DYMIND

Instructions for Hematology Analyzer Reagents

LYN-G Lyse

Product Name

Hematology Analyzer Lyse

Packing Specifications

Model: LYN-G

Specifications: 1 L, 500 mL, 200 mL

Intended Use

It is used to destroy red blood cells, lyse out hemoglobin, and maintain the shape of the cells to be tested before blood cell analysis, thereby facilitating cell differential count or quantitative determination of hemoglobin.

Principle

The product determines the hemoglobin content and count the total number of white blood cells by lysing red blood cells and combining with the released hemoglobin to produce stable compounds.

Components

The product consists of the reagent (surfactant, buffer, and antibacterial agent) and RF card (including reagent batch code, date of manufacture, use-by date, volume, etc.).

Storage and Stability

The product can be stably stored for 2 years at 2°C~30°C.

The product can be stably used for 60 days at 15°C~32°C after first opening.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DH-600, DH-602, DH-605, DH-610, DH-612 and DH-615.

Sample Requirement

Human anticoagulant whole blood

Test Method

Restore the lyse reagent to the use temperature, open the reagent package, and insert the corresponding tube into the reagent bottle according to the color correspondence between the reagent bottle cap and the device bottle cap component joint. Tighten the cap component, and follow the operator's manual of the device to perform the reagent replacement operation. And then perform background test to make sure that the measured value is within the blank count range required by the operator's manual of the device before testing the sample. For detailed information, please refer to the operator's manual of the device.

Performance Characteristics

- Appearance: the product is a clear liquid without sediment, particles or floccules.
- Background count: WBC≤0.1×10³/L, HGB≤1 g/L
- pH value: 2.20±0.20
- Max absorption peak wavelength: (539±10) nm
- Between-batch variation:
  - pH value between-batch variation: ΔpH≤0.40
  - Between-batch variation of max absorption peak wavelength: $\Delta\lambda_{max}$≤10 nm
- Accuracy:

WBC	within ±7.5%	HGB	within ±3.5%

- WBC histogram:
  - With small cell and large cell population peaks.
  - With the peak shape and peak position mark that meet the requirements of the above-mentioned applicable devices for WBC classification.

Warning

Do not ingest. Avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If accidentally taken or splashed into eyes, please seek medical attention immediately.

Precautions

- Do not use after the expiry date.
- If it is frozen, thaw it at room temperature, mix well, and make sure that the background result is within the range required by the device before use.
- If the background result is abnormal when the reagent is used after transportation, please let it stand for 24 hours at room temperature before use.
- Please dispose of waste, waste liquid and remaining reagents according to local regulations and relevant environmental-protection requirements.
- The following elements will interfere with the test: the reagent is expired or invalid; dust in the air contaminates the reagent; sample processing is not clean; the reagent is mixed or used together with reagents of other factories.

LYN-D Lyse

Product Name

Hematology Analyzer Lyse

Packing Specifications

Model: LYN-D

Specifications: 4 L, 2 L, 1 L, 500 mL

Intended Use

It is used to destroy red blood cells, lyse out hemoglobin, and maintain the shape of the cells to be tested before blood cell analysis, thereby facilitating cell differential count or quantitative determination of hemoglobin.

Principle

The product facilitates nucleic acid staining of nucleated cells with FDN-D dye by lysing red blood cells and processing white blood cells to a certain extent, thus facilitating the differential count of white blood cells.

Components

The product consists of the reagent (surfactant, buffer, and antibacterial agent) and RF card (including reagent batch code, date of manufacture, use-by date, volume, etc.).

Storage and Stability

The product can be stably stored for 2 years at 2°C~30°C.

The product can be stably used for 60 days at 15°C~32°C after first opening.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DH-600, DH-602, DH-605, DH-610, DH-612 and DH-615.

Sample Requirement

Human anticoagulant whole blood

Test Method

Restore the lyse reagent to the use temperature, open the reagent package, and insert the corresponding tube into the reagent bottle according to the color correspondence between the reagent bottle cap and the device bottle cap component joint. Tighten the cap component, and follow the operator's manual of the device to perform the reagent replacement operation. And then perform background test to make sure that the measured value is within the blank count range required by the operator's manual of the device before testing the sample. For detailed information, please refer to the operator's manual of the device.

Performance Characteristics

- Appearance: the product is a clear liquid without sediment, particles or floccules.
- pH value: 6.00±0.20
- pH value between-batch variation: ΔpH≤0.40
- WBC scattergram:
  - With no less than four WBC classification scatter clusters.
  - With the scatter cluster shape and scattergram mark that meet the requirements of the above-mentioned applicable devices for WBC classification.

Warning

Do not ingest. Avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If accidentally taken or splashed into eyes, please seek medical attention immediately.

Precautions

- Do not use after the expiry date.
- If it is frozen, thaw it at room temperature, mix well, and make sure that the background result is within the range required by the device before use.
- If the background result is abnormal when the reagent is used after transportation, please let it stand for 24 hours at room temperature before use.
- Please dispose of waste, waste liquid and remaining reagents according to local regulations and relevant environmental-protection requirements.
- The following elements will interfere with the test: the reagent is expired or invalid; dust in the air contaminates the reagent; sample processing is not clean; the reagent is mixed or used together with reagents of other factories.

FDN-D Dye

Product Name

Hematology Analyzer Dye

Packing Specifications

Model: FDN-D

Specifications: 42 mL, 22 mL

Intended Use

It is used to stain blood cells to observe their morphology and structure, so that the hematology analyzer can perform blood cell differential count.

Principle

The product is used in conjunction with LYN-D lyse to perform white blood cells differential count by lysing red blood cells, changing the morphology of white blood cells and staining nucleic acids.

Components

The product consists of the reagent (nucleic acid fluorescent dye, isopropanol, and ethylene glycol) and RF card (including reagent batch code, date of manufacture, use-by date, volume, etc.).

Storage and Stability

The product can be stably stored for 1 year at 2°C~30°C and protected from light.

The product can be stably used for 90 days at 15°C~32°C after first opening.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DH-600, DH-602, DH-605, DH-610, DH-612 and DH-615.

Sample Requirement

Human anticoagulant whole blood

Test Method

Restore the dye reagent to the use temperature, open the reagent package, and insert the corresponding tube into the reagent bottle according to the color correspondence between the reagent bottle cap and the device bottle cap component joint. Tighten the cap component, and follow the operator's manual of the device to perform the reagent replacement operation. And then perform background test to make sure that the measured value is within the blank count range required by the operator's manual of the device before testing the sample. For detailed information, please refer to the operator's manual of the device.

Performance Characteristics

- Appearance: the product is a blue clear liquid without sediment, particles or floccules.
- Absorbance value: 0.509±0.0509
- Max absorption peak wavelength: (635±10) nm
- Between-batch variation of max absorption peak wavelength: $\Delta\lambda_{max}$≤10 nm
- WBC scattergram:
  - With no less than four WBC classification scatter clusters.
  - With the scatter cluster shape and scattergram mark that meet the requirements of the above-mentioned applicable devices for WBC classification.

Warning

Do not ingest. Avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If accidentally taken or splashed into eyes, please seek medical attention immediately.

Precautions

- Do not use after the expiry date.
- Please connect the dye reagent with the cap component of the device immediately after opening the dye reagent to avoid keeping it opened on the outside.
- Before disposal, please seal the spout of the reagent container to prevent leakage of residual reagent. Using sticky tape to seal the spout is recommended.
- Please dispose of waste, waste liquid and remaining reagents according to local regulations and relevant environmental-protection requirements.
- The following elements will interfere with the test: the reagent is expired or invalid; dust in the air contaminates the reagent; sample processing is not clean; the reagent is mixed or used together with reagents of other factories.

FDN-R Dye

Product Name

Hematology Analyzer Dye

Packing Specifications

Model: FDN-R

Specifications: 24 mL, 12 mL, 6 mL

Intended Use

It is used to stain blood cells to observe their morphology and structure, so that the hematology analyzer can perform blood cell differential count.

Principle

The product is used in conjunction with DIN-R diluent to perform reticulocytes differential count by diluting the blood, making the cells spherical, and staining the reticulocytes in the sample.

Components

The product consists of the reagent (nucleic acid fluorescent dye, isopropanol, and ethylene glycol) and RF card (including reagent batch code, date of manufacture, use-by date, volume, etc.).

Storage and Stability

The product can be stably stored for 1 year at 2°C~30°C and protected from light.

The product can be stably used for 90 days at 15°C~32°C after first opening.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DH-600, DH-602, DH-605, DH-610, DH-612 and DH-615.

Sample Requirement

Human anticoagulant whole blood

Test Method

Restore the dye reagent to the use temperature, open the reagent package, and insert the corresponding tube into the reagent bottle according to the color correspondence between the reagent bottle cap and the device bottle cap component joint. Tighten the cap component, and follow the operator's manual of the device to perform the reagent replacement operation. And then perform background test to make sure that the measured value is within the blank count range required by the operator's manual of the device before testing the sample. For detailed information, please refer to the operator's manual of the device.

Performance Characteristics

- Appearance: the product is a blue clear liquid without sediment, particles or floccules.
- Blank count: RET#≤0.01×10^{12}/L
- Absorbance value: 0.666±0.0666
- Max absorption peak wavelength: (635±10) nm
- Between-batch variation of max absorption peak wavelength: $\Delta\lambda_{max}$≤10 nm
- Repeatability:

Parameter	Test Range	Precision (whole blood)
RET%	RBC≥3.00×10^{12}/L; RET% (1.00~3.00)%	≤15.0%

- RET scattergram:
  - RET and normal RBC scatter clusters have distinct characteristics.
  - Consistent with the characteristics of the RET scattergram claimed by Shenzhen Dymind Biotechnology Co., Ltd.

Warning

Do not ingest. Avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If accidentally taken or splashed into eyes, please seek medical attention immediately.

Precautions

- Do not use after the expiry date.
- Please connect the dye reagent with the cap component of the device immediately after opening the dye reagent to avoid keeping it opened on the outside.
- Before disposal, please seal the spout of the reagent container to prevent leakage of residual reagent. Using sticky tape to seal the spout is recommended.
- Please dispose of waste, waste liquid and remaining reagents according to local regulations and relevant environmental-protection requirements.
- The following elements will interfere with the test: the reagent is expired or invalid; dust in the air contaminates the reagent; sample processing is not clean; the reagent is mixed or used together with reagents of other factories.

DIL-N Diluent

Product Name

Hematology Analyzer Diluent

Packing Specifications

Model: DIL-N

Specifications: 10 L, 20 L

Intended Use

For sample dilution and preparation of cell suspension before sample analysis.

Principle

The product is a solution with a certain ionic strength and conductivity, which can dilute the blood, form the sheath flow, and provide a stable environment for blood cell count.

Components

The product consists of the reagent (sodium chloride, sodium sulfate, buffer, antibacterial agent, and preservative) and RF card (including reagent batch code, date of manufacture, use-by date, volume, etc.).

Storage and Stability

The product can be stably stored for 2 years at 2°C~30°C.

The product can be stably used for 60 days at 15°C~32°C after first opening.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DH-600, DH-602, DH-605, DH-610, DH-612 and DH-615.

Sample Requirement

Human anticoagulant whole blood

Test Method

Restore the diluent reagent to the use temperature, open the reagent package, and vertically insert the corresponding tube into the diluent bottle according to the color correspondence between the reagent bottle cap and the device bottle cap component joint. Tighten the cap component, and follow the operator's manual of the device to perform the reagent replacement operation. And then perform background test to make sure that the measured value is within the blank count range required by the operator's manual of the device before testing the sample. For detailed information, please refer to the operator's manual of the device.

Performance Characteristics

- Appearance: the product is a clear liquid without sediment, particles or floccules.
- Particle count: particle volume≥2.5 fL, particle count≤2.5×10^{5}/L
- pH value: 7.30±0.20
- Conductivity: (17.8±0.5) mS/cm
- Osmotic concentration: (300±10) mOsm/Kg
- Between-batch variation:
  - pH value between-batch variation: ΔpH≤0.40
  - Conductivity between-batch variation: Δρ≤100 mS/m (or 1.0 mS/cm)
  - Osmotic concentration between-batch variation: Δπ≤20 mOsm/kg
- Accuracy:

WBC	within ±7.5%	**RBC**	within ±3.0%	**HGB**	within ±3.5%
MCV/HCT	within ±3.0%	**PLT**	within ±12.5%		

Warning

Do not ingest. Avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If accidentally taken or splashed into eyes, please seek medical attention immediately.

Precautions

- Do not use after the expiry date.
- If it is frozen, thaw it at room temperature, mix well, and make sure that the background result is within the range required by the device before use.
- Please dispose of waste, waste liquid and remaining reagents according to local regulations and relevant environmental-protection requirements.
- The following elements will interfere with the test: the reagent is expired or invalid; dust in the air contaminates the reagent; sample processing is not clean; the reagent is mixed or used together with reagents of other factories.

DIN-R Diluent

Product Name

Hematology Analyzer Diluent

Packing Specifications

Model: DIN-R

Specifications: 4 L, 1 L, 500 mL, 200 mL

Intended Use

For sample dilution and preparation of cell suspension before sample analysis.

Principle

The product is a solution with a certain ionic strength and conductivity. It is used in conjunction with FDN-R dye to perform reticulocytes differential count by diluting the blood, making the cells spherical, and staining nucleic acids.

Components

The product consists of the reagent (sodium chloride, sodium sulfate, buffer, antibacterial agent, and preservative) and RF card (including reagent batch code, date of manufacture, use-by date, volume, etc.).

Storage and Stability

The product can be stably stored for 2 years at 2°C~30°C.

The product can be stably used for 60 days at 15°C~32°C after first opening.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DH-600, DH-602, DH-605, DH-610, DH-612 and DH-615.

Sample Requirement

Human anticoagulant whole blood

Test Method

Restore the diluent reagent to the use temperature, open the reagent package, and vertically insert the corresponding tube into the diluent bottle according to the color correspondence between the reagent bottle cap and the device bottle cap component joint. Tighten the cap component, and follow the operator's manual of the device to perform the reagent replacement operation. And then perform background test to make sure that the measured value is within the blank count range required by the operator's manual of the device before testing the sample. For detailed information, please refer to the operator's manual of the device.

Performance Characteristics

- Appearance: the product is a clear liquid without sediment, particles or floccules.
- Particle count: particle volume≥2.5 fL, particle count≤2.5×10^{5}/L
- pH value: 9.15±0.20
- Conductivity: (13.1±0.5) mS/cm
- Osmotic concentration: (230±10) mOsm/Kg
- Between-batch variation:
  - pH value between-batch variation: ΔpH≤0.40
  - Conductivity between-batch variation: Δρ≤100 mS/m (or 1.0 mS/cm)
  - Osmotic concentration between-batch variation: Δπ≤2 0mOsm/kg
- Repeatability:

Parameter	Test Range	Precision (whole blood)
RET#	RBC≥3.00×10^{12}/L; RET% (1.00~3.00)%	≤15.0%
RET%	RBC≥3.00×10^{12}/L; RET% (1.00~3.00)%	≤15.0%

Warning

Do not ingest. Avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If accidentally taken or splashed into eyes, please seek medical attention immediately.

Precautions

- Do not use after the expiry date.
- If it is frozen, thaw it at room temperature, mix well, and make sure that the background result is within the range required by the device before use.
- Please dispose of waste, waste liquid and remaining reagents according to local regulations and relevant environmental-protection requirements.
- The following elements will interfere with the test: the reagent is expired or invalid; dust in the air contaminates the reagent; sample processing is not clean; the reagent is mixed or used together with reagents of other factories.

CLE-P Cleanser

Product Name

Cleanser

Packing Specifications

Model: CLE-P

Specifications: 4 mL

Intended Use

For regular cleaning of the device.

Principle

The product is a strong alkaline solution that can effectively clean out residual blood components (deposited proteins, etc.) and other particles that affect blood cell count.

Components

Surfactant, NaClO, NaOH

Storage and Stability

The product can be stably stored for 2 years at 2°C~30°C.

The product can be stably used for 60 days at 15°C~32°C after first opening.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DH-600, DH-602, DH-605, DH-610, DH-612 and DH-615.

Test Method

Follow the instructions of the device, uncap the cleanser bottle, immerse the sampling probe into the cleanser, and press the aspiration key. For detailed information, please refer to the operator's manual of the device.

Performance Characteristics

- Appearance: the product is a clear liquid without sediment, particles and floccules.
- pH value: 12.90±0.30

Warning

- Do not ingest. Avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If accidentally taken or splashed into eyes, please seek medical attention immediately.
- The product can cause severe skin burns and eye damage. Please use it with care.

Precautions

- The product should only be used together with its applicable device. Please read the instructions carefully before use.
- Do not use after the expiry date.
- This product needs to be stored away from light, and do not expose it to direct sunlight.
- Please dispose of waste, waste liquid and remaining reagents according to local regulations and relevant environmental-protection requirements.
- The following elements will interfere with the test: the reagent is expired or invalid; dust in the air contaminates the reagent; sample processing is not clean; the reagent is mixed or used together with reagents of other factories.

Interpretation of Symbols

	Consult instructions for use or consult electronic instructions for use	CE	CE MARKING OF CONFORMITY
IVD	In Vitro diagnostic medical device		Date of manufacture
LOT	Batch code		Temperature limit
	Use-by date		Keep away from sunlight
	Manufacturer	EC REP	Authorized representative in the European Community/European Union
	(Only applicable to FDN-D dye and FDN-R dye) Warning: H302: Harmful if swallowed P270: Do not eat, drink or smoke when using this product. H319: Causes serious eye irritation P280: Wear eye protection/face protection.		Causes severe skin burns and eye damage

Contact Information

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