

Technical Document

Medonic M-series M32 Hematology Analyzer



Product name Medonic M-series M32

Manufacturer Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
Telephone: +46 8 744 77 00
Fax: +46 8 744 77 20

Country of origin Sweden

Product Description The Medonic M-series M32 is a fully automatic, 3-part differential, hematology analyzer intended for in vitro diagnostic testing of blood specimens under laboratory conditions.

Intended Use

Model configuration

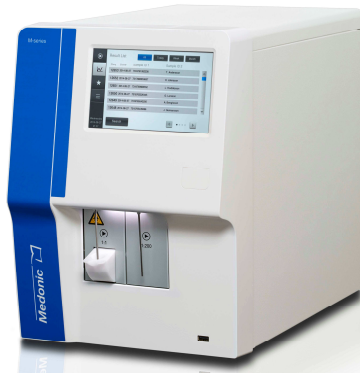


Figure 1
Medonic M-series M32B



Figure 2
Medonic M-series M32M



Figure 3
Medonic M-series M32C



Figure 4
Medonic M-series M32S

Recycling information For recycling of the instrument see www.medonic.se/support/downloads

Instructions for use Use in accordance with manufacturer's instructions for use in Medonic M-series M32 User's Manual.

Instrument Specifications

Physical

Size (Instrument versions with sampler)	HWD \leq 395 x 340 x 475
Size (Instrument version without sampler)	HWD \leq 395 x 295 x 475
Weight (Instrument)	\leq 18 kg
Weight (Autoloader additional weight)	The additional weight of the Autoloader including two sample wheels is less than 6 kg
Display	Depth: True color (24-bit); Resolution: 800 x 480 pixels
Keyboard	Virtual incorporated keyboard
Communication interface ports	1 USB device/4 USB host/1 LAN port
Barcode reader input	Yes (via USB)

Operating Environment

Temperature	18 - 32 °C
Humidity	10% - 90%

Electrical

Main Voltage	100 - 240 V
Frequency	50 - 60 Hz
Maximum power consumptions	100 VA (operating); 50 VA (standby)

Measuring principles

MCV, MPV, RBC, WBC, and PLT	Impedance
HGB	Photometric
Sampling system	Closed shear valve
Floating RBC/PLT discriminator	Yes (position printed)
Programmable WBC Discriminator	Yes
Mathematical 3-part diff. WBC calculation	Yes
Parameters Reported	20-parameters: RBC, MCV, HCT, PLT, MPV, HGB, MCH, MCHC, WBC, RDW%, RDW abs, PCT, PDW, LPCR, LYM abs, MID abs, GRAN abs, LYM%, MID%, GRAN%

Performance

Sample volume (Open Tube)	\leq 110 μ L
Sample volume (Sampling Device)	\leq 300 μ L
Sample volume (Cap Piercer)	\leq 250 μ L
Sample volume (Micro Pipette Adapter)	20 μ L
Pre-diluted mode	1:200 to 1:300 using min. 20 μ l e.g. 20 μ l sample to 4.5 mL diluent (1:225)
Dispenser precision (CV)	\leq 0.9%
Number of Samples per hour (Open Tube)	\geq 60 samples
Number of Samples per hour (Cap Piercer)	\geq 45 samples
Number of Samples per hour (Sampling Device)	\geq 43 samples
Built-in test / adjustment programs	Yes
QC capabilities	Mean, SD, CV, Levey-Jennings and Xb
System Information Indicators on parameter abnormalities	Yes
Memory capacity	\geq 50,000 samples
Reagent Stability	36 months



Performance

Parameter	Correlation(R)	Carry-over (%)	Reproducibility (%)
RBC	≥ 0.98	≤ 1	≤ 0.8
MCV	≥ 0.98	N/A	≤ 0.5
HGB	≥ 0.98	≤ 1	≤ 0.6
PLT	≥ 0.95	≤ 1	≤ 2.9
WBC	≥ 0.97	≤ 0.5	≤ 1.6

* Typical values measured as an average of 10 measurements each on 9 different vein K2-EDTA collected normal samples, on 3 instruments, in open tube mode.

Product Conformity

Directives	Standards
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure
2004/108/EEC Electro Magnetic Compatibility Directive (EMC) with amendment 92/31/EEC	Emission: EN 61326-1:2006, SS-EN55011:2009, +A1:2010, Class B, EN 61000-3-2:2006 Immunity: EN 61326-1:2006, EN 61000-4-2, -3, -4, -5, -6, -11
2006/95/EEC Low Voltage Directive (LVD)	IEC 61010-1: 2001 IEC 61010-2-081:2001 + A1 IEC 61010-2-101:2002 CAN/CSA-C22.2 No 61010-1: second edition UL 61010-1: second edition
2012/19/EU Waste of electrical and electronic equipment (WEEE)	--

Quality Control/Calibration

The instrument has been factory calibrated by Boule prior to shipment. Customers are advised to check the daily performance of the Medonic M-series M32 system with a certified blood control authorized by Boule.

Packaging and Weight

≤ 24 kg (standard version); Double corrugated cardboard outer packaging with shock absorbent inner packaging.

Warning and Precautions

As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, blood controls, calibrators and waste, these products should be handled as potentially biohazardous. See User manual for biohazard symbol placement and further instructions.

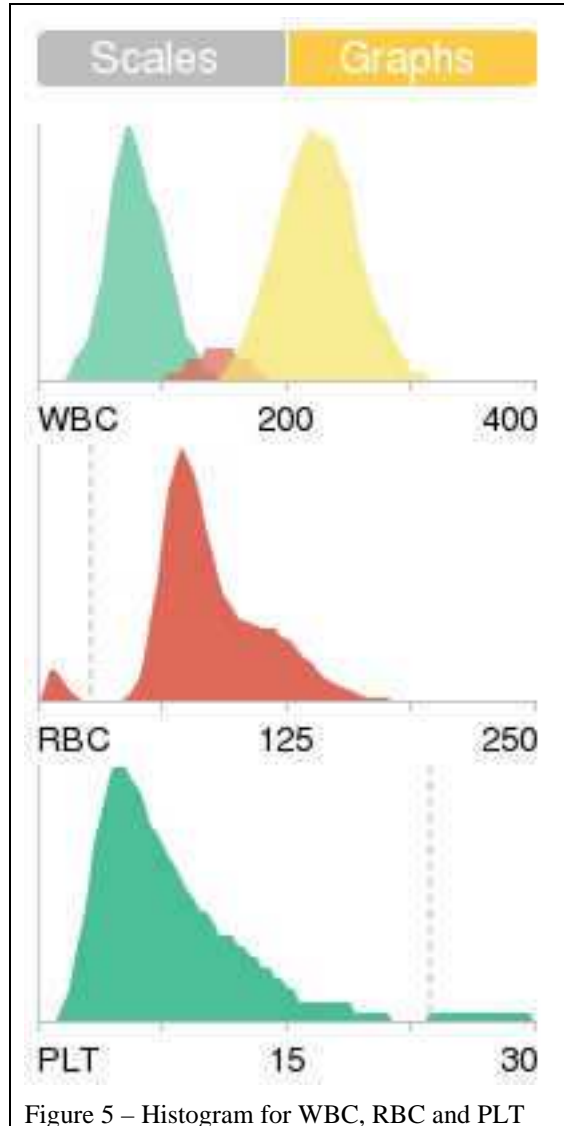
Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the content of effluent streams, before disposing of waste in public sewer systems or recycling decontaminated equipment. The instructions for decontamination can be found on the Medonic home page, www.medonic.se, under Support.

Histograms

The measuring principles of the Medonic M-series M32 analyzers are based on impedance and spectrophotometry principles. The number of cells for determining RBC and WBC values are counted from a suspension of 1:40,000 for the RBC and 1:400 for the WBC dilution ratio of whole blood.

Serial number label

See Figure 6 – Serial number label.



Manufacturing Process

For the manufacturing process and the specific process control points for this analyzer see the flowchart below. The process starts with components for the manufacturing of the analyzer being checked in by the content of specification (e.g. drawings, specifications for incoming inspection) against acceptance limits. The process is completed with final QC testing, the release by QA, and the approved analyzer moved to stock.

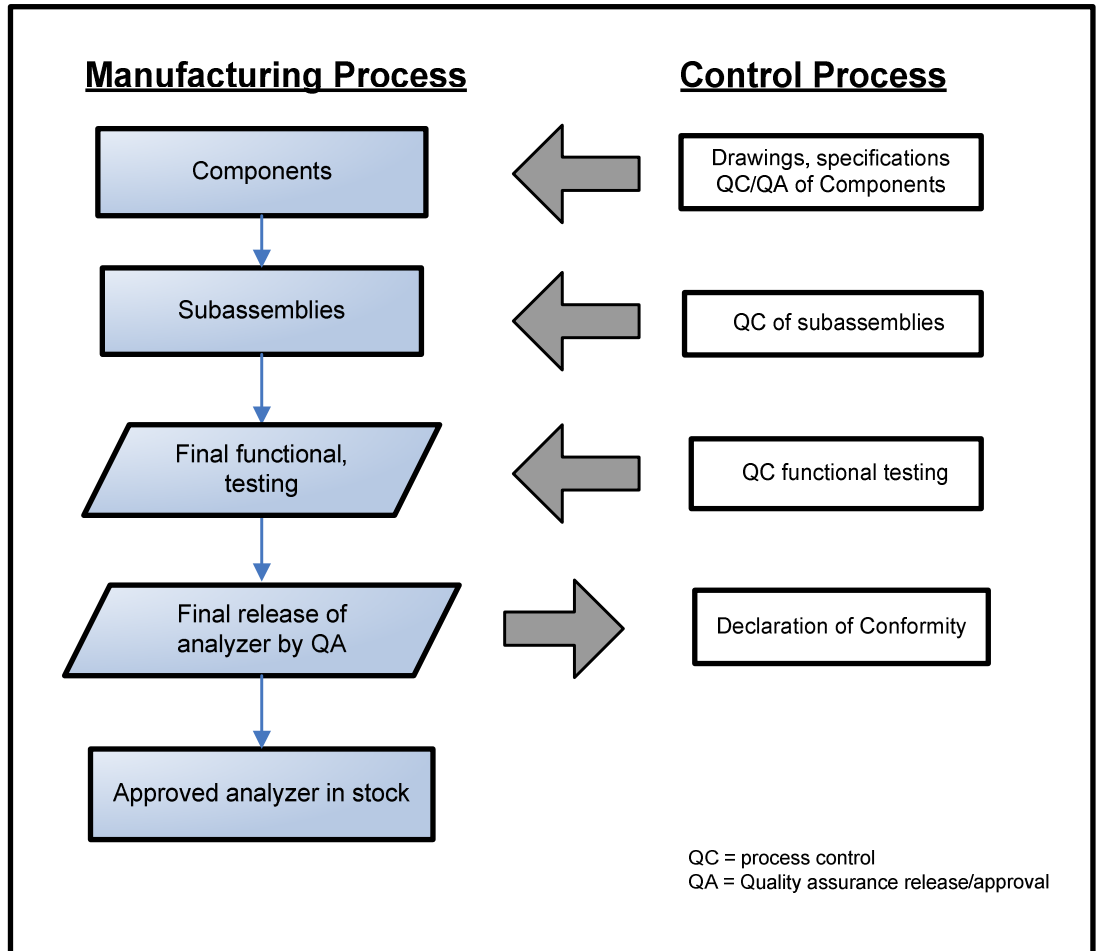


Figure 7 Flow chart for manufacturing and quality control

Product name Quintus Hematology Analyzer

Manufacture Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
Telephone: 0046 8 744 77 00
Fax: 0046 8 744 77 20

Country of origin Hungary - Sweden

Product Description The Quintus is a fully automatic, 5-part differential, hematology analyzer intended for in vitro diagnostic testing of blood specimens under laboratory conditions.

Model configuration

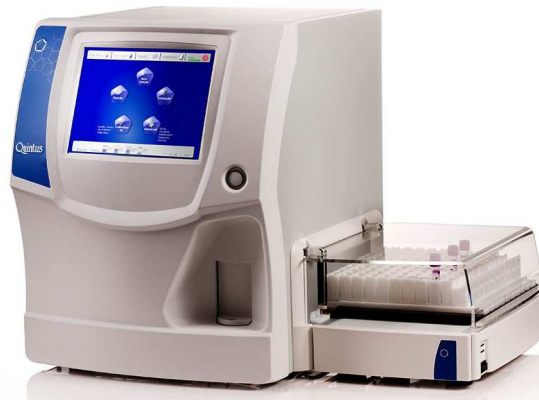


Figure 1 – Quintus Hematology Analyzer with Autoloader

Instructions for use Use in accordance with manufacturer's instructions for use in Quintus User's Manual.

Storage +5 to +35 °C (41 to 95 °F)

Packaging and Weight Instrument 35 kg + autoloader 12 kg. Double corrugated cardboard outer packaging with shock absorbent inner packaging

Product Conformity Quintus analyzer is in conformance with the 98/79/EC In Vitro Diagnostic Medical Device Directive (IVD) using Annex III as the conformity assessment procedure.
SS-EN 61010-2-101 (Low Voltage 2014/35/EU)
EN 61326 (2006) (EMC 2014/30/EU)
2012/19/EU WEEE
2011/65/EU RoHS

Quality Control/Calibration The instrument has been factory calibrated by Boule prior to shipment. Customers are advised to check the daily performance of the Quintus system with a certified blood control authorized by Boule.

Warning and Precautions As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, blood controls, calibrators and waste, these products should be handled as potentially biohazardous. See User manual for biohazard symbol placement and further instructions.

Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the content of effluent streams, before disposing of waste in public sewer systems or recycling decontaminated equipment. The instructions for decontamination can be found on the Boule home page, www.quintus5part.com, under User Support

Instrument Specifications

Measuring principle, RBC, WBC, PLT	Impedance
Measuring principle HGB	Light source: green LED with 540 nm wavelength Detector: light to frequency converter
Measuring principle 5-part Differential	Light scattering measurement:
Optical measurement	Light source: semiconductor laser diode with 650 nm wavelength and 7mW (Class IIIB laser module if the protective housing is closed) Quartz flow cell with hydro-dynamic focusing Detector: fiber optic coupled PIN Si photodiodes Internal safety interlock
Aperture length and diameter	WBC: 80 µm, RBC/PLT: 70 µm
Sampling system	Ceramic shear valve with 3 separated primary loops
Aspirated blood volume	< 110 µl
Number of Samples per hour	> 60 samples
Sample type	Human whole blood (K3-EDTA anticoagulant)
Parameters reported	WBC, LYM, MONO, NEU, EOS, BASO, LYM%, MONO%, NEU%, EOS%, BASO%, RBC, HCT, MCV, RDWsd, RDW cv, HGB, MCH, MCHC, PLT, PCT, MPV, PDWsd, PDWcv, LPCR%, LPCRa
Size distributions printed for	RBC, PLT and WBC differential
QC capabilities	Mean, SD, CV, Levey-Jennings plots and Xb plots
Carry-over	< 0.5%
Warning flags on parameter abnormalities	Yes
Setable normal ranges (profile limits)	Yes
Reagent and Instrument alerts	Yes
Built-in test / adjustment programs	Yes
Calibration	Manual and SW supported automatic mode
Language available	English menu and support for other languages
Software upgrade	Via USB
Memory capacity	100,000 records including flags, scatter- and histograms
Data processing	Intel Atom 1.6 GHz
Data store	Windows® 8.1 Embedded
Display	800 x 600 color graphic LCD, portrait layout
External printing	Via USB port, any Windows® 8.1 compatible printer
Keyboard	Virtual incorporated keyboard (External keyboard option via PS/2 or USB)
Barcode reader	External via USB port Built-in barcode reader in Autoloader unit
Peripheral ports	4 USB (2.0), Ethernet, PS/2
Barcode reader input	Yes
Serial output	Yes (Conformed to standard EN 60950)
Main Voltage	100 – 240 V AC
Power consumption (maximum)	Max 400VA
Frequency	50 / 60 HZ
Main fuse	F 10A H 250V
Operating Temperature	15-30° C (59-86 °F)
Humidity (non-condensing)	Up to 80%
Instrument Dimensions	HxWxD = 515 x 410 x 465 mm
Autoloader Dimensions	HxWxD = 190 x 380 x 322 mm
Instrument weight	≤ 35 kg
Autoloader weight	≤ 12 kg
Diluent Consumption	Approximately 51 ml per analysis cycle.
Lyse Consumption	Approximately 7 ml per analysis cycle.
Stopper Consumption	Approximately 1 ml per analysis cycle.



Total System Precision

Parameter	CV (%)	Range (precision achieved within)
WBC	≤ 3.0	$4.7 \times 10^3 / \mu\text{L} \leq \text{WBC} \leq 38 \times 10^3 / \mu\text{L}$
RBC	≤ 1.5	$\text{RBC} \geq 2.5 \times 10^6 / \mu\text{L}$
MCV	≤ 1.0	60 – 140 fL
PLT	≤ 5	$\text{PLT} \geq 100 \times 10^3 / \mu\text{L}$
HGB	≤ 1.5	$\text{HGB} \geq 6.0 \text{ g/dL}$

Scatter diagrams

Quintus displays the results of the optical measurements in a scatter diagram representation.

- Scatter diagrams represent data in a two-dimensional plane.
- There are two scatter diagrams in the patient report: the 4-DIFF and the BASO

Population (4-diff diagram)	Color on scatter diagram
Artifact	BLACK
Lymphocytes	BLUE
Monocytes	GREEN
Neutrophilic granulocytes	MAGENTA
Eosinophilic granulocytes	ORANGE

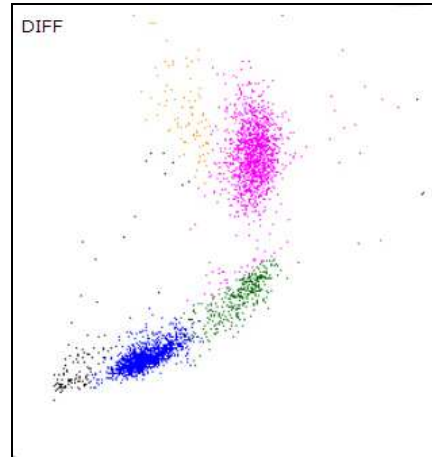


Figure 2 – Scatter 4-part diff

Population (Basophil diagram)	Color on scatter diagram
WBC without Basophiles	BLUE
Basophilic granulocytes	MAGENTA

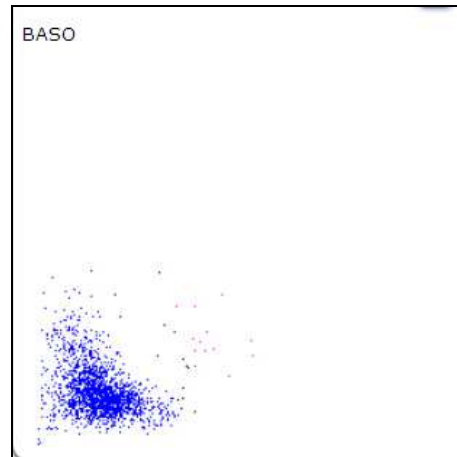


Figure 3 – Scatter basophils

Histograms

Impedance based measurements are represented on histograms. These diagrams show the number of cells against cell size.

- There are two histograms: RBC and PLT.
- Discriminators (thresholds) are displayed with red color.
- The PLT histogram is the magnified section of the left-hand side of the RBC curve.

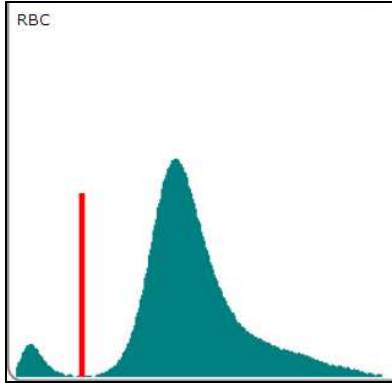


Figure 4 – Histogram RBC

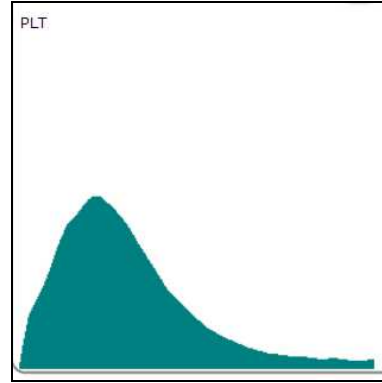


Figure 5 – Histogram PLT

Serial Number label

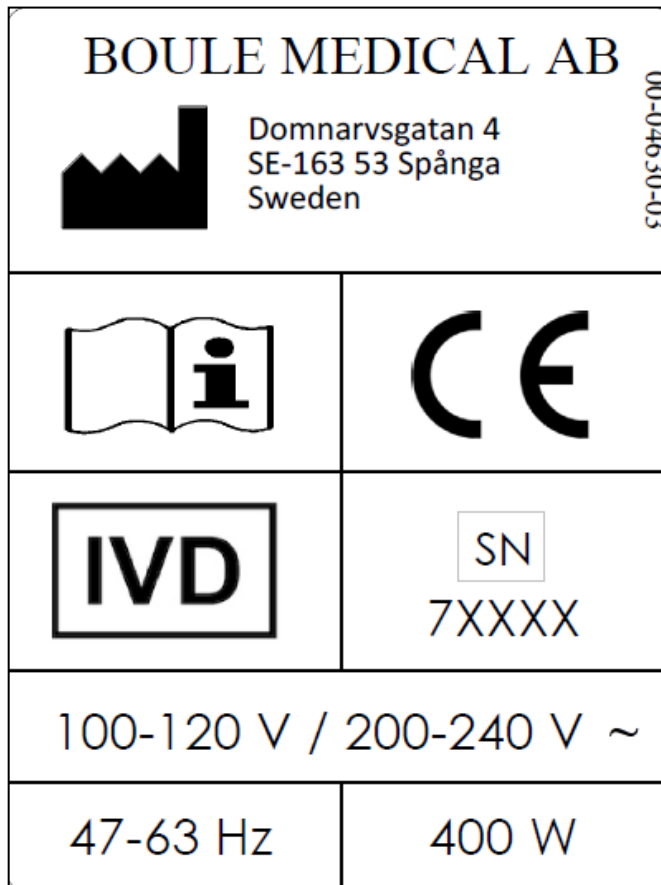


Figure 6 – Serial number label

Manufacturing Process

For the manufacturing process and the specific process control points for this analyzer see the flowchart below. The process starts with components for the manufacturing of the analyzer being checked in by the content of specification (e.g. drawings, specifications for incoming inspection) against acceptance limits. The process is completed with final QC testing, the release by QA, and the approved analyzer moved to stock.

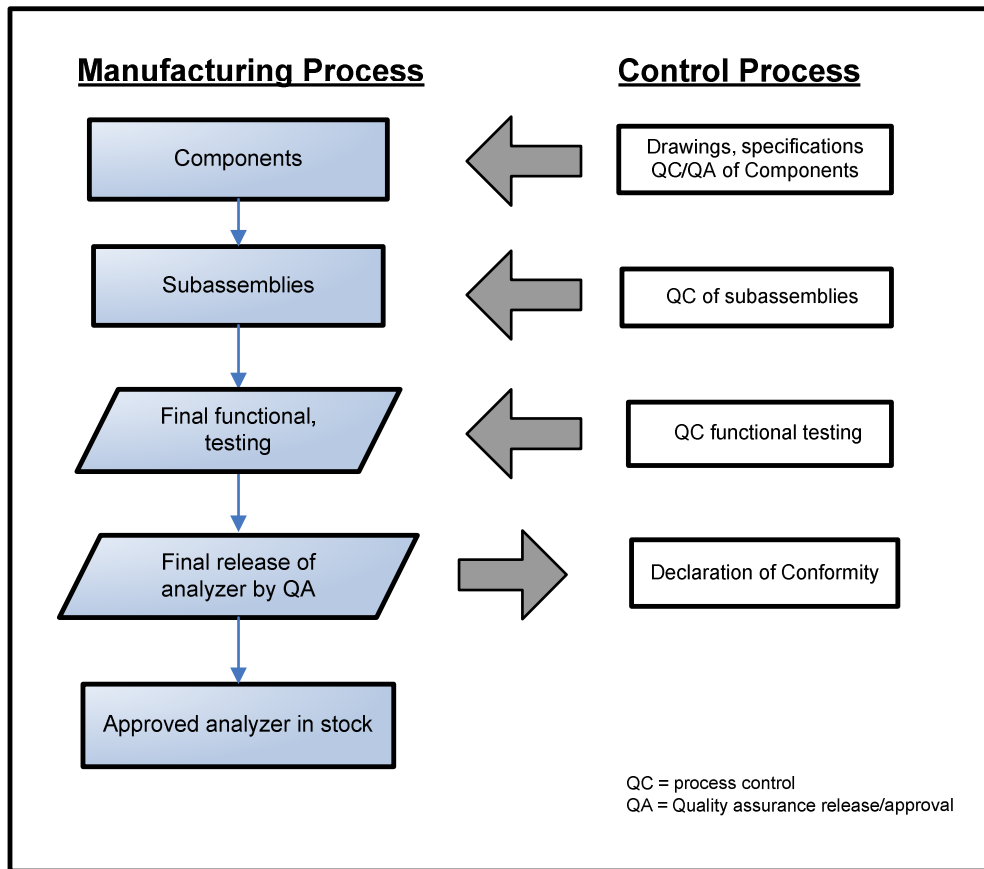


Figure 7 - Flow chart for manufacturing and quality control

Product name Quintus Autoloader

Manufacture Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
Telephone: 0046 8 744 77 00
Fax: 0046 8 744 77 20

Country of origin Sweden – Hungary

Product Description The Quintus Autoloader is a compact, easy-to-use option for users who value letting their instrument to get on with the analyses. It makes Quintus the perfect walk-away system for laboratories with high workload. Just pre-load up to 10 x 10 samples and let the Autoloader do the work. It tilts and rotates every tube, to get a proper mixing, and reads its barcode. Most standard closed EDTA tubes fit and the cap will be detected by a cap recognition sensor. Note that emergency samples can easily be analyzed in the middle of an automated run.

Model configuration



Figure 1 – Quintus Autoloader

Instructions for use Use in accordance with manufacturer's instructions for use in Quintus User's Manual

Storage +5 to +35 °C (41 to 95 °F)

Packaging and Weight Autoloader 12 kg, Double corrugated cardboard outer packaging with shock absorbent inner packaging

Product Conformity Quintus Autoloader is in conformance with the 98/79/EC In Vitro Diagnostic Medical Device Directive (IVD) using Annex III as the conformity assessment procedure.
SS-EN 61010-2-101 (Low Voltage 2014/35/EU)
EN 61326 (2006) (EMC 2014/30/EU)
2012/19/EU WEEE
2011/65/EU RoHS

Quality Control/Calibration The autoloader has been factory calibrated by Boule prior to shipment. Customers are advised to check the daily performance of the Quintus system with a certified blood control authorized by Boule.

Warning and Precautions As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, blood controls, calibrators and waste, these products should be handled as potentially biohazardous. See User manual for biohazard symbol placement and further instructions.

Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the content of effluent streams, before disposing of waste in public sewer systems or recycling decontaminated equipment. The instructions for decontamination can be found on the Boule home page, www.quintus5part.com, under User Support



Manufacturing Process

For the manufacturing process and the specific process control points for this analyzer see the flowchart below. The process starts with components for the manufacturing of the analyzer being checked in by the content of specification (e.g. drawings, specifications for incoming inspection) against acceptance limits. The process is completed with final QC testing, the release by QA, and the approved analyzer moved to stock.

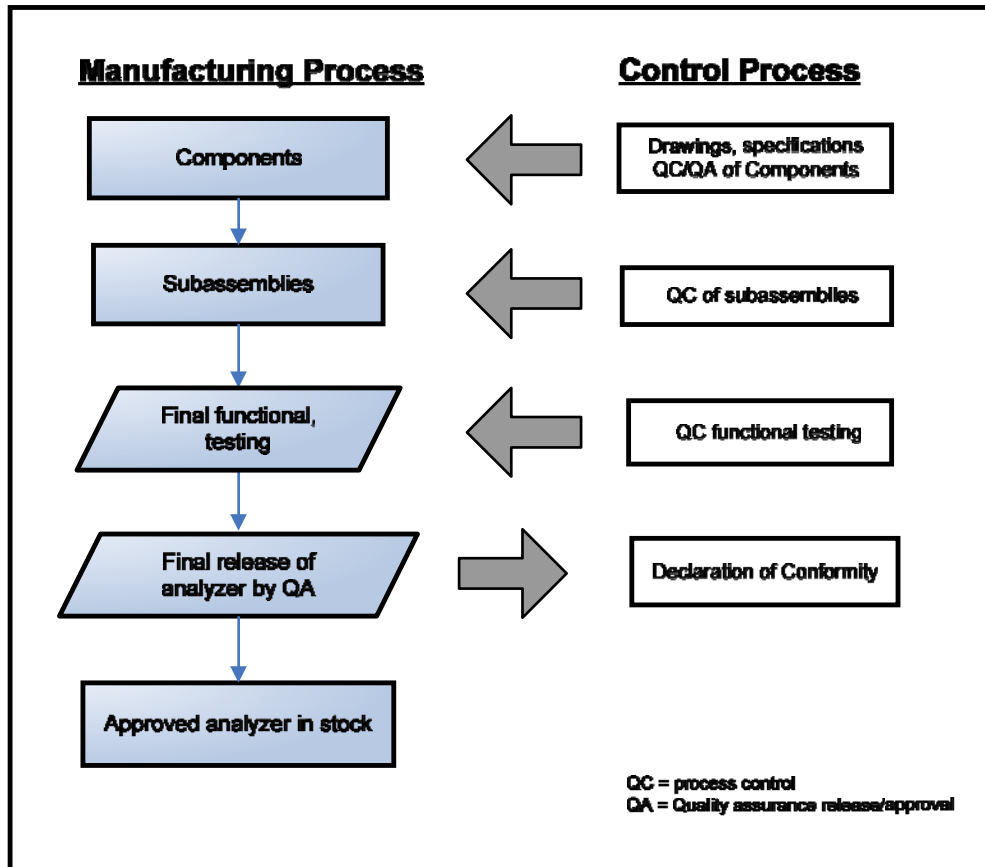


Figure 7 - Flow chart for manufacturing and quality control

Product name:	Quintus 5-Part Diluent	
Article No:	1504291 (20 liter)	
Manufacturer:	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone: 0046 8 744 77 00 Fax: 0046 8 744 77 20	
Country of origin	Sweden	
Product Description:	Quintus Diluent is a hematology diluent used for cell counting and sizing in the Quintus automated, hematology analyzers.	
Active Ingredients:	Salts for isotonic stability	< 1.5 %
	Antimicrobials	< 0.2 %
	Buffering agents	< 0.5 %
Preservatives:	The stabilizing solution contains buffer salts with anti-microbial substances to prevent contamination of bacteria or molds, these substances are biodegradable.	
Shelf life:	24 months from day of manufacture. The shelf life of this product is based on accelerated and real-time stability studies.	
Open container stability	3 months	
Storage:	+4 °C and +35 °C. (~39-95 °F). Avoid freezing.	
Packaging and Weight:	20 liter (21.2 kg) LDPE cubitainer packed in a cardboard box.	

Package and labels



Figure 1 – Quintus 5-part Diluent package

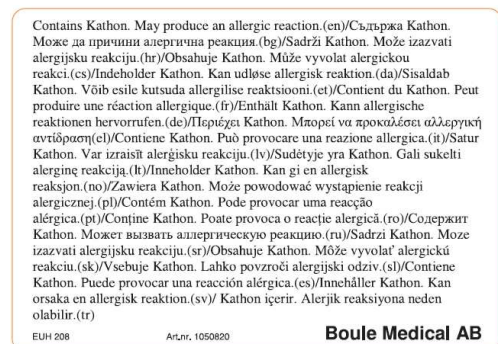


Figure 2 – Additional CLP information

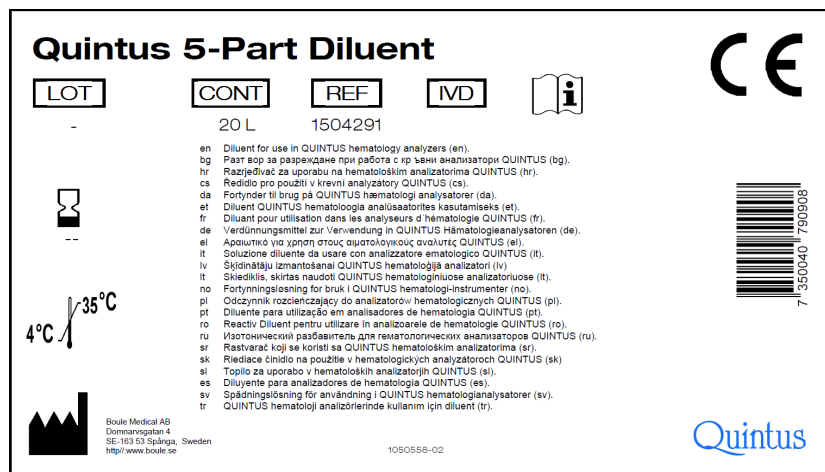


Figure 3 – Label on cardboard box

Recycling information

Part	Material	Weight (g)
Box	Cardboard	670
Politaîner including cap	Plastic	230

Warning and Precautions

Not classified as hazardous according to CLP (EC regulation 1272/2008), information given on added label. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Do not swallow.

Warning and Precautions:

Contains no ingredients at hazardous concentrations. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Harmful if swallowed.

Instructions for use:

Use in accordance with manufacturer's instructions for use and follow Operator manual for connection and fill instruction.

Quality Control Specifications

Test	Specifications
pH	6.8 - 7.2
Osmolality (mOsm/kg)	315 - 350
Conductivity (mS/cm)	18.8 - 19.2
Particles (PLT/RBC channel)	≤ 5
Appearance	Clear, colorless liquid

Product Conformity

Directives	Standards/Comments
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure

Precision Testing (Instrument):

Parameter	RBC	MCV	HGB	PLT	WBC
CV	≤ 1.5 %	≤ 1.0 %	≤ 1.5 %	≤ 5 %	≤ 3.0 %

Scatter diagrams

Quintus displays the results of the optical measurements in a scatter diagram representation.

- Scatter diagrams represent data in a two-dimensional plane.
- There are two scatter diagrams in the patient report: the 4-DIFF and the BASO

Population (4-diff diagram)	Color on scatter diagram
Artifact	BLACK
Lymphocytes	BLUE
Monocytes	GREEN
Neutrophil granulocytes	MAGENTA
Eosinophil granulocytes	ORANGE

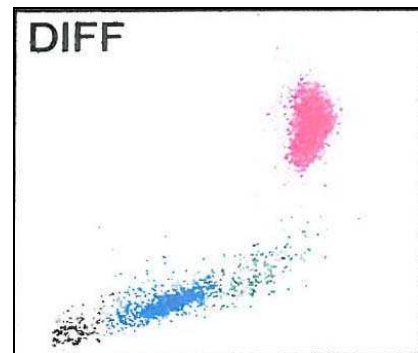


Figure 4 – 4-diff diagram

Population (Basophil diagram)	Color on scatter diagram
WBC without Basophil	BLUE
Basophil granulocytes	MAGENTA

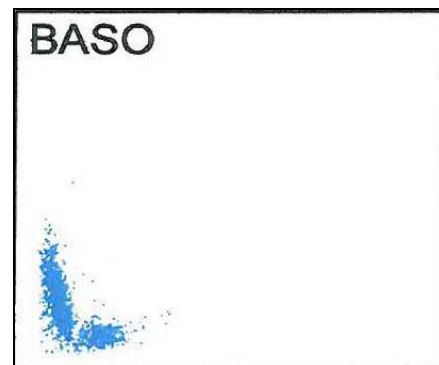


Figure 5 – Basophil diagram

Histograms

Impedance based measurements are represented on histograms. These diagrams show the number of cells against cell size.

- There are two histograms: RBC and PLT.
- Discriminators (thresholds) are displayed with red color.
- The PLT histogram is the magnified section of the left-hand side of the RBC curve.

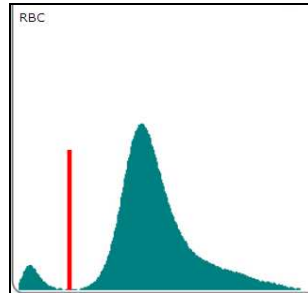


Figure 6 – RBC histogram

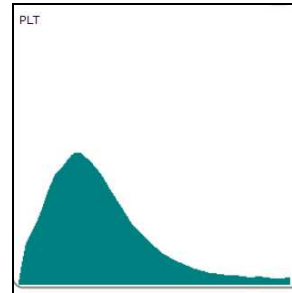


Figure 7 – PLT histogram

Manufacturing Process

For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved reagent moved to stock.

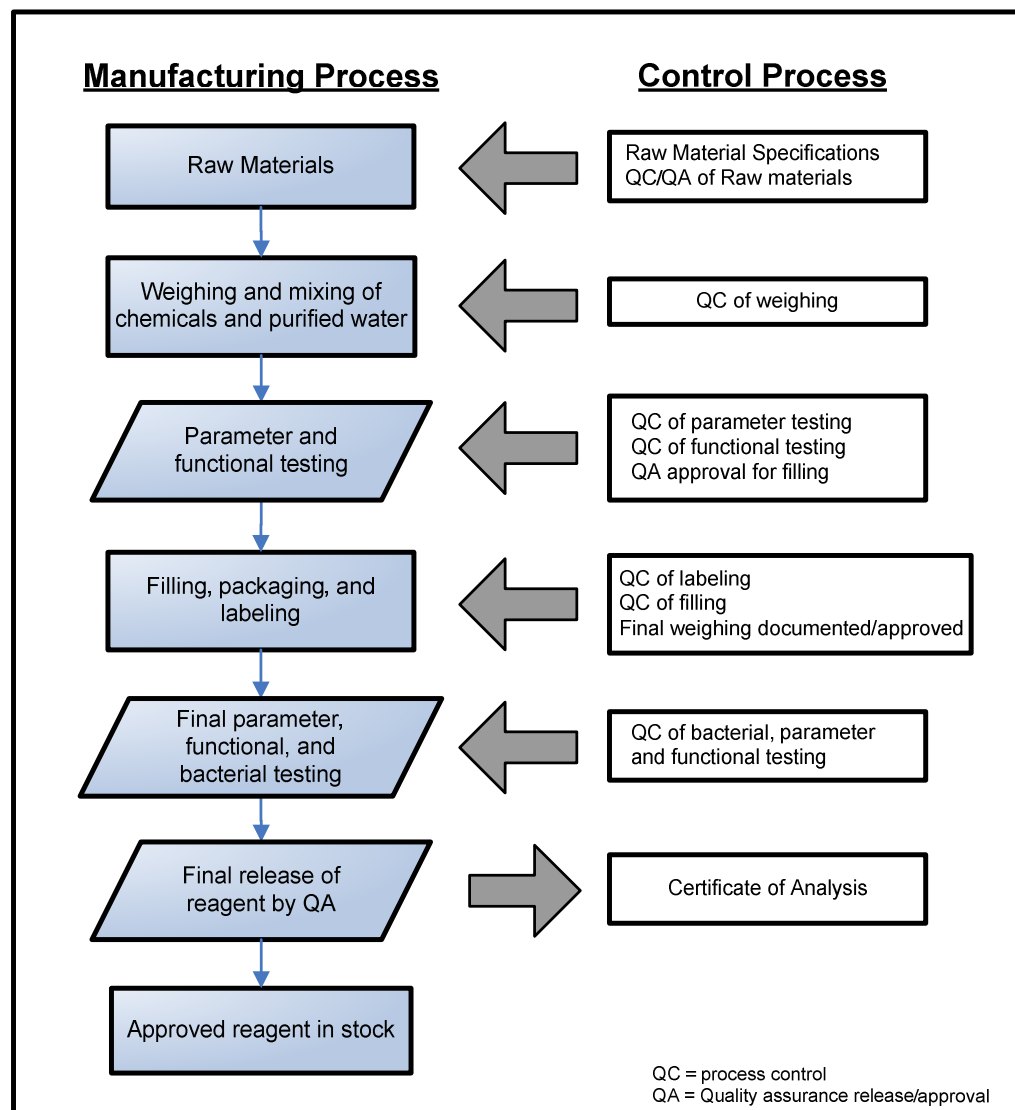


Figure 8 - Flow chart for manufacturing and quality control

Product name	Quintus 5-Part Lyse	
Article No	1504292 (5 liter)	
Manufacturer	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone: 0046 8 744 77 00 Fax: 0046 8 744 77 20	
Country of origin	Sweden	
Product Description	Quintus 5-Part Lyse is a hematology cyanide free lytic reagent used for cell counting and sizing in the Quintus Series, automated, hematology analyzers.	
Active Ingredients	Surfactants	< 1.8 %
	Salts (Buffering substances)	< 0.5 %
Shelf life	18 months from day of manufacture. The shelf life of this product is based on accelerated and real-time stability studies.	
Open container stability	3 months	
Storage	+4 °C and +35 °C. (~39-95 °F). Avoid freezing.	
Packaging and Weight	5 liter (5.4 kg) LDPE cubitainer packed in a cardboard box.	

Package and Labels



Figure 1 – Quintus 5-part Lyse package, politainer in cardboard box

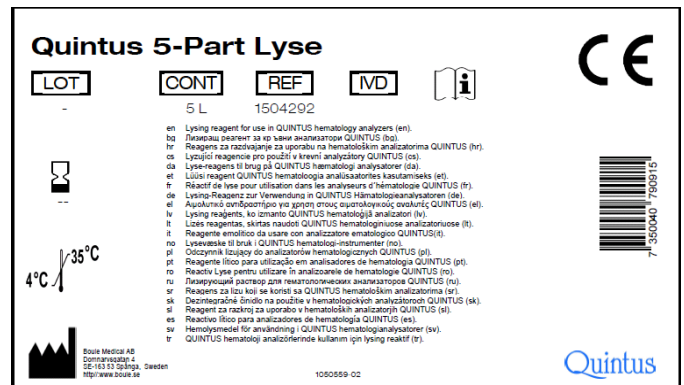


Figure 2 – Label on cardboard box

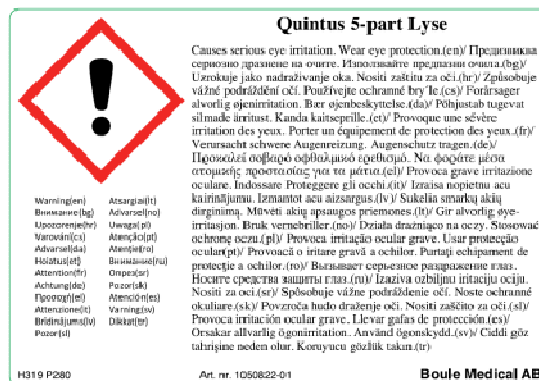


Figure 3 – Additional warning information

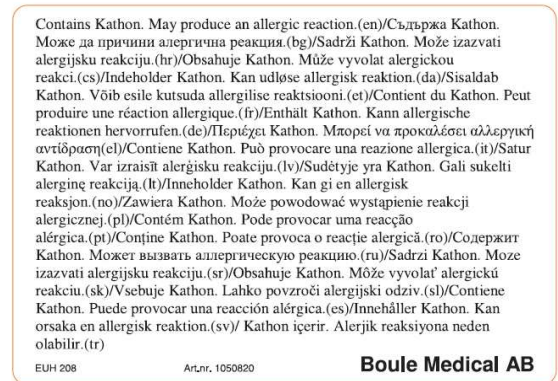


Figure 4 – Additional CLP information

Recycling information

Part	Material	Weight (g)
Box	Cardboard	220
Politainer including cap	Plastic	100

Warning and Precautions

Not classified as hazardous according to CLP (EC regulation 1272/2008), information given on added label. Use good laboratory practice. Avoid contact with skin, eyes, and clothing. Do not swallow.

Instructions for use

Use in accordance with manufacturer's instructions for use and follow Operator manual for connection and fill instruction.

Quality Control Specifications

Test	Specifications
pH	2.7 – 3.0
Osmolality (mOsm/kg)	35 - 44
Conductivity (µS/cm)	1117 - 1541
CBC Performance*	Passed test
Particles (WBC channel)	≤ 0.1
Appearance	Clear, colorless liquid

*Performance test using calibrated blood cell counter at Boule Medical reference laboratory. All parameters except mid cells are tested. Accepted reference 95% to 105% of expected control blood sample values.

Product Conformity

Directives	Standards/Comments
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure

Precision Testing (Instrument)

Parameter	RBC	MCV	HGB	PLT	WBC
CV	≤ 1.5 %	≤ 1.0 %	≤ 1.5 %	≤ 5 %	≤ 3.0 %

Scatter diagrams

Quintus displays the results of the optical measurements in a scatter diagram representation.

- Scatter diagrams represent data in a two-dimensional plane.
- There are two scatter diagrams in the patient report: the 4-DIFF and the BASO

Population (4-diff diagram)	Color on scatter diagram
Artifact	BLACK
Lymphocytes	BLUE
Monocytes	GREEN
Neutrophil granulocytes	MAGENTA
Eosinophil granulocytes	ORANGE

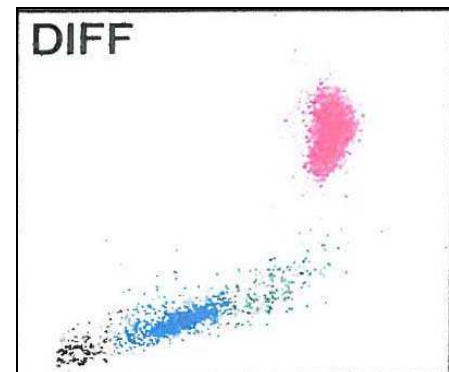


Figure 5 – 4-diff diagram

Population (Basophil diagram)	Color on scatter diagram
WBC without Basophil	BLUE
Basophil granulocytes	MAGENTA

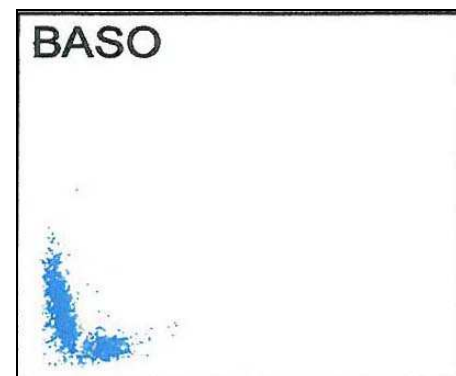


Figure 6 – Basophil diagram



Histograms

Impedance based measurements are represented on histograms. These diagrams show the number of cells against cell size.

- There are two histograms: RBC and PLT.
- Discriminators (thresholds) are displayed with red color.
- The PLT histogram is the magnified section of the left-hand side of the RBC curve.

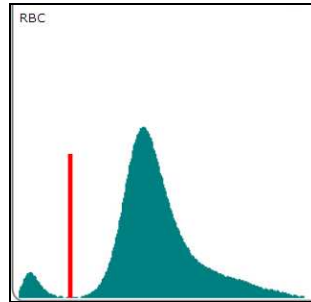


Figure 7 – RBC histogram

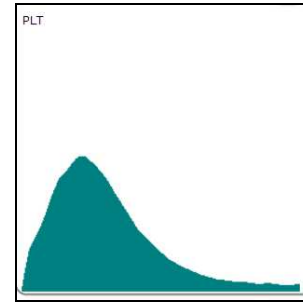


Figure 8 – PLT histogram

Manufacturing Process

For the manufacturing process and the specific process control points for this reagent see the flowchart below. The process starts with raw materials for the manufacturing of the reagent being checked in by the content of certificates (e.g. Batch Specific Certificate of Analysis) against acceptance limits and by follow-up analysis of at least one specific characteristic chemical property (e.g. pH in solution). The process is completed with final QC parameter, functional, and bacterial testing, the release by QA accompanied by the Certificate of Analysis, and the approved reagent moved to stock.

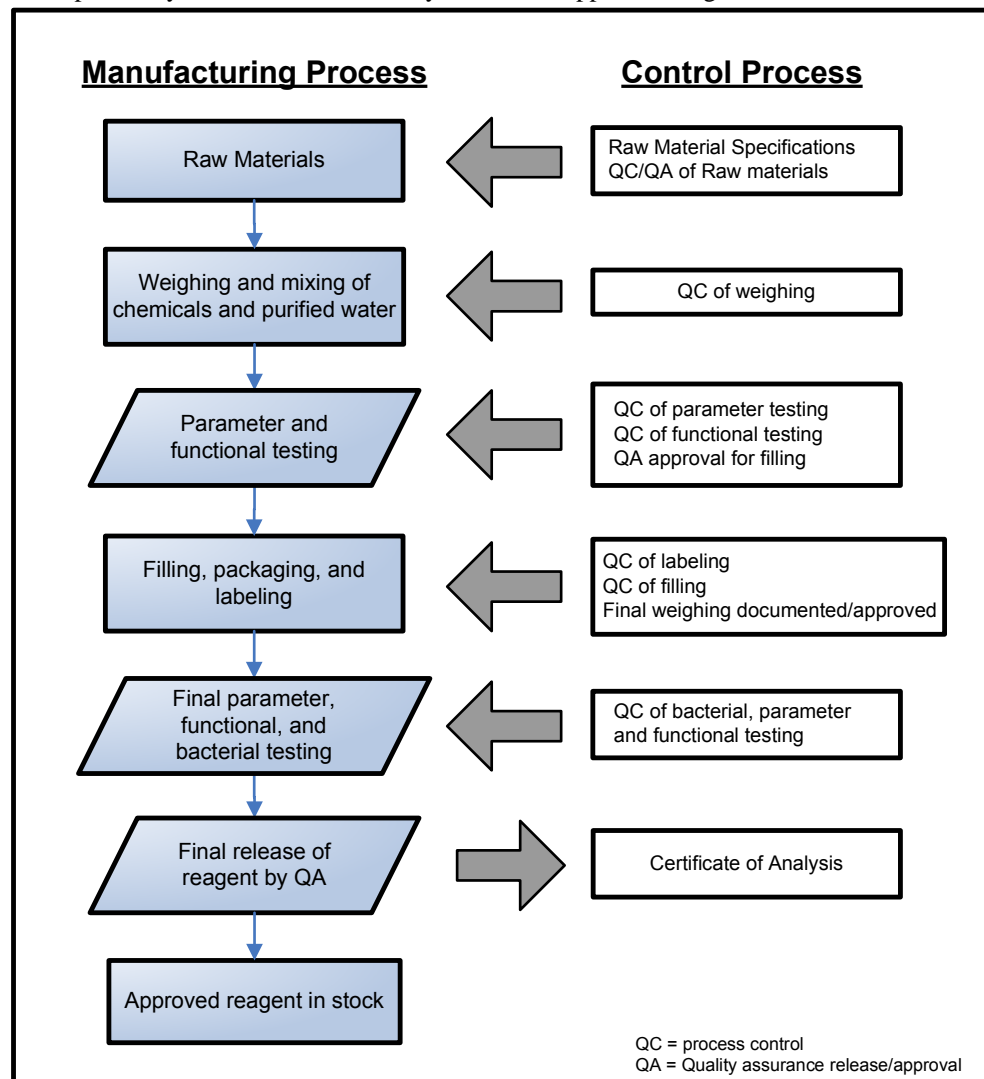


Figure 9 Flow chart for manufacturing and quality control