SIEMENS Healthineers

Atellica® HEMA Control

Current Revision and Date	Rev. 02, 2021-11	
Product Name	Atellica HEMA Control	
Abbreviated Product Name	HEMA Control (L)	REF 11374313
	HEMA Control (N)	REF 11374314
	HEMA Control (H)	REF 11374315
Systems	Atellica HEMA 520 OT Atellica HEMA 520 CT Atellica HEMA 530 Atellica HEMA 570 Atellica HEMA 580	

CE

Intended Use

Atellica® HEMA Control is a tri-level multiparameter control intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of Atellica HEMA Analyzers.

Principles of the Procedure

Atellica HEMA Control is a stable preparation used to monitor the accuracy and precision of blood cell counters. Reference values have been obtained from replicate analyses on instruments which have been whole blood calibrated to values obtained from reference methods. Atellica HEMA Control is run on the instrument in the same way as a patient blood sample (resistivity, absorbance and spectrophotometry measurements).

Reagents

Material Description	Storage[a]	Stability[a]
Atellica HEMA Control **Composition:** HEMA Control contains mammalian leukocytes (WBC), erythrocytes (RBC) and thrombocytes (PLT) suspended in a plasma-like fluid. **Description:** HEMA Control is similar in appearance to fresh whole blood. A light pink-tinted supernatant is normal.	**Unopened**: 2–8°C **Opened:** 2–8°C	Until expiration date on product 16 sampling events over a maximum of 16 days at 2–8°C after opening and within the expiration limit.

[a] Refer to *Storage and Stability*

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

For Prescription Use Only.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens-healthineers.com.

Warning! Potential Biohazard

Contains human source material.

No known test method can ensure that products derived from human source materials will not transmit infection. These materials should be handled using good laboratory practices and universal precautions.[1-3]

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Storage and Stability

Store all reagents in an upright position, away from light and heat. Do not use products beyond the expiration date printed on the product labeling.

Do not freeze. Storage in the door compartments of the refrigerator is not recommended.

For information about product storage and stability, refer to *Reagents*.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Volume
11374313	Atellica HEMA Control (L) CONTROL L	4 x 3 mL
11374314	Atellica HEMA Control (N) CONTROL N	4 x 3 mL
11374315	Atellica HEMA Control (H) CONTROL H	4 x 3 mL

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

Description
Atellica Hematology Analyzer
Quality control assigned value sheet CONTROL LOT VAL

Performing Quality Control

For monitoring the accuracy and precision of Atellica HEMA QC.

An analysis of the control must be carried out on a daily basis at the same time as the patient samples, including each time a calibration or a maintenance is carried out.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Test quality control samples after a successful calibration.

Preparing the Quality Control

Prepare quality control material using the following steps:

1. Bring Atellica HEMA Control to room temperature by rolling the tube between the palms of your hands until the red blood cell sediment is completely suspended. Do not shake.
2. Refer to the user manual to identify Atellica HEMA Control using the barcode reader or manually.
3. Run Atellica HEMA Control according to the procedure described in the user manual.
4. When ran in manual mode, gently invert the tube 8 to 10 times immediately before sampling.
5. Wipe threads and cap of the tube after use with lint free gauze.
6. Recap and refrigerate the tube promptly after use.

Note Use quality control material within the stability limits specified in *Reagents* and discard any remaining material.

Quality Control Procedure

Use the following lot-specific materials to perform quality control:

- For the quality control (QC) definitions, refer to the lot-specific value sheet available at siemens.com/eifu.

For instructions about how to perform the quality control procedure, refer to the instrument user manual.

Taking Corrective Action

If the quality control results do not fall within the expected control interval, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the system online help.

Expected Values

The mean assay values of each Atellica HEMA Control parameter are obtained from replicated assays performed on analyzers that have been calibrated using whole blood. The assays were performed using reagents recommended by Siemens. Values obtained with Atellica HEMA Control (if used before its expiration date) should fall within the expected range. The expected ranges are representative of estimates of the variation between different laboratories for each parameter. Inter-laboratory variations are the consequence of instrument calibration, maintenance, and operating technique. The reference results are therefore only indicative for control purposes and should not be used for calibration. Refer to *Standardization*.

Limitations

Packaging Damage

In case of protective packaging damage, do not use product. Damages to the product might have an effect on the product performance.

Signs of Deterioration

In the event of any signs of physical or chemical deterioration (turbidity, change in color, etc.) Atellica HEMA Control should be replaced.

Incorrect Mixing

Incomplete mixing of the tube prior to use invalidates both the sample that is withdrawn and the remainder of Atellica HEMA Control in the tube.

Temperature Limits

Do not use product if it has been frozen or kept at excessive heat.

Before using, make sure the product has reached the operating temperature conditions as described in the system online help.

Standardization

Siemens Healthineers controls are traceable to standard reference methods. Hematology analyzers in the Quality Assurance Laboratory are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within 6 hours of collection. The White Blood Cells (WBC) and Red Blood Cells (RBC) are analyzed on a commercially available instrument. All counts are corrected for coincidence. Hemoglobin is measured using the Clinical Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method.[4] Readings are made at 540 nm in a colorimeter/ spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations.[5] The hematocrit (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document.[5] No correction is made for trapped plasma. Platelets are assayed using a hemocytometer and phase contrast optics.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

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References

1. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
2. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
4. Clinical and Laboratory Standards Institute. *Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2000. CLSI Document H15-A3.
5. Clinical and Laboratory Standards Institute. *Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2001. CLSI Document H7-A3.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Batch code
	Catalog number		Contains sufficient for <n> tests
	Consult Instructions for Use		Version of Instructions for Use
	Internet URL address to access the electronic instructions for use		Revision
	*In vitro* diagnostic medical device		Unique Device Identifier
RxOnly	Prescription device (US only)		CE Marking
	CE Marking with Notified Body		Keep away from sunlight
	Temperature limit		Lower limit of temperature
	Upper limit of temperature		Do not freeze
	Do not re-use		This way up
	Recycle		Caution
	Biological risks	**YYYY-MM**	Date format (year-month)
YYYY-MM-DD	Date format (year-month-day)		Interval
	Target		

Legal Information

Atellica is a trademark of Siemens Healthineers.

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