HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Tài liệu được xác nhận bằng chữ ký số.

Hà Nội, ngày 14 tháng 02 năm 2022

Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

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von Willebrand Factor Controls - 0009802119

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CE

Intended use

For the Quality Control of HemosIL AcuStar von Willebrand Factor Antigen, von Willebrand Factor Ristocetin Cofactor Activity, von Willebrand Factor Collagen Binding Activity and HemosIL AcuStar ADAMTS13 Activity assays performed on the ACL AcuStar®.

Summary and principle

HemosIL AcuStar Normal VWF Control is an assayed control for the quality control of the HemosIL AcuStar von Willebrand Factor Antigen, von Willebrand Factor Ristocetin Cofactor Activity, von Willebrand Factor Collagen Binding Activity and ADAMTS13 Activity assays in the normal level. The HemosIL AcuStar Normal VWF Control is prepared using human citrated plasma from healthy donors.

HemosIL AcuStar Low VWF Control is an assayed control for the quality control of the HemosIL AcuStar von Willebrand Factor Antigen, von Willebrand Factor Ristocetin Cofactor Activity, von Willebrand Factor Collagen Binding Activity and ADAMTS13 Activity assays in the abnormal (low) level. The HemosIL AcuStar Low VWF Control is prepared from human citrated plasma from healthy donors and modified, by means of a dedicated process, to simulate an abnormal coagulation sample.

Composition

The **AcuStar VWF Controls** kit consists of:

L **AcuStar Low VWF Control** (Cat. No. 0009802121) contains 6 vials: 3 vials x 1 mL of lyophilized diluted human plasma containing buffer and stabilizers, without preservative, and 3 Low VWF Control barcoded plastic tubes.

N **AcuStar Normal VWF Control** (Cat. No. 0009802120) contains 6 vials: 3 vials x 1 mL of lyophilized human plasma containing buffer, stabilizers, and preservatives, and 3 Normal VWF Control barcoded plastic tubes.

Use of the two controls is recommended for a complete quality control program.

Please note: The target mean, the target standard deviation (SD) and the acceptance range for each control level and assay are provided in the value sheet enclosed with the kit. This information is included in the respective barcode of the value sheet for each assay and can be automatically transferred to the instrument by using the hand held barcode reader. Control information may also be introduced manually in the AcuStar. Please, refer to the value sheet.

Precautions and warnings

The AcuStar VWF Controls kit contains bovine source material. All donor animals were sourced from BSE-free herds. The cattle received ante-and post-mortem health inspection by a veterinarian, and they were free from infectious and contagious material, however, the material should be treated as potentially infectious.[1]

The AcuStar VWF Controls kit contains human source material that was tested by FDA approved methods and found non-reactive for HIV 1/2, HCV antibodies and Hepatitis B Surface Antigen at the donor stage. This product, like all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

The AcuStar VWF Controls are not classified as hazardous.
Hazard class: None
Hazard statements: None
Precautionary statements: None
Supplemental hazard information:
AcuStar Low VWF/Normal VWF Controls: ≈ 100% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and unknown hazard to the aquatic environment.
This product is For *in vitro* Diagnostic Use.

Preparation

1. Dissolve the contents of the vial with 1 mL of CLR Type water or equivalent.[2]
2. Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product.
3. Keep the controls at 15- 25°C for 30 minutes and gently invert to mix before use. Do not shake.

Once reconstituted, pour the entire contents of the control vials into the appropriately labeled empty barcoded plastic tubes, for use on the ACL AcuStar System.

Note: Avoid foam formation when homogenizing and pouring reconstituted controls. Bubbles on top of the liquids may interfere with the instrument's liquid sensors.

Reagent storage and stability

Unopened controls are stable until the expiration date shown on the vial labels when stored at 2-8°C.

Stability after reconstitution:

For the quality control of HemosIL AcuStar von Willebrand Factor Antigen and HemosIL AcuStar von Willebrand Factor Ristocetin Cofactor Activity assays - 8 hours continuously on-board the ACL AcuStar System (in open plastic barcode tube), or 5 days when placed twice daily on-board (in open plastic barcode tube) for 45 minutes and then recapped and placed at 2-8°C.

For the quality control of HemosIL AcuStar von Willebrand Factor Collagen Binding Activity assay - 8 hours continuously on-board the ACL AcuStar System (in open plastic barcode tube), or 2 days when placed twice daily on-board (in open plastic barcode tube) for 30 minutes and then recapped and placed at 2-8°C.

For the quality control of HemosIL AcuStar ADAMTS13 Activity assay - 7 hours continuously on-board the ACL AcuStar System (in open plastic barcode tube), or 4 days when placed once daily on-board (in open plastic barcode tube) for 30 minutes and then recapped and placed at 2-8°C.

For optimal stability remove controls from the system, cap, and store at 2-8°C in the barcoded plastic tubes. Do not freeze.

Instrument/test procedures

After reconstitution, the VWF Controls should be handled in the same manner as fresh citrated plasma. Refer to the ACL AcuStar Operator's Manual for the complete assay procedure instructions.

Additional reagents

The following are not supplied with the kit and must be purchased separately.

HemosIL AcuStar von Willebrand Factor Antigen	Cat. No. 0009802020
HemosIL AcuStar von Willebrand Factor Ristocetin Cofactor Activity	Cat. No. 0009802024
HemosIL AcuStar von Willebrand Factor Collagen Binding Activity	Cat. No. 0009802044
HemosIL AcuStar ADAMTS13 Activity	Cat. No. 0009802048

Traceability of control materials

The reported values were determined over multiple runs on the ACL AcuStar system, using specific lots of reagents, which are traceable to the current International Reference material for VWF and factor VIII (HemosIL AcuStar von Willebrand Factor Antigen, HemosIL AcuStar von Willebrand Factor Ristocetin Cofactor Activity, and HemosIL AcuStar von Willebrand Factor Collagen Binding Activity) or ADAMTS13 (HemosIL AcuStar ADAMTS13 Activity).[3,4]

Results

HemosIL AcuStar VWF results are reported in % which is equivalent to IU/dL. HemosIL AcuStar ADAMTS13 Activity results are reported in % which is equivalent to IU/dL. Refer to the ACL AcuStar Operator's Manual for additional information. QC requirements should be performed in accordance with local, state, and/or federal regulations or accreditations requirements.

Limitations/Interfering substances

These products are designed as controls for monitoring the HemosIL AcuStar von Willebrand Factor Antigen, Ristocetin Cofactor Activity, Collagen Binding Activity, and ADAMTS13 Activity assays. These controls are subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system. Please refer to the respective assay inserts for relative interference claims.

Expected values

The HemosIL AcuStar Low VWF Control and HemosIL AcuStar Normal VWF Control concentration acceptance ranges listed below were determined over multiple runs on the ACL AcuStar System using specific lots of HemosIL AcuStar von Willebrand Factor Antigen, von Willebrand Factor Ristocetin Cofactor Activity, von Willebrand Factor Collagen Binding Activity, and ADAMTS13 Activity reagents. The mean of the control range determined in each laboratory may vary due to the lot of reagent used.

Please Note: Each laboratory should determine its own mean and standard deviation based on their instrument/reagent combination.

Performance characteristics

Precision

Within run precision was assessed over multiple runs using specific lots of reagents and controls.

The coefficients of variation obtained in this study were < 8.0% for HemosIL AcuStar von Willebrand Factor Ristocetin Cofactor Activity, 8.0% for HemosIL von Willebrand Factor Antigen, <8% for HemosIL AcuStar von Willebrand Factor Collagen Binding Activity, and < 8% for HemosIL AcuStar ADAMTS13 Activity. Please refer to the insert of the corresponding assays for additional performance characteristics.

Bibliography

1. Richmond JY, McKinney RW eds.: Bio-safety in Microbiological and Biomedical Laboratories, U.S. Dept. of Health and Human Services, Public Health Service, 4th Edition, 1999.
2. Clinical and Laboratory Standards Institute. Preparation and Testing of Reagent Water in the Clinical Laboratory, 4th Edition, CLSI Document GP40-A4-AMD.
3. WHO International Standard: Factor VIII and Von Willebrand Factor In Plasma, NIBSC code: 07/316 (most current version).
4. WHO International Standard: ADAMTS13 Plasma, NIBSC code: 12/252 (most current version).

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Symbols used

CONTROL NAME	IL Control name
NAME	Name
ASSAY NAME	Assay name
TARGET DOSE	Target dose
ACCEPTANCE RANGE	Acceptance range
UNITS	Measurement units

IVD *In vitro* diagnostic medical device

LOT Batch code

Use by

Temperature limitation

Consult instructions for use

CONTROL Control

Biological risks

Manufacturer

EC REP Authorised representative

Instrumentation Laboratory
A Werfen Company

Instrumentation Laboratory Company - Bedford, MA 01730-2443 (USA)
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