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
GIÁM ĐỐC
M.S.D.N: 0316765196 C.T.T.N.H.H
CÔNG TY TNHH ASIA ACTUAL VIETNAM
THÀNH PHỐ HỒ CHÍ MINH
Võ Trung Việt

Digitally signed by CÔNG TY TNHH ASIA ACTUAL VIETNAM
Location: TP.HCM

noul
Beyond Diagnostics

CE IVD

miLab™ Cartridge BCM

CBCA

with miLab™ Platform and miLab Viewer™

Instructions for Use

Preface

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Chapter 1. Before Reading Document

This Instructions for Use document provides a detailed description of the miLab™ Cartridge BCM 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™ Cartridge BCM.

Always use the miLab™ Cartridge BCM in the safest manner possible. Using the miLab™ Cartridge BCM 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 model number
  - Product lot number
  - Product serial number
- 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.
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

Chapter 2. Introduction

For In Vitro Diagnostic Use Only.

2.1. Proprietary Name / Model Name

miLab™ Cartridge BCM / CBCA

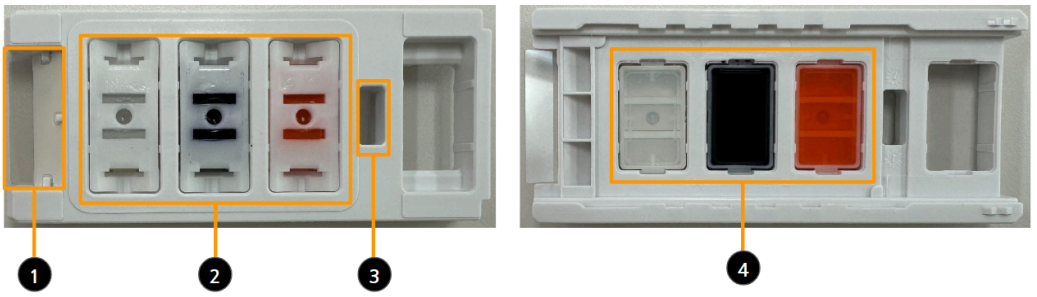
2.2. Cartridge Overview

2.2.1. Parts Names and Functions

miLab™ Cartridge BCM is composed of top assembly and bottom assembly, which MUST be correctly assembled before use.

Top Assembly

Top View **Bottom View**



① **Spreader film**

- Smear blood specimens onto the microscope slide of the bottom assembly.

② **Staining stamps** & ④ **Staining patches**

- Contains eosin, methylene blue, and buffer reagents for sample staining.
- Protected by removable easy-peel films on both the bottom and the top.

③ **Loading port**

- An opening for dispensing blood specimens onto the microscope slide.

Bottom Assembly

Top View **Bottom View**

① **Microscope slide**

- A work surface for sample preparation.

② **Serial number**

- Contains a unique serial number in barcode format for slide identification.

2.2.2. Reagents Provided

Part	Raw material	Mass (g)
Eosin Patch	Eosin Y sodium salt, Agarose	Up to 1.23
Methylene Blue Patch	Methylene Blue, Azure B, Agarose	Up to 1.23
Buffer Patch	Potassium phosphate monobasic, Sodium phosphate dibasic, Agarose	Up to 1.23

2.2.3. Optional Products

The following products are sold separately for optional use with the miLab™ Platform:

- miLab™ Slide Case (Model Name: ASCA) for miLab slide storage.
- miLab™ Slide Microscope Adapter (Model Name: ASAA) for mounting miLab slides on microscope stages.
- miLab™ Local Storage Solution (Model Name: ASSA) for expanded external data storage.

2.2.4. Equipment and materials required but not provided

- Adjustable pipettes to cover a range of volumes from 4 µl (such as four Gilson pipettes capable of delivering volumes of 1-10 µl, 2-20 µl).
- Pipette tips from capable of delivering volumes of 1-10 µl.

2.3. Intended Use

The miLab™ Cartridge BCM is designed for in vitro diagnostic use, intended to smear and stain blood cells to support CBC and morphology testing.

2.4. Principle of miLab™ Cartridge BCM

This cartridge consists of an upper plate containing a smear film for blood cell smear and a hydrogel patch for blood cell staining, and a lower plate equipped with a slide glass. The collected blood is loaded on the slide glass, and by the movement of the upper and lower plates, the blood comes into contact with the smear film for blood cell smear and spreads between the film and the slide glass, and the blood is spread on the slide glass by the movement of the upper and lower plates. The blood smeared in this way is fixed by the fixative discharged from the fixative container in the equipment after drying and then comes into contact with three types of hydrogel patches included in the top plate kit, and the dye contained in each hydrogel patch is smeared on the patch. WBC, RBC, and platelets are stained while moving toward the blood. The hydrogel patch included in the top kit consists of a total of three patches: an eosin patch, a methylene blue patch, and a buffer patch, and the blood cell staining process is performed in the order of the eosin patch, methylene blue patch, and buffer patch. Eosin, an acid dye contained in the eosin patch, has a negative charge (-) in aqueous solution, so it binds to the protein component in the cytoplasm that has a positive charge in the RBC and stains the cytoplasm red. Methylene blue, a basic dye contained in the methylene blue patch, has a positive charge (+) in aqueous solution, so it binds to DNA in the cell with a negative charge and stains the nucleus blue. In the case of the buffer patch, it absorbs excess dye on the cells and plays a role in clearly distinguishing the cytoplasm and the cell nucleus stained with eosin and methylene blue, respectively.

2.5. Specimen Collection

2.5.1. Intravenous Blood Sampling

- Mix the specimen tube well by inverting it at least ten times immediately before loading the sample into the cartridge to ensure that the specimen is homogeneously mixed. **Poorly mixed specimens may affect the results.**
- If the specimen was not stored in an EDTA K2 container, the collected specimen should be used IMMEDIATELY.
- If the specimen was stored in an EDTA K2 container, the collected specimen is recommended to be used within 4 hours. **Specimens stored for more than the recommended time may affect the results.**
- The cartridge top and bottom assemblies should be assembled in advance so that blood can be loaded into the cartridge immediately after the specimen collection.

2.6. Packaging Information

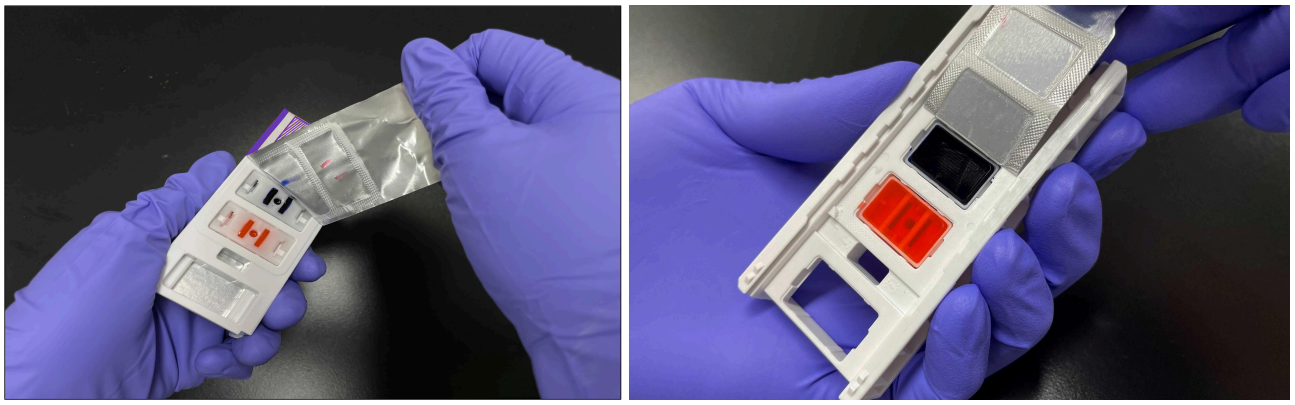
- miLab™ Cartridge BCM (10 cartridges/pack)
- miLab™ Cartridge BCM (200 cartridges/carton)

Chapter 3. Operation Instructions

3.1. Cartridge Preparation

3.1.1. Precautions before Assembling the Cartridge

1. Remove the aluminum seals on the cartridge top assembly.
    a. The top assembly of the Cartridge has two aluminum seals; one on the top and one on the bottom.
    b. Remove the seal on the top first, and then the one on the bottom.
    c. Pull the seal straight along the cartridge with adequate force.



[Remove the aluminum seals]

Important

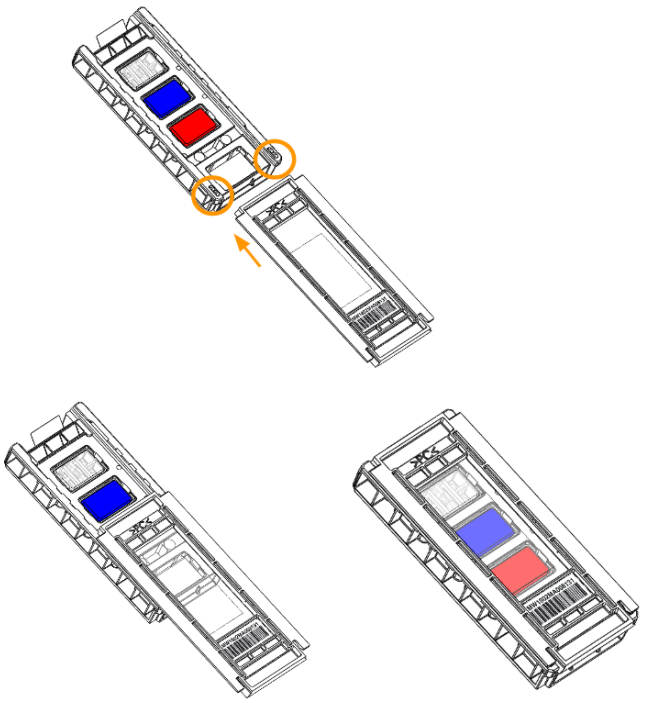
- When removing the aluminum seals, ensure the staining stamps are not damaged or contaminated.
- Pulling the seal to the side or not pulling with too much or too little force may damage the staining stamps and result in low-quality staining.
- Once the seals are removed, use the cartridge immediately. Staining stamps exposed to air may become dry and result in low staining quality.
- Check for any damages or contaminants on the stamps. DO NOT use the cartridge if any damages or contaminants are found on the stamps. Damaged or contaminated stamps will affect the sample staining quality and, consequently, the test results.
- Keep the cartridge bottom assembly tray closed when not in use. Extended exposure may contaminate the glass slide on the bottom assembly.

3.1.2. Assembling the Cartridge

1. Slide the bottom assembly into the top assembly.

Important

- Make sure the cartridge assemblies are put together in the correct direction and assembled securely.

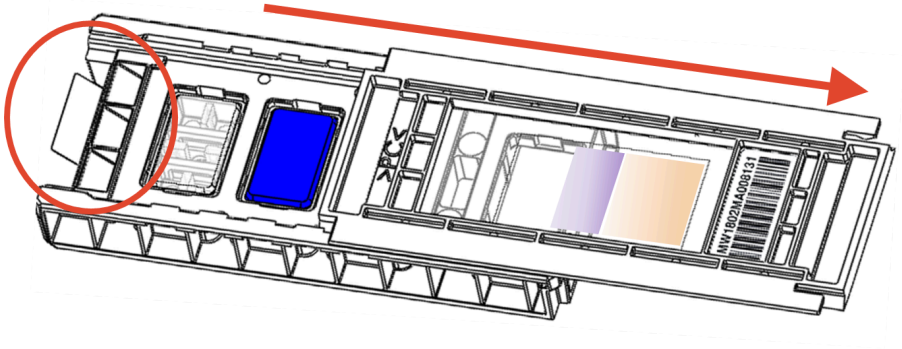


- Make sure the barcode on the bottom side of the cartridge bottom assembly is firmly attached.
- Even if the Slide ID barcode on the bottom side of the cartridge bottom assembly is not properly recognized, you will be guided to manually enter the Slide ID after the test is completed.

3.2. Cartridge Handling

3.2.1. Disassemble the cartridge bottom assembly from the cartridge top assembly.

- The cartridge bottom assembly now contains the peripheral blood smear.
- **The cartridge bottom assembly MUST be removed in the direction away from the spreader film.**
- The cartridge bottom assembly MUST be removed as shown below.



[Disassemble the cartridge bottom assembly]

Important
- Make sure the cartridge assemblies are disassembled in the correct direction.
- DO NOT remove the cartridge bottom assembly in the direction of the spreader film.
- If the cartridge is disassembled in the wrong direction, the spreader film on the top assembly can damage the smeared sample.

3.2.2. Dispose of the cartridge top.

The cartridge top MUST be disposed of as potential biohazardous waste.

Warning
- DO NOT forcibly remove the glass slide from the cartridge bottom. The glass slide is bonded to the cartridge bottom. Forcibly removing the slide may break the glass and result in injury.

Caution
- miLab™ Cartridge BCM is a SINGLE-USE REAGENT CARTRIDGE. DO NOT reuse the cartridge under any circumstances.

Chapter 4. Specifications

Category	Specifications
Equipment type	Reagent cartridge
Components	Top assembly / Bottom assembly
Staining Principle	Romanowsky
Weight	28 g
Dimension (W x D x H, mm)	Cartridge: 92.4 x 40.4 x 14.6 Microscope slide: 25 x 75 x 1
Packaging	10 cartridges/set 200 cartridges/box

Chapter 5. Stability

5.1. Cartridge Shelf-life

Category	Specifications
Operating condition	15-35 °C: 25-80 % Relative Humidity
Storage condition	4-30 °C: 15-80 % Relative Humidity
Unopened	24 months from the date of manufacture

5.2. 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, 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.

5.3. Specimen Storage

We recommend if the specimen was stored in an EDTA K2 container, the collected specimen should be used IMMEDIATELY. If the specimen was stored in an EDTA K2 container, the **collected specimen is recommended to be used within 2 hours**. Specimens stored for more than the recommended time may affect the results. DO NOT freeze the specimen. Dispose of used specimens and any other material that may have been in contact with the specimen in a medical waste container.

Chapter 6. Warranty

Noul instruments are warranted against defective material or workmanship for a period of the expiry date, commencing on the date of installation at the customer's premises. This warranty does not however 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 in accordance with the applicable Noul Instruction for Use.
- Failure to use the appropriate reagents and supply parts specified for the product.

Chapter 7. Internal Quality Control

7.1. Self-diagnostic Test

Check the concordance rate within sample stability with known blood results by a laboratory.

Chapter 8. Operational Precaution

8.1. General Safety Information

⚠ Caution

- Bring all cartridges and specimens to operating temperature before use.
- All reagents are for use exclusively with the miLab™ Platform. DO NOT use the reagents for any other purposes.
- Please follow the warnings and precautions when handling the reagents.
- Only use reagents manufactured by Noul Co., Ltd. Using other reagents not manufactured by Noul may lead to misleading results, device damage, or personal injury. Noul is not liable for any damage or injury caused by the use of any third-party products not indicated in this document.

8.2. Reagent

⚠ Caution

- The reliability of the analysis results cannot be guaranteed if the cartridge is used beyond the scope of the intended use or not in accordance with the provided directions for use.
- DO NOT press the easy-peel film surface.
- DO NOT touch the staining stamp surface. Handle the cartridge with care to prevent reagent damage or contamination by hand. Reagent contamination may result in a low-quality blood smear.
- DO NOT touch the spreader film. The contamination of the spreader film may result in a low-quality blood smear.
- Open the cartridge just before use. Prolonged exposure to air may cause the reagents to dry and result in a low-quality stain.
- Keep the cartridge bottom assembly tray closed when not in use. Extended exposure to the open air may cause contamination of the glass slide on the bottom assembly.
- DO NOT use expired cartridges. The analysis results cannot be guaranteed when expired cartridges are used.
- miLab™ Cartridge BCM is a SINGLE-USE REAGENT CARTRIDGE. DO NOT reuse the cartridge under any circumstances.

8.3. Storage and Handling

⚠ Caution

- In case the cartridge was stored at a temperature above or below the range mentioned above, the staining reagents may become denatured or frozen. Analysis results cannot be guaranteed if the storage conditions are not kept.
- Avoid environments where dust can accumulate.
- DO NOT store the cartridges under high pressure.

Appendix A. Symbol

A1. Symbols on the Reagents and Reagent Packaging

Symbol	Explanation	Symbol	Explanation
	Manufacture date		Fragile
	Manufacturer		Stacking limit by number
	Product catalog number		Stacking limit by mass
	European Authorized Representative		CE marking; European Conformity
	Temperature limitation		*In vitro* diagnostic medical device
	Keep away from sunlight		Caution
	Keep away from rain		Consult instruction for use
	DO NOT use it if the package is damaged		Use by date
	Contains sufficient material for <n> test		GHS; Harmful
	DO NOT re-use		GHS; Health hazard
	This way up		GHS; Flammable
	Batch code		Unique device identifier

Appendix B. Troubleshooting

B1. 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 following circumstances: - Presence of vacuole in the middle of the smear. - Smear failure due to contamination of the slide glass.	Perform a retest by inserting the loaded cartridge immediately into the device 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)

B2. 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.**

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