Result	Flag	Ref. Interval	Unit
WBC Count	6.8		4.0-10.0	10^3/µL
RBC Count	2.74	Low	4.00-5.40	10^6/µL
Hemoglobin	7.8	Low	12.0-16.0	g/dL
Hematocrit	23.6	Low	36.0-48.0	%
Platelet Count	80	Low	130-400	10^3/µL
MCV	86.1		85.5-101.9	fL
MCH	28.4		27.3-38.0	pg
MCHC	33.0		31.5-36.5	g/dL
Neutrophil	39.8	Low	50.0-75.0	%
Lymphocyte	22.9		20.0-44.0	%
Monocyte	10.4	High	2.0-9.0	%
Eosinophil	4.5		1.0-5.0	%
Basophil	4.0	High	0.0-2.0	%
Immature Granulocyte	12.9	High	0.0-1.0	%
Blast	5.0	High	0.0-0.0	%
Reactive Lymphocyte	0.5		0.0-5.0	%
Custom 1	0.0		-	%
Neutrophil (Abs)	2.7		1.4-7.0	10^3/µL
Lymphocyte (Abs)	1.6		0.7-3.1	10^3/µL
Monocyte (Abs)	0.7		0.1-0.9	10^3/µL
Eosinophil (Abs)	0.3		0.0-0.4	10^3/µL
Basophil (Abs)	0.3	High	0.0-0.2	10^3/µL
Immature Granulocyte (Abs)	0.9		0.0-2.0	10^3/µL

11. Detailed Functions

You can enter the patient name, institution name and address that will be included in the report. The patient name is entered or received from the host computer in the patient information for each test, and the institution name and address are entered for each device. This information can only be entered in the Viewer.

11.1. Patient Information

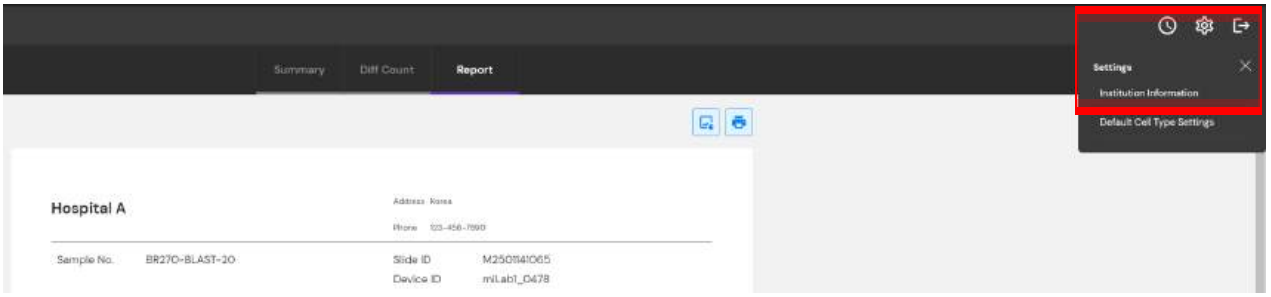
Click on the patient ID (e.g., UNKNOWN OR 9002XXXXX) to check the patient information. In the Viewer the Sample No., Patient ID, and Patient Name is displayed. However, only Patient name can be edited through the Viewer, which will also be reflected in the miLab Device.
**Patient Information is linked with information entered or received in miLab Device.*



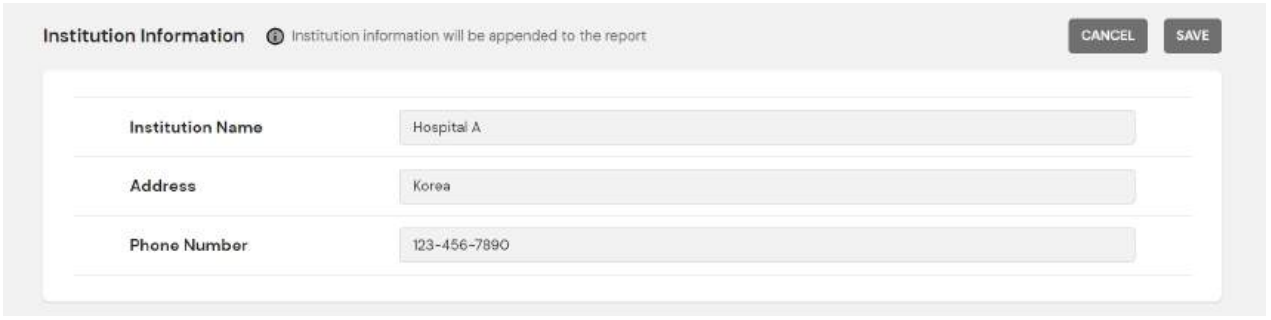
[Patient Information]

11.1.1. Institution Information

If you click button on the top right corner, further settings information will be displayed. Click [Institution Information] on the page under settings, you can enter and edit institutional information. The added hospital information is included in the miLab Report.



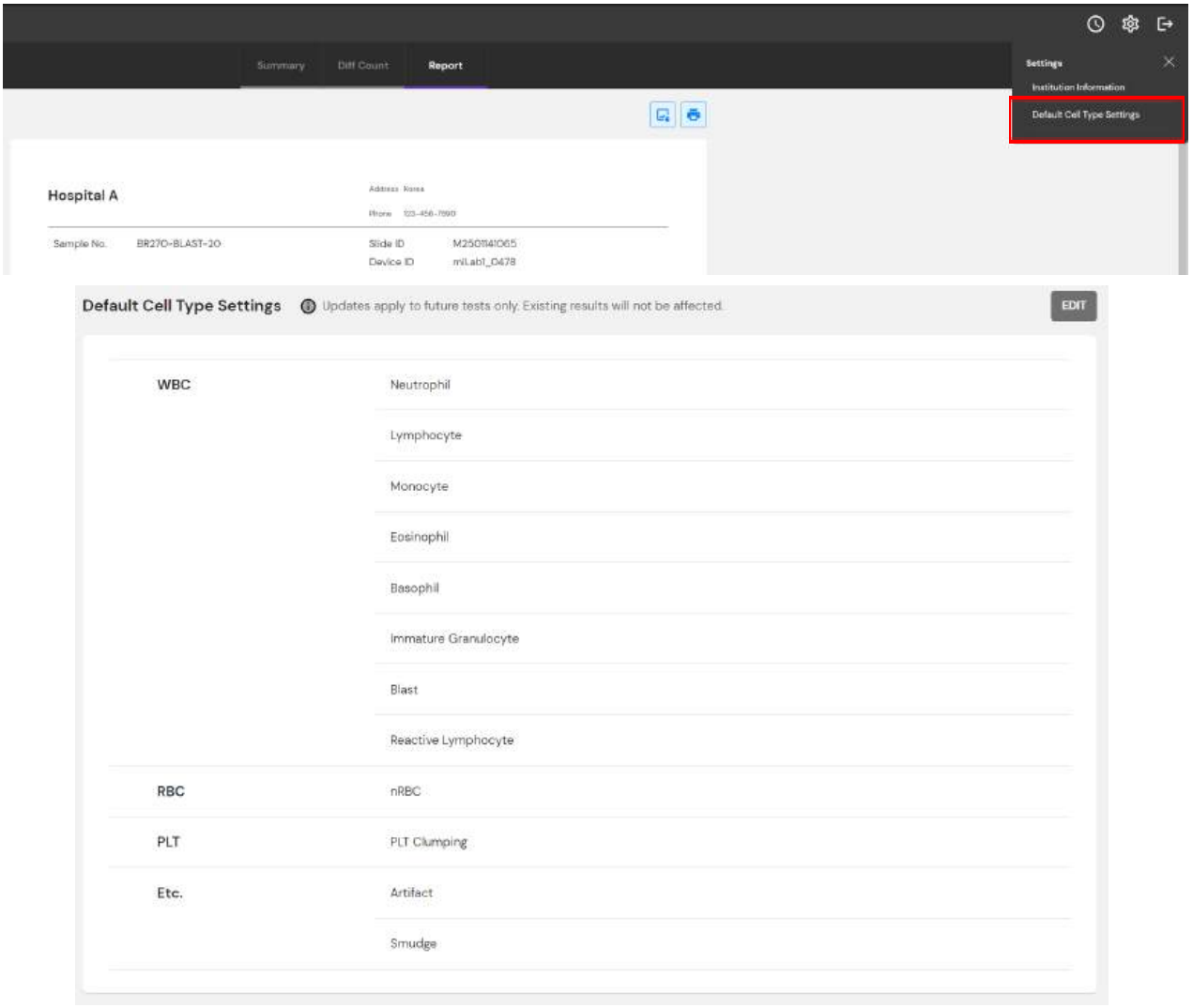
[Settings - Institution Information]



[Settings - Institution Information]

11.1.2. Default Cell Type Settings

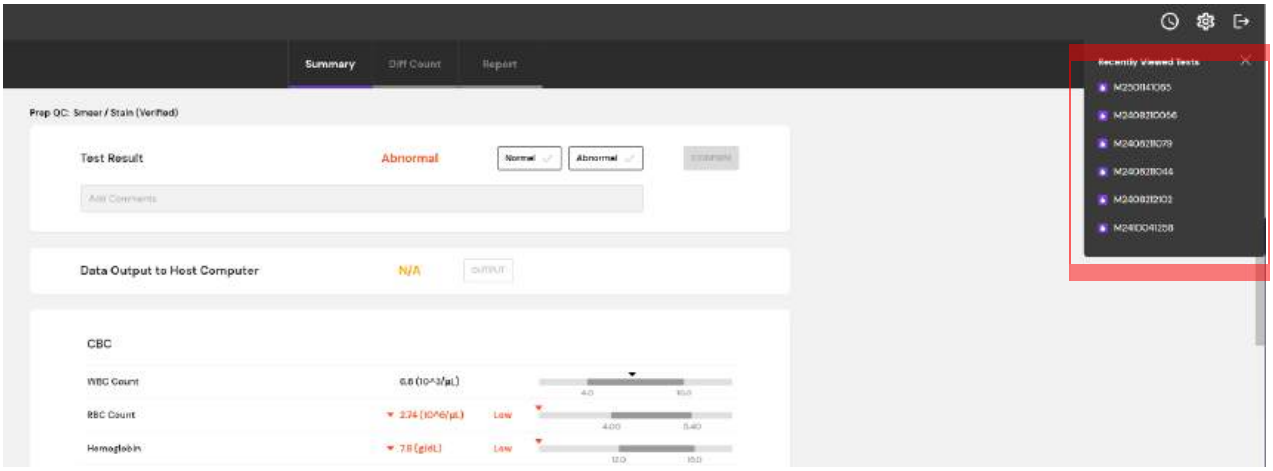
- If you click [Default Cell Type Settings] under the settings menu, you can set a default cell type that will be available for all tests made without the need to create a new custom cell type for each test. However, the default cell type updates apply to future tests only. Existing results will not be affected.
  ** However, please note that the new default cell type is not measured as one of the parameters the test provides.*



[Default Cell Type Settings]

11.1.3. Recently Viewed Tests

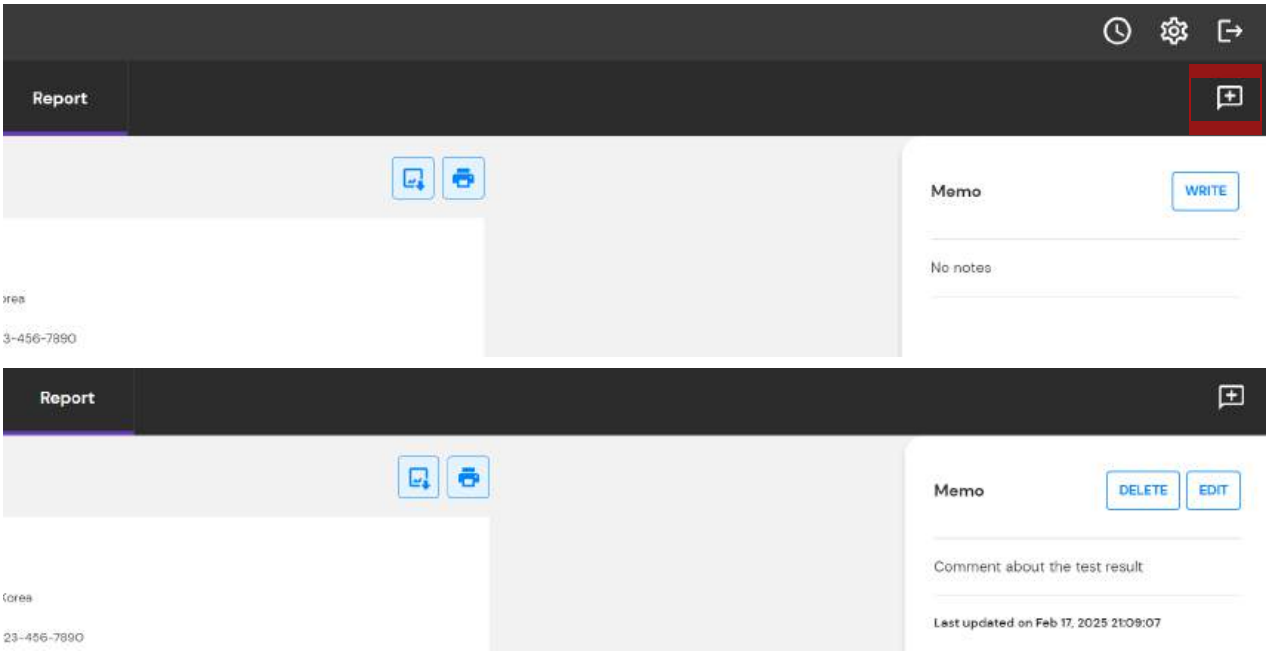
It provides a feature that allows quick access to recently opened tests. You can click on the button in the upper right corner to expand the list of recent tests.



[Recently viewed tests]

11.1.4. Memo

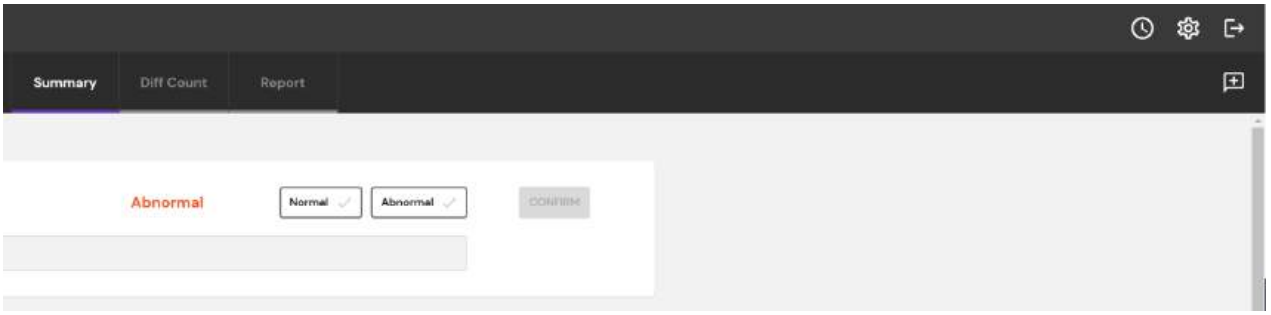
You can write a memo by clicking on the memo icon (). Click [Write] to add in a memo. If there is already a memo, [DELETE] and [EDIT] buttons are displayed.. Saved memos show the latest date and time modified.



[Cell Tap - Memo]

11.1.5. Back to Viewer Home Screen

Upon clicking the button, you will move to the protocol selection screen.



[Back to Viewer Home Screen]

12. Specifications and Performance

Analytical performance

Precision-Repeatability (*n* = 110)			
Parameter	Grand Mean	Within-run SD	Repeatability CV(%)
WBC	5.34	0.31	5.79
RBC	4.78	0.18	3.69
Hb	14.22	0.46	3.22
HCT	43.19	1.59	3.68
PLT	306.65	14.34	4.68
MCV	90.50	1.71	1.89
MCH	29.81	0.77	2.59
MCHC	32.95	0.56	1.69
Neutrophil	53.77	3.49	6.49
Lymphocyte	36.08	3.46	9.59
Monocyte	6.28	1.43	22.86
Eosinophil	2.71	0.99	36.43
Basophil	0.71	0.68	95.67

Precision-Reproducibility (*n* = 45)

Measurand	Overall Mean	Between-device SD	Between-device CV%	Between-run SD	Between-run CV%	Total SD	Total CV%
WBC	4.91	0.08	1.53	0.28	5.63	0.29	5.83
RBC	4.75	0.05	0.95	0.15	3.19	0.16	3.33
Hb	14.46	0.24	1.65	0.41	2.82	0.47	3.27
HCT	43.81	0.76	1.73	1.17	2.67	1.39	3.18
PLT	240.22	12.89	5.37	9.82	4.09	16.21	6.75
MCV	92.26	1.47	1.60	1.42	1.54	2.05	2.22
MCH	30.46	0.47	1.55	0.57	1.86	0.74	2.42
MCHC	33.02	0.10	0.32	0.27	0.81	0.29	0.87
Neutrophil	53.21	0.84	1.58	3.54	6.65	3.64	6.84
Lymphocyte	35.45	1.25	3.54	3.22	9.09	3.46	9.75
Monocyte	5.98	0.00	0.00	1.47	24.51	1.47	24.51
Eosinophil	3.70	0.54	14.45	1.71	46.27	1.79	48.48
Basophil	1.03	0.16	15.23	0.68	65.76	0.69	67.50

Clinical performance

Category	Specifications (N=293)
Clinical Performance	— Correlation coefficient (R) ○ WBC Count: 0.96 ○ RBC Count: 0.96 ○ Hemoglobin: 0.96 ○ Hematocrit: 0.96 ○ PLT Count: 0.91 ○ MCV: 0.80 ○ MCH: 0.83 ○ MCHC: 0.45 ○ NEUT%: 0.97 ○ LYMPH%: 0.94 ○ MONO%: 0.82

	○ EO%: 0.92 ○ BASO%: 0.75 ○ IG%: 0.85 ○ Blast%: 0.94 ○ Reactive Lymphocyte%: 0.17

13. Parameters and Calculations

13.1. Parameters

The system provides an array of useful parameters, which are calculated from the measurement values of each sample.

Parameter	Unit
Total WBC	10^3/μl
Total RBC	10^6/μl
Hemoglobin	g/dL
Hematocrit	%
Total PLT	10^3/μl
MCV	fL
MCH	pg
MCHC	g/L
RDW-CV	%
WBC 5-Differential (Count/%/Absolute)	#/%/10^3/μl
Immature Granulocyte (Count/%/Absolute)	#/%/10^3/μl
Blast (Count/%/Absolute)	#/%/10^3/μl
Reactive Lymphocyte (Count/%/Absolute)	#/%/10^3/μl
nRBC	#
PLT clumping	#
Smudge	#
Artifacts	#

13.2 Analytical Measurement Range

Parameter	Range
WBC Count [10^3/μl]	1.5 - 340.0
RBC Count [10^6/μl]	1.33 - 7.00
Hemoglobin [g/dL]	5.0 - 20.0
Hematocrit [%]	13.0 - 60.0
Platelet Count [10^3/μl]	20 - 870

13.3 Reference Interval

Parameter	Range
WBC Count [10^3/μl]	3.1 - 10.4
RBC Count [10^6/μl]	3.73 - 5.90
Hemoglobin [g/dL]	10.7 - 17.4
Hematocrit [%]	33.3 - 52.7
Platelet Count [10^3/μl]	140 - 440
MCV [fL]	80.0 - 100.0
MCH [pg]	26.0 - 33.0
MCHC [g/dL]	32.0 - 36.0
Neutrophil (Abs)	0.92 - 6.56
Lymphocyte(Abs)	0.75 - 2.97
Monocyte (Abs)	0.08 - 0.83
Eosinophil (Abs)	0 - 0.4
Basophil (Abs)	0 - 0.17
Immature Granulocyte (Abs)	0 - 0.1
Blast (Abs)	< 0 (Less than 0)
Reactive Lymphocyte (Abs)	0.0 - 5.0

13.4 Calculations

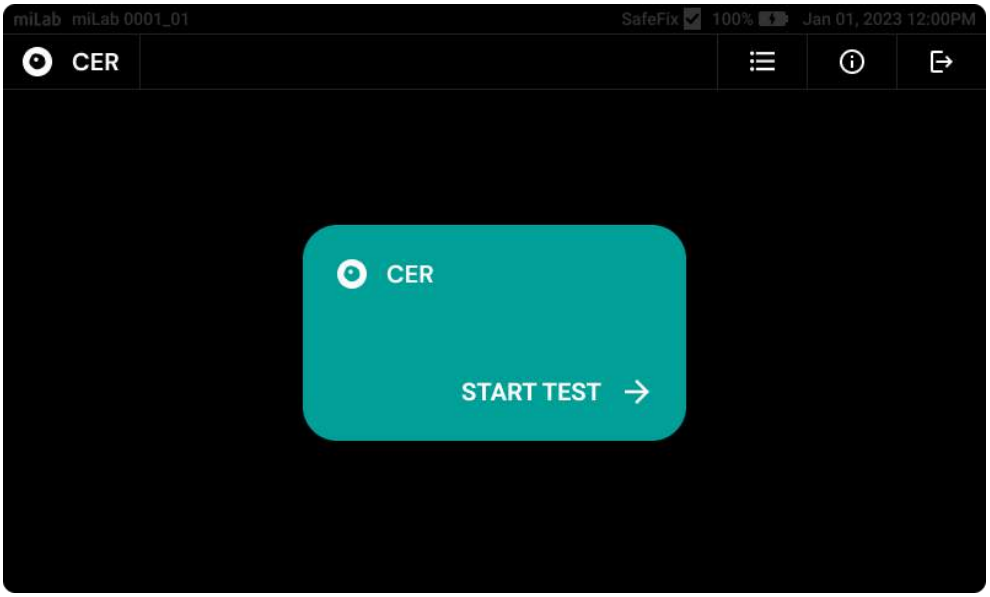
Parameter	Equation
MCV	Hemoglobin x 10 / RBC Count

MCH	Hematocrit x 10 / RBC Count
MCHC	Hemoglobin x 100 / Hematocrit
WBC Differential Ratio	(Each WBCs* ÷ Total WBC Count) × 100 % ** The ratio obtained by dividing the count of each WBC type by the total WBC count. The WBC types include neutrophils, lymphocytes, monocytes, eosinophils, basophils, Immature granulocytes, Blast, and Reactive lymphocytes.*

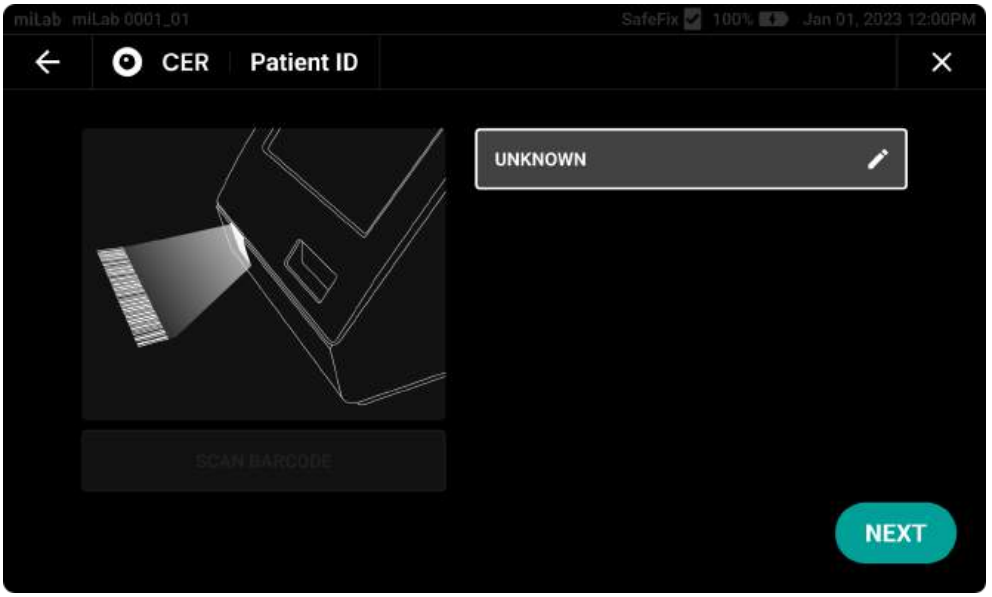
14. CER Instruction details

14.1. Test Procedures

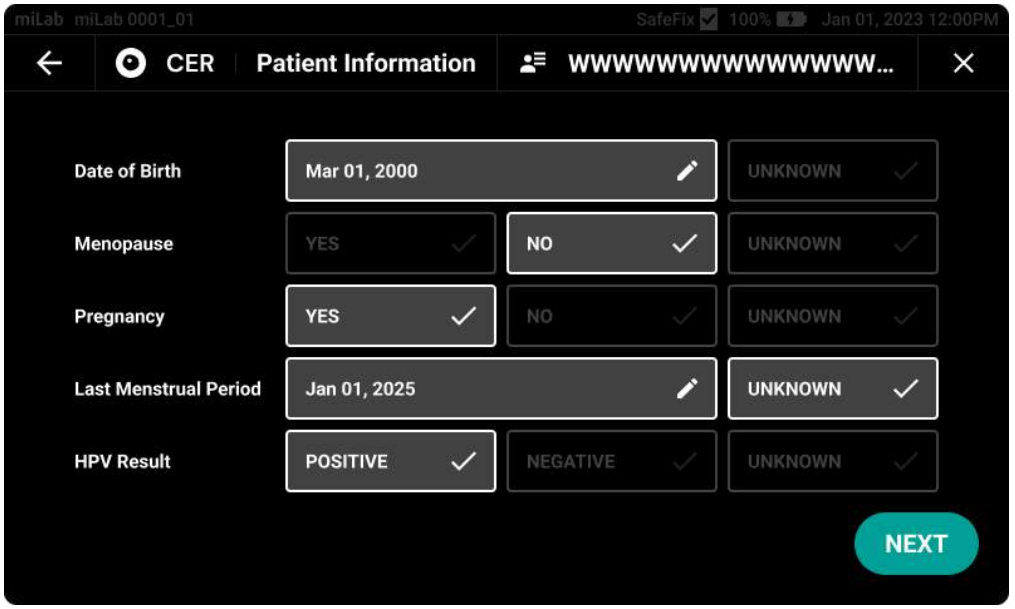
1. To start the test, click the  button on the screen.



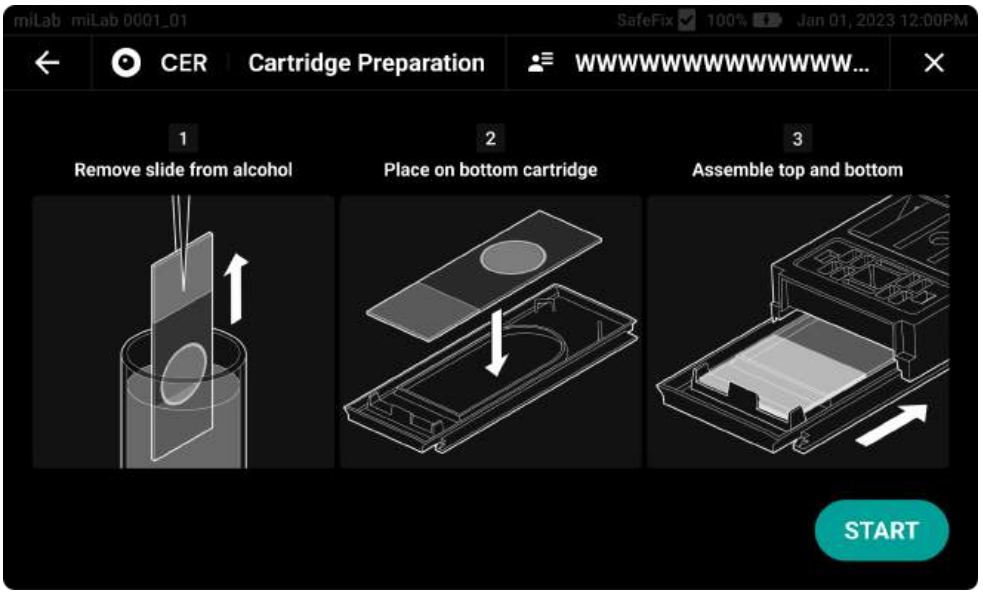
2. Scan the barcode or manually enter the patient ID on the screen.
    - The barcode scanner can recognize barcode information with 1-dimensional or 2-dimensional barcode format (1-D or 2-D)
    - The barcode scanner will be deactivated in 10 seconds, so activate it again by pressing [SCAN BARCODE].
    - If entering a Patient ID is unnecessary, please press the [NEXT] button without entering any information. Before entering a Patient ID, the default is set as “UNKNOWN.”



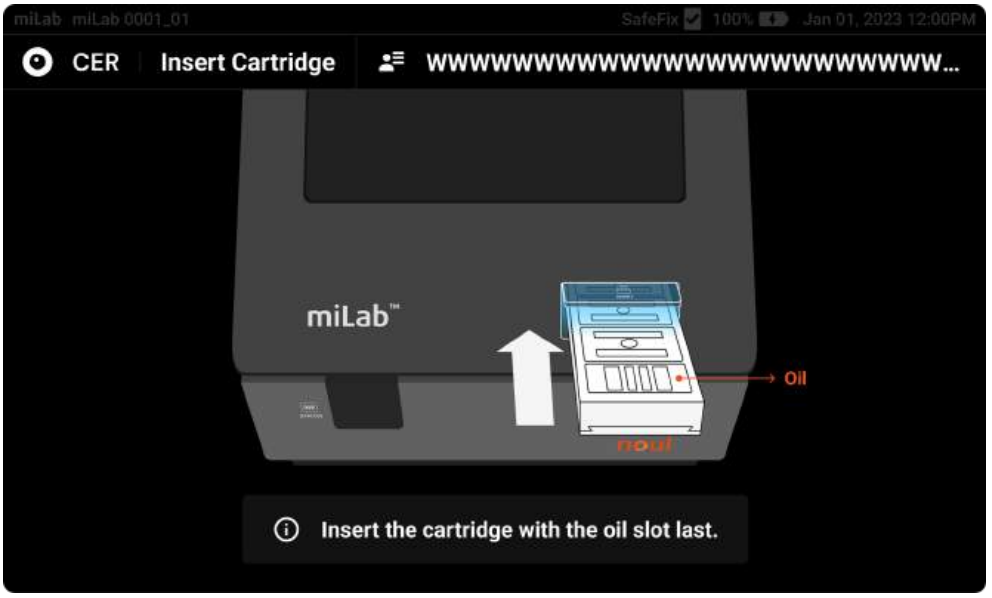
3. Enter the Date of Birth, Menopause status, Pregnancy, Last Menstrual Period and HPV Result on the Patient Information page and press the [NEXT] button.



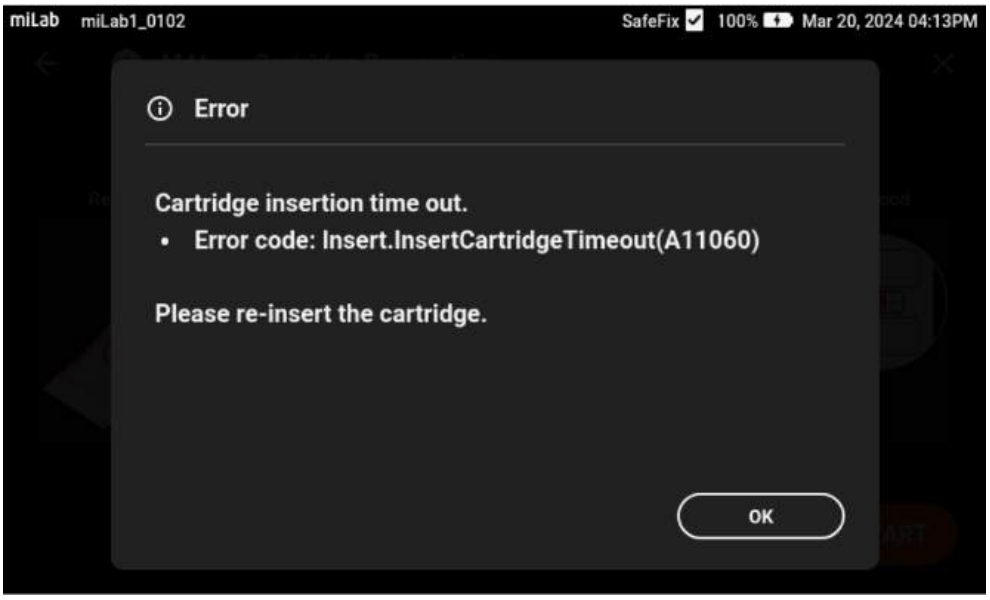
4. Place the assembled cartridge into the device cartridge inlet and touch the [START] button on the Cartridge Preparation screen. You will hear a whirring sound, indicating that the cartridge is being inserted automatically and the test is starting.



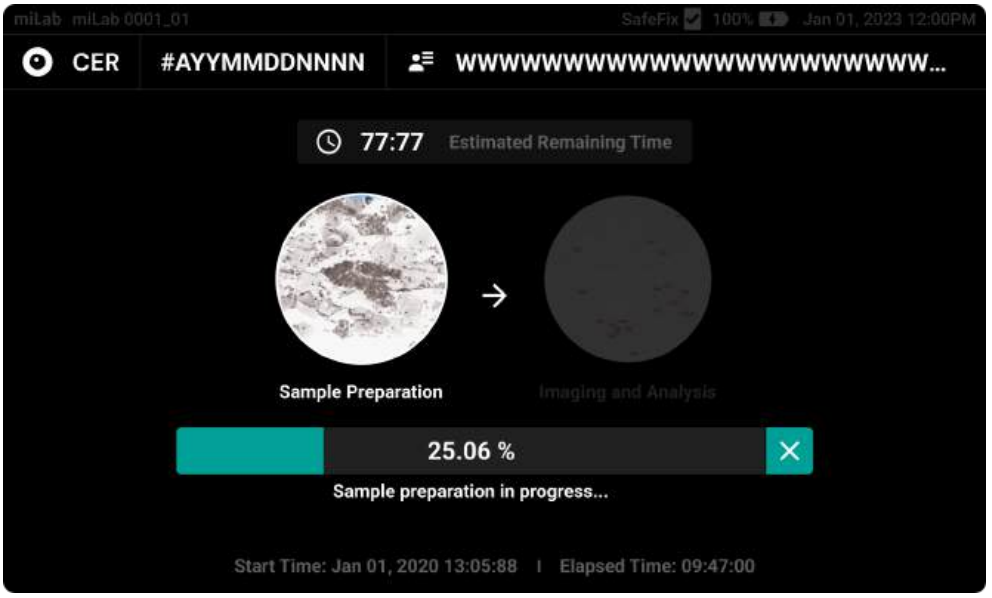
- When placing the cartridge into the device cartridge inlet, ensure that the top assembly of the cartridge faces upward with the hook on the bottom assembly pointing away from the device.
- A correctly inserted cartridge will be automatically pulled in.
- When correctly inserted, the internal barcode scanner will automatically read the barcode on the cartridge bottom assembly. This will be regarded as the slide ID.



- If the cartridge is not inserted properly, an error message will appear. Press [OK] and try again.



5. Once the cartridge is inserted, the device will automatically begin the test. The status screen displays the estimated remaining time.

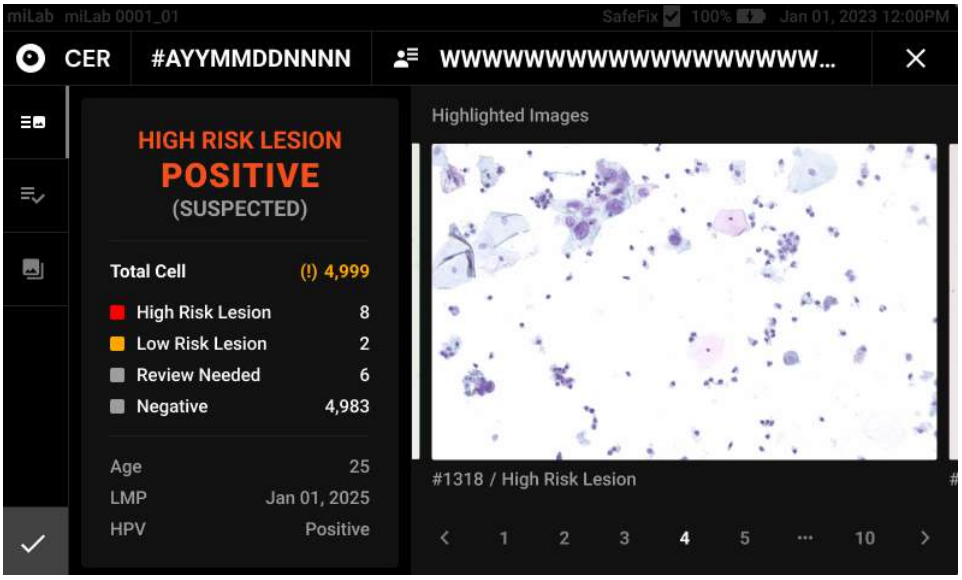


- The test start time and the elapsed time will be shown on the bottom part of the screen, while being able to abort by clicking on the ✕ button any time during the test. However, the slide or the cartridge cannot be reused once it has been aborted in the middle of the process.

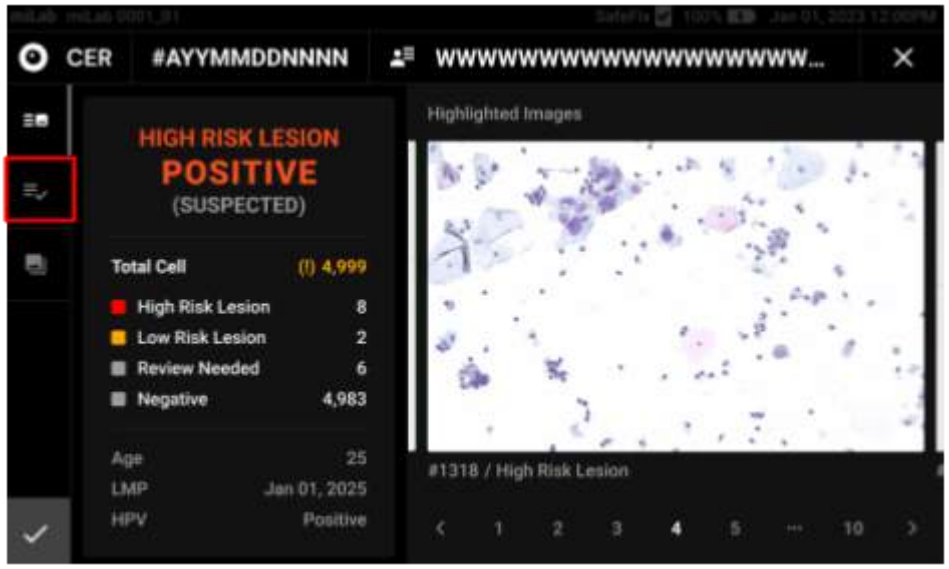
> Caution!
> - Cartridge inserted in the wrong direction might result in a test or device failure.
> - If the cartridge was inserted in the wrong direction to result in device failure, shut down the device using the main power button, and contact Noul service representatives.

14.2. Results Details

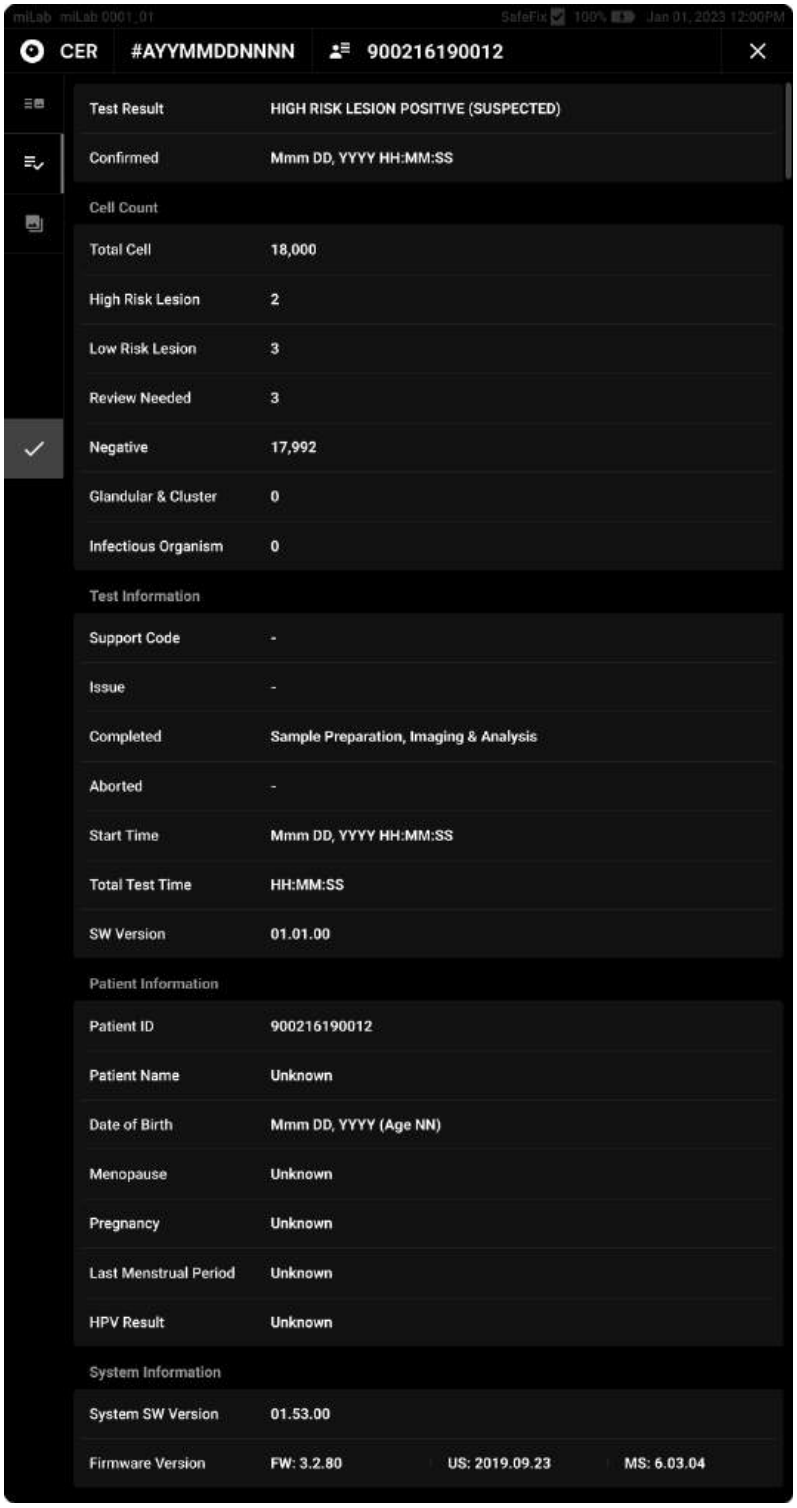
1. Once the test is complete, the cartridge will automatically be ejected.
    - Carefully remove the cartridge from the cartridge inlet.
2. The analysis results of this product are displayed on the screen
    - The main result page will be initially displayed on the device when the miLab completes the analysis or when the results are accessed from the history page.



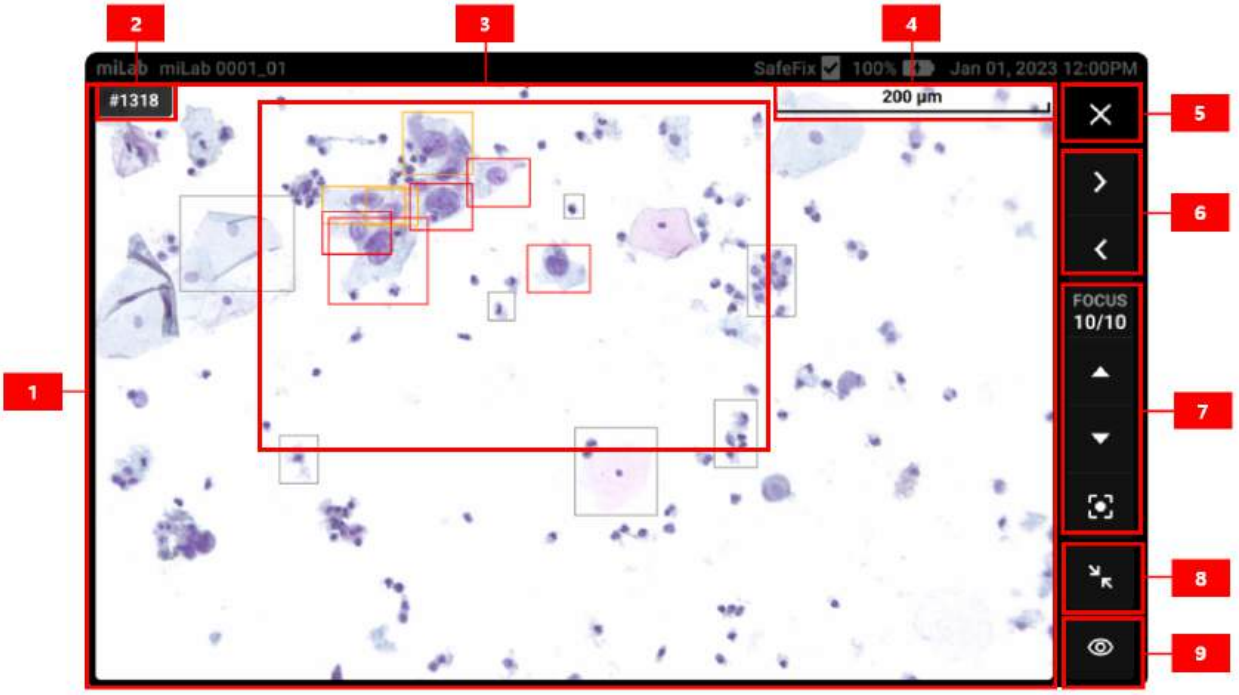
3. The Test Result (Details Tab) page will be initially displayed on the device when users click the details tab  on the left side of the result page. For a precise diagnosis, it's recommended to check this page.



4. Clicking the detail tab (icon) enables a comprehensive view of the Result details, including Test results, Confirmed Result, Cell Count, Test Information, Patient Information including factors such as DOB, Menopause, Pregnancy and HPV Result, and System Information.



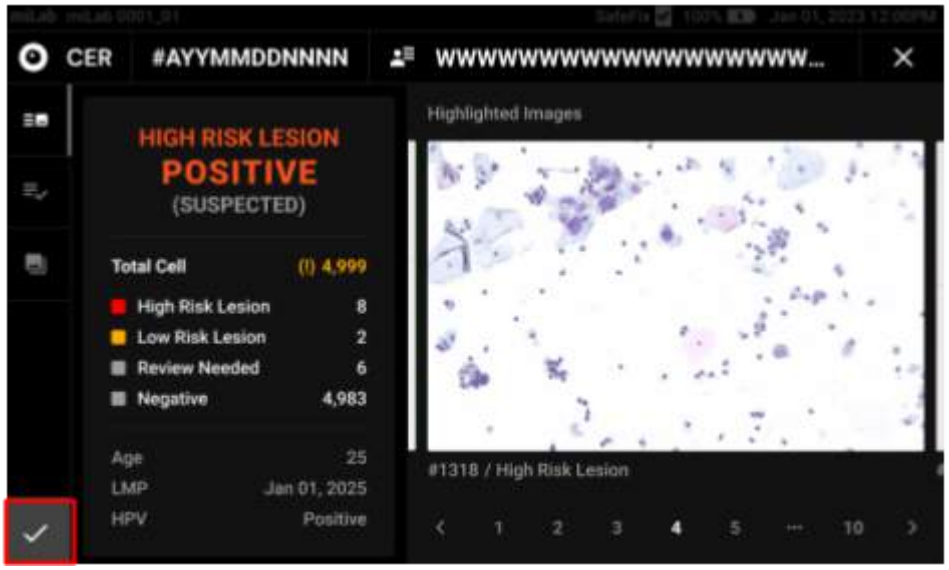
5. The Field of View can be enlarged on the screen when touching the field twice



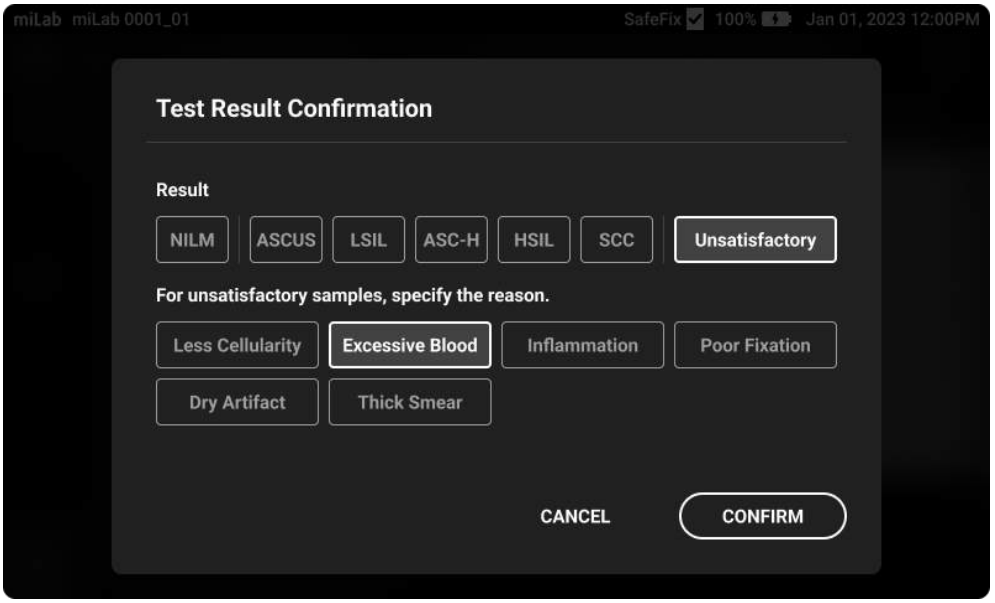
No.	Name	Description
1	Field image	Displays the field image Supports pinch zoom in/out and panning
2	Field number	Shows the number of the selected field
3	Suspected cell mark	Indicates suspected positive cells • Red box represents the High Risk Lesion • Orange/Yellow box represents the Low Risk Lesion • Grey box represents the Review Needed cells ○ These are “predicted negative cells” that are requested to have additional review for confirmation
4	Scale bar	Displays a scale bar
5	Close	Navigates to the previous page when tapped
6	Next / Previous	Shows the next/previous field image when tapped
7	Focus adjustment	Adjusts and displays the focus of the image to lower, upper, or best focus
8	Fit to screen	When tapped, adjusts the zoomed-in image to fit the screen level
9	Hide / Show	Toggles the display of suspected cell mark information when tapped

6. This process can be done either via Viewer system or on the device. The result confirmation on the viewer can be done by following section 5.2. Using miLab Viewer™.

- **Review Process**: Carefully review the information provided on the field image.
- **Expert Judgment**: After reviewing the entire classification and the digital images, the cytologist (CT) and/or pathologists (PT) provide an interpretation and diagnosis of the image per The Bethesda System for Reporting Cervical Cytology. It is the responsibility of qualified CTs and PTs to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using this system. The result interpretation should be done in conjunction with professional screening and management guidelines to guide patient care. Users must always review the entire gallery prior to rendering an interpretation to minimize interpretive errors. After review of the digital images, if there is uncertainty in the diagnosis, then direct examination of the glass slide by light microscopy is performed. This evaluation should determine the stage of atypical cell progression based on the Bethesda diagnostic classification system (e.g., NILM, ASCUS, LSIL, ASC-H, HSIL, SCC, or Unsatisfactory).
- **Confirmation**: The Confirmation page will be displayed on the device when users click the Confirmation button  on the bottom-left side of the result page.

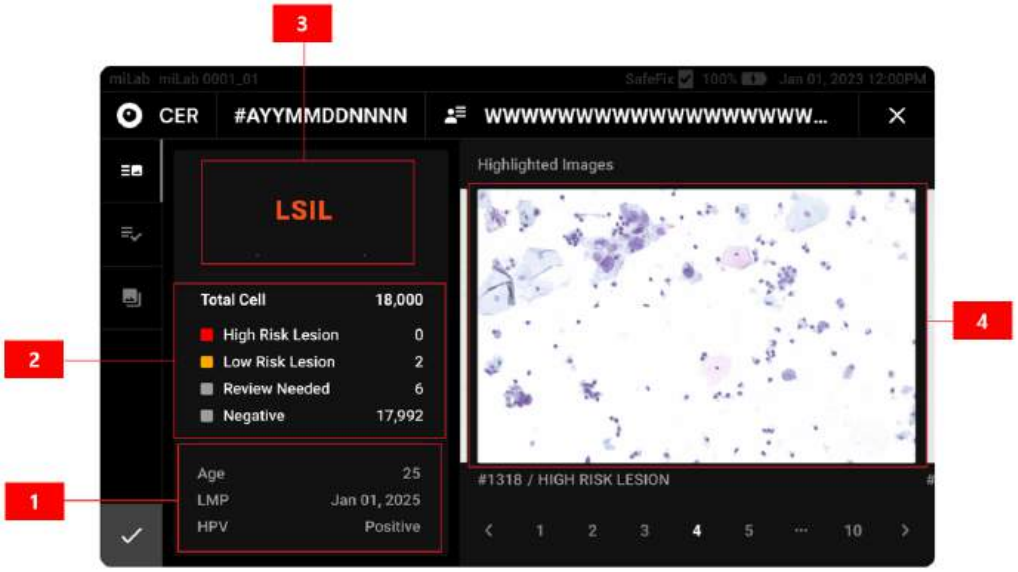


The expert confirms the final results by clicking the "Confirm" button after selecting the appropriate diagnostic category.



7. Handling **Unsatisfactory Samples**: If the expert determines that the sample is "Unsatisfactory" for evaluation, they should select the reason for the unsatisfactory result from the available list (e.g., Less Cellularity, Excessive Blood, Inflammation, Poor Fixation, Dry Artifact, Thick Smear). Following this selection, a new sample procedure should be initiated.

8. The Confirmed sample will be shown like the below:



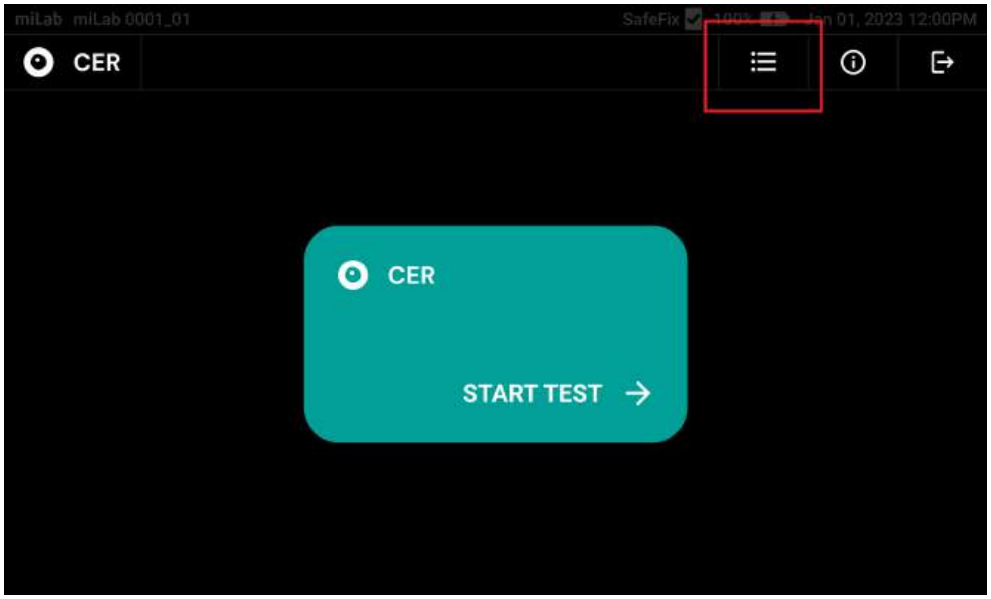
1 **Review Patient Information:** The system allows to review the patient details entered into the platform

2 **Review Detected Cells:** Total number of cells detected by AI and number of cells classified in each category are displayed for review. Total Cell count less than 5,000 will be marked with the (!) sign to signal cell insufficiency

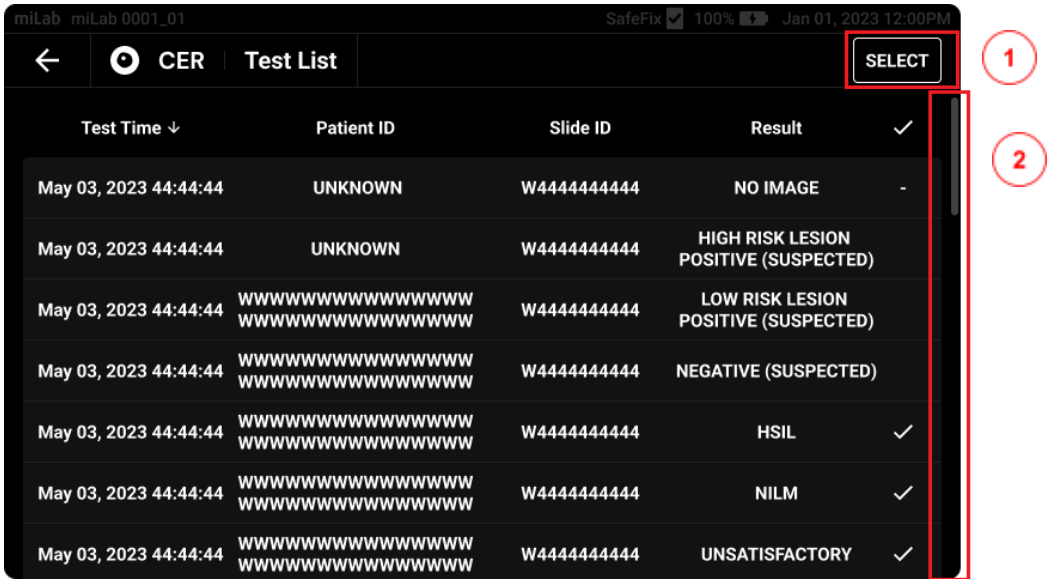
3 **AI Analysis Summary:** The AI provides an analysis summary for each slide, indicating one of the following outcomes: [Negative suspected], [Low-risk lesion suspected], or [High-risk lesion suspected].

4 **Image Review:** Users can access and examine images of cells and fields of view, facilitating a detailed visual inspection.

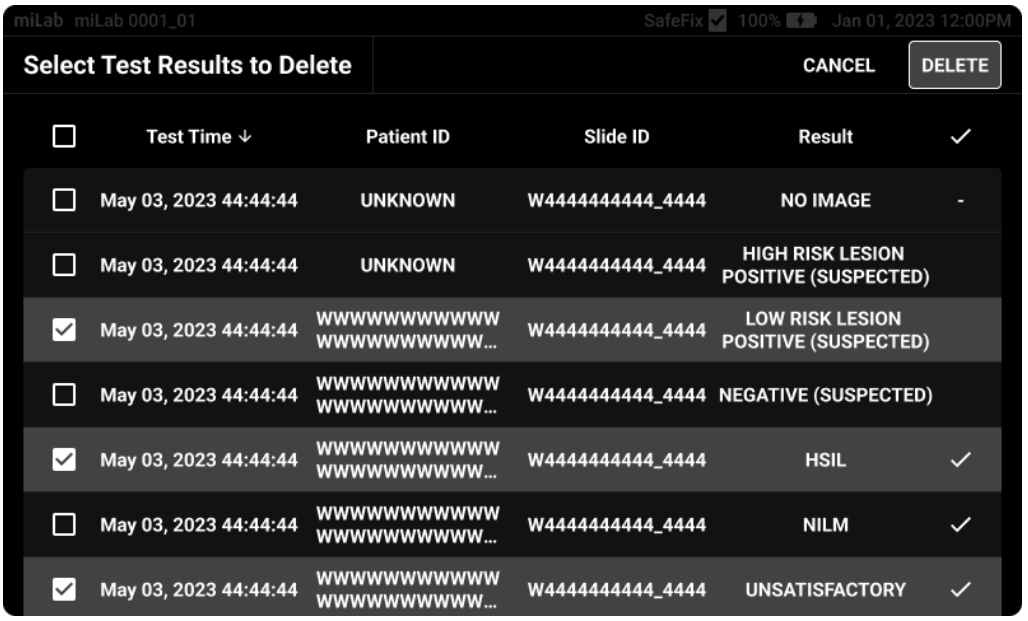
9. Click the [X] button to finish the test.
10. To review the complete test history, users should press the  button, which will display the subsequent screen.



11. Test time, Patient ID, Slide ID and Result can be checked in this history. Selecting a test list will take you to the test results page.
    - ① SELECT: This button is used to choose a specific test to delete from the device.
      ② Scroll Bar: To navigate the list, a thin scroll bar is located on the right side of the screen.

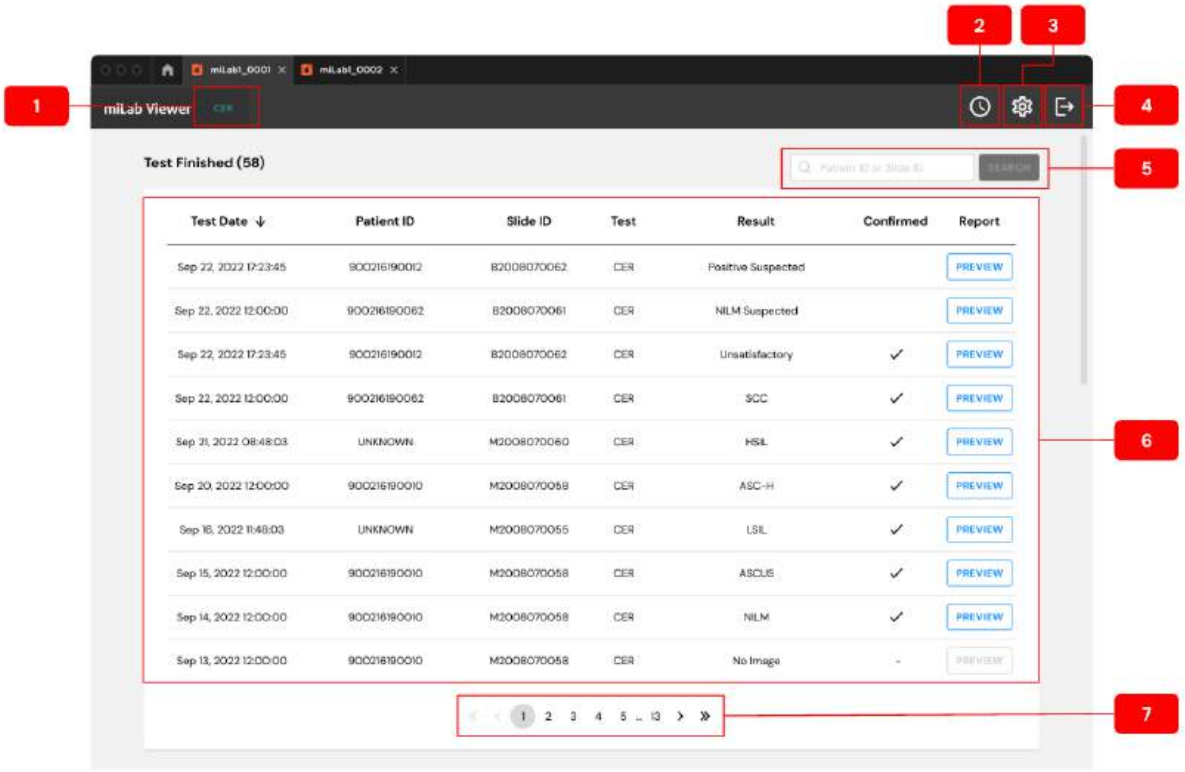


12. After pressing the [SELECT] button, check boxes will appear on the left side of the list, allowing specific tests to be selected for deletion.
    - Check box (☐): Specific tests can be chosen.
    - DELETE: After checking checkboxes, pressing the 'DELETE' button will remove the chosen tests from the device.



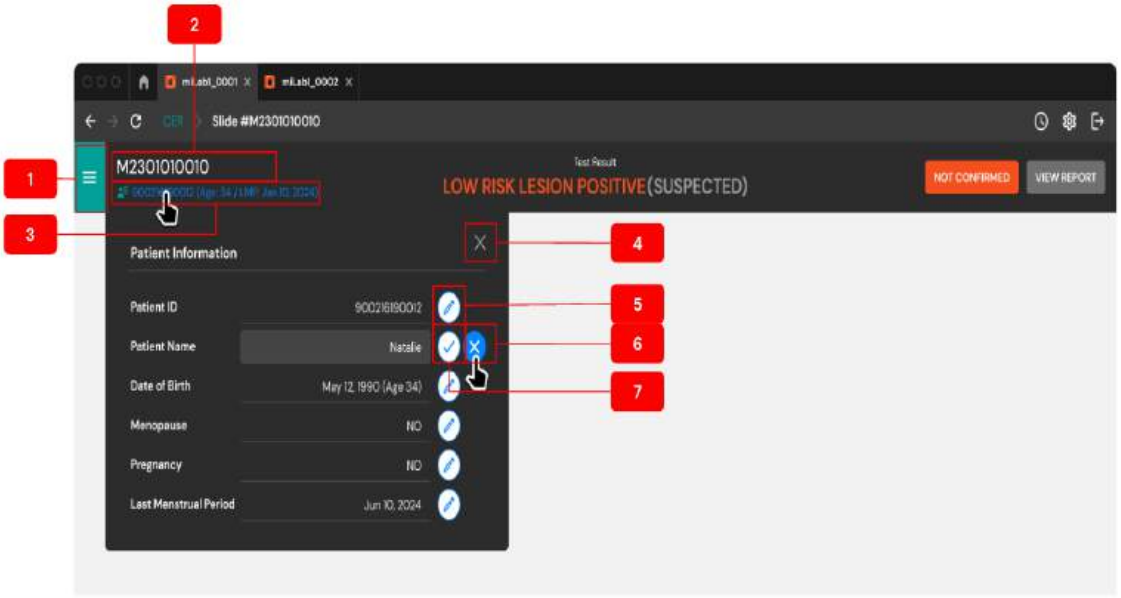
14.3. miLab Viewer™

1. Once logged into miLab Viewer, the main page titled [CER] will display all previous tests.



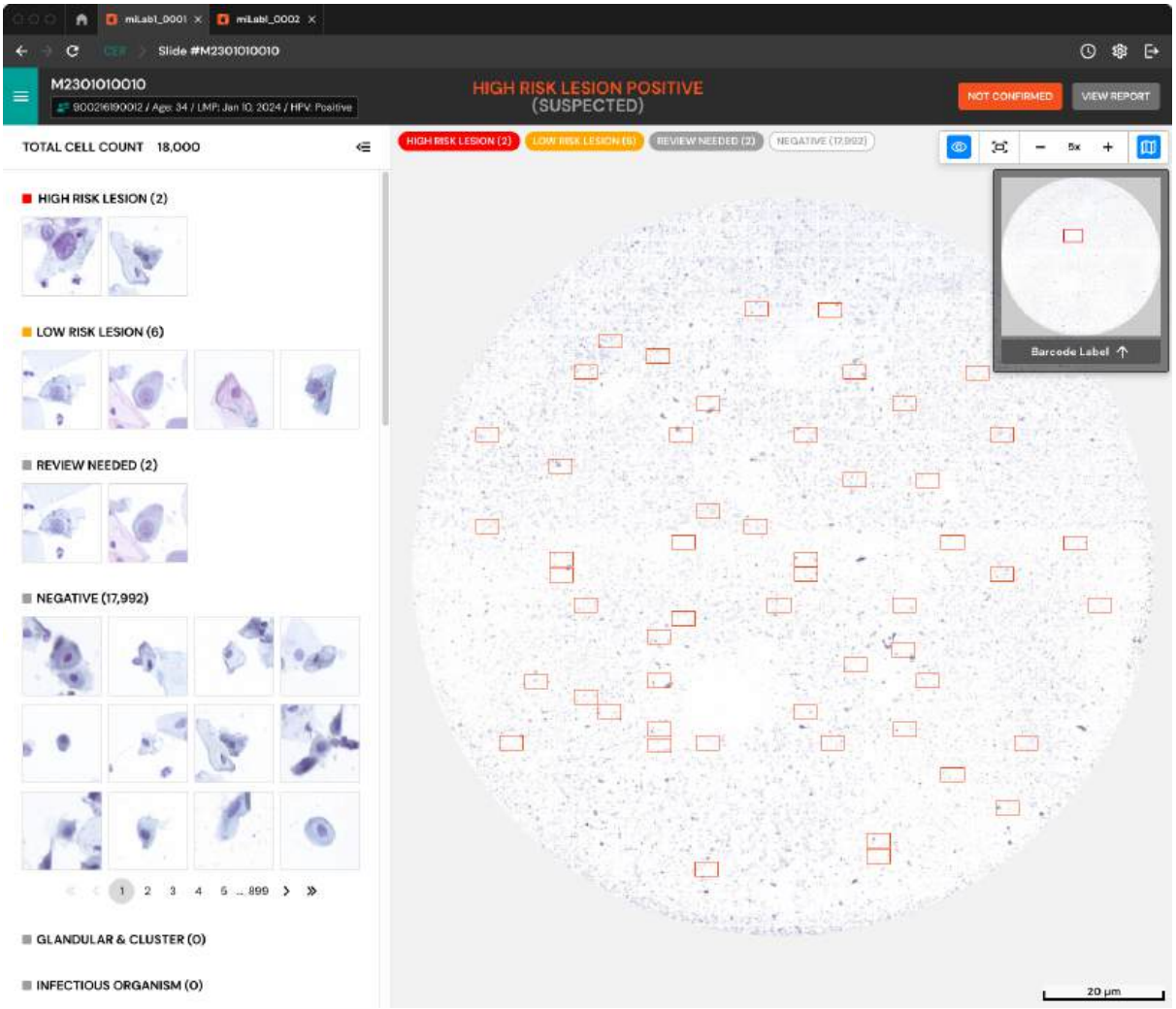
No.	Name	Description
1	Test name	Displays CER for cervical screening
2	Recently viewed tests	Shows up to 8 recently viewed tests by the user
3	Settings	Allows access to the settings menu
4	Logout	Logs out the user
5	Search	Enables searching by Patient ID and Slide ID
6	Test List	Displays a list of completed test results in the latest order
7	Pagination	If the list is long, it is paginated for navigation

2. Click on the Patient ID of interest to further navigate the details.
3. In Viewer mode, you can enter and edit the patient information of the selected slide.



No.	Name	Description
1	Test list	Displays a list of completed test results in the latest order
2	Slide ID	Shows the ID of the selected slide
3	Patient ID	Displays the Patient ID of the selected slide, and when clicked, a patient information popup appears below
4	Close	Closes the patient information popup
5	Write	Allows input for the specified field
6	Cancel	Cancels the entered content in the specified field
7	Save	Saves the entered content in the specified field

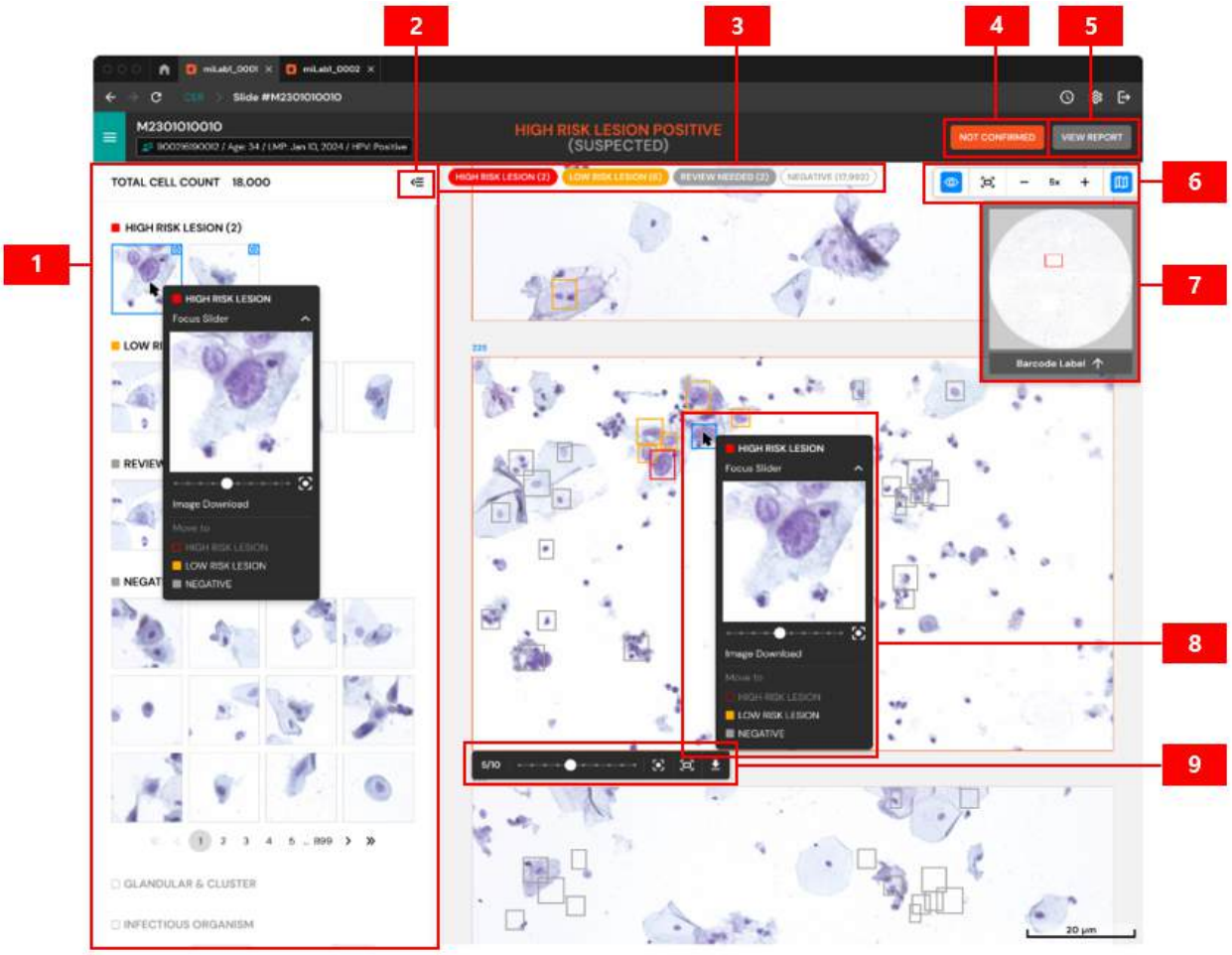
Images can be reviewed with classification grouping and a comprehensive map view of all images being utilized.



Display a total of 6 categories in the left Cell Gallery: High Risk Lesion, Low Risk Lesion, Review Needed, Negative, Glandular & Cluster and Infectious Organism.

Cell Category	Description
High Risk Lesion	Suspected cells for SCC (Squamous Cell Carcinoma), HSIL (High-grade Squamous Intraepithelial Lesion), and ASC-H (Atypical Squamous Cells, cannot exclude HSIL)
Low Risk Lesion	Suspected cells for LSIL (Low-grade Squamous Intraepithelial Lesion) and ASCUS (Atypical Squamous Cells of Undetermined Significance)
Review Needed	Suspected cells that appear potentially negative but fall within borderline parameters, requiring expert review for definitive classification

Negative	Suspected normal cells or cells determined to be without lesions
Glandular & Cluster	Glandular cells and cells observed in cluster formations
Infectious Organism	Cases where infectious microorganisms are observed, such as Candida spp.



No	Name	Description
1	Cell Gallery	Displays the cells categorized into each category
2	Collapse button	Cell Gallery can be collapsed to provide a full screen view
3	Cell toggle button	Provides a toggle function to show/hide positively analyzed and review needed cells. Each category filter can be toggled on/off instantly for quick verification • Red box represents the High Risk Lesion • Orange/Yellow box represents the Low Risk Lesion • Grey box represents the Review Needed cells
4	Confirm button	Clicking the button, the confirmation tab opens to select the final result of the sample
5	View Report	Provides a preview of the report sheet.

6	Field Image Control		**Show/Hide** Provides a toggle function to show/hide positively analyzed and review needed cells
			**Fit to screen** Allows the field image to fit the screen from zoomed in and out field view
			**Zoom** Allows zooming in and out of the slide image
			**Minimap** Provides a toggle function to show/hide the minimap when clicked
7	Minimap	Displays the entire smeared cell area on the slide and indicates the current position	
8	Cell info and labeling	After selecting a cell, right-clicking allows access to cell info and labeling, both in the field view and the cell gallery. Multiple cells can be selected at once: ● Press on the 'Ctrl' key and select the cells or Press on the 'Shift' key to select multiple cells at once. ● Right-clicking after selecting multiple cells opens a context menu to view information and perform labeling.	
9	Field tool bar	When hovering over a field image in the slide view, the field toolbar appears.	
			Adjust field focus
			Show best focus
			Display the field image as "Fit to Screen"
			Download field image

- The AI-recommended test results provided by the software are Positive High Risk Lesion (suspected), Positive Low Risk Lesion (suspected), and Negative (suspected). The user reviews and interprets the analysis results through this software, selecting the diagnostic unsatisfactory status of the specimen and confirming the results by choosing one of the six diagnostic categories of the Bethesda system.

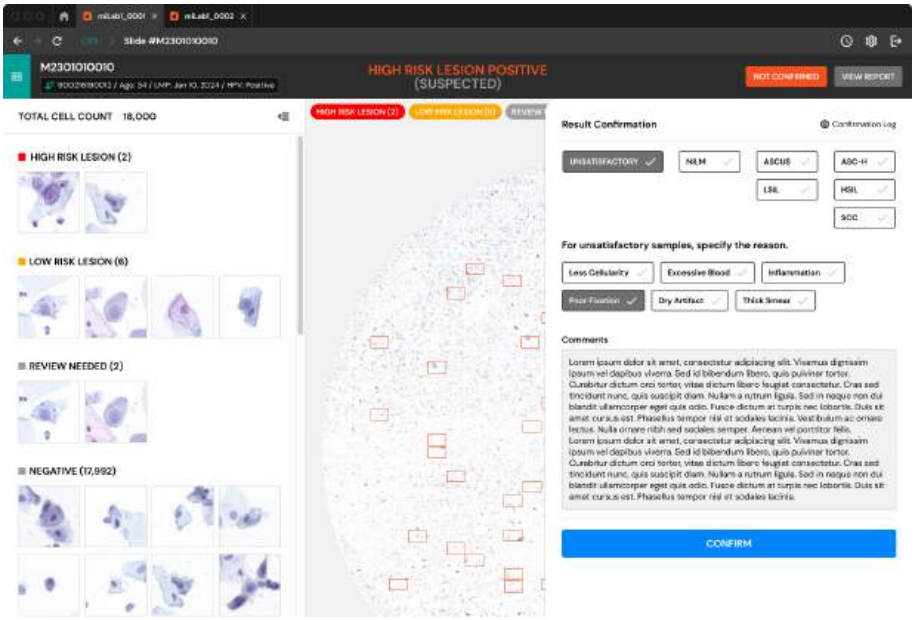
miLab AI-based Result	Results Based on User Selections
(1) Negative (suspected)	● UNSATISFACTORY ● NILM ● ASCUS ● LSIL ● ASC-H ● HSIL ● SCC
(2) Positive Low risk lesion (suspected)	
(3) Positive High risk lesion (suspected)	

- After reviewing the entire classification and the digital images, the cytologist (CT) and/or pathologists (PT) provide an interpretation and diagnosis of the image per The Bethesda System for Reporting Cervical Cytology. It is the responsibility of qualified CTs and PTs to

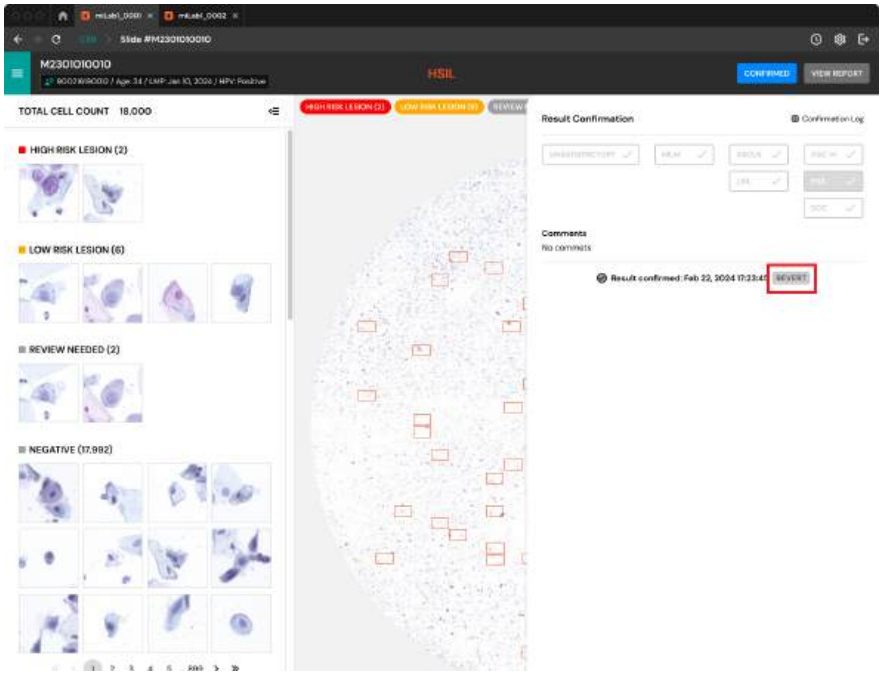
employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using this system. The result interpretation should be done in conjunction with professional screening and management guidelines to guide patient care. Users must always review the entire gallery prior to rendering an interpretation to minimize interpretive errors. After review of the digital images, if there is uncertainty in the diagnosis, then direct examination of the glass slide by light microscopy is performed.

- After review, Click on the 

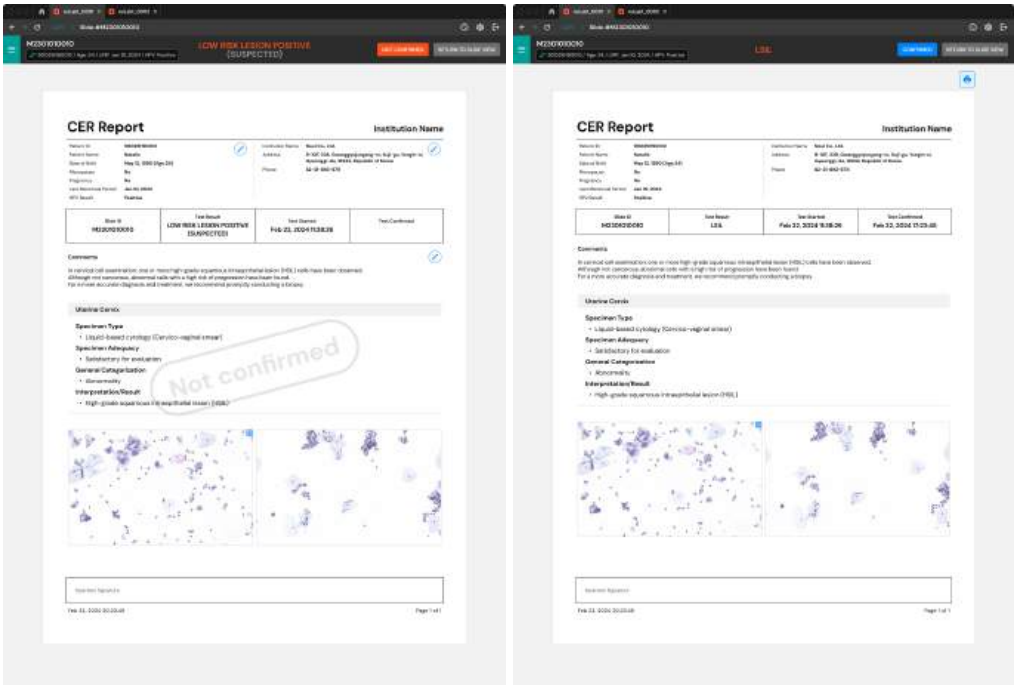
button to select the final result of the sample. Additional comments can be written regarding the sample. The final step is to click on the [Confirm] button to compile the report.



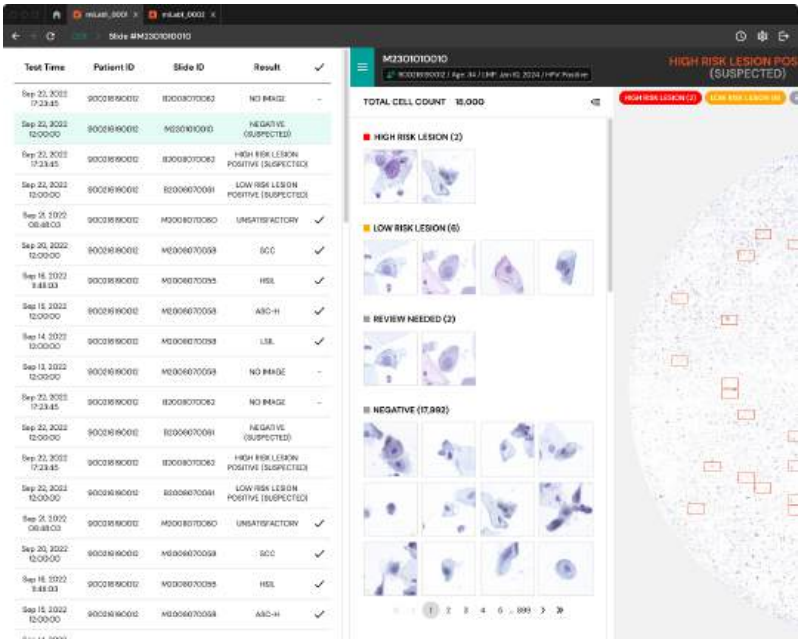
- If the test results have already been confirmed - whether on the device or on the viewer - the results will be displayed based on the user's selection. To modify the results, the user can click the [REVERT] button on the confirmation tab to make adjustments to the test results.



- A report can be generated based on the results confirmed by the user, and it can be saved as a PDF or printed. The confirmed report will look like the one on the right side below.



- To review the complete test history, users should press the  button, which will display the subsequent screen.
- Select the sample of interest to directly view the cell and field information



15. Specifications and Performance

	TBS Category	Sensitivity	Specificity
miLab Standalone AI** (*N = 80)	Low Risk +	93.75%	60.42%
	High Risk +	77.78%	83.10%
miLab Reviewed By Cytologist *** (*N = 80)	ASCUS+	96.09%	87.50%
	LSIL+	84.48%	98.04%
	ASC-H+	77.78%	99.30%
	HSIL+	55.00%	97.00%

* N = Sample
** Results can be altered by setting the threshold
*** Cytologist reviews clinical results using miLab

16. Parameters and Calculations

16.1. Cell Category

Category	Category
Squamous Cell Abnormality	High Risk Lesion / Low Risk Lesion

Infectious Organism	Infectious organisms that include viruses, bacteria, fungi, and parasites
Cluster & Glandular	Glandular epithelial cells, clustered or aggregated Squamous cells are included in this category
Review needed	Cells that are negative but suspected to be positive and require user review

16.2. Calculations

Parameter	Equation
Total Cell Count	Sum of detected cells *In case of total detected Cells are below 5000, (!) is marked

17. Specifications and Performance

17.1. Device Specifications

Category	Specifications		
	DMLA-AP50	DMLA-AC50	DMLA-SA20
Equipment type	Portable instrument		
Operating condition	15 ~ 35°C		
Storage condition	4 ~ 30 °C 30% ~ 60% Relative Humidity		
Unit weight	11 kg		
Exterior Dimension (W x D x H)	212 x 390 x 244 (mm)		
Outdoor use	Indoor use only		
Overvoltage category	None (battery pack operate) or OVC II (AC/DC switching adaptor)		
Pollution degree	Degree 2		
For use in wet locations	Unsuitable		

Operating conditions	Continuous operation		
Marked degree of protection to IEC 60529	IPX0		
Short-term temporary overvoltage	1440 V (AC/DC SWITCHING ADAPTOR)		
Long-term temporary overvoltage	490 V (AC/DC SWITCHING ADAPTOR)		
Processing speed	1) Automatic staining process per hour: 6 samples 2) Total (staining and imaging) process per hour: 2 samples		
Data storage capacity	225 samples (based on 400 images per sample)	225 samples (based on 400 images per sample)	780 samples(based on 1270 images per sample)
Number of specimens processed per test	1 sample (tissue or cell) slide per test		
Objective lens	50X (EFL 3.6mm) NA 0.95	50X (EFL 3.6mm) NA 0.75	20x NA 0.45
Camera	1) CMOS sensor 1920 X 1200 2) Pixel size: 5.86 um		
LED	White LED (CCT 6500K)		
Condenser	NA 0.63		
Scan mode	Auto		
Scan resolution	approx. 0.142 um/pixel		
Scan Time	8 minutes (When shooting 400 FOVs within a 10 mm x 6 mm area)	8 minutes (When shooting 400 FOVs within a 10 mm x 6 mm area)	15min(When shooting 1270FOVs within a diameter 21mm area)
Barcode	1-dimensional barcode, 2-dimensional barcode		
Focusing method	1) Auto-focusing	3) Auto-focusing	5) Auto-focusing

	2) 10 Z-stack images per spot	4) 5 Z-stack images per spot	6) 10 Z-stack images per spot
Image format	jpeg		

17.1.1. Battery

Category	Specifications		
	DMLA-AP50	**DMLA-AC50**	**DMLA-SA20**
Model number	miLab-A-BAT3000		miLab-A-BAT3600
Normal voltage	12.8 V		
Rated capacity	3,000 mAh / 38.4 Wh		
Type	4IFpR19/66-2		

17.1.2. AC/DC adaptor

Category	Specifications		
	DMLA-AP50	**DMLA-AC50**	**DMLA-SA20**
Model number	GST90A12	GST90A12	GST120A12
Input	100-240VAC, 50/60Hz, 1.3A	100-240VAC, 50/60Hz, 1.3A	100-240VAC, 50/60Hz, 1.4A
Output	12V, 6.67A, 80W	12V, 6.67A, 80W	12V, 8.5A, 102W

17.2. SafeFix Variants Specifications

Category	Specifications	
	SafeFix™ (Applicable Models: DMLA-AP50, DMLA-AC50)	**SafeFix™ CER** (Applicable Model: DMLA-SA20)
Equipment type	Fixative solution	Dehydrating and decolorizing solution

Category	Specifications	
	SafeFix™ (Applicable Models: DMLA-AP50, DMLA-AC50)	**SafeFix™ CER** (Applicable Model: DMLA-SA20)
Operating condition	15 ~ 35°C	
Shelf-life and Storage condition	4 ~ 30°C for 12 months	
Shelf-life	(Unopened) 12 months from the date of manufacture (Installed) 6 months from installation	
Volume	220 ml	

17.3. Device Performance

Category	Performance		
	DMLA-AP50	**DMLA-AC50**	**DMLA-SA20**
Throughput	MAL: Automatic staining process per hour-up to 6 slides	Automatic full process(staining and image analysis) per hour- 2 slides	Automatic full process(staining and image analysis) per hour- 2 slides
Storage	Total 1TB	Total 1TB	Total 4TB

18. Parameters and Calculations

The system provides an array of useful parameters, which are calculated from the measurement values of each sample. The specific parameters of the IVD examination can be found in the IFU (Instructions For Use) of each cartridge.

19. Stability

19.1. Shelf-life

Category	Specifications
Storage condition	4 ~ 30 °C 30% ~ 60% Relative Humidity
Unopened	5 years from the date of manufacture

19.2. Prepared Slides

For long-term storage of the prepared slides, commercially available mounting solutions may be used to preserve the stains in their current state. However, once the slides are stored using the mounting solution with a cover glass or immersion oil, etc., the images CANNOT be read by the miLab™ Platform, and subsequent morphology can only be further observed using microscopy.

20. Warranty

Noul instruments are warrantied against defective material or workmanship for 1 year, commencing on the date of installation at the customer's premises. This warranty does not cover any defect, malfunction, or damage due to:

- Accident, neglect, or willful mistreatment of the product.
- Failure to use, operate, service, or maintain the product under the applicable Noul Instruction for Use.
- Failure to use the appropriate reagents and supply parts specified for the product.

21. Internal Quality Control

21.1. Self Check-Up

When the device is turned on, the system performs a self-diagnostic test. All communication systems, including electrical, mechanical, and software, are checked to ensure that they work properly. If any malfunction occurs, it will be indicated on the user interface. Contact an authorized service provider or Noul Customer Service if the system does not work or if any recurring errors exist.

21.2. Post Scan Check

The device will perform functional tests after slide imaging and slide review to guarantee the quality of the data acquired during imaging and review. If any malfunction occurs, it will be indicated on the user interface. Contact authorized service providers or Noul Customer Service if the system does not work or if any recurring errors exist.

22. Operational Precaution and Hazards

22.1. General Safety Information

⚠ **Caution!**

- The device should be serviced by authorized personnel only.
- If the device is used in a manner not specified by the manufacturer, the protection provided may become void.

- Ensure that the device is placed on a steady surface and not exposed to bumps, excessive vibrations, excessive temperature variations, or direct sunlight.
- Ensure that there is enough space clearance around the device for ventilation purposes.
- Spillage of fluid on the surfaces of the device may cause malfunction or deterioration. Wipe off spilled fluids immediately with a soft tissue.

22.2. Warnings and Precautions for Safety

Warning!

- DO NOT disassemble or manipulate the device. Any unauthorized tampering of the device may result in personal injury or inaccurate results and will void the warranty.
- DO NOT wet the device.
- DO NOT touch the power plug and cord with wet hands.
- DO NOT forcibly pull on the cord and connector.
- In the following cases, stop the operation of the device. Notify Noul customer service or an authorized service representative for further instructions.
    - The power plug is visibly damaged or not functional.
    - The device is visibly damaged or not functional.
    - A heavy object fell onto the device, or the device fell from a height.
    - None of the above, but device damage or failure is suspected.
- Inappropriate use and handling of the device may shorten the lifetime of the device.
- DO NOT drink the SafeFix variants solution.
- The SafeFix variants insertion area on the device contains sharp needles. Avoid contact with the needles.

22.3. Precautions Before Use

Caution!

- This device is an in vitro diagnostic (IVD) medical device.
- As an IVD medical device, it should be used by healthcare professionals, such as trained technicians and medical doctors.
- This device should not be used for any purpose other than what was indicated in this document.
- Read the manual carefully before using the device.
- miLab cartridges are single-use and should not be used again.
- This device MUST be placed on a flat surface and kept in place while in use.
- Wear protective gloves when handling the miLab cartridges.

22.4. Cautions during Use

Caution!

- Read the manual carefully before using the device.
- Ensure that there is enough solution for the SafeFix variants in the container.
- Check the expiration date on the cartridge.
- DO NOT press the reagent part and smear film from the cartridge top assembly.
- When handling, grab only the sides of the cartridge.
- Be careful not to contaminate the cartridge with dust and other substances.
- DO NOT leak the SafeFix variant solution in the device.
- Wear protective gloves when handling the cartridge.
- DO NOT cover the ventilation holes on the back of the device to allow for uninterrupted airflow, prevent overheating, and ensure the proper operation of the device.

22.5. Cautions for Storage

Caution!

- The device shall be stored at a temperature between 4°C and 30°C with adequate ventilation.
- The device shall be placed on a flat surface to keep it from falling.
- The device and SafeFix shall be stored out of direct sunlight.
- The device shall not be stored in areas above 60% relative humidity or wet areas for MAL and BCM.

22.6. Cautions for Disposal

Caution!

- After the cartridge is used, it MUST be disposed of as medical waste.
- When the device MUST be disposed of due to its lifetime, the national regulations and their proper disposal guidelines MUST be followed.

22.7. After Use

- Use a soft cloth with water to clean the outside of the device, put a cover onto the device, and store it in a well-ventilated area.
- DO NOT store the device on a tilted surface or surface on which there is an excessive vibration or shock.
- Unplug the power cord when the device is not in use.

22.8. Maintenance and Repair

- Check whether the device has any issues before use.
- Consult customer service for a general inspection annually.

22.9. Electromagnetic compatibility(EMC)

*This instrument complies with the following IEC (EN) standards:

- EN 55011:2016+A1:2017
- EN 61326-1:2013
- IEC 61326-2-6:2013
- IEC 61000-3-2:2014
- IEC 61000-3-3:2013+A1:2019
- Reference standard: CISPR 32:2015 + A1:2019 Class A.

22.10. Electromagnetic safety

- IEC 61010-1:2010
- IEC 61010-1:2010/AMD1:2016

Warning!

- The system MUST be connected to grounded electrical sockets only.
- Only use the power cord and AC/DC adaptor provided by Noul.

23. Serious Incident & Vigilance

Any serious incident that has occurred with the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient are established.

Please send information about serious incidents with the device to the address listed in section *1.2. Support*.

24. Troubleshooting

24.1. Device Operation (Applicable Models: DMLA AP-50, DMLA AC-50)

Problem	Possible Causes	Action
The cartridge is ejected right after inserting it.	The cartridge was inserted in the opposite direction.	Ensure that the cartridge is assembled and inserted correctly. Retry the test with a new cartridge, including reloading the sample on the new slide to prevent clots.
	The cartridge was inserted in an	Confirm that the cartridge is

	incompletely assembled state.	assembled in the correct direction. To prevent clots, retry after checking the assembled state using a new cartridge.
	Only the cartridge bottom assembly was inserted.	Ensure the cartridge is assembled correctly and both assemblies are inserted. Then, retry the test with a new cartridge.
	The cartridge was forcibly pulled out while being fed.	DO NOT hold or pull on the cartridge while being fed into the device. Retry the test with a new cartridge.
The full process is aborted, and the cartridge is ejected after smearing.	The sample volume loaded is insufficient.	Use the correct amount of the sample and retry the test with a new cartridge.
	The sample is not loaded.	Ensure the sample is loaded on the slide glass before inserting the cartridge. Retry the test with a new cartridge loaded with the sample.
	The sample was clotted on the slide glass.	Insert the cartridge as soon as the sample is loaded on the slide. Otherwise, it is recommended that you collect the sample using an EDTA K2 container. Retry the test with a new cartridge loaded with the sample.
	The smear film on the cartridge was damaged and made an irregular smear form.	DO NOT press or damage the smear film when preparing the cartridge. Retry the test with a new cartridge loaded with the sample.
	The microscopic lens is contaminated.	Contact an authorized service provider or Noul Customer Service.
The cartridge is ejected with an error message during the process.	The sample hematocrit level is too low.	The sample hematocrit level may be too low for proper sample preparation analysis. Check the cartridge-specific

		recommended hematocrit level.
	The sample is not adequately mixed.	Ensure the sample is mixed homogeneously before loading. Retry the test with a new cartridge.
	One or more staining stamps are separated from the cartridge.	Ensure all three staining stamps are present in the cartridge top assembly. Then, retry the test with a new cartridge.
	The remaining SafeFix variants are insufficient.	Ensure the remaining SafeFix variants are sufficient. If they are not, replace them with new SafeFix variants and retry the test with a new cartridge.
	The environment is not suitable for running a test, such as vibration, forcibly lighting the inside of the device, exposure to a dusty area, etc.	Ensure the working area is free of vibration and clean. DO NOT compromise the device when it's running. Retry the test with a new cartridge.
The slide was ejected wet with liquid remaining.	One or more staining stamps were damaged.	Ensure the staining stamps are not damaged before use. DO NOT touch or alter the staining stamp. Retry the test with a new cartridge.
	The cartridge was not used immediately after the easy-peel film was removed from the cartridge top assembly.	Ensure the cartridge is used immediately after opening. Retry the test with a new cartridge.
The cartridge was not ejected after test completion. -or- The cartridge was internally stuck during the test process.	Contact Noul Customer Service at cs@noul.com immediately. DO NOT tamper with or open the device without Customer Service guidance.	
The device was lagging.	The operating temperature was too high.	Check the recommended operating temperature range

24.2. Device Operation (Applicable Model: DMLA SA-20)

Problem	Possible Causes	Action
The cartridge is ejected right after inserting it.	The cartridge was inserted in an incompletely assembled state.	Confirm that the cartridge is assembled in the correct direction. To prevent specimen

Problem	Possible Causes	Action
		dry, retry after checking the assembled state using a new cartridge.
	Only the cartridge bottom assembly was inserted.	Ensure the cartridge is assembled correctly and both assemblies are inserted. Then, retry the test with a new cartridge.
	The cartridge was forcibly pulled out while being fed.	DO NOT hold or pull on the cartridge while being fed into the device. Retry the test with a new cartridge.
The full process is aborted, and the cartridge is ejected	Expired or unrecognized cartridge	Ensure the cartridge is within its expiration date and properly recognized.
The cartridge is ejected with an error message during the process.	The remaining SafeFix variants are insufficient.	Ensure the remaining SafeFix variants are sufficient. If they are not, replace them with new SafeFix variants and retry the test with a new cartridge.
	The environment is not suitable for running a test, such as vibration, forcibly lighting the inside of the device, exposure to a dusty area, etc.	Ensure the working area is free of vibration and clean. DO NOT compromise the device when it's running. Retry the test with a new cartridge.
The cartridge was not ejected after test completion. -or- The cartridge was internally stuck during the test process.	Contact Noul Customer Service at cs@noul.com immediately. DO NOT tamper with or open the device without Customer Service guidance.	
The device was lagging.	The operating temperature was too high.	Check the recommended operating temperature range

24.3 Error Codes

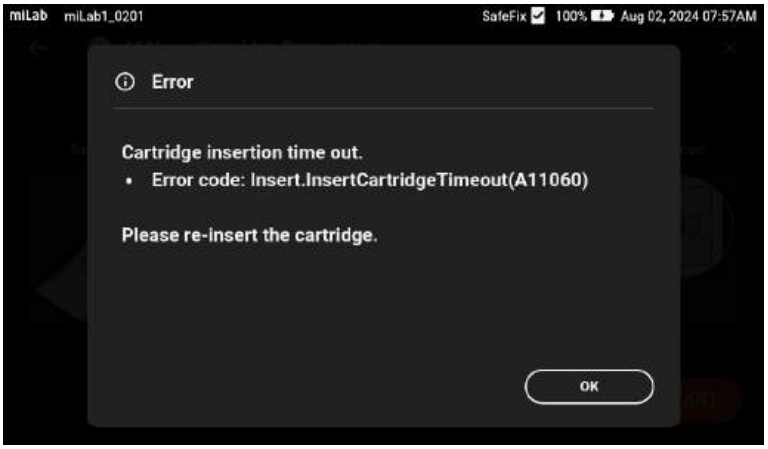
Error Code	Message	Solution
Auto Exposure Error	An error has occurred during the test.	Please restart the test or the device.
Auto Focus Error	An error has occurred during the test.	Please restart the test or the device.

Error Code	Message	Solution
Barcode Reader Error	An error has occurred.	Please restart the device.
Boot loader Error	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
Camera Error	An error has occurred during the test.	Please restart the device.
Barcode Read Canceled	Barcode scan has been canceled.	-
Cartridge Not Inserted	An error has occurred during the test.	Please restart the test.
Communication Canceled	User canceled operations.	-
Communication Error	An error has occurred.	Please restart the device.
Device Module Error	An error has occurred.	Please restart the device.
DiskIo Error (Disk Input/Output Error)	An error has occurred.	Please contact authorized service provider or Noul Customer Service.
Ethanol Dispense Error	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
Ethanol Expired	The SafeFix variants expired.	Please replace the SafeFix variant with a new one.
Ethanol Expired Soon	SafeFix variant expiration date: {Expire date} (D-{days})	Please replace the SafeFix variant with a new one.
Ethanol Level Low	SafeFix variant replacement warning.	Please replace the SafeFix variant with a new one.
Ethanol Not Found	SafeFix variant not detected.	Please check that the SafeFix variant is properly installed.
Ideal Zone Not Found	Unable to find stained monolayer. The sample preparation quality of the inserted slide may be poor.	Please check the sample preparation quality of the slide being used and restart the test.
Image Sensor Error	An error has occurred.	Please restart the device.
Imaging Canceled	Imaging canceled.	-
Imaging Completed For All Areas	Imaging completed	Imaging has been done for the entire imaging area.
Insert Cartridge Error	The cartridge is not assembled correctly or inserted in the wrong direction.	Make sure the cartridge is assembled correctly and inserted in the right direction.
Insert Cartridge Time out	Cartridge insertion time out.	Please re-insert the cartridge.
Insufficient Battery	Insufficient Battery	Please make sure the provided AC adapter is securely connected.
Internal Error	An error has occurred.	Please contact an authorized service provider or Noul Customer

Error Code	Message	Solution
		Service.
Invalid Configuration	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
Invalid Update File	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
Limit Sensor Error	An error has occurred.	Please restart the device.
Mechanical Load Warning	An error has occurred.	The mechanical load has exceeded the normal range, but it is usable.
Motor Driver Error	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
Operation Failed	An error has occurred.	Please restart the device.
Patch Over Pressed	An error has occurred during the test.	Please restart the test.
Press Patch Time out	An error has occurred.	Please restart the test.
Registration Error	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
Unsupported FW Installed	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
Unsupported USB File System	A USB backup error has occurred.	Please check the USB DISK and retry.
Unupdatable Status	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
Update Error	An error has occurred.	Please contact an authorized service provider or Noul Customer Service.
USB Disk Error	A USB backup error has occurred.	Please check the USB DISK and retry.
USB Disk Not Mounted	A USB backup error has occurred.	Please check the USB DISK and retry.
Insufficient Storage	Insufficient Storage	Not enough storage space
Slide Glass Not Detected	The cartridge is not inserted with a slide glass.	Please re-insert the cartridge with a slide glass.

24.4. Device-recognized Problems

If miLab recognizes a problem, an error message will appear to provide detailed information necessary for error resolution.



To address any persistent issues or request technical assistance, please contact the **Noul Customer Service team at cs@noul.com** with the device's serial number, product LOT number, Lot number of a cartridge, slide ID, version of Software(SW), Firmware(FW), and Microscope(MS), and error code.

24.5. Device-related Serious Incident

If any serious incident has occurred to the device shall be reported to the manufacturer directly(**cs@noul.com, +82 (0) 31 308 6310**) and the competent authority of the Member State of EU in which the user and/or the patient is established;

In this chapter, 'serious incident' means any incident that directly or indirectly led, might have led, or might lead to any of the following:

(a) the death of a patient, user, or other people,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat;

'serious public health threat' means an event that could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness that may require prompt remedial action and that may cause significant morbidity or mortality in humans or that is unusual or unexpected for the given place and time;

Appendix A. Troubleshooting for MAL

A1. User-recognized Issues based on the Result of the test

The table below provides a list of measures and items to check in order to identify the cause of suspected issues that may occur due to factors that users can perceive or internal problems in the product that cause malfunctions. Please refer to the table below to solve the problem.

Result	Possible Causes	Action
Negative (with suspected patients)	Loading too much blood into the cartridge can cause RBCs to appear as multilayer instead of monolayer, resulting in the system being unable to detect malaria-infected cells.	Retry the test using a new cartridge with 5 µL of blood loaded and inserted immediately into the equipment.
	Using an old blood sample after 24 hours from the blood draw might cause the degradation of the parasite.	Retry the test using a fresh sample or repeat the test making at least 3 slides.
	Low parasitemia or infection in the very early stage, may cause the system not to detect infected cells.	Repeat the test using a new cartridge or perform the retest after 1-3 days
Review Needed	It may either detect one or more suspected infected cells as a review needed under the below situations. 1) The patient took medication and the morphology of the parasite has been deformed. 2) The parasite outside of red blood cells is detected. 3) The image of the parasite is distorted due to cells around 4) Using an old blood sample after 24 hours from a blood draw might cause the degradation of the parasite.	Review the images thoroughly, including field images. Reclassify the cells using miLab Viewer and confirm the test result. Or retry the test using a new cartridge with 5 µL of blood loaded and inserted immediately into the equipment.
	It may detect one or more normal cells under the below situations. 1) The artifact on the normal red blood cells may cause 'Review Needed'. 2) The shadow of the bi-concave shape of red blood cells may	Review the images thoroughly, including field images. Reclassify the cells using miLab Viewer and confirm the test result.

	cause 'Review Needed'.	
No image	**[At smear stage]**	
	If the blood is not loaded onto the slide immediately and left to dry, it will coagulate on the slide and not spread properly, resulting in a failed smear.	Perform a retest by inserting the loaded cartridge immediately into the device using a new cartridge.
	The blood sample was not loaded or loaded onto a surface other than the slide glass.	Perform a retest by loading the sample on the slide glass.
	The volume of the blood sample was loaded with less than 5 µL.	Perform a retest by loading the exact volume of the sample on the slide glass.
	If physical force is applied to the smear film, causing damage, or if solid staining reagents or foreign substances are present, they can affect the smear and result in a failed smear.	Perform a retest using a new cartridge that is not damaged.
	[At Fixation stage]	
	There is damage to the SafeFix tube.	Since the replacement is required after 30,000 tests[1], contact customer service (CS@noul.com).
	No cells have been detected due to the quality of the SafeFix.	Perform a retest after replacing the SafeFix.
	Others	Perform retesting after rebooting or contact customer service (CS@noul.com).
	[At Staining stage]	
	Using an expired cartridge Lot.	Perform a retest with a new cartridge after confirming the expiration date.
	The solid reagent is dried out and fails to stain the appropriate area, resulting in partial staining.	Remove the cartridge sealing immediately, load blood, and insert it into the device for retesting.
	Others	Perform retesting after rebooting or contact customer service (CS@noul.com)

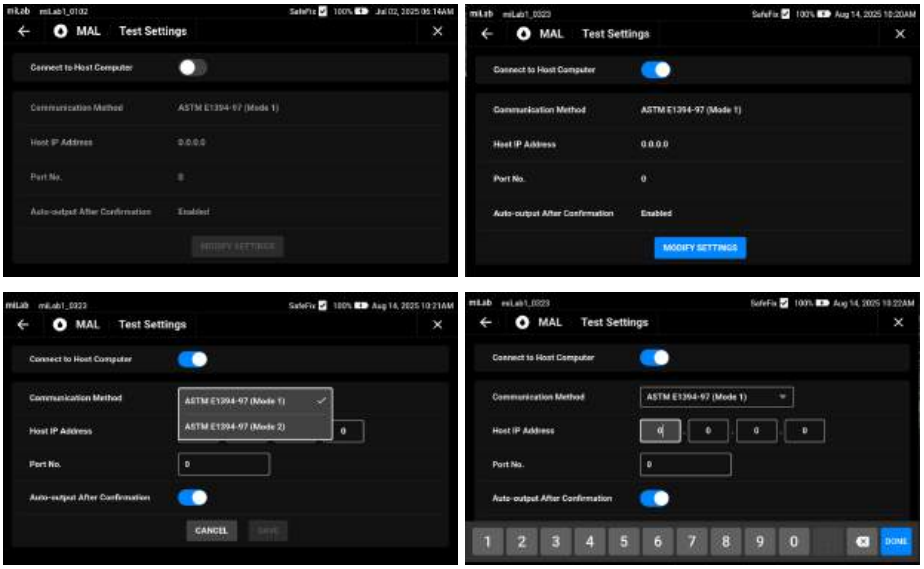
[1] This test number may vary depending on usage environment and conditions

	[At Imaging stage]	
	The desk where the device is on is unstable or physically shocked when the imaging process is started.	Since shocks around the device should not occur during the entire test, perform retesting in a stable environment.
	Others	Perform retesting after rebooting, or contact customer service (CS@noul.com)
Possible early finish of imaging process	It could happen under the below situations 1) The desk is physically shocked during the imaging process 2) Hematocrit is 20 or less. 3) The blood sample was not adequately mixed. 4) There are blank spaces in the blood smear in the staining area 5) Total RBC count was set too high for the patient's low red blood cell count.	It can be solved by performing following directions. 1) Make sure the blood specimen has been mixed properly. Confirm the specimen's HCT or set the Total RBC value lower and perform retesting. 2) Even if the result is Negative(suspected), if the patients have symptoms or the total RBC counts are so low, please repeat the test using a new cartridge or perform the retest after 1-3 days.

Appendix B. Data output and QC mode usage for MAL

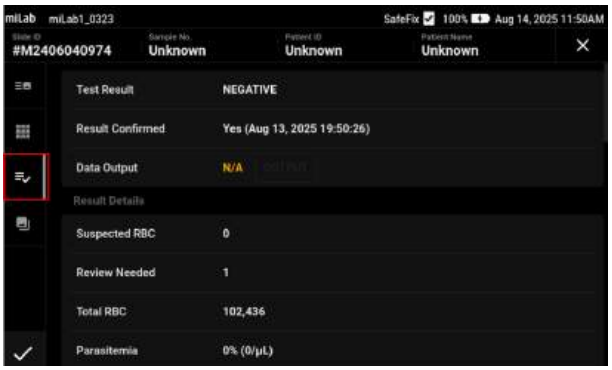
B1. Data output to LIS system

1. **[Setup Host Connection]** When set to **[On]**, miLab data can be transmitted to the LIS.
    - Turn on the **[Connect to Host Computer]** on the **[SETTINGS]** page. And tap the **[MODYFY SETTING]**
    - Select the **[Communication Method]**. The method selection may vary depending on the user environment. For further details, refer to the ‘MAL ASTM specification document’.

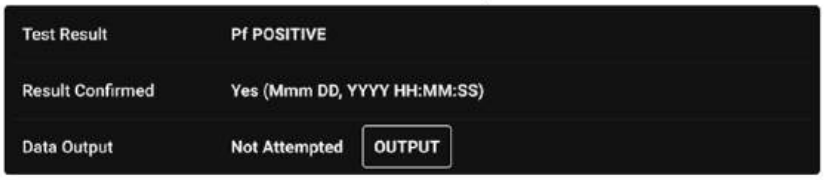


- Enter the Host IP Address and Port No. via keypad.
- If you turn on the **[Auto-output After Confirmation]**, test data is transmitted automatically after confirmation. Data Output is available only when all of the following conditions are met:
    a. Host connection: ON
    b. Sample No.: user entry completed
    c. Network connection: established
    d. LIS connection: established
    e. Sample No. entered in LIS: successfully registered

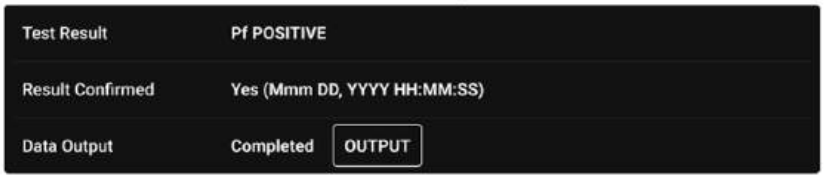
2. **[Data Output]** In [Result Details] Page, the display for each data output case is as follows:



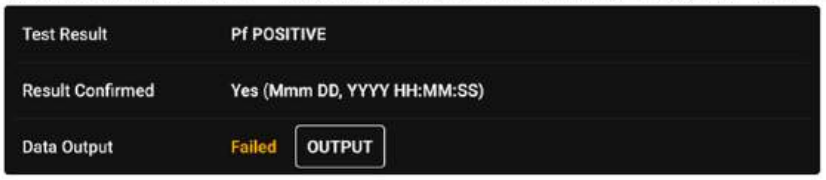
[Not Attempted]
After Result Conformation – No transmission attempt made



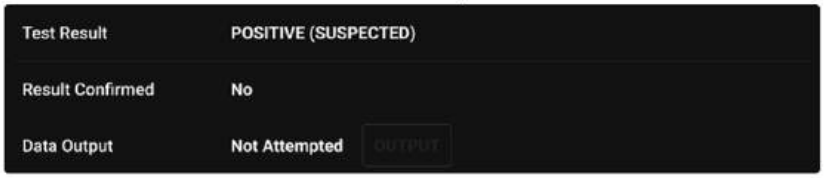
[Completed]
After Result Conformation – Transmission attempt successful



[Failed]
After Result Conformation – Transmission attempt failed (Warning displayed in 'Test List')



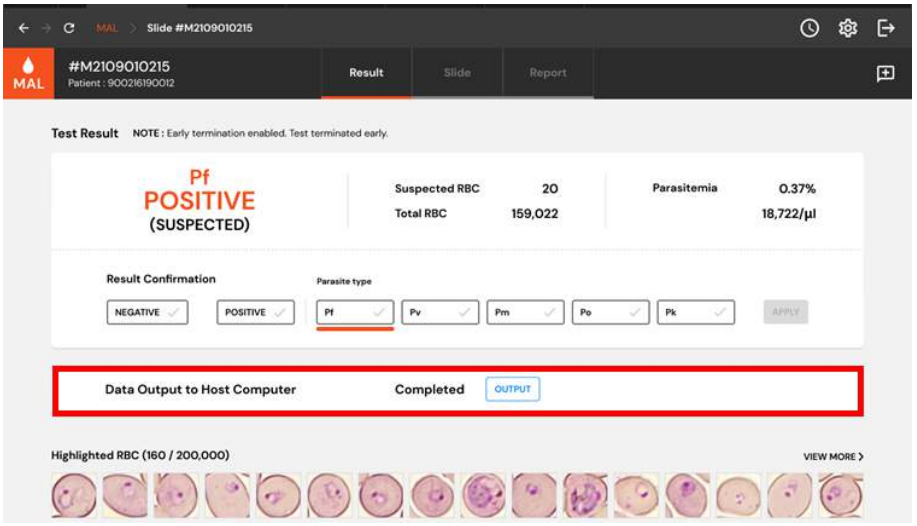
[Not Attempted] and [OUTPUT] button disabled
Beford Result Conformation – Transmission not possible

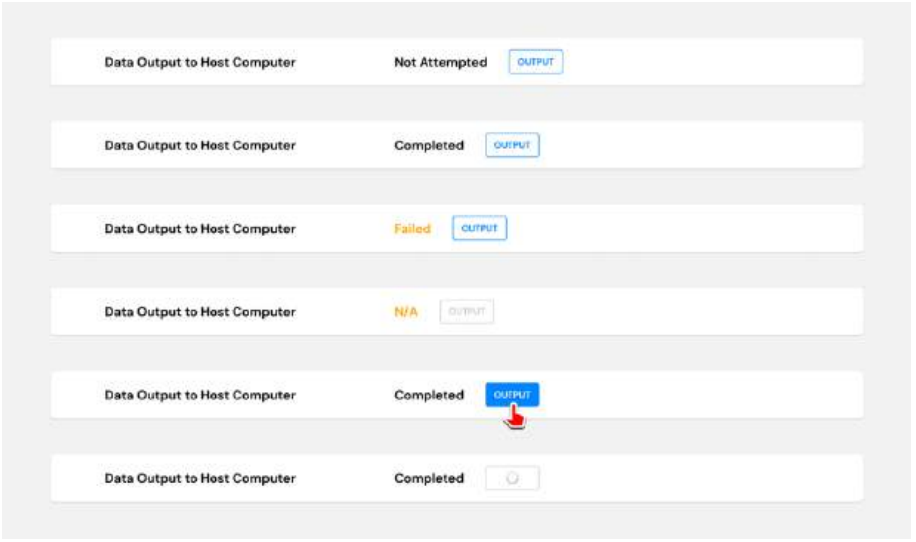


[N/A]
No Image – Transmission not possible (Warning displayed in 'Test List')

[Data Output] category disabled
[Host Connection] set to OFF & No transmission attempt made

- If the host computer is properly connected, confirmed results will be transmitted to the LIS system. The transmitted results include the following:
  - Positive / Negative
  - Species name (Plasmodium falciparum or Plasmodium vivax, if species is identified)
  - P. level (%)
- Information on result transmission can also be checked in the Viewer. In the Result page, the display for each data output case is as follows:





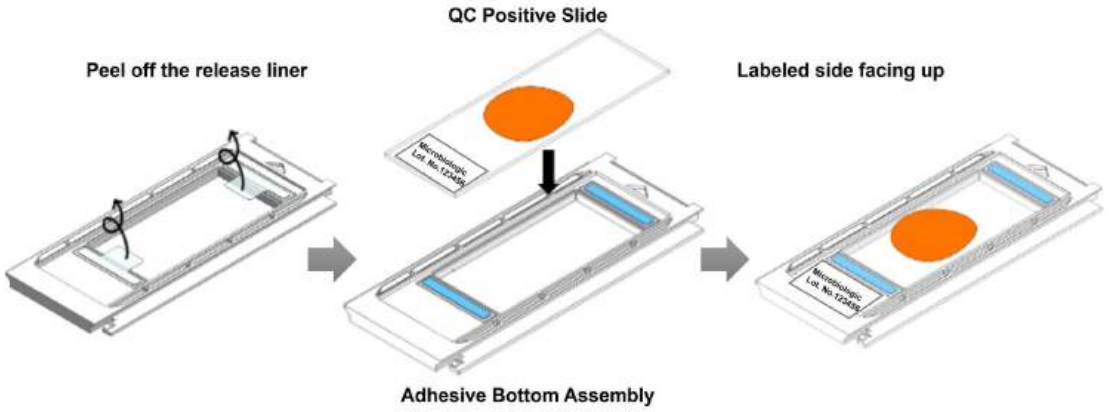
B2. [QC] for internal quality control

1. Intended use of QC mode is to perform internal quality control to verify the performance of the miLab device and software. QC includes assessment of staining consistency, and accuracy of image analysis, helping ensure reliable test results before processing patient samples.

2. In order to perform quality control (QC), the miLab™ MAL QC Adapter and a parasite-positive human blood slide are required. It is recommended to use a Positive QC slide approved by Noul.
    - Recommended product: *Blood Parasite Control Slide* (Microbiologics)

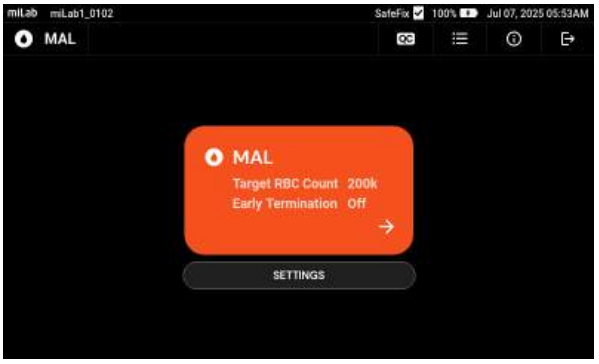
Follow the steps below to conduct the QC procedure properly.

3. For first-time registration of the positive QC slide, complete the miLab QC cartridge setup
    - Attach the positive slide to the adhesive bottom assembly of the miLab™ MAL QC Slide Adapter, then assemble it with the staining top assembly to complete the miLab QC cartridge setup.

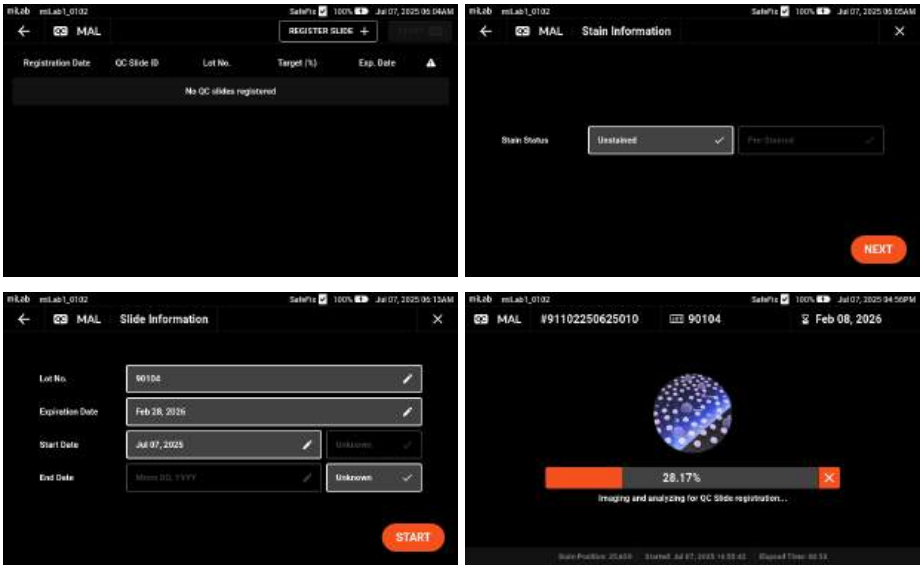


4. First, prepare the QC cartridge:
    - Remove the transparent sealing tape from the bottom part of the cartridge.
      Attach the positive QC slide, ensuring the labeled side is facing up.
    - Unpack the upper part A of the cartridge, which contains the dye and buffer patch.
    - Attach the upper part to the bottom part with the slide.
      Assemble the bottom and top assemblies with the positive slide attached, ensuring the correct orientation.

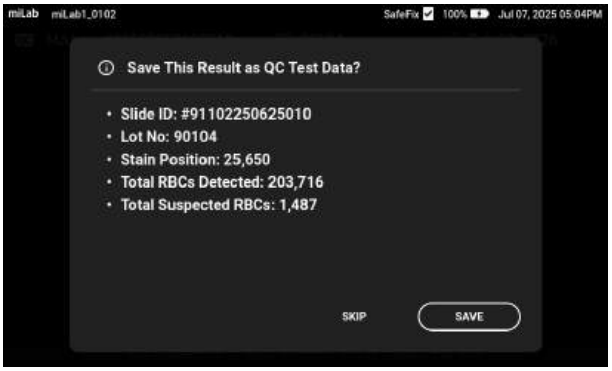
5. Next, enter QC mode by clicking the QC icon on the analyzer.



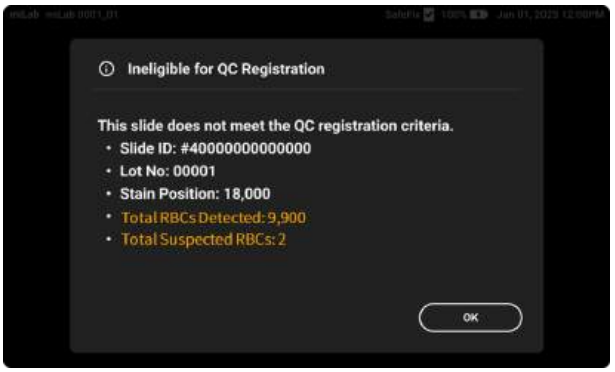
6. For first-time registration of the positive QC slide, select ‘REGISTER SLIDE +’.
   Enter the following information:
   - Slide Type: Choose either Unstained or Pre-Stained depending on the slide you are using.
   - Lot No. & Expiration Date: Refer to the label or packaging box of the positive slide.
   - Start Date: Select the date the slide will begin to be used.
   - End Date: Select the desired end date, or choose ‘Unknown’ if not applicable.



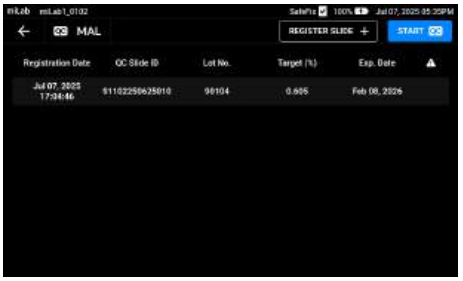
7. After tapping the ‘START’ button, immediately insert the cartridge adapter into the analyzer. To save the QC result, tap the ‘SAVE’ icon after the test is complete.

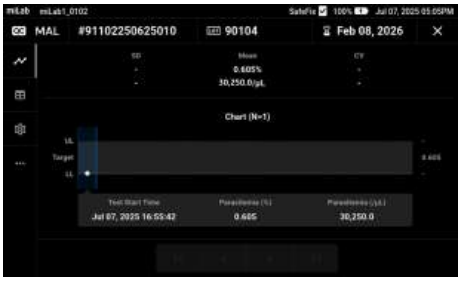


- Even if the initial QC data entry is skipped, the QC registration will still proceed. A pop-up will appear asking whether to record this information in the QC Record & history.
- If the minimum requirements for QC slide registration and testing are not met, an alert popup will appear, and the slide will not be registered or saved.
  * The minimum requirements are as follows:
    - # of total RBC < 10,000
    - # of suspected RBC < 5



8. Once registered, a QC slide can be reused in QC mode. Each test result will be recorded accordingly.
   - After analyzing a new QC slide for the first time, the system will prompt you to enter reference values to complete registration. This includes both a qualitative result "Positive" and a quantitative reference value based on the P. level (%, /μl).





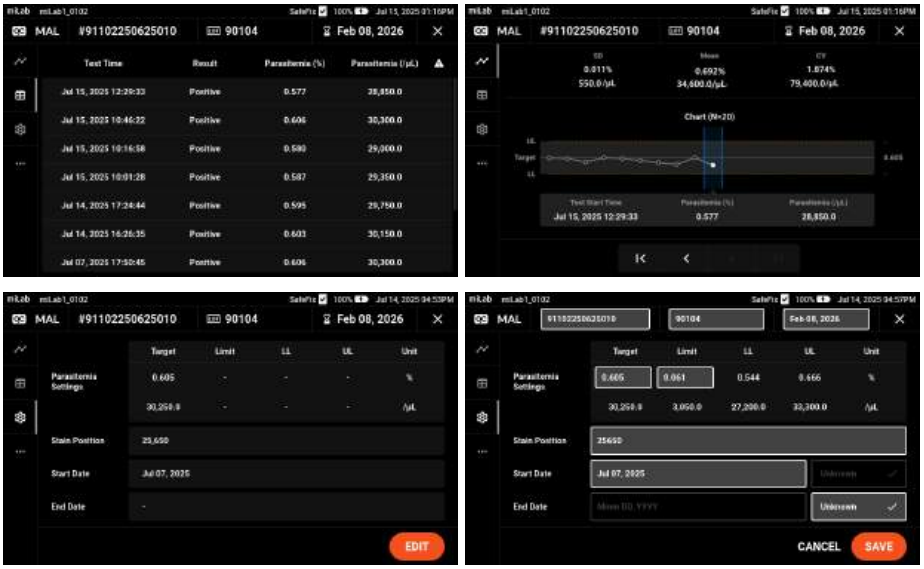
- Establishing QC Baseline

a. To establish QC limits suitable for your lab environment, perform QC testing four times daily (twice in the morning and twice in the afternoon) for five consecutive days, totaling 20 measurements. This commonly recommended protocol (e.g., CLSI EP15-A3) enables calculation of the mean and standard deviation (SD) of P. level (%), forming the basis for your lab's QC acceptance range.

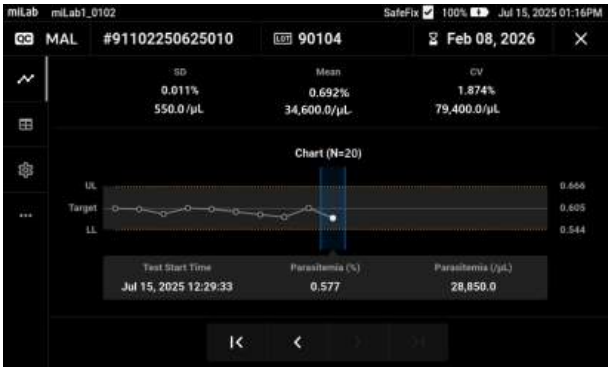
- After collecting 20 results
  a. Calculate the mean and standard deviation (SD) of the measured P. level (%).
  b. Define the control limits based on your lab's internal policy. Common approaches include
     - Statistical range: e.g., ±2SD, or 10–20% CV
     - Fixed range: e.g., 25% of the P.level mean value
  c. Example : If the average P. level is **1.2%** and the SD is **0.15%** the control limits are:
     - 2SD is 0.3% and 25% of p.level is also 0.3%
       - Upper limit: 1.2% + (2 × 0.15%) = 1.5%
       - Lower limit: 1.2% – (2 × 0.15%) = 0.9%

These limits can be used as your routine QC acceptance criteria.

9. To enter limit values, tap  icon, then select ‘EDIT’. Enter the desired upper and lower limit values for the P. level (%), based on your site’s QC criteria. Once entered, tap ‘SAVE’.



10. Once the limit values are saved, you can check on the graph page whether the QC result falls within the specified range.



Important!

- If QC results exceed the acceptable limit range more than the allowed number of times, check the following:
  - Usage environment (temperature 20–35 °C, humidity 30–60%)
  - Expiration date of adaptors and slide
- If the environment is out of spec, adjust to recommended conditions and repeat QC.
- If the product is expired, discontinue use as performance cannot be guaranteed even after adjustment.
- If results still exceed the limit, replace the positive QC slide and repeat QC.
- If the issue persists, contact your authorized distributor or Noul (cs@noul.com).

Appendix C. Troubleshooting for BCM

C1. Incomplete test process with the error messages

- In the following scenarios, the test may not be completed until the end and can be terminated midway with an error code:

Process	Possible Causes	Action
Smear	If the cartridge is not inserted into the device immediately after loading the sample, the blood may clot on the slide and not spread properly, leading to an unsuccessful smear.	Perform a retest by inserting the loaded cartridge immediately into the device using a new cartridge
	The blood sample was not loaded or loaded onto a surface other than the slide glass.	Perform a retest by loading the sample on the slide glass.
	The volume of the blood sample was loaded with less than 4 µL or more than 4 µL.	Perform a retest by loading the exact volume of the sample on the slide glass.
	If physical force is applied to the smear film, causing damage, or if solid staining reagents or foreign substances are present, they can affect the smear and result in a failed smear	Perform a retest using a new cartridge that is not damaged
Fixation	If it fails to detect the ideal zone, the fixation process will not proceed. This can occur under the	Perform a retest by inserting the loaded cartridge immediately into the device

	following circumstances: - Presence of vacuole in the middle of the smear. - Smear failure due to contamination of the slide glass.	using a new cartridge
	Damage to the SafeFix tube	Since the replacement is required after 300,000 tests, contact customer service (CS@noul.com)
	Others	Perform retesting after rebooting or contact customer service (CS@noul.com)
Staining	Using an expired cartridge Lot.	Perform a retest with a new cartridge after confirming the expiration date
	Others	Perform retesting after rebooting or contact customer service (CS@noul.com)
Imaging	The device's desk is physically shocked during the imaging process	Please conduct a retest without causing any shocks to the surrounding environment.
	Others	Perform retesting after rebooting or contact customer service (CS@noul.com)

C2. Early Termination and Result

- The test is terminated with a count of fewer than 200 WBCs. Or the difference of 5-diff values between BCM analysis and CBC is too significant.

Possible Causes	Action
Loading too much blood into the cartridge can make the larger area of multilayer of RBCs, resulting in the system being unable to detect the ideal zone	Retry the test using a new cartridge with 4 µL of blood loaded and inserted immediately into the equipment
When examining the field images, there are many instances where multilayers are captured. - The last 10 field images are from multilayers	Repeat the test using a new cartridge.
When the Total WBC count is lower than the reference range from CBC.	In this case, counting less than 200 WBCs is normal. Please proceed with reclassification.
The AI classified the precursors of WBCs as normal.	Please proceed with reclassification.
If the test is conducted 24 hours after the sample is collected	Please retry the test with a fresh sample.
The blood sample was not adequately mixed.	Make sure the blood specimen has mixed properly and retry the test.

- The staining is not uniformly purple, and there are areas where it appears partially blue or red.

Possible Causes	Action
If the cartridge is left unattended for a long time after removing the seal, the reagents may dry out.	Remove the cartridge sealing and immediately load blood and insert it into the device for retesting
Using an expired cartridge Lot.	Perform a retest with a new cartridge after confirming the expiration date
Due to the nature of solid staining, partial staining may occur on the side portions of the staining area.	Reclassify the cells as unstained and remove them from the 5-diff values.
If the upper and lower parts of the staining area are only stained with eosin or methylene blue, those areas are captured in the imaging.	It may happen during the test. Reclassify the cells as unstained and remove them from the 5-diff values.
The testing environment is excessively dry.	Please use a humidifier or other means to adjust the humidity to the room humidity level, and proceed with a retest.

For inquiries on detailed software versions and any information on updates, contact the Noul Customer Service team at **cs@noul.com.**

Appendix D. Troubleshooting for CER

D1. User-recognized Issues based on the Result of the test

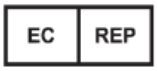
The table below provides a list of measures and items to check in order to identify the cause of suspected issues that may occur due to factors that users can perceive or internal problems in the product that cause malfunctions. Please refer to the table below to solve the problem.

Stage	Result	Possible Causes	Action
Slide Prep	No result	A slide was not mounted or the slide was mounted in the wrong direction.	Perform a retest by mounting the slide correctly.
	Poor staining & imaging quality	A slide that does not conform to the specifications was used.	Use the slides of the supported specifications.
		A slide was not fixed in 95% ethanol.	Perform a retest after fixing a slide in 95% ethanol solution for more than 30 minutes.
		The test was initiated before the fixative on the slide had completely dried.	Perform a test after the fixative on the slide has completely dried.
Staining	Poor staining &	Using an expired cartridge Lot.	Perform a retest with a new cartridge after confirming the expiration date.

Stage	Result	Possible Causes	Action
	imaging quality	The solid reagent is dried out and fails to stain the appropriate area, resulting in partial staining.	Remove the cartridge sealing immediately and insert it into the device for retesting.
		The remaining SafeFix variants are insufficient.	with new SafeFix variants and retry the test with a new cartridge.
		Others	Perform retesting after rebooting or contact customer service (CS@noul.com).
Imaging	Poor imaging quality	The desk where the device is on is unstable or physically shocked when the imaging process is started.	Since shocks around the device should not occur during the entire test, perform retesting in a stable environment.
		Others	Perform retesting after rebooting, or contact customer service (CS@noul.com).
	Possible early finish of imaging process	It could happen under the situations below: 1) The desk is physically shocked during the imaging process, 2) There are few cells fixed on a slide, and/or 3) There are blank spaces in the smear in the staining area.	It can be solved by following the directions below: 1) Conduct tests in a stable environment without vibrations, and 2) Use slides that have sufficient cells fixed and uniformly distributed.
End of Test	Possible interference in re-examination	If a cartridge was not disassembled in the correct direction, the solution may fall on the slide and interfere with microscopic examination.	Disassemble the cartridge in the correct direction.

Appendix E. Symbols on the Product and Product Packaging

Symbol	Explanation	Symbol	Explanation
CE	CE marking; European Conformity		Keep dry
IVD	*In vitro* diagnostic medical device		DO NOT use if the package is damaged
	DO NOT touch		Waste Electrical and Electronic Equipment

	Caution		This way up
	Manufacturer		Stacking limit (by number)
	Manufacture date		Stacking limit (by mass)
	Serial number		Fragile0
	European Authorised Representative		Direct Current
	Product catalog number		Use by date
	Instructions for use must be read		GHS; Harmful
	Consult instruction for use		GHS; Health hazard
	Temperature limitation		GHS; Flammable
	Humidity limitation		Keep away from sunlight
	Model number		Unique device identifier

noul
Beyond Diagnostics

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EC REP **Medical Technology Promedt Consulting GmbH**

CH REP **Decomplix AG**