Body Fluid Cell Count Control (Manual)

Principle

Cell-Chex Body Fluid Cell Count Control is an assayed bi-level control, designed to standardize the way CLSs do the manual body fluid cell count. In addition, each day of use, the diluting fluid, will be checked for non-specimen background particulates to ensure the accuracy and precision of RBC and WBC manual counting procedures of CLS' assigned performing manual body fluid cell counts.

Analysis of Cell-Chex cannot be performed on an automated hematology analyzer. The stabilization process of the red blood cells will cause them to interfere with the white blood cell count. For manual method ONLY.

Safety

All reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance.
Refer to: Policy and Procedures Safety Manual Infection Control and Procedures 11-085-01

Reagents and Materials

Cell-Chex body fluid control
Cytology Funnel and Caps
In-Cyto disposable C-Chip hemocytometer
10% Glacial Acetic Acid (Prepared by Sherman Way Regional Laboratory)
Microscope
Cytology Clips
Cytospin Centrifuge

Storage and Stability

Cell-Chex body fluid control is stable through the expiration date when stored at 2- 10 °C degrees. After opening, Cell-Chex is stable throughout the open-vial dating (30 days) when stored at 2-10 degrees centigrade.

NOTE: OPEN AND DISCARD VIALS IN PAIRS.

Indication of product deterioration:

Inability to obtain expected values for total cell counts may indicate product deterioration. If the recovered values are not within the expected range:

1. Review the control product package insert instructions for Use and Limitations sections.
2. Check the expiration dates of Cell-Chex. Discard outdated product.
3. Assay an unopened vial of Cell-Chez. If the values are still outside the expected range, contact Technical Services at 800-843-0912 or www.streck.com.

Intended Use

Cell-Chex is an assayed control intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient cerebrospinal fluid and body fluid samples including: pleural, pericardial, peritoneal and synovial fluid.

Procedure

During each eight-hour shift:

1) Run a minimum of one control in duplicate. Counts from each chamber must agree within 10%.
2) Document the values obtained on each run, date and shift of testing, and the initials of who performed the testing.
3) Make sure that the correct level of control is being performed e.g. AM shift performed Level 2 control and then the PM shift will perform the Level 1. It goes back to Level 2 if the night shift has a cell count test to be performed.
4) Evaluating diluting fluid acceptability:
    a. Each day of use, place a drop of diluent on a clean slide and evaluate to ensure the diluent is clear of any particulates.
    b. If the diluent is clear, it is **acceptable** and it may be used for sample testing.
    c. Document acceptability on QC log together with diluent lot number, and expiration date.
    d. If diluent is not clear, it is **not acceptable** and cannot be used for sample testing. Open a new one and check for acceptability before use.

Follow these steps:

Step	Action
1	Remove the controls from the refrigerator. It is not necessary to warm the controls to room temperature before using.
2	To Mix: **DO NOT MIX MECHANICALLY** a) Hold vial horizontally between the palms of the hands and roll the vial back and forth for 30 seconds. b) Hold vial on cap end and mix by rapid inversion, using 20 quick flicks of the wrist, to ensure the cells are completely resuspended. c) Vials stored for an extended period of time may require extra mixing repeating steps a) and b). d) Invert the vials 8 to 10 times immediately before sampling.

3	Samples must be removed using a clean capillary tube or pipette tip. The vial must be closed immediately after sampling is complete. Care should be taken to prevent cross-contamination of the control. Hemocytometer should be clean and free of scratches. An approved cover glass must be used with the hemocytometer (0.4mm thickness and 20x26mm rectangular). Charge both sides of the hemocytometer chamber and allow the cells to settle before counting. Counts from each chamber must agree within 10%. Use the following formula to calculate number of cells/mm3: $\frac{\text{Number of cells counted x depth (10) x dilution}}{\text{Number of large squares counted}}$ = cells/mm3
4	After sampling return to refrigerator for maximum open-vial stability. Wipe the threads of both the vial and cap before replacing and returning to refrigeration.

Intended Use

The assayed values for the red blood cells and white blood cell are found on the package insert. **EACH LOT NUMBER HAS DIFFERENT RBC AND WBC RANGES. MAKE SURE THAT THE CLS PERFORMING THE TEST PROCEDURE IS DOCUMENTING THE CORRECT LOT NUMBER AND RANGES**.

Refer to the package insert for the expected range.

Reference

Streck Cell-Chex 2009-12

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Implemented
Minor	Updated format and revised Index No.	Julius Salomon, 7/1/17			