EDAN Agile PLM Electronic Signature Information

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

文件名称(Document Name)：H30校准物使用说明书（英文）
文件编号(Number)：01.54.457966
版本(Version)：1.7
产品型号(Product Model)：H30
项目编码(Project Code)：3303L001

Digitally signed by Ceaicovschi Tudor
Date: 2025.11.04 16:07:38 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

签批信息(Signature):

作者(Originator) : 王 文雯 (wangwenwen)　2024-09-26 15:09:54

审核人(Reviewers) : 林 荣听 (linrongting)　2024-09-29 11:50:12

审核人(Reviewers) : 龙 昱瑄 (longyuxuan)　2024-09-27 11:21:07

审核人(Reviewers) : 李 旭平 (lixuping)　2024-09-30 09:01:56

批准人(Approvers) : 陈 广鑫 (chenguangxin)　2024-10-08 19:41:48

批准人(Approvers) : 钟 勇锋 (zhongyongfeng)　2024-10-09 14:44:30

Hematology Calibrator User Manual

[Product Name]

Hematology Calibrator

[Model]

ED-CAL PLUS

[Volume]

3mL/tube

[Indications for Use/Intended Use]

Hematology Calibrator is intended for the calibration of EDAN Hematology Analyzer to maintain the analyzer’ s analytical performance. It is only operated by trained medical personnel or health care professionals.

[Sample type]

Whole blood sample

[Principle]

Hematology Analyzer requires periodic calibration in order to ensure the patient test results are accurate and valid. The Hematology Calibrator is a stable, whole blood preparation that can be used to calibrate the targeted hematology analyzer.

Calibrator values for Hematology Calibrator are derived from replicate tests on instruments operated in accordance with the manufacturer’ s instructions.

NOTE:Please refer to Targets Ranges Table for calibrator values.

[Components]

Hematology Calibrator is an IVD (in vitro diagnostic) reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

NOTE: Hematology Calibrator is intended for in vitro diagnostic use only by trained professional.

[Transportation, Storage and Shelf Life]

Transportation, Storage Condition: The Hematology Calibrator should be stored at 2°C～8°C (35～46 °F) to avoid overheating and freezing.

Shelf Life: The Hematology Calibrator with sealed package is valid before the expiration date. While it is only valid for 7 days once opened under the precondition that it is handled properly. If the customer needs to repack the goods after receiving the goods, be careful not to contact the ice bag directly with the product, and it needs to be separated by foam.

[Warnings and Precautions]

The Hematology Calibrator provided by Edan has been tested negative in the following serological infectious disease indicators, including HBsAg, HIV-1/HIV-2 antibodies, HCV antibodies, but it cannot rule out the risk of potential infection. The operators should treat

them as blood samples, taking safety measures (such as wearing protective coat, gloves, etc.) when working with them and deal with them according to local laws and regulations.

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, product should be similar in appearance to fresh whole blood. If the supernatant appears cloudy and reddish in unmixed tubes, this is normal and doesn't indicate deterioration. While other discoloration such as very dark red supernatant, or unacceptable test results may indicate deterioration of the product. Don't use the product if deterioration is suspected or identified.

[Materials List]

Device/Accessories	Type	Manufacturer
Hematology Analyzer	H30/H30 Pro/H60/H60S CRP & SAA /H80/H50 series Hematology Analyzer	Edan Instruments, Inc.
Hematology Control	ED-30D, ED-60D, ED-50D	Edan Instruments, Inc.
Cleaner	HC310, HC600, HC500	Edan Instruments, Inc.
Lyse	HL310, HL600, HL500,HL610,HL620	Edan Instruments, Inc.
Diluent	HD310, HD600, HD500	Edan Instruments, Inc.

[Instructions for Use]

A. Mixing and Handling Instructions:

1) Take the tubes from refrigerator and equilibrate it at room temperature (15°C～32°C or 59°F～89.6 °F) for 15 minutes prior to mixing.
2) Hold a tube/vial between the palms of the hands for mixing. Don't mix the product with a mechanical mixer.
   a) Roll the tube back and forth for 20-30 seconds and occasionally invert the tube/vial. Mix it thoroughly but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
   c) Gently invert the tube/vial 8-10 times immediately before running each sample.
3) Carefully wipe the cap of the tube with a lint-free tissue and replace the cap.
4) Return tubes to refrigerator within 30 minutes of use.

B. Conduct calibration test:

Analyze the sample as instructed in the Calibration section of the Operator's Manual for

your instrument.

NOTE:

- ✓ If the room temperature changes more than 10°C during the working day, the instrument must be calibrated.
- ✓ 3-12 samples are required to be tested for calibration.

C. Calibrate Coefficients and Verify Results:

1) Calibrate coefficients in accordance with the procedures described in the Hematology Analyzer User Manual.
2) Verify calibration test results by running QC test.

[Metrological Traceability information]

Parameters	Reference Materials/ Reference Measurement Procedure
WBC、RBC	ICSH: Reference method for the enumeration of erythrocytes and leucocytes
HGB	ICSH: Reference method for haemoglobinometry in human blood
HCT	ICSH: Reference method for hematocrit
PLT	ICSH: Reference method for platelet counting

[Precision]

Parameters	WBC	RBC	HGB	MCV	PLT
Calibrator	2.5%	1.5%	1.5%	1.0%	5.0%

[Limitations]

The performance of Hematology Calibrator is only assured only if it is properly stored and used in accordance with the requirements specified in this manual.

[Manufacturer Information]

EDAN Instruments, Inc..
#15 Jinhui Road,Jinsha Community, Kengzi Sub-District, Pingshan District,518122 Shenzhen, P.R. China.
Email:info@edan.com
TEL: ＋86-755-2689 8326 Fax: ＋86-755-2689 8330 Website: www.edan.com

[EC Representative]

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, D-20537 Hamburg Germany
Telephone: +49-40-2513175 Fax: +49-40-255726 E-mail: shholding@hotmail.com

[Date of Approval for Package Inserts]

June, 2023

[Labeling and Information]

Symbol	Symbol Meaning	Symbol	Symbol Meaning

IVD	In vitro diagnostic device		Use-by date
	Consult instructions for use		Temperature limit
LOT	Batch code		Manufacturer
EDAN	Trademark		Biological risks
EC REP	Authorized representative in the European Community	CE 0123	CE Mark
			Caution
	Date of manufacture		Not for self-testing
	Not for near patient testing	UDI	Unique device identifier
BIO	Contains biological material of animal origin	BIO	Contains biological material of human origin

[References]

WBC/RBC: Reference method for the enumeration of erythrocytes and leucocytes, ICSH Expert Panel on Cytometry, Clin Lab Haematol. 1994; 16, 131-138. Countson 1:500 dilutions performed on SCC (Semi-automated Single Channel counter), a volumetric manometer semi-automated electronic impedance cell counter.

HGB:Recommendation for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specification for international haemiglobincyanide standard(4th edition), ICSH Expert Panel on Haemoglobinometry,J Clin Pathol 1996; 49:271-274. CLSI H15-A3: Reference and selected procedures for the quantitative determination of hemoglobin in blood; Approved Standard - Third edition (2000).

HCT: Recommendations for Reference Method for the Packed Cell Volume (ICSH Standard 2001), ICSH Expert Panel on Cytometry, Clin Lab Hematol.2001; 7:148-170. CLSI H7-A3:Procedure for determining Packed Cell Volume by the Microhematocrit Method; Approved Standard - Third edition.

PLT:Platelet counting by the RBC / Platelet Ratio Method - A Reference method, ICSH Expert Panel on Cytometry and ISLH Task Force on Platelet Counting, Am JClin Pathol 2001; 115,460-464.

P/N:01.54. 457966
MPN:01.54.457966017

EDAN Agile PLM Electronic Signature Information

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

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)：1.8
产品型号(Product Model)：ED-60D;ED-CAL PLUS;HC600;HD600
项目编码(Project Code)：00001Q001

签批信息(Signature):

作者(Originator) : 刘 伟 (liuwei-sed)　　2023-07-26 14:56:37

审核人(Reviewers) : 林 荣听 (linrongting)　　2023-07-27 09:05:15

审核人(Reviewers) : 欧阳 艳芳 (ouyangyanfang)　　2023-07-28 16:25:23

批准人(Approvers) : 钟 勇锋 (zhongyongfeng)　　2023-08-05 14:44:29

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 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%.，H_2O 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 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(ϕ12*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≤0.2×10^{9}/L,RBC≤0.02×10^{12}/L,HGB≤1g/L,PLT≤5×10^{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.

EDAN Instruments, Inc. #15 Jinhui Road,Jinsha Community, Kengzi Sub-District, Pingshan District,518122 Shenzhen, P.R.China Tel:+86-755-26898326 Fax:+86-755-26898330 http://www.edan.com	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg Germany Telephone: +49-40-2513175 E-mail: shholding@hotmail.com

Email: info@edan.com	

[Date of Approval for Manual]

June. 2023

[Labeling and Information]

Symbol	Symbol Meaning	Symbol	Symbol Meaning
IVD	In vitro diagnostic medical device		Use-by Date
	Consult instructions for use	35℃ 2℃	Temperature limit
LOT	Batch code		Manufacturer
EDAN	Trademark		Date of manufacture
EC REP	Authorized representative in the European Community	CE	The symbol indicates that the device complies with the European Council Directive 98/79/EC concerning medical devices.
Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.	UDI	Unique device identifier
	Not for self-testing		Not for near patient testing

P/N: 01.54.458576

MPN: 01.54.458576018

EDAN Agile PLM Electronic Signature Information

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

文件名称(Document Name)：HD600稀释液英文使用说明书
文件编号(Number)：01.54.458577
版本(Version)：1.7
产品型号(Product Model)：H60
项目编码(Project Code)：00004M001

签批信息(Signature):

作者(Originator) : 辛 佩轩 (xinpeixuan)　　2024-05-11 15:09:33

审核人(Reviewers) : 林 荣听 (linrongting)　　2024-05-13 08:52:58

审核人(Reviewers) : 龙 昱瑄 (longyuxuan)　　2024-05-13 09:36:36

审核人(Reviewers) : 欧阳 艳芳 (ouyangyanfang)　　2024-05-11 17:26:44

批准人(Approvers) : 陈 广鑫 (chenguangxin)　　2024-05-15 13:42:52

批准人(Approvers) : 黄 洪富 (huanghongfu)　　2024-05-15 09:18:19

HD600 Diluent

[Product Name]

Diluent

[Model]

HD600

[Specification]

20L/Bottle

[Intended Use]

HD600 Diluent applies to EDAN H60/H60S CRP&SAA/H80/H90 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 Hematology Analyzer Operation Manual before using HD600 Diluent. If you have any question and/or need assistance, please contact EDAN or the authorized local distributors.

[Principle]

HD600 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, 0.2～2g/L;
2) Na_2CO_3, 5～20g/L;
3) ProClin 300, 0.2～5g/L.

[Storage and Transportation and Expiration]

HD600 Diluent 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%. Under the storage conditions, HD600 Diluent will be effective in two years. 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 -20～50°C.

[Warnings and Precautions]

- HD600 Diluent is for in vitro diagnostic use only.
- Use HD600 Diluent before its expiration date as labeled on the package. Store HD600 Diluent 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 HD600 Diluent is 2~35°C，and the relative humidity should be less than 90%.Avoid freezing during transport and storage. If HD600 Diluent 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]

H60/H60S CRP&SAA/H80/H90 series Hematology Analyzer made by EDAN Instruments, Inc.

[Examination procedure]

Open the package of HD600 Diluent, put the cap assembly of correspond apparatus into the reagent bottle, screw up the cap, and click “**Diluent Icon**” in the “**Reagents**”, scan the NFC card authorized by EDAN at specified location and click “**Confirm**”. 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 carious 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 2.5×10^5/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 -8.0% ～ 8.0%
	MCV	Relative deviation is within -3.0% ～ 3.0%
pH		±0.20 (25°C)
Conductivity (ρ)		±50mS/m (25°C)
Osmotic Pressure (π)		±10mmol/L（mOsm/kg)
ΔpH		⩽0.40
Δρ		⩽100mS/m
Δπ		⩽20 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.

EDAN Instruments, Inc. #15 Jinhui Road,Jinsha Community, Kengzi Sub-District, Pingshan District,518122 Shenzhen, P.R.China Tel:+86-755-26898326 Fax:+86-755-26898330 http://www.edan.com Email: info@edan.com	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg Germany Telephone: +49-40-2513175 E-mail: shholding@hotmail.com

[Date of Approval for Manual]

June. 2023

[Labeling and Information]

Symbol	Symbol Meaning	Symbol	Symbol Meaning
IVD	In vitro diagnostic medical device		Use-by Date
	Consult instructions for use	35℃ 2℃	Temperature limit
LOT	Batch code		Manufacturer
EDAN	Trademark		Date of manufacture
EC REP	Authorized representative in the European Community	CE	CE MARK
		UDI	Unique device identifier
	Not for self-testing		Not for near patient testing

P/N: 01.54.458577

MPN: 01.54.458577017

EDAN Agile PLM Electronic Signature Information

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

文件名称(Document Name)：HL600溶血剂英文使用说明书
文件编号(Number)：01.54.458578
版本(Version)：1.6
产品型号(Product Model)：H60
项目编码(Project Code)：00004M001

签批信息(Signature):

作者(Originator) : 辛 佩轩 (xinpeixuan)　　2024-05-11 15:09:33

审核人(Reviewers) : 林 荣听 (linrongting)　　2024-05-13 08:52:58

审核人(Reviewers) : 龙 昱瑄 (longyuxuan)　　2024-05-13 09:36:36

审核人(Reviewers) : 欧阳 艳芳 (ouyangyanfang)　　2024-05-11 17:26:44

批准人(Approvers) : 陈 广鑫 (chenguangxin)　　2024-05-15 13:42:52

批准人(Approvers) : 黄 洪富 (huanghongfu)　　2024-05-15 09:18:19

HL600 Lyse

[Product Name]

Lyse

[Model]

HL600

[Specification]

500mL、1000mL、500mL*4、1000mL*4

[Intended Use]

HL600 Lyse applies to EDAN H60 series Hematology Analyzer 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 H60 Operation Manual before using HL600 Lyse. If you have any question and/or need assistance, please contact EDAN or the authorized local distributors.

[Principle]

HL600 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, HL600 Lyse partly dissolves the leukocytes and releases cytoplasm, so the Analyzer can achieve the classification and quantity of the leukocytes based on the difference of size and inner structure to the leukocytes.

[Active Ingredients]

1）Dodecyl trimethyl ammonium chloride, 1～5g/L;

2）Sodium Chloride, 0.5～5g/L;

3）ProClin 300,1～3g/L.

[Storage and Transportation and Expiration]

HL600 Lyse 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%. Under the storage conditions, HL600 Lyse will be effective in two years. 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 -20～50°C.

[Warnings and Precautions]

- HL600 Lyse is for in vitro diagnostic use only.
- Use HL600 Lyse before its expiration date as labeled on the package. Store HL600 Lyse 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 HL600 Lyse is 2~35°C，and the relative humidity should be less than 90%.Avoid freezing during transport and storage. If HL600 Lyse 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.

[Applied Apparatus]

H60 Hematology Analyzer made by EDAN Instruments, Inc.

[Examination procedure]

Open the package of HL600 Lyse, put the cap assembly of correspond apparatus into the bottle, screw up the cap, and click **“Lyse Icon”** in the **“Reagents”**, scan the NFC card authorized by EDAN at specified location and click **“Confirm”**. The apparatus will automatically prime HL600 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 carious 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		±0.20(25°C)
Absorption Wavelength (λ_{max})		±10 nm
Blank Count	WBC	⩽0.2×10^9/L
	RBC	⩽0.02×10^{12}/L
	HGB	⩽1g/L
	PLT	⩽5×10^9/L
Accuracy (compared with standard controls or samples)	WBC	Relative deviation is within -5.0% ～ 5.0%
	HGB	Relative deviation is within -3.5% ～ 3.5%
ΔpH		⩽1.0
$\Delta\lambda_{max}$		⩽10nm
WBC Scatter Plot		For health people, the result of white blood cell scatter plot should conform to: a. With two or more white blood cell classification scater groups; b. Meet the shape and mark of the white blood cell scatter group with the applied hematology analyzer.

[Limitations]

- HL600 Lyse is only applied to additional test of people blood cells, not to body fluid or other animal blood.
- HL600 Lyse isn’ t applied to the testing of blood serum or blood plasma samples.

[Reference]

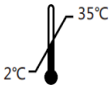
Not Applicable.

EDAN Instruments, Inc. #15 Jinhui Road,Jinsha Community, Kengzi Sub-District, Pingshan District,518122 Shenzhen, P.R.China Tel:+86-755-26898326 Fax:+86-755-26898330 http://www.edan.com Email: info@edan.com	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg Germany Telephone: +49-40-2513175 E-mail: shholding@hotmail.com

[Date of Approval for Manual]

Jan. 2022

[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		CE MARK
			Unique device identifier
	Not for self-testing		Not for near patient testing

P/N: 01.54.458578

MPN: 01.54.458578016

EDAN Agile PLM Electronic Signature Information

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

文件名称(Document Name)：ED-60D Hematology Control User Manual
文件编号(Number)：01.54.458828
版本(Version)：1.4
产品型号(Product Model)：ED-60D;ED-CAL PLUS;HC600;HD600
项目编码(Project Code)：00001Q001

签批信息(Signature):

作者(Originator) : 刘 伟 (liuwei-sed)　　2023-07-26 14:56:37

审核人(Reviewers) : 林 荣听 (linrongting)　　2023-07-27 09:05:15

审核人(Reviewers) : 欧阳 艳芳 (ouyangyanfang)　　2023-07-28 16:25:23

批准人(Approvers) : 钟 勇锋 (zhongyongfeng)　　2023-08-05 14:44:29

Hematology Control

[Product Name]

Hematology Control

[Model]

ED-60D Control L, ED-60D Control N, ED-60D Control H

[Volume]

3mL/tube

[Indications for Use/Intended Use]

ED-60D Hematology Control is designed to quantitatively monitor values on H60/H60S /H60S CRP & SAA/H80 series Hematology Analyzer to ensure the analyzer's performance before patient's sample tests. It is only operated by medical personnel or health care professionals.

[Sample type]

Whole blood sample

[Principle]

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is prepared by some stable materials, which can be used to monitor the performance of blood cell counters.

[Components]

ED-60D Hematology Control is an in vitro diagnostic reagent composed of mammalian erythrocytes, leukocytes and platelets suspended in a plasma-like fluid with preservatives.

[Transportation, Storage and Shelf Life]

Transportation, Storage Condition: ED-60D Hematology Control should be stored at 2°C～8°C (35～ 46 °F) to avoid overheating and freezing.

Shelf Life: ED-60D Hematology Control with sealed package under the storage condition is valid in 90 days. While it is only valid for 14 days once opened under the precondition that it is handled properly.

If the customer needs to repack the goods after receiving the goods, be careful not to contact the ice bag directly with the product, and it needs to be separated by foam.

[Warnings and Precautions]

The ED-60D Hematology Control provided by Edan has been tested negative in the following serological infectious disease indicators, including HBsAg, HIV-1/HIV-2 antibodies, HCV antibodies, but it cannot rule out the risk of potential infection. The operators should treat them

as blood samples, taking safety measures (such as wearing protective coat, gloves, etc.) when working with them and deal with them according to local laws and regulations.

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, product should be similar in appearance to fresh whole blood. If the supernatant appears cloudy and reddish in unmixed tubes, this is normal and does not indicate deterioration. While other discoloration such as very dark red supernatant, or unacceptable test results may indicate deterioration of the product. Do not use the product if deterioration is suspected or identified.

[Materials List]

Device/Accessories	Type	Manufacturer
Hematology Analyzer	H60/H60S /H60S CRP & SAA/H80 series	Edan Instruments, Inc.
Hematology Calibrator	ED-CAL PLUS	Edan Instruments, Inc.
Cleaner	HC600	Edan Instruments, Inc.
Lyse	HL600/HL610/HL620	Edan Instruments, Inc.
Diluent	HD600	Edan Instruments, Inc.

[Examination procedure]

A. Mixing and Handling Instructions:

1) Take the tubes/vials from refrigerator and equilibrate it at room temperature (15°C～32°C or 59°F～89.6 °F) for 15 minutes prior to mixing.
2) Hold a tube/vial between the palms of the hands for mixing. Do not mix the product with a mechanical mixer.
   a) Roll the tube/vial back and forth for 20-30 seconds and occasionally invert the tube/vial. Mix it thoroughly but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Tubes/vials stored for a long time may require extra mixing.
   c) Gently invert the tube/vial 8-10 times immediately before running each sample.
3) Carefully wipe the cap of the tube/vial with a lint-free tissue and replace the cap.
4) Return tubes/vials to refrigerator within 30 minutes of use.

B. Conduct QC test:

Analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.

[Explanation of Test Results]

The Hematology Control is designed to monitor the performance of Hematology Analyzer before patient’ s sample tests. The QC test results should be within the target range listed on the Target value table, otherwise the test results may be inaccurate.

[Performance of Characteristics]

Assigned values are presented as a Mean and Range. The Mean is derived from replicate tests on analyzers operated in accordance with manufacturer’ s instructions. The Range is an estimate of variation between laboratories and takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Before using hematology control of a new lot, please make sure the analyzer is in good condition and QC test results are acceptable.

For greater control sensitivity, each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Target value table, if the control is suitable for the method.

[Metrological Traceability information]

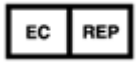
Parameters	Reference Materials/ Reference Measurement Procedure
WBC、RBC	ICSH: Reference method for the enumeration of erythrocytes and leucocytes
HGB	ICSH: Reference method for haemoglobinometry in human blood
HCT	ICSH: Reference method for hematocrit
PLT	ICSH: Reference method for platelet counting

[Precision]

Parameters	WBC	RBC	HGB	MCV	PLT
QC (High)	2.5%	1.5%	1.5%	1.0%	5.0%
QC (Normal)	2.5%	1.5%	1.5%	1.0%	5.0%
QC (Low)	5.0%	3.0%	3.0%	2.0%	10.0%

[Limitations]

The performance of ED-60D Hematology Control is only assured only if it is properly stored and used in accordance with the requirements specified in this manual.



EDAN Instruments, Inc. #15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China Tel: +86-755-26898326 Fax: +86-755-26898330 http://www.edan.com	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg, Germany Telephone: +49-40-2513175 E-mail: shholding@hotmail.com

[Date of Approval for Package Inserts]

June, 2023

[Labeling and Information]

Symbol	Symbol Meaning	Symbol	Symbol Meaning
IVD	In vitro diagnostic device		Use-by date
	Consult instructions for use		Temperature limit
LOT	Batch code		Manufacturer
EDAN	Trademark		Biological risks
EC REP	Authorized representative in the European Community	CE 0123	CE Mark
			Caution
	Date of manufacture		Not for self-testing
	Not for near patient testing	UDI	Unique device identifier
BIO	Contains biological material of animal origin	BIO	Contains biological material of human origin

[References]

1.Henry, JB Clinical Diagnostic and Management by LaboratoryMethods.Ed.17.WB Saunders. Philadelphia, PA 1984

2.Wintrobe,MM 'Clinical Hematology',8th Edition, Lea and Febiger,Philadelphia,1981.

3.Department of Labor, Occupational Safety and HealthAdministration.29 CFR PART 1910.1030: Occupational Exposure to Bloodborne Pathogens: Final Rule.

P/N: 01.54.458828

MPN: 01.54.458828014