

iMOST-L Hematology Q-Card

(Hemoglobin/White blood cell test card)

instructions for use

【Product Name】

Generic name: iMOST-L Q-Card (Hemoglobin/White blood cell test card)

【Packing specifications】

Packaging specifications: 10 tests/box, 25 tests /box, 50 tests /box, 100 tests /box

Model: LQ001

【Intended Use】

This product is used for in vitro quantitative detection of hemoglobin concentration, total leukocyte count, leukocyte differential including neutrophil percentage, lymphocyte percentage, monocyte percentage, eosinophil percentage, basophil percentage, neutrophil count, lymphocyte count, monocyte count, eosinophil count and basophil count in human capillary whole blood or venous whole blood.

Blood cell analysis is one of the most commonly used tests in clinical diagnostics. By quantitatively measuring hemoglobin levels and white blood cell parameters in blood samples, this test provides essential information for disease diagnosis, monitoring, and evaluation of treatment effectiveness. Hemoglobin is the primary component of red blood cells and plays a critical role in transporting oxygen and carbon dioxide throughout the body. White blood cells are essential for immune function, including the phagocytosis of foreign particles, antibody production, tissue repair, defense against pathogens, and general immune response. Clinical indications for this product include, but are not limited to: early detection and monitoring of anemia, blood loss, infectious and inflammatory diseases, hematologic disorders affecting white blood cells, unexplained fatigue or general weakness, chronic disease follow-up, preoperative evaluations, pregnancy assessments, monitoring of drug efficacy and adverse reactions, and routine health check-ups ^[6-16].

iMOST-L is intended for use in community clinics, hospital emergency departments, inpatient wards, health centers, testing centers, point-of-care settings, and similar settings, and is suitable for children aged 2 years and above, adolescents and adults.

【Test principle】

Hemoglobin Measurement: The iMOST-L Hematology Q-Card uses approximately 10 microliters of whole blood, which is pressed into a micrometer thin layer on the card. Hemoglobin concentration is quantitatively determined by measuring the optical absorbance of the blood sample at two different wavelengths.

White Blood Cell Count and Differential: The Q-Card contains pre-coated reagents that stain white blood cells. Images of the stained cells are captured under various lighting conditions by the optical system in the blood cell analyzer. The system software then processes these images to count the total number of white blood cells and perform a differential analysis, including the percentages and absolute counts of neutrophils, lymphocytes, monocytes, eosinophils, and basophils.

The iMOST-L Hematology Q-Card is a single-use, disposable device. Once the sample is applied, the card is inserted into the blood cell analyzer, and results are available within approximately 3 to 4 minutes.

【Detection range】

Hemoglobin (HGB): 50 - 200 g/L

White blood cell count (WBC): $1 - 30 \times 10^9/L$

【Main ingredients】

iMOST-L hematology Q-Card is composed of a polymethyl methacrylate plastic base card, a polymethyl methacrylate plastic cover sheet, aluminum foil, etc., and contains the following reagents: acridine orange, dimethyl-(3- sulfopropyl) tetradecyl ammonium.

【Storage conditions and validity period】

1. -5 - 40 °C, humidity < 90%, valid for 12 months;

Please ensure that the test card packaging is airtight and protected from light. Please use the test card within the expiration date printed on the packaging. All unused test cards must be kept in the original packaging bag and box and protected from light.

2. Validity period after opening

After opening the sealed packaging bag, it is recommended to use it immediately. The opened hemoglobin /leukocyte test card can be stored at room temperature for 2 hours.

3. The production date and expiration date of the product can be found on the outer packaging label.

【Applicable instruments】

【Sample requirements】

It can be used to measure capillary or venous whole blood.

1. Capillary Blood Sampling (Fingertip)

Capillary blood refers to blood collected from the fingertip. Two recommended sampling methods are outlined below:

1.1 Direct Fingertip Sampling:

Collect blood directly from the fingertip using a disposable, quantitative micropipette (10 μ L, without anticoagulant), and immediately dispense the sample onto the iMOST-L Hematology Q-Card. Testing must be performed immediately after sample collection, as the small volume of capillary blood may clot quickly, potentially affecting test accuracy.

1.2 Fingertip Sampling Using Anticoagulant Tube:

Recommended for professional use to ensure reliable and optimal performance.

Use a micro-collection tube containing a specified concentration of K₂EDTA anticoagulant (e.g., 0.5–1.5 mg/mL), **as recommended by Essenlix**. Mix the sample thoroughly, and then apply it to the test card using a disposable quantitative micropipette or standard pipette. Testing should be performed immediately, and recommended be completed within 1 hour of sample collection.

2. Venous Blood Sampling (For Professional Use Only)

Collect venous blood using a standard blood collection tube containing K₂EDTA. Store the sample at room temperature and test within 8 hours of collection. Before testing, mix the sample thoroughly by either:

Using a blood mixer or shaker for 1–2 minutes, or

Gently inverting the tube 10–20 times by hand.

【Test method】

1. Required Materials

1.1 Capillary blood

Items provided: iMOST-L hematology Q-Card

Fingertip (direct): Required items (not provided): iMOST-L hematology analyzer (LA001), disposable finger prick, alcohol pad, gauze or cotton ball and quantitative micropipette;

Fingertip (anticoagulant tube) : Required items (not provided): hematology analyzer (LA001), disposable finger prick, alcohol pad, gauze or cotton balls, micro-collection tube (K2EDTA anticoagulant tube recommended by Essenlix), pipette and pipette tip (10 µL) or disposable quantitative micropipette ;

1.2 Venous blood

Items provided: iMOST-L hematology Q-Card

Items required (not provided): Hematology analyzer (LA001), venous anticoagulation K2EDTA tube, pipette and pipette tip (10 µL) or disposable quantitative micropipette (10 µL).

2. Operation environment

Temperature range: 15°C ~ 30°C

Relative humidity: ≤ 80% (non-condensing)

3. Operation Steps

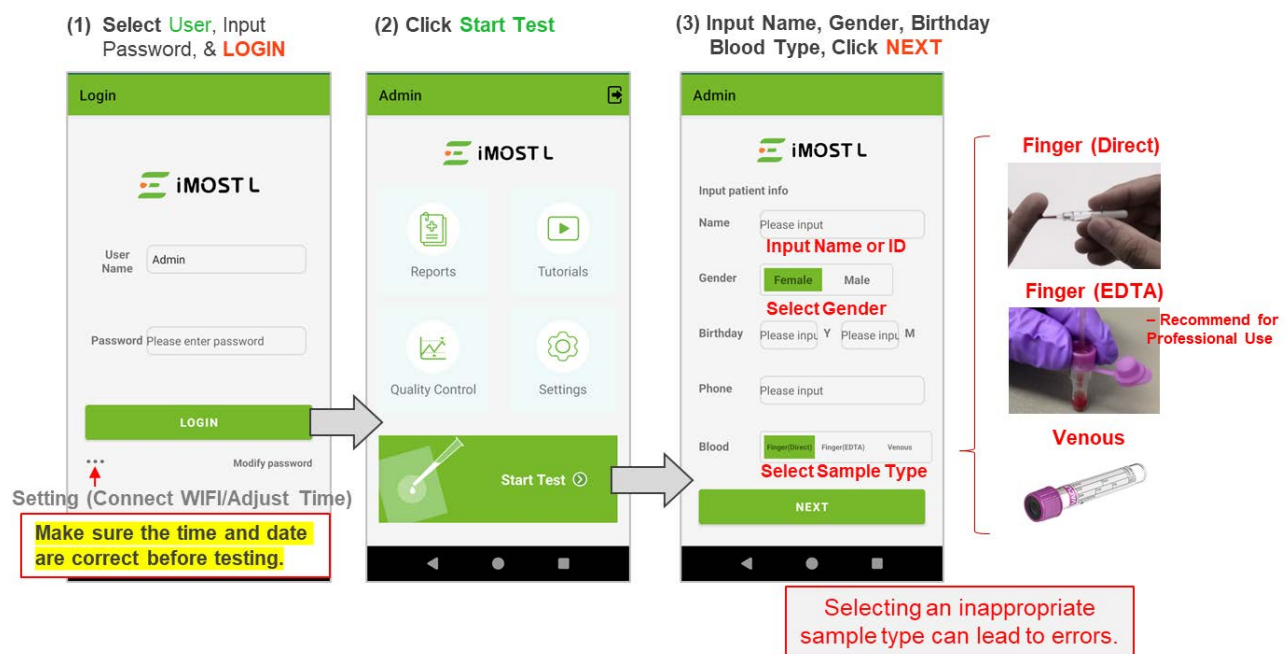
Before testing

- Ensure that both the analyzer and the test card are in a suitable operating environment. Testing must be performed within the specified temperature range of 15–30°C.
- Use only authorized iMOST-L test cards. Use of unauthorized or incompatible cards may result in damage to the analyzer or invalid test results.
- Store test cards in a cool, dry environment that complies with the specified storage conditions.
- Do not conduct measurements if there is condensation (e.g., visible water droplets) on the analyzer. Move both the analyzer and test cards to a dry, temperature-controlled area and allow surfaces to dry completely before use.
- Before opening any packaging, verify that the test card, disposable capillary blood collection device, and disposable quantitative micropipette are within their validity period.
- Open the sealed pouch of the test card only when ready to perform a measurement. Use the test card immediately after removing it from the pouch.
- Test cards are single-use only. Do not reuse test cards that have been exposed to blood, control solution, or any contaminants.
- Disposable capillary blood collection devices and quantitative micropipettes are also for single use only.
- Do not touch the surface of the test card.
- Do not bend, cut, or modify the test card under any circumstances.
- If another person assists with sample collection or measurement, ensure they clean the analyzer thoroughly before use.

3.1 APP login and preparation (administrator or operator)

- Log in as an administrator or operator

- Click the "Start" button to start the test
- User information entry
- After clicking "Start", the user is prompted to enter basic information (name, gender, date of birth, mobile phone number) and blood type;
- **Blood type :**
 - **Fingerstick (direct):** **Directly** add fingertip blood to the test card using a disposable quantitative micropipette (10 µl, without anticoagulant) ;
 - **Fingertip (anticoagulant tube) :** **Recommended for professional use to ensure reliable and optimal performance.** Use the micro-collection tube (containing a specific concentration of K₂ EDTA) recommended by Essenlix Company to collect samples (for more types of collection tubes, please consult Essenlix Customer Service Center). After mixing, use a disposable quantitative micro-pipette (10 microliters, without anticoagulant) or a pipette to add the capillary blood sample to the test card;
 - **Venous :** Add a venous blood (K₂ EDTA) sample to the Test Card using a pipette or disposable quantitative micropipette (10 µl, without anticoagulant) .



Selecting the wrong blood type may lead to inaccurate measurement results!

3.2 Test Card Preparation

Notice:

* It is recommended to use the test card immediately after opening . Do not use the test card if the packaging is damaged or the packaging bag has been opened for more than 2 hours. Otherwise, it may cause error information or inaccurate measurement results. If the packaging bag of the test card is found to be damaged, please contact Essenlix Customer Service Center immediately for consultation.

*** The entire process from blood collection, card making to card insertion and testing should be continuous. Do not pause or wait in the middle to avoid sample evaporation, blood cell coagulation or changes that may lead to errors or failures in test results.**

* The surface of the test card contains chemical reagents that may irritate the skin or eyes and cause harm if inhaled or swallowed.

- 1) Scan the QR code on Q-Card packaging and enter the test card information ;
- 2) Hold sides of the test card or the silver strip with your fingers to take out the test card ;
- 3) Lift the upper cover at the notch with your fingers , keeping the angle between 30 ° and 70 ° , place the thick lower plate underneath, and put it into the groove of the card press in the direction shown in the figure below.



(a) Hold the Q-Card by its sides with two fingers.



(b) Open Q-Card by lifting the thin film of the top plate at the notch.



(c) Hold Q-Card by its sides.



(d) Put Q-Card on and secure it in the "Card Slot" of Presser.

**Blood
Landing Zone
(White Spot)**



Notice:

Do not touch the inner surface of the test card. If there is direct skin contact, please rinse the contacted skin with clean water for about 5 minutes.

Please be sure to keep the surface of the test card clean and avoid contamination with oil, fingerprints, etc. A dirty surface of the test card may lead to erroneous test results.

3.3 The user completes blood collection and sample addition according to the following instructions

Note: To reduce the chance of infection and ensure accurate results:

*This product has not been evaluated for other blood collection sites and can only be used with fingertip blood or venous whole blood.

* Before capillary blood collection, make sure your fingers are warm. You can use hot water or warm your hands to facilitate smooth flow of capillary blood.

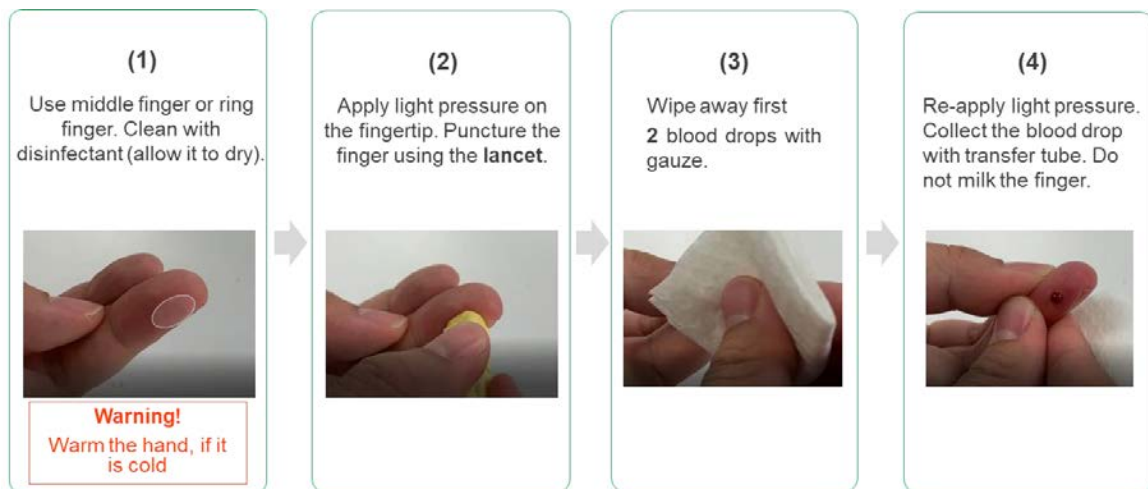
* Before blood collection, please wipe the blood collection site with alcohol cotton and wipe it dry after cleaning.

* The disposable blood collection device is for one person only. Do not reuse it or share it with anyone else .

* Always keep the analyzer and blood collection equipment clean.

* Each time you measure, you should choose a different acupuncture point. Repeated acupuncture at the same site can cause soreness and produce nodules.

3.3.1 Capillary blood sampling



 During the blood collection process, ensure that the blood flows out smoothly to avoid excessive squeezing of tissue fluid, which may lead to incorrect results.

 Before taking blood , wipe off the first 2-3 drops of blood with gauze or cotton balls to avoid contamination by alcohol residue and residual substances on the finger surface.

3.3.2 Add blood sample to the test card

1) Fingertip (direct) pipetting steps

Immediately use a disposable quantitative micropipette to collect blood directly from the fingertip and apply the sample to the test card. This method is suitable when sample collection and application can be performed smoothly and without interruption, with steady blood flow from the fingertip and prompt transfer to the test card. Avoid delays, improper collection techniques, or situations where the blood clots too quickly, as these may lead to inaccurate or invalid test results.



When sampling, make sure the blood drop is large enough, such as the size of a soybean, and draw out 10 microliters at ONE time.



When adding sample to the test card, do not squeeze too much and push air bubbles into the blood drop.



Add the sample to the designated white spot on the card presser. Otherwise, the result will be inaccurate.

- (1) Ensure that **the blood drop on the finger is large enough** to prevent air bubbles during collection.



- (2) To collect the blood, touch the tip of the transfer tube or pipette to the blood drop.



Ensure **the opening at the end remains unobstructed** during collection. Collect blood to the **indicated line**.



- (3) Dispense the blood onto the **"blood landing zone"** by slowly pressing the plunger of the transfer tube or pipette.

Ensure **the opening at the end is blocked** during dispensing.



Blood Landing Zone (White Spot)

If the sample is not applied at the white spot, it may lead to measurement errors.



Leave last bit of blood inside the tube. Stop pushing before all sample is dispensed out.



Do not push air bubble into droplet.

2) Finger tip (anticoagulant tube) sampling steps

Recommended for professional use to ensure reliable and optimal performance.

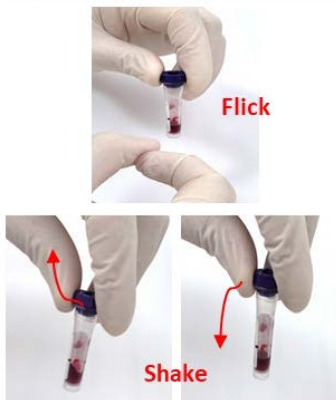
Use capillaries (containing a specific concentration of K_2EDTA) recommended by Essenlix Company to collect blood into blood collection tubes (this method can effectively avoid rapid blood coagulation leading to inappropriate test results):



Notice:

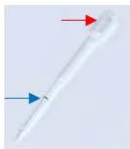
Please mix the sample thoroughly before adding it to the blood test card: Please strictly follow the manufacturer's recommended method to operate and mix well. Insufficient shaking will lead to incorrect results.

**Flick bottom 10-15 times.
Shake tube 10 times.
Before Adding to Q-Cards!**



Use a disposable micropipette or pipette (10 μ l) to draw blood from the capillary to the "indicator line" , or use a pipette to take 10 μ l of blood and add it to the test card.

Dispense the blood onto the "**blood landing zone**" by slowly pressing the plunger of the transfer tube or pipette.



Ensure that the **top opening** is closed during the pressing process.



Blood Landing Zone (White Spot)

If the sample is not applied at the white spot, it may lead to measurement errors.



Leave last bit of blood inside the tube. Stop pushing before all sample is dispensed out.



Do not push air bubble into droplet.

3) Venous blood collection and sampling steps:



Note: Venous blood sampling is only allowed by professional medical personnel.

Using standard tubes containing K_2 EDTA.

Venous blood is stored at room temperature, and it is recommended to complete the test within 8 hours.

Mix the sample thoroughly before adding to the blood test card: gently invert the tube 10-15 times by hand or use an intravenous tube mixer for two minutes.

Use a disposable quantitative micropipette to draw blood from the anticoagulant tube to the "indicator line" (about 10 μ L), or use a pipette to draw 10 μ L of blood and add it to the test card:

Dispense the blood onto the "**blood landing zone**" by slowly pressing the plunger of the transfer tube or pipette.



Ensure that the **top opening** is closed during the pressing process.



Blood Landing Zone (White Spot)

If the sample is not applied at the white spot, it may lead to measurement errors.



Leave last bit of blood inside the tube. Stop pushing before all sample is dispensed out.



Do not push air bubble into droplet.

3.4 The user **immediately** completes the card making with the card presser as following. The whole process should be continuous and not stopped midway.



Add the sample to the white spot on the card presser. Otherwise, the result will be inaccurate.



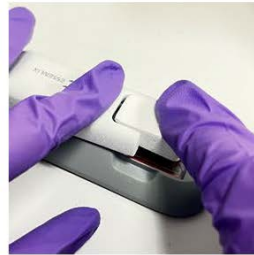
Immediately (within 15 sec), smoothly close the card by pressing the arm at (A).



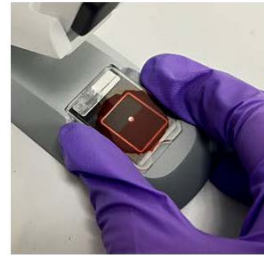
Press the arm at (A) gently and smoothly at a rate of ~4 sec from beginning to end until the blood stops spreading (wait ~2 sec).



Press the front head (B) against the Q-Card ~3 sec to make sure the Q-card is tightly closed.

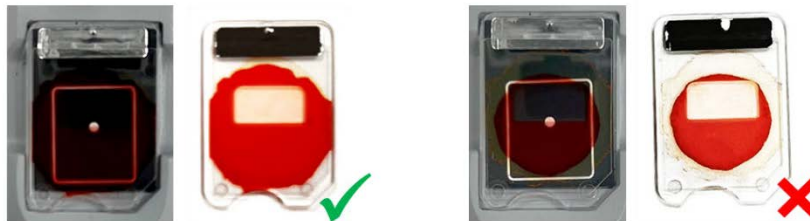


Lift by holding sides of Q-Card



3.5 Check the sample in the test card

- (1) The blood must cover the white reference square, otherwise discard the Q-Card and make a new one.



- (2) No large visible air bubble or dust, otherwise discard the Q-Card and make a new one.



Notice:

If the above adverse conditions occur during the card pressing process, please discard the test card and make a new one.

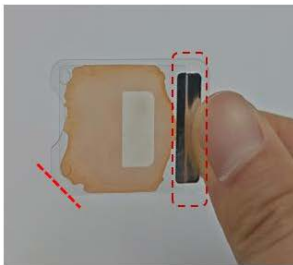
Do not reopen the test card before testing. If you accidentally open the test card, discard the test card and make a new one. Test cards that do not meet the card making requirements will cause incorrect test results.

3.6 Insert the test card **immediately** into the card reader socket of the analyzer

After the card is made, the user needs to **immediately** insert the prepared test card into the designated position and close the card slot cover;

Hold the card on silver strip, with the **front side** facing you

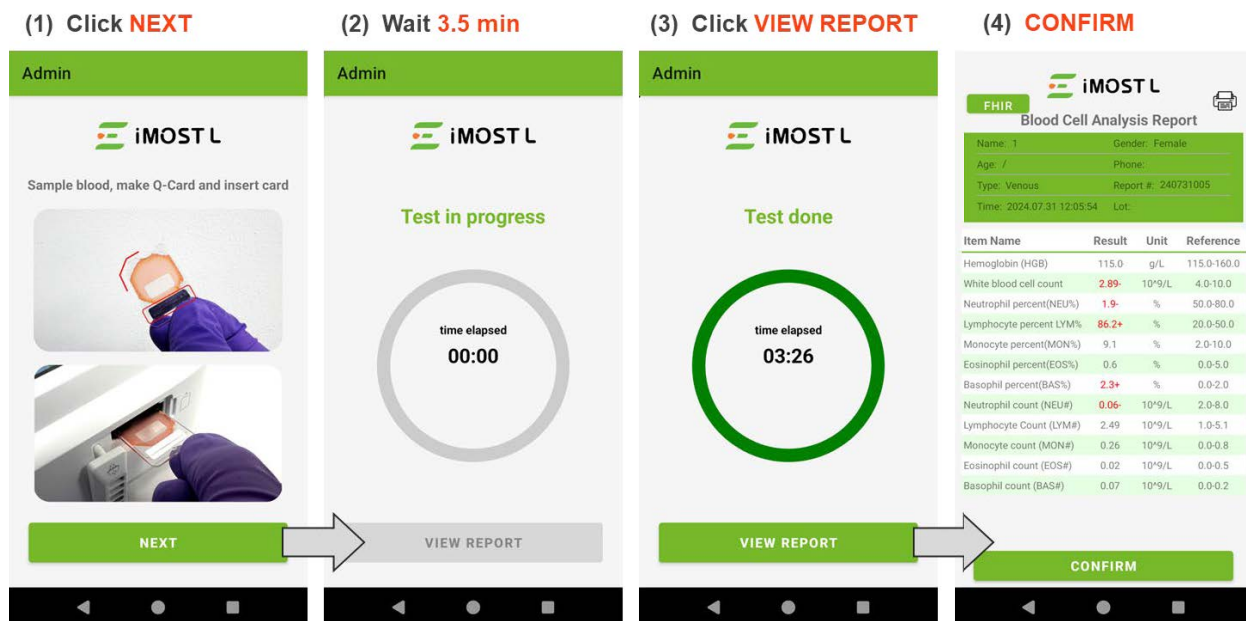
Immediately, gently insert the Q-Card into the analyzer until a **physical stop is reached**.



Note: If blood overflows from the edge of the test card, please do not insert it into the card reader slot of the analyzer! Please prepare a qualified test card for testing again!

4. Testing

Click "Next" on the analyzer interface, the test will start, the interface will prompt the test process, and the required time will be prompted; please wait patiently. Please refer to the manual of the hematology analyzer for more detailed operation steps.



Notice:

During the test, keep the work surface stable and do not tilt or move the instrument until the test is completed.

If the battery level is less than 15% when the test starts, charge the battery to at least 30% before testing again.

After the test is completed, the analyzer directly gives the test results. After the user confirms the operation, the next test can be carried out. The results can be printed or uploaded to the relevant medical data management system via FHIR (if the medical institution requires it).

Go back to the main interface and click the test report button to see the user's test report.

In the result display interface,

Click "FHIR" to upload the test results to the LIS system.

Click  the button to choose to output the test results to a Wi-Fi printer or a Bluetooth printer .

5. Quality Control

The iMOST-L Hematology Q-Card (LQ001), used in conjunction with the compatible blood cell analyzer (LA001), constitutes a complete blood cell analysis system. The system is factory-calibrated and does not require additional calibration prior to use.

Quality control procedures consist of two key components: Routine maintenance of the analyzer and Regular testing using liquid quality control (QC) materials. To support this, the iMOST-L system provides dedicated liquid QC solutions for validating hemoglobin and white blood cell measurements. For additional guidance or information of the suitable QC solutions, please contact the Essenlix Customer Service Center.

Liquid Quality Control Materials:

The iMOST-L hematology system uses liquid QC materials specifically formulated for hemoglobin and leukocyte testing. These materials must be stored and handled according to the manufacturer's instructions.

Recommended QC Frequency:

Routine quality control testing using liquid QC materials is advised to ensure accurate and consistent results. The frequency of QC testing may follow standard laboratory practice or be adjusted based on the user's operational needs.

Please refer to the quality control procedures outlined in the system manual. It is recommended to use iMOST-L approved QC materials for optimal compatibility and performance. For additional guidance or information, please contact the Essenlix Customer Service Center.

【Reference interval】

Venous blood reference interval (adults)

Parameters	Unit	Age	Reference interval	
			Male	Female
Hemoglobin (HGB)	g/L	≥18	130 - 175	115 - 150
White blood cell count (WBC)	× 10 ⁹ /L	≥18	3.5-9.5	
Neutrophil count (NEU#)	× 10 ⁹ /L	≥18	1.8-6.3	
Lymphocyte count (LYM#)	× 10 ⁹ /L	≥18	1.1-3.2	
Monocyte count (MON#)	× 10 ⁹ /L	≥18	0.1-0.6	
Eosinophil count (EOS#)	× 10 ⁹ /L	≥18	0.02-0.52	
Basophil count (BAS#)	× 10 ⁹ /L	≥18	0-0.06	
Neutrophil percentage (NEU%)	%	≥18	40-75	
Lymphocyte percentage (LYM%)	%	≥18	20-50	
Monocyte percentage (MON%)	%	≥18	3-10	
Eosinophil percentage (EOS%)	%	≥18	0.4-8.0	
Basophil percentage (BAS%)	%	≥18	0-1	

Capillary blood reference interval (people aged 2 years and above)

Parameters	Unit	Age	Reference interval	
			Male	Male
Hemoglobin (HGB)	g/L	≥13	130.6~177.8	113.9~157.3
White blood cell count (WBC)	× 10 ⁹ /L	≥13	3.71~10.98	3.84~10.94
Neutrophil count (NEU#)	× 10 ⁹ /L	≥13	1.82~7.48	1.79~7.62
Lymphocyte count (LYM#)	× 10 ⁹ /L	≥13	1.23~4.17	1.16~4.09
Monocyte count (MON#)	× 10 ⁹ /L	≥13	0.12~0.85	0.11~0.81
Eosinophil count (EOS#)	× 10 ⁹ /L	≥13	0.04~0.63	0.04~0.64
Basophil count (BAS#)	× 10 ⁹ /L	≥13	0.00~0.07	0.00~0.07
Neutrophil percentage (NEU%)	%	≥13	35.1~74.6	34.9~75.2
Lymphocyte percentage (LYM%)	%	≥13	19.2~53.6	19.8~54.2
Monocyte percentage (MON%)	%	≥13	2.3~10.9	2.1~10.8
Eosinophil percentage (EOS%)	%	≥13	0.5~8.1	0.6~7.8
Basophil percentage (BAS%)	%	≥13	0.0~0.7	0.0~0.7

Parameters	Unit	Age	Reference interval
Hemoglobin (HGB)	g/L	2-13	117.3~156.7
White blood cell count (WBC)	× 10 ⁹ /L	2-13	4.58~12.54
Neutrophil count (NEU#)	× 10 ⁹ /L	2-13	1.46~7.44
Lymphocyte count (LYM#)	× 10 ⁹ /L	2-13	1.71~6.37
Monocyte count (MON#)	× 10 ⁹ /L	2-13	0.14~0.90
Eosinophil count (EOS#)	× 10 ⁹ /L	2-13	0.05~0.69
Basophil count (BAS#)	× 10 ⁹ /L	2-13	0.00~0.07
Neutrophil percentage (NEU%)	%	2-13	25.8~70.5
Lymphocyte percentage (LYM%)	%	2-13	23.7~64.8
Monocyte percentage (MON%)	%	2-13	1.9~10.4
Eosinophil percentage (EOS%)	%	2-13	0.6~8.2
Basophil percentage (BAS%)	%	2-13	0.0~0.7

The reference values provided may vary due to a range of physiological and external factors, including gender, blood type, circadian rhythms, physical activity, stress or trauma, pregnancy, digestive status, and smoking.

Venous blood sampling is recommended for adult testing to ensure greater consistency and reliability. Capillary blood testing is not recommended for infants under 2 years of age due to potential variability and difficulty in sample collection.

Interpretation of test results

If the measured value falls within the reference range of the iMOST-L hemoglobin/leukocyte test card, the result will be displayed as a specific numerical value (g/L, /L, or %).

If the measured value is outside the reference range, the result will be displayed in red, along with a "+" (above range) or "-" (below range) indicator next to the value.

If the measured value exceeds the detection range of the system, a ">" (greater than) or "<" (less than) symbol will follow the result to indicate that the value is beyond the measurable limits.

Important Notes:

Test results are for reference only. If your results fall outside the normal range recommended by your healthcare provider, it is advised to consult a physician.

Interpretation of test results should consider the patient's medical history, clinical symptoms, and other diagnostic findings.

Use of the device outside the intended operating environment specified by the manufacturer, or use of incompatible accessories or materials, may lead to inaccurate results.

Limitations of the test method

The following operational guidelines must be strictly followed to ensure accurate and reliable test results:

Always adhere to the instructions for use and operation provided by the manufacturer.

Hemoglobin/Leukocyte test cards must only be used within the indicated expiration date.

The Hemoglobin/White Blood Cell test card is exclusively compatible with the iMOST-L Hematology Analyzer (Model LA001). It must not be used with any other device or in a non-instrument-based manner.

In performance validation, the following potential interfering substances were tested and found not to affect hemoglobin or white blood cell count results:

D-glucose at a concentration of 55 mmol/L (1 g/dL);

Triglycerides at 1500 mg/dL;

Conjugated/Unconjugated Bilirubin at 40 mg/dL;

No interference was observed with leukocytosis ($WBC > 30 \times 10^3/\mu L$) or thrombocytosis (platelet count $> 500 \times 10^3/\mu L$);

Other potential interfering substances, whether not yet studied or currently under clinical evaluation, may impact test results and should be considered when interpreting measurements.

【Product performance characteristics】

Limit of Detection:

Parameter	LoB	LoD	LoQ
Hemoglobin (g/L)	1.15	4.52	29.84
WBC ($10^3/\mu\text{L}$)	0.00	0.10	0.77

Linear Range:

Parameter	Linear range	Linear correlation coefficient r
HGB	50 g/L ~ 200 g/L	≥ 0.990
WBC	$1.0 \times 10^9/\text{L} \sim 30.0 \times 10^9/\text{L}$	≥ 0.990

Precision:

Parameter	CV/% or SD	In Detection range
HGB	$\leq 3.0\%$ or 3 g/L	115 g/L - 175 g/L
WBC	$\leq 6.0\%$ or $0.3 \times 10^9/\text{L}$	$3.5 \times 10^9/\text{L} - 9.5 \times 10^9/\text{L}$

Accuracy:

Parameter	Relative deviation range/%	In Detection range
HGB	$\leq 7.0\%$ or 7 g/L	115 g/L - 175 g/L
WBC	$\leq 15.0\%$ or $0.5 \times 10^9/\text{L}$	$3.5 \times 10^9/\text{L} - 9.5 \times 10^9/\text{L}$

Lot Difference

The three batches of test cards were used to test one sample within the detection range repeatedly for 10 times, and the inter-batch relative ranges among the three batches of test cards met the accuracy requirements.

Parameter	Batch Difference/%	In Detection range
HGB	$\leq 7.0\%$ or 7 g/L	115 g/L - 175 g/L
WBC	$\leq 15.0\%$ or $0.5 \times 10^9/\text{L}$	$3.5 \times 10^9/\text{L} - 9.5 \times 10^9/\text{L}$

In our internal product release and quality control procedures for HGB, a stricter in-house acceptance range is applied: coefficient of variation (CV) $\pm 2.5\%$ for precision and $\pm 6.0\%$ for accuracy (relative deviation). This ensures higher product consistency and quality.

Clinical evaluation (compared with the reference instruments and reagents Sysmex XN):

A paired clinical trial was conducted to evaluate the accuracy of the iMOST-L device compared to a reference laboratory system (Sysmex XN-10), following CLSI EP09 “Measurement Procedure Comparison and Bias Estimation Using Patient Samples.”

This study included 319 participants, divided into two main groups: adults (18+ years, n=210) and children (n=109). The adult group provided 210 blood samples (105 venous and 105 capillary), while the pediatric group provided 109 capillary samples. All operators received training and were given a Quick Reference Guide (QRG) detailing the test procedure. The QRG is available to all system users.

The correlation between the test results of the iMOST and the reference is significant, with indicating that the consistency between the iMOST and Sysmex.

Sample Stability:

Based upon CLSI Guidance EP25, whole blood stability was evaluated. Whole Blood Sample Stability Claim as:

The venous whole blood sample is stable at controlled room temperature 20–25°C (68–77°F) for 8 hours.

The capillary whole blood sample is stable at controlled room temperature 20–25°C (68–77°F) for 4 hours.

Test Kit Shelf-Life:

Real-time stability study is being conducted to establish the shelf-life stability of the Q-Card when it is stored at the recommended storage conditions (-10°C to +40°C). Three lots of test kits are tested. Each test lot is stored at the recommended storage conditions and tested at defined time points (3, 6, 9, 12 months), including baseline. At each predefined time point, the test kits are subjected to functional tests and analytical tests. The initial shelf life for the test kit was set at 12 months at the recommended temperature.

【Notes】

If your test results appear too low, too high, or inconsistent with how you feel, consult your healthcare provider. Do not adjust your treatment plan without your provider’s guidance.

This product is not intended to diagnose or rule out diseases.

For in vitro diagnostic use only.

Keep the surface of the test card clean. Avoid contamination with stains, fingerprints, or other debris, as this may lead to inaccurate results.

Blood samples may pose a biohazard risk. Handle all samples with care and dispose of them according to local environmental and medical waste regulations.

The inner surface of the Hemoglobin/White Blood Cell Test Card contains chemical reagents that may irritate the skin or eyes, and can be harmful if inhaled or ingested. In case of skin contact, rinse immediately with clean water for at least 5 minutes.

The test card is a single-use device. Do not reuse, modify, or tamper with the card in any way. After testing, dispose of the used test card promptly in accordance with local regulations for infectious medical waste.

Always operate the device in accordance with the "Intended Use Environment" specified by the manufacturer.

Children or individuals requiring supervision must only use this product under adult supervision, and the product should be kept out of reach of children.

【Explanation of logo】

	Notice		No secondary use
	batch number		Storage temperature
	In vitro diagnostic use		Expiration date (year month day)
	Production Date		See instructions
	Manufacturer		Do not use if packaging is damaged
	CE Marking		

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【Basic Information】

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