

EDAN Agile PLM Electronic Signature Information

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文件名称(Document Name) : HC600清洗液英文使用说明书

文件编号(Number) : 01.54.458576

版本(Version) : 2.0

产品型号(Product Model) : HC600

项目编码(Project Code) : 00004M001

签批信息(Signature):

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HC600 Cleaner

[Product Name]

Cleaner

[Model]

HC600

[Specification]

50mL、50mL*6

[Intended Use]

HC600 Cleaner applies to EDAN H30 Pro/DS500/H60/H30/H50/H60S CRP&SAA/H80/H90 series Hematology Analyzer. It is used to clean the fluidic channels and tubing, and get rid of blood albumin and sediment. It is only operated by trained medical personnel or health care professionals.

[Important]

Please read this manual and the Hematology Analyzer Operation Manual before using HC600 Cleaner. If you have any question and/or need assistance, please contact EDAN or the authorized local distributors.

[Principle]

HC600 Cleaner is alkaline solution with strong clean capacity. The hypochlorite in the Cleaner has the capacity of oxidation and sterilization, the surfactant has the function of permeation, emulsification, dissolution and washing. So HC600 Cleaner can clean the sampling system and tubes, and make the Analyzer keep in normal condition. It is used for daily

maintenance of the Analyzer.

[Active Ingredients]

Triton X-100 0.2%, NaClO 0.1%, H₂O 99.7%

[Storage and Transportation and Expiration]

HC600 Cleaner should be transported and stored at 2~35°C, the use temperature is 15~32°C and the relative humidity should be less than 90% and avoid light. Under storage conditions, HC600 Cleaner will be effective in one year. Once unsealed, it will keep stable for 90 days under the use conditions. It is recommended that the transportation duration not exceed 30 days at -20~35°C.

[Warnings and Precautions]

- HC600 Cleaner is for in vitro diagnostic use only.
- Use HC600 Cleaner before its expiration date as labeled on the package. Store HC600 Cleaner properly after opening its package. Close the bottle tightly after every use, and keep it in cool and dry environments.
- The transportation condition of the HC600 Cleaner is 2~35°C, and the relative humidity should be less than 90%. Avoid freezing during transport and storage. If HC600 Cleaner has been frozen, equilibrate it to room temperature in natural condition and mix it by gentle inversion.
- If the package has any damage, the product can be used. Do not use the product if the bottle has any damage.
- Do not inhale and/or ingest. Please wear protective equipment (such as rubber gloves, goggles) when using. Avoid contacting with skin and eyes. In case of contacting with skin or eyes, rinse immediately with plenty of water. Seek medical assistance immediately if necessary.
- Dispose of the wastes generated during a test, remained and expired solutions, and contaminated packages according to the local guidelines.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the

competent authority of the Member State in which the user and/or the patient is established.

[Indications of Deterioration]

After mixing, the reagent should be in a clear state. If there is a crystalline precipitate in unmixed tubes, this is normal and doesn't indicate deterioration. While other sediments such as black or light yellow precipitates appear which cannot be dissolved after mixing, or unacceptable test results may indicate deterioration of the product. Don't use the product if deterioration is suspected or identified

[Applicable Instruments]

H30 Pro/DS500/H60/H30/H50/H60S CRP&SAA/H80 series Hematology Analyzer made by EDAN Instruments, Inc.

[Instructions for Use]

Use H30 Pro/H60/H60S CRP&SAA/H80/H90 series Hematology Analyzer:

1)Press Cleaner Maintenance. According to the guidance, open HC600 cleaner, put it under the sample probe (for the automatic machine, 3mL HC600 Cleaner should be added into disposable plastic test tube($\phi 12 \times 75$). Put the tube into closed injection position and close the injection bin) and press Start. The sample probe starts to draw up the cleaner..

2)A progress bar of cleaner maintenance appears.

3)After the progress bar runs out, a prompt "Completed" will pop up. Press Exit.

Use DS-500 series Hematology Analyzer:

Put the sample probe into the bottle, and click "Cleaner soak" in the maintenance, then select "Whole device cleanout liquid maintenance" and click "Start" . The apparatus will automatically prime the Cleaner.

Use H30 / H50 series Hematology Analyzer:

1)HC600 Cleaner needs to be used to clean the counting baths when analyzer is in permanent rejection for one measured parameter..

2)On the analyzer's main software screen, press

“MENU” → “SERVICE” → “TROUBLESHOOTING” → “BLEACH” to start the operation

3)Open the door on the right side of the instrument

4)Put 4ml of bleach in each counting chamber.

Please refer to the Analyzer operation manual for the details.

[Explanation of Test Results]

Not Applicable

[Performance Index of the Cleaner]

Physical Characteristics	Transparent solution without deposits, suspended matters or flocks.
pH	± 0.30 (25°C)
Blank Count	$WBC \leq 0.2 \times 10^9/L$, $RBC \leq 0.02 \times 10^{12}/L$, $HGB \leq 1g/L$, $PLT \leq 5 \times 10^9/L$
ΔpH	≤ 0.60

[Limitations]

- HC600 Cleaner is only applied to routine maintenance of the supporting apparatus, and not to other equipments..

[Reference]

Not Applicable





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[Date of Approval for Manual]

May.2025

[Labeling and Information]

Symbol	Symbol Meaning	Symbol	Symbol Meaning
	In vitro diagnostic medical device		Use-by Date
	Consult instructions for use		Temperat ure limit

	Batch code		Manufacturer
	Trademark		Date of manufacture
	Authorized representative in the European Community		Unique device identifier
	CE MARK		
	Not for self-testing		Not for near patient testing

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MPN: 01.54.458576020

EDAN Agile PLM Electronic Signature Information

--Signatures related to this document and performed in EDAN Agile PLM.

文件名称(Document Name) : HD310稀释液英文说明书

文件编号(Number) : 01.54.458593

版本(Version) : 1.9

产品型号(Product Model) : H30 Pro

项目编码(Project Code) : 3303M001

签批信息(Signature):

作者(Originator) : 朱 亮 (zhuliang) 2025-06-18 14:44:54

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批准人(Approvers) : 钟 勇锋 (zhongyongfeng) 2025-06-24 16:58:26

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HD310 Diluent

[Product Name]

Diluent

[Model]

HD310

[Specification]

10L/Bottle; 20L/Bottle

[Intended Use]

HD310 Diluent applies to EDAN H30 Pro series Hematology Analyzer for diluting the patient samples. It is only operated by trained medical personnel or health care professionals

[Important]

Please read this manual and the H30 Pro Operation Manual before using HD310 Diluent. If you have any question and/or need assistance, please contact EDAN or the authorized local distributors.

[Principle]

HD310 Diluent is an electrolytic balance solution, which has an acid-base buffer effect, appropriate ionic strength and conductivity. It can be used as diluents when counting and sizing people blood cells, differentiating and counting leukocytes

[Active Ingredients]

- 1) NaCl: 2-8g/L
- 2) Na₂CO₃: 0.5-3g/L.

[Storage and Transportation and Expiration]

HD310 Diluent should be transported and stored at 2°C to 35°C. The relative humidity should be less than 90%. Under these conditions, HD310 Diluent will be effective in two years. Once unsealed, it will keep stable for 180 days under the same conditions as that for the sealed. It is recommended that the transportation duration not exceed 30 days at -20~50°C.

[Warnings and Precautions]

- HD310 Diluent is for in vitro diagnostic use only.
- Use HD310 Diluent before its expiration date as labeled on the package.
- Avoid freezing during transport and storage. If HD310 Diluent has been frozen, equilibrate it to room temperature in natural condition and mix it by gentle inversion.
- Store HD310 Diluent properly after opening its package. Close the bottle tightly after every use, and keep it in cool and dry environments.
- Do not inhale and/or ingest. Avoid contacting with skin and eyes. In case of contacting with skin or eyes, rinse immediately with plenty of water. Seek medical assistance immediately if necessary.
- Dispose of the wastes generated during a test, remained and expired solutions, and contaminated packages according to the local guidelines.
- If the reagent is contaminated or affected by other factors, causing the reagent to become abnormal, stop using it and replace the normal reagent.
- Please wear protective equipment (such as rubber gloves, goggles) when using.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

[Indications of Deterioration]

After mixing, the reagent should be in a clear state. If there is a crystalline precipitate in unmixed tubes, this is normal and doesn't indicate deterioration. While other sediments such as black or light yellow precipitates appear which cannot be dissolved after mixing, or unacceptable test results may indicate deterioration of the product. Don't use the product if deterioration is suspected or identified.

[Applicable Instruments]

H30 Pro series Hematology Analyzer made by EDAN Instruments, Inc

[Examination procedure]

Open the package of HD310 Diluent, put the cap assembly of correspond apparatus into the reagent bottle, screw up the cap, and click **“Replace diluent”** in the maintenance, scan the RFID card authorized by EDAN at specified location. The apparatus will automatically prime the diluent. Before testing blood samples, make sure the background value is in required scope. Please refer to the Analyzer operation manual for the details

[Explanation of Test Results]

- The measurement results will show the measurement values of various blood cells.
- If “↑” or “↓” appears, the result is out of the normal reference range.

[Performance Index of the Diluent]

Physical Characteristics	Transparent solution without deposits, suspended matters or flocks.
Particles Counts	The counts of particles which volume is no less than



		2.5fL should be no more than $2.5 \times 10^5/L$.
Accuracy (compared with standard controls or samples)	WBC	Relative deviation is within -5.0% ~ 5.0%
	RBC	Relative deviation is within -3.0% ~ 3.0%
	HGB	Relative deviation is within -3.5% ~ 3.5%
	PLT	Relative deviation is within -12.5% ~ 12.5%
	MCV	Relative deviation is within -3.0% ~ 3.0%
pH		± 0.20 (25°C)
Conductivity (ρ)		$\pm 50\text{mS/m}$ (25°C)
Osmotic Pressure (π)		$\pm 10\text{mmol/L}$ (mOsm/kg)
ΔpH		≤ 0.40
$\Delta\rho$		$\leq 100\text{mS/m}$
$\Delta\pi$		$\leq 20 \text{ mmol/L}$ (mOsm/kg)

[Limitations]

- The product is only applied to additional test of people blood cells, not to body fluid or other animal blood.
- The product isn't applied to the testing of blood serum or blood plasma samples.

[Reference]

Not Applicable.







	
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




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[Date of Approval for Manual]

May. 2025

[Labeling and Information]

Symbol	Symbol Meaning	Symbol	Symbol Meaning
	In vitro diagnostic medical device		Use-by Date
	Consult instructions for use		Temperature limit
	Batch code		Manufacturer

	Trademark		Date of manufacture
	Authorized representative in the European Community		Unique device identifier
	CE MARK		
	Not for self-testing		Not for near patient testing

P/N: 01.54.458593

MPN:01.54.458593019

EDAN Agile PLM Electronic Signature Information

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文件名称(Document Name) : HL310溶血剂英文说明书

文件编号(Number) : 01.54.458595

版本(Version) : 2.0

产品型号(Product Model) : H30 Pro

项目编码(Project Code) : 3303M001

签批信息(Signature):

作者(Originator) : 朱 亮 (zhuliang) 2025-06-18 14:44:54

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批准人(Approvers) : 曾 永华 (zengyonghua) 2025-06-23 18:54:17

HL310 Lyse

[Product Name]

Lyse

[Model]

HL310

[Specification]

200 mL、500mL、1000mL、200mL*4、500mL*4、1000mL*4

[Intended Use]

For use on H30 Pro Hematology Analyzer produced by EDAN, HL310 Lyse is used to react on blood samples for quantitatively determining hemoglobin and for differentiating and counting leukocytes. It is only operated by trained medical personnel or health care professionals.

[Important]

Please read this manual and the H30 Pro Operation Manual before using HL310 Lyse. If you have any question and/or need assistance, please contact EDAN or the authorized local distributors.

[Principle]

HL310 Lyse mainly contains surfactant, it can quickly dissolve erythrocytes to release the hemoglobin, and combine with the hemoglobin to become stable compound. The compound is used to determine the concentration of hemoglobin. On the other hand, HL310 Lyse partly dissolves the leukocytes and releases cytoplasm, so the Analyzer can achieve the classification and quantity of the le

ukocytes based on the difference of size and inner structure to the leukocytes

[Active Ingredients]

- 1) Surfactant(Dodecyltrimethylsodium chloride): 10-24 g/L;
- 2) Buffer(NaCl): 0.5-3g/L

[Storage and Transportation and Expiration]

HL310 Lyse should be transported and stored at 2°C to 35°C. The relative humidity should be less than 90%. Under these conditions, HL310 Lyse will be effective in two years. Once unsealed, it will keep stable for 180 days under the same conditions as that for the sealed. It is recommended that the transportation duration not exceed 30 days at -20~50°C.

[Warnings and Precautions]

- HL310 Lyse is for in vitro diagnostic use only
- Use HL310 Lyse before its expiration date as labeled on the package
- Avoid freezing during transport and storage. If HL310 Lyse has been frozen, equilibrate it to room temperature in natural condition and mix it by gentle inversion.
- Store HL310 Lyse properly after opening its package. Close the bottle tightly after every use, and keep it in cool and dry environments
- Do not inhale and/or ingest. Avoid contacting with skin and eyes. In case of contacting with skin or eyes, rinse immediately with plenty of water. Seek medical assistance immediately if necessary
- Dispose of the wastes generated during a test, remained and expired solutions, and contaminated packages according to the local guidelines.
- If the reagent is contaminated or affected by other factors, causing the reagent to become abnormal, stop using it and replace the normal reagent.

- Please wear protective equipment (such as rubber gloves, goggles) when using.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

[Indications of Deterioration]

After mixing, the reagent should be in a clear state. If there is a crystalline precipitate in unmixed tubes, this is normal and doesn't indicate deterioration. While other sediments such as black or light yellow precipitates appear which cannot be dissolved after mixing, or unacceptable test results may indicate deterioration of the product. Don't use the product if deterioration is suspected or identified.

[Applied Apparatus]

H30 Pro Hematology Analyzer made by EDAN Instruments, Inc.

[Examination procedure]

Open the package of HL310 Lyse, put the cap assembly of correspond apparatus into the bottle, screw up the cap, and click "Replace lyse" in the maintenance, scan the RFID card authorized by EDAN at specified location. The apparatus will automatically prime HL310 Lyse when test blood samples. Please refer to the apparatus operation manual for the details.

[Explanation of Test Results]

- The measurement results will show the measurement values of various blood cells.
- If "↑" or "↓" appears, the result is out of the normal reference range.

[Performance Index of the Lyse]

Physical Characteristics		Transparent solution without deposits, suspended matters or flocks.
pH		$\pm 0.20(25^{\circ}\text{C})$
Absorption Wavelength (λ_{\max})		$\pm 10 \text{ nm}$
Blank Count	WBC	$\leq 0.2 \times 10^9/\text{L}$
	RBC	$\leq 0.02 \times 10^{12}/\text{L}$
	HGB	$\leq 1\text{g/L}$
	PLT	$\leq 5 \times 10^9/\text{L}$
Accuracy (compared with standard controls or samples)	WBC	Relative deviation is within $-5.0\% \sim 5.0\%$
	HGB	Relative deviation is within $-3.5\% \sim 3.5\%$
ΔpH		≤ 1.0
$\Delta\lambda_{\max}$		$\leq 10\text{nm}$

[Limitations]

- HL310 Lyse is only applied to additional test of people blood cells, not to body fluid or other animal blood.
- HL310 Lyse isn't applied to the testing of blood serum or blood plasma samples.

[Reference]



Not Applicable












	
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[Date of Approval for Manual]

May. 2025

[Labeling and Information]

Symbol	Symbol Meaning	Symbol	Symbol Meaning
	In vitro diagnostic medical device		Use-by Date

	Consult instructions for use		Temperature limit
	Batch code		Manufacturer
	Trademark		Date of manufacture
	Authorized representative in the European Community		Unique device identifier
	CE MARK		
	Not for self-testing		Not for near patient testing

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