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Body Fluid

CONTROL CE

HEMATOLOGY CONTROLS
DIMDI Reg.-Nr.: DE/CA22/1115-37-IVD

LOT **1218**

2019-03-05

ASSAY VALUES AND EXPECTED RANGES

Method	Parameter	LEVEL 1 LOT 1218-1		LEVEL 2 LOT 1218-2	
		MEAN	RANGE	**MEAN**	RANGE
Hemocytometer Count	WBC/uL	**8**	1 - 15	**318**	193 - 443
Hemocytometer Count	RBC/uL	**0**	-	**1130**	830 - 1430

INTENDED USE

Body Fluid Control is a control designed to monitor values obtained using a hemocytometer to validate the quantitation of red and white blood cells in patient body fluid samples.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials which provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

REAGENTS

Body Fluid is an *in vitro* diagnostic reagent composed of mammalian erythrocytes and leukocytes suspended in a plasma-like fluid with preservatives.

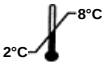
PRECAUTION

Body Fluid Control is intended for ***in vitro* diagnostic use** only by trained personnel.

WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL. This product contains human-sourced and/or potentially infectious components. For specifics please refer to the REAGENT section of this package insert. Components from human donors used in preparation of this product were tested by FDA approved methods for the presence of the antibodies to Human Immunodeficiency Virus (HIV-1 and HIV-2) and Hepatitis C Virus (HCV), as well as for Hepatitis B Virus surface antigen and found to be negative.

No known method can offer complete assurance that products derived from human sources or containing inactivated microorganisms will not transmit infection. When handling or disposing of product, follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (OSHA 29 CFR Part 1910.1030) or other equivalent biosafety procedures.



STABILITY AND STORAGE

Store Body Fluid upright at 2 - 8° C when not in use**. Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable 90 days or 31 thermal cycles (uses), whichever comes first, provided they are handled properly.

INDICATIONS OF DETERIORATION

Body Fluid Control should be similar in appearance to cerebrospinal Fluid. In unmixed vials the supernatant should appear clear and colorless. Discoloration of the vials may indicate deterioration or contamination. **Do not use the product if deterioration is suspected.**

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INSTRUCTIONS FOR USE

1. Remove vials from the refrigerator and allow to warm to room temperature (15 - 30°C or 59 - 86°F) for 15 minutes before mixing.
2. To mix, hold a vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer**.
   a) Roll the vial back and forth for 20 - 30 seconds; occasionally invert the vial. Mix vigorously, but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Vials stored for a long time may require extra mixing.
   c) Gently invert the vial 8 - 10 times immediately before sampling.
3. Prepare a sample of Body Fluid for analysis with the same technique used for a patient specimen.
4. After sampling:
   a) If vial has been open for sampling, clean residual material from the cap and vial rim with a lint-free tissue. Replace the cap tightly.
   b) Return vials to refrigerator within 30 minutes of use.

EXPECTED RESULTS

Verify that the lot number on the vial matches the lot number on the table of assay values. Operating technique may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean Value is derived from replicate testing analysis of hemocytometer counts. The Range is an estimate of variation between laboratories and also takes into account 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. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range. 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 Assay Sheet, if the control is suitable for the method.

LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call Technical Service at (02551) 2097. For additional information on Günter Keul GmbH hematology controls and calibrators, or to place an order, call Customer Service at (02551) 2097.

QUALITY CONTROL PROGRAM

For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (02551) 2097.

IVD CE

Aktuelle Werteblätter zu den Chargen von Body Fluid finden Sie im Internet unter

www.werteblatt.de