Procedure
Dignity Health Central Coast Service Area

**SUBJECT**: Beckman DxH Body Fluid Cell Count

**ORIGIN**: Hematology

**NUMBER**: 7500.H.CC.49

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| --- |
| **Applies to:** |
| [x]  Santa Maria Campus,Marian Regional Medical Center | [x] Arroyo Grande Campus,Marian Regional Medical Center | [x] French Hospital Medical Center |
| [ ] St. John’s Pleasant Valley Hospital | [ ] St. John’s Regional Medical Center |

# Principle:

The Beckman Coulter DxH Analyzer is a quantitative, automated hematology analyzer which can be used to enumerate total nucleated cells and red blood cells in body fluids for in vitro diagnostic purposes. CSF fluid is obtained to assist in diagnosing central nervous system infection, tumors or vascular accidents. In Body fluids (pleural, peritoneal, synovial, etc.), results are used to determine if a specimen is a transudate due to increased hydrostatic or decreased plasma oncotic pressure, or an exudate secondary to a wide variety of diseases such as increased capillary permeability, infection, infarction, rheumatoid disease, collagen disease, or secondary to malignancy. Cell concentrations in body fluids are used to diagnose or rule out these disease processes.

# Specimen Collection:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sample Type | Container | Minimum Volume | Storage Temperature | Stability |
| CSF, body fluids | EDTA vacutainer tubesVacutainer tubes w/o anticoagulantsPlastic specimen containers |  | Room temperature | 1 hour optimal |

## CSF samples are collected into sterile numbered tubes. Unless otherwise specified by the physician, the cell count is performed on tube #3 or #4. If an additional cell count is request, the additional cell count is performed on tube #1. Body fluid samples are collected into EDTA vacutainers tubes, vacutainer tubes without anticoagulants, or plastic specimen containers.

## Body fluid samples should be stored at room temperature and analyzed as soon as possible after collection (preferably within 1 hour). Cell counts and differentials should not routinely be performed on samples >24 hours old. Any delay in analysis could cause cell lysis, cellular degeneration, and bacterial growth which can affect the test results.

## All body fluid samples are closely examined for the presence of clots, fibrin, tissue, or cellular clumps before testing. Automated cell counts are not performed on any turbid samples or samples containing clots, clumps, or tissue.

## Because of the invasive nature in collecting body fluids, specimens submitted to the laboratory that are unlabeled, improperly labeled, submitted in inappropriate containers or outside of stability are not rejected if possible. If the specimen is improperly labeled, a nurse or physician involved in the collection may come to the lab to properly label the specimen. An exception report must be completed and all information documented. If the specimen is collected in an inappropriate container or outside of stability, the testing will be performed if possible and a detailed comment is attached to the results explaining the exception.

## Automated body fluid cell counts may be performed on the following fluid types:

### Cerebral Spinal Fluid (visibly bloody or cloudy)

### Pleural Fluid

### Peritoneal Fluid

### Pericardial Fluid

### Synovial Fluid

## Body fluid WBC counts which fall below the automated count linearity will be performed using the manual method described in Policy 7500.H.CC.50 Manual Body Fluid Cell Count.

# Materials:

|  |  |  |
| --- | --- | --- |
| **Reagents / Media*** Three levels of Beckman Coulter DxH Body Fluid Controls
	+ Store at 2-8°C
	+ Stable for 16 days after opening
* Beckman Coulter DxH Diluent
* Lyophilized hyaluronidase (stored at <-20°C)
 | **Supplies / Materials*** Aliquot tubes
* Adjustable pipette and pipette tips
 | **Equipment*** Beckman Coulter DxH Series analyzer
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# Calibration:

## Calibration Frequency

Instrument calibration is performed every six (6) months or as needed according to procedure using Coulter S-Cal.

Reproducibility and Carryover are performed every 6 months according to procedure.

Body Fluid Linearity is performed every 6 months using Beckman Coulter Analyzer Diluent and Beckman Coulter Body Fluid Controls.

## Procedure: Body Fluid Linearity

There is no commercial Lin-X product for Beckman Coulter Body Fluids. Therefore, the following procedure was established by Beckman Coulter for this purpose.

NOTE: Before starting or restarting the Repeatability process, the SPM must be offline.

### On the Beckman Database find REPEATABILITY (REPRODUCIBILITY) by clicking on the left hand side of the screen in the following order:

Menu > QA > Repeatability > Repeatability Setup

### From the Repeatability Setup dialog box, select a test panel from the Test Panel drop-down list.

NOTE The Repeatability Setup dialog box defaults to Cassette Presentation. Body Fluids are not run by cassette methods.

### Run the Beckman Coulter Diluent 6 times using the Body Fluid Mode. Print Summary.

### Continue by running each level of Beckman Coulter DXH Body Fluid Control 6 times.

### Print the summary report after each completed run.

### Perform this linearity test on the second DxH analyzer.

### Login and access the Beckman Coulter iQAP Website.

<https://www.beckmancoulter.com/qapSSO/qapSSO.portal?_nfpb=true&_pageLabel=login&lt=LT-115768-kNrUdVTYf8GLMiO9St5W&service=https://www.beckmancoulter.com/qap/m_hema/index.jsp#wlp_login>

### Select the iQAP number associated with the analyzer.

### Note the following choices:

#### Linearity Control Data Entry

##### View submitted data entry form(s)

##### Create a new Body Fluid Control Linearity data entry form

##### Create a new Lin-X Linearity Control data entry form

### Select Create a new Body Fluid Linearity data entry form.

### Enter SHIFT 0, test date, KIT # is the lot number on the control box (not the tubes).

### Enter background counts. Suggested low linearity for Beckman Coulter DxH series analyzer is diluent:

#### TNC < 20

#### RBC < 500

#### Diluent counts are not entered into the linearity data sheet.

### Enter each control tube’s lot number and select CONTINUE.

### Enter results for each of 6 runs for TNC and RBC.

### Select SAVE and continue for each of the three levels of control material.

### Select DONE when finished entering results. OPEN the FORM and recheck to be sure numbers were entered correctly and select SUBMIT FORM when ready.

### Within twenty-four (24) hours, results will be ready for review. Access the Beckman Coulter iQAP website as previously described and select the reports option for Last Body Fluid Linearity Test Data. A full report with graphs is created by Beckman Coulter and is saved to the MMC Laboratory’s hard drive.

# Quality Control:

## Beckman Coulter DxH Diluent is used to perform a background count on each instrument prior to running DxH Body Fluid controls.

### Select the Single-Tube Presentation icon  at the top of any screen to display the Single-Tube Presentation dialog box.

### Select DISPENSE DILUENT and when prompted, place an aliquot tube into the left side of the sampler. The instrument will dispense 1 mL of diluent into the aliquot tube.

### If necessary, select YES at the prompt to dispense additional aliquots of diluent into the same tube. This serves to further clear the aspiration probe of any residual cells.

### When the diluent dispense is complete, select NO at the prompt and remove the aliquot tube. Retain the final aliquot of diluent for background testing.

### Identify the background sample by typing “Diluent” or “Background” into the Specimen Identifier prompt. A message may display stating “test order not found.” Select OK. Change the specimen type from Whole Blood to any of the available Body Fluid types and select OK. Highlight the BFC order under the Available Panels heading, select ADD and then SUBMIT.

### At the prompt, insert the diluent into the left side of the sampler. Remove the tube when the analysis is complete.

### Record background counts in the appropriate Cerner QC file and save the printout. The following background counts are considered acceptable:

#### TNC <20

#### RBC <500

If the background counts are not within acceptable range, repeat steps A. through G. Do not perform patient testing until QC is resolved.

## Beckman Coulter DxH Body Fluid Levels I, II and III are run each 24 hours of use, after maintenance, calibration, or while troubleshooting. Do not report patient results if quality control is not within an acceptable range.

### Remove controls from the refrigerator approximately 15 minutes prior to use.

### To mix, roll tubes between palms eight (8) times and then manually rock tubes back and forth 8 times. Repeat this procedure (roll X 8 and rock X 8) a total of 3 times. Never place controls on a mechanical mixer.

### Select the Single-Tube Presentation icon  at the top of any screen to display the Single-Tube Presentation dialog box.

### Ensure a background count has been performed and is within acceptable range.

### STARTING WITH THE LEVEL 1 CONTROL, scan the barcode by placing the specimen tube on the bar-code reader platform of the Single-Tube Presentation Station.

### Place the well-mixed control tube in the left hand side of the sampler when prompted. Remove the sample when sampling is complete.

### Repeat steps E.-F. for all three control levels making sure the controls are run in order of 1-3.

### If controls fall outside of established Cerner ranges, mix and repeat once. Further failure requires additional troubleshooting steps. Document all corrective action. Do not perform patient testing until QC is within range. Additional troubleshooting steps include:

#### Open new vial of control and repeat.

#### Perform Aperture Clean procedure. DIAGNOSTICS -> DX TOOLS -> MAINT -> CLEAN APERTURES (follow instructions on the screen).

#### Perform shutdown/startup procedure

#### Call Beckman Coulter technical service.

# Procedure:

## Ensure that all 3 levels of body fluid controls have been performed and are in range for the specific analyzer being used for patient testing.

## Before each patient sample is tested, perform a background count using Beckman Coulter DxH Diluent. The following background counts are considered acceptable:

### TNC <20

### RBC <500

## Perform a visual examination of the fluid.

### Record the total volume if possible.

### Document the color and clarity of the unspun specimen.

### For CSF specimens, record the color and clarity of the supernatant if the unspun sample is bloody.

### Inspect the sample for the presence of clots, fibrin, large cellular clumps, or tissue.

### Any body fluid which appears to contain tissue is referred to the pathology department.

### Synovial fluids can be pretreated with hyaluronidase to reduce sample viscosity. Add approximately 5 mg (enough to coat the end of a wooden applicator stick) of lyophilized hyaluronidase to a well-mixed 1 mL aliquot of fluid. Mix and let sit for 5 minutes.

## Select the Single-Tube Presentation icon  at the top of any screen to display the Single-Tube Presentation dialog box.

## Scan the sample accession number barcode by placing the specimen tube on the bar-code reader platform of the Single-Tube Presentation Station.

## A message will display stating “test order not found.” Select OK. Change the specimen type from Whole Blood to the sample’s appropriate body fluid type (i.e. synovial fluid, pleural fluid, etc.) and select OK. Highlight the BFC order under the Available Panels heading, select ADD and then SUBMIT.

## Place the well-mixed sample tube in the left hand side of the sampler when prompted. Remove the sample when sampling is complete.

## Observe the printout for any system flags. Results with “P” flags must be repeated if possible or performed by manual method. Results with “R” flags must be checked by manual method for accuracy if they cannot be resolved by repeat testing. System flags may sometimes be resolved by performing a manual dilution of the fluid (using Coulter diluent) and rerunning the sample.

## If no system flags are present, review the results to verify the linear limits have not been exceeded.

### TNC Linearity 40.0-65,000

### RBC Linearity 1000-5,500,000

NOTE: Body fluid TNC cell counts which are less than established linearity will be repeated using the manual method described in Policy # 7500.H.CC.50 Manual Body Fluid Cell Count. TNC and RBC count results exceeding the upper limit of linearity will be diluted using Beckman Coulter Diluent. Dilutions will be at the discretion of the Clinical Laboratory Scientist. Dilution calculations must be performed manually and are recorded and retained on the DxH printout.

## Make at least one cytospin slide on each body fluid specimen regardless of the cell count.

## Stain the cytospin slide according to procedure and scan the slide on low power. The scan is performed regardless of cell count.

## Scan each slide looking for malignant cells. Confirm the accuracy of the manual count by comparing the cell concentrations observed on the cytospin slide to the calculated manual count.

## Perform a differential on all body fluid specimens in which the WBC count is >5 cells/mm3.

# Interpretation of Results:

## CSF normal ranges:

|  |  |  |
| --- | --- | --- |
| Age | WBC | RBC |
| 0-29 days old | 0-19 cells/mm3 | 0-5 cells/mm3 |
| ≥30 days old | 0-5 cells/mm3 | 0-5 cells/mm3 |

## CSF WBC critical ranges:

|  |  |
| --- | --- |
| Age | WBC |
| 0-29 days old | >19 cells/mm3 |
| ≥30 days old | >5 cells/mm3 |

## A CSF WBC count of >5 is considered critical. Refer to 7500.CC.AD.16 Critical Value Laboratory Notification policy for information on reporting critical values.

## Body fluids other than CSF do not have normal/critical ranges in Cerner. Results should always be interpreted in light of the total clinical presentation of the patient including clinical history, data from additional tests, and other appropriate information.

## Any body fluids with suspected malignancy, abnormal/suspicious cells or unidentified cells are sent to pathology for review. Refer to 7500.H.CC.13 Submission of Slides for Pathology Review for instruction on submitting slides for pathology review.

## Any body fluids that appear to contain tissue should be referred to the pathology department.

## Cell counts are not routinely perform on body fluid specimens containing clots, fibrin, or cellular clumps as the results will be inaccurate.

# Result Reporting:

## In Accession Result Entry, scan the patient/QC barcode or manually enter the accession number.

## In the appropriate field, enter or review the BF TNC and RBC counts obtained from the DxH analyzer printout. Retain all printouts and file appropriately. BF RBC results less than linearity should be entered as <1000.

NOTE: A diluent Background count must be performed and entered into Cerner for EVERY patient sample reported.

## Review results to ensure accurate manual entry. If necessary, add a Result Comment or Result Note to document collection or processing problems and/or communications with nurses or physicians.

## Select VERIFY when compete.

# Limitation of Procedure:

## Cell lysis may begin shortly after the collection of a body fluid. Cell counts should be performed as soon as possible after collection.

## Body Fluid TNC counts which are less than established linearity will be performed using the manual method described in Policy # 7500.H.CC.50 Manual Body Fluid Cell Count. Body Fluid counts exceeding the upper limit of linearity will be diluted using Beckman Coulter Diluent and rerun. Dilutions will be at the discretion of the Clinical Laboratory Scientist.

## The presence of cellular clumping is noted on the analyzer printout by an “R” flag. Place a drop of patient sample on a slide and cover-slip. Examine under 50X light microscopy for the presence of TNC clumps or RBC clumps. Marked clumping and all clots found preclude enumeration. Tests are resulted as TNP (test not performed) and a comment is added explaining the reason the count cannot be performed. Manual estimations of FEW, MODERATE or MANY TNCs and RBCs are noted in the comment. WBC differentials are performed and resulted.

# References:

## UniCel DxH 800 Coulter Cellular Analsis System, Instructions for Use. Beckman Coulter, Inc.: Brea, CA, November, 2010.

## Beckman Coulter. Instructions for Verifying the measuring Range of the Body Fluid Cycle on the UniCel DxH 800 Coulter Cellular Analysis System. QSSC 2.1.04. 2011. Beckman coulter Inc.

## Collage of American Pathologists, Hematology and Coagulation Checklist. Northfield, IL, Current Revision.