TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	5/22/2019
Department:	Core Lab	**Due Date:**	2/28/2019
		Implementation:	**6/2/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

CSF Cell Count and Differential by Sysmex XN Series SGAH.H1004 v5

Description of change(s):

TWO major changes to SOP:

Section	Reason
2	Modified local test codes
8.3	Added color and appearance instructions
10.6	Corrected instruction for TC >10,000 *(removed step to multipye result by dilution factor)*
Add A	Added DTYPE and CSF grouping; updated color choices. Added examples of various resulting scenarios. Revised order of release – *this is needed for SQ upgrade* Added manual RBC for pediatric patients – *this was requested by the Pediatric physician group*

This revised SOP will be implemented on June 2, 2019

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**CSF Cell Count and Differential by Sysmex XN Series**
Prepared by	Ashkan Chini Date: 8/15/2018
Owner	Robert SanLuis Date: 8/15/2108

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Codes
Cell Counts, Total RBC and Total Nucleated Cells, CSF (tube specific)	Sysmex XN Series 1000/3000	CT1, CT2, CT3, CT4

Synonyms/Abbreviations
CSF Cell Count

Department
Hematology

2. ANALYTICAL PRINCIPLE

The RBC detector counts the RBC via the Hydro Dynamic Focusing. The RBC is calculated as a particle count between lower and upper discriminators, which are automatically setup in the ranges of 25 – 75 fL and 200 – 250 fL. The particle size distribution is checked for abnormal relative frequencies at each discriminator level existence of more than one peak and abnormal distribution width.

Flow Cytometry is used to analyze physiological and chemical characteristics of cells and other biological particles. It is also used to analyze those cells and particles as they are passed through extremely small flow cells.

The WNR Channel uses flow cytometry to create a scatter gram and is primarily used to count the white blood cells. This scatter gram displays groups of basophil, non-basophil WBC and hemolyzed RBC.

The WDF Channel uses flow cytometry to create a scatter gram and is primarily used for classifying WBCs. This scatter gram displays groups of lymphocytes, monocytes, eosinophils, basophils and neutrophils.

The WPC Channel uses flow cytometry to create a scatter gram and is used for detecting immature WBCs such as myeloblasts and abnormal lymphocytes. This scatter gram displays groups of immature/abnormal WBCs and mature WBCs.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	Not Applicable
Specimen Collection and/or Timing	Not Applicable
Special Collection Procedures	Specimens are collected in sterile tubes labeled in the order in which they are withdrawn (1, 2, 3, 4). • Tube 1 is used for color, appearance, cell count and Chemistry tests (see addendum A to report diff if requested by physician) • Tube 2 is used for Serology tests • Tube 3 is used for color, appearance, cell count and differential • Tube 4 is used for Microbiology **Note**: If there is a Cytology order, process core lab testing per 3 tube protocol and use tube 4 for Cytology.

Component	Special Notations
Special Collection Procedures continued	If 3 tubes are received: • Tube 1 is used for color, appearance, cell count and Chemistry tests • Tube 2 is used for Serology tests, color, appearance, cell count and differential • Tube 3 is used for Microbiology **Note**: If there is a Cytology order, after Microbiology has taken their sample from tube 3, send remainder of tube 3 for Cytology.
	If less than 3 tubes are received, contact the physician for specific tests to be performed.
Other	Hematology is responsible for resulting color and appearance.

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	CSF: tube #1 and #3 (See section 3.1 if less than 4 tubes) None	
Collection Container	CSF – Sterile Plastic Conical Tube	
Volume - Optimum **- Minimum**	2 mL 200 µL	
Transport Container and Temperature	CSF: Transport at room temperature in collection tube	
Stability & Storage Requirements	Room Temperature:	Process Immediately. Rapid deterioration and cell lysis occurs on prolonged standing in CSF.
	Refrigerated:	Not recommended
	Frozen:	Not acceptable
Timing Considerations	Not Applicable	
Unacceptable Specimens & Actions to Take	**Due to the nature of these specimens, do not reject unless frozen.** **Clotted specimens:** Perform counts and append the code SCLOT (*Specimen contains clots, counts may not be accurate*). **Specimens received after 24 hours:** Perform counts and append the code SAGE (*Counts may not be accurate due to the age of the specimen*). **If the specimen is received frozen:** Cancel the test with the reason code SFRZ (*Specimen unsuitable for assay; received frozen*). Notify the attending nurse or physician. Note: In Cerner reason for cancellation will be "improper collection".	

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Criteria	
Compromising Physical Characteristics	Not Applicable
Other Considerations	Not Applicable

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Cell Pack DCL	Sysmex Corporation, Cat. No. DCL-300A
Cell Pack DFL	Sysmex Corporation, Cat. No. BT965910
Fluorocell WDF	Sysmex Corporation, Cat. No. CV377552
Fluorocell WNR	Sysmex Corporation, Cat. No. CP066715
Lysercell WDF	Sysmex Corporation, Cat. No. ZA900001
Lysercell WNR	Sysmex Corporation, Cat. No. ZA900002
Sulfolyser SLS	Sysmex Corporation, Cat. No. BJ350971

4.2 Reagent Preparation and Storage

Reagents	Cell Pack DCL, Cell Pack DFL
Storage	Store at 2 - 35°C. Avoid exposing to direct sunlight
Stability	Once in use, these remain stable for 60 days.
Preparation	None

Reagents	Fluorocell WDF, Fluorocell WNR, Lysercell WDF
Storage	Store at 2 - 35°C. Avoid exposing to direct sunlight
Stability	Once in use, these remain stable for 90 days.
Preparation	None

Reagent	Lysercell WNR
Storage	Store at 2 - 35°C. Avoid exposing to direct sunlight
Stability	Once in use, stable for 60 days.
Preparation	None

Reagent	Sulfolyser SLS 1.5 L
Storage	Store at 2 - 30°C. Avoid exposing to direct sunlight
Stability	Once in use, stable for 60 days.
Preparation	None

5. CALIBRATORS/STANDARDS

Calibration is not specific for body fluid mode. Refer to *Sysmex XN Series Operation for CBC and Reticulocytes* SOP for details on calibration.

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
XN CHECK BF, Levels 1 & 2	Sysmex Corporation, Cat. No. 213516

6.2 Control Preparation and Storage

Control	XN CHECK BF
Preparation	Allow to come to room temperature, mix by manually inverting samples 4 times.
Storage	Store at 2 - 8°C
Stability	**Unopened**: manufacturer's expiration date **Opened**: 30 days when stored at 2 - 8°C after each use.

6.3 Frequency

Both levels of control must be run on all Sysmex XN instruments every 8 hours of patient testing.
QC must also be performed after shutdown, maintenance or instrument repairs.

Refer to addendum 4 "QC Instructions on Sysmex the XN" of the procedure *Sysmex XN Series Operation for CBC and Reticulocytes* to perform parallel testing for new lots of QC materials.

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Tolerance Limits

The Hematology QC program is monitored in the instrument and should be set up using the Evidence-based QC Limit % Range specific for XN analyzers. These limits are provided by Sysmex and are intended to ensure reasonable error detection capability and minimal false rejection rates. Target values for each

level of control will be calculated based on the data collected in the new lot evaluation.

B. Criteria for Acceptable QC

- All Controls must be within the acceptable range.
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

C. Corrective Action

- All rejected runs must be effectively addressed and include the following documentation:
    - Control(s) that failed and/or atypical or unexpected patient results
    - Actions taken
    - Statement of what was done with the patient samples from the affected run/batch,
    - Date and initials of the person recording the information.
- Patient samples in failed analytical runs must be reanalyzed.
- **Precision Statistics:** When there is a significant shift/bias on QC data, the root cause of the increased imprecision must be investigated and a resolution needs to be considered immediately. All of these actions must be documented including an evaluation of whether or not this affected patient care.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

- QC tolerance limits are programmed on the instrument; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Lead Technologist or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance

- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.

- QC is submitted to Sysmex for peer group comparison as it is run
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Sysmex XN Series 1000/3000

7.2 Equipment

Refrigerator

7.3 Supplies

Pipettes
12 x 75mm disposable culture tubes
Glass Micro cups

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	QC Run
1.	Verify the indicator LED light is solid green (not flashing)
2.	Press the mode switch, the tube holder slides out forward
3.	Select the **Change Analysis Mode** and choose **Body Fluid**, the instrument will automatically perform a background check. Wait until the background check is completely finished before moving on to the next step. **Note:** When the instrument is in the Body Fluid mode, background checks are done before and after each sample. Operator does not need to manually initiate a background check. The instrument automatically verifies background checks and if these are not acceptable it will repeat the background check until it passes.
4.	Select **Manual Analysis** button
5.	Click the **Read ID** box
6.	Ensure the **Cap Open** box is not checked. Run QC with the cap on. Only check this box if QC gets down to 1 mL in the vial, at that time remove the cap on the vial.
7.	Mix the QC vial by inverting it 4 times and then place the vial in the tube holder on the instrument.
8.	Press the **Start** switch on the analyzer

8.2	Test Run
1.	Verify the indicator LED light is solid green (not flashing)
2.	Press the mode switch, the tube holder slides out forward
3.	Select the **Change Analysis Mode** and choose **Body Fluid**, the instrument will automatically perform a background check. Wait until the background check is completely finished before moving on to the next step. **Note:** When the instrument is in the Body Fluid mode, background checks are done before and after each sample. Operator does not need to manually initiate a background check. The instrument automatically verifies background checks and if these are not acceptable it will repeat the background check until it passes.
4.	Select the **Manual Analysis** button
5.	Click the **Read ID** box, and scan the patient barcode so that the accession number populates. If the sample does NOT have a bar code, then click **Query to Host** and manually type the accession number into Sample ID field.
6.	Choose (click) the **Cap Open** box
7.	• Label a 12 x 75 mm tube with the patient label and confirm ID by matching to the original sample. • Mix the sample in its original container and then pipette 0.5 mL into the labeled 12 x 75 mm tube. • Place the 12 x 75 mm tube in the tube holder on the instrument. **Note**: For small volume samples, label a micro cup with an LIS small label (foot) and pipette 200 µL into it. Place the cup on the instrument.
8.	Press the **Start** switch on the analyzer

8.3	Color and Appearance
1.	Examine the CSF for appearance and color.
2.	**Appearance**: Indicate what the fluid looks like before centrifugation; use the descriptions shown in DI (refer to addenda).
3.	**Color**: Centrifuge an aliquot for the time and speed posted on centrifuge to remove the cellular elements. Examine the supernatant and report the color using the descriptions shown in DI (refer to addenda).

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

All calculations will be performed by Data Innovations (DI).

TC-BF# count from the Sysmex is reported as (number) x 10^3 cells/µL.
Count must be converted to cells/µL (DI will multiply Sysmex result by 1,000).

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Examples:

a. TC-BF# count (Sysmex) = 20.5 x 10^3 cells/μL
20.5 x 1000 = 20,500 cells/μL

b. TC-BF# count (Sysmex) = 0.5 x 10^3 cells/μL
0.5 x 1000 = 500 cells/μL

RBC-BF# count from the Sysmex is reported as (number) x 10^6 cells/μL.
Count must be converted to cells/μL (DI will multiply Sysmex result by 1,000,000.

Example:

a. RBC-BF# count (Sysmex) = 0.004 x 10^6 cells/μL
0.004 x 1000,000 = 4,000 cells/μL

WBC-BF# count from the Sysmex is reported as (number) x 10^3 cells/μL.
Count must be converted to cells/μL (DI will multiply Sysmex result by 1,000).

Examples:

a. WBC-BF# count (Sysmex) = 20.5 x 10^3 cells/μL
20.5 x 1000 = 20,500 cells/μL

b. WBC-BF# count (Sysmex) = 0.5 x 10^3 cells/μL
0.5 x 1000 = 500 cells/μL

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

TC-BF (total nucleated cell count, body fluid) is the total cell count in a body fluid; this parameter includes WBCs and high-fluorescing non-WBCs. TC-BF value has taken the WBC count and added in the unknown larger cells that Sysmex has seen in the sample. The instrument may see some high fluorescent cells that it cannot identify; they are NOT WBCs but typically are malignant cells, tumor cells, mesothelial cells, and etc.; those large unknown cells that are seen in body fluids. The instrument provides the known WBC count (the true white blood cells) and then adds in any of these unknown cells to calculate the Total Nucleated cell count (TC-BF).
If the TC-BF count and the WBC-BF count are significantly different it will alert the physician that there is some other type of cells present in the body fluid besides just white blood cells.

When the difference between TC-BF and WBC-BF exceeds the TEa (see table below), a manual differential count will be required. TEa will be calculated by DI.

Fluid	TEa
CSF	20 %

WBC-BF (white blood cell count, body fluid) this parameter includes WBCs.

RBC-BF (red blood cell count, body fluid) this parameter includes RBCs.

PMN is the polymorphonuclear (Granulocytes: Neutrophil, Eosinophil, and Basophil) cell count in a body fluid. These cells are consistent with acute inflammatory conditions. PMN is reported as both whole number and percent.

MN is the mononuclear (cells with a single granulated cytoplasm: Lymphocyte and Monocyte) cell count in a body fluid. These cells are consistent with chronic inflammatory response. MN is reported as both whole number and percent.

10.2 Rounding

Any result rounding is performed at the interface level.

10.3 Units of Measure

Cells	Result from Sysmex	Final result in LIS
TC – BF#	10^3/ µL	cells / µL
WBC – BF#	10^3/ µL	cells / µL
RBC – BF#	10^6/ µL	cells / µL
MN #	10^3/ µL	cells / µL
MN %	%	%
PMN #	10^3/ µL	cells / µL
PMN %	%	%

10.4 Analytical Measurement Range (AMR)

Parameter	Sysmex XN Series	LIS Range
TC – BF#	0.003 – 10.000 x 10^3/µL	3 – 10,000 cells/µL
WBC – BF#	0.003 – 10.000 x 10^3/µL	3 – 10,000 cells/µL
RBC – BF#	0.002 – 5.000 x 10^6/µL	2,000 – 5,000,000 cells/µL
MN #	0.003 – 10.000 x 10^3/µL	3 – 10,000 cells/µL
PMN #	0.003 – 10.000 x 10^3/µL	3 – 10,000 cells/µL
MN %	0.0 – 100.0 %	0 – 100 %
PMN %	0.0 – 100.0 %	0 – 100 %

10.5 Review Patient Data

- Review patient results for unusual patterns, trends or distribution.
- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

10.6 Repeat Criteria and Resulting

Parameters to be reported are listed in section 10.3.

IF the TC-BF# or WBC-BF# result is…		THEN…
From Sysmex	**From DI/LIS**	
<0.003 x 10^3/µL	<3 cells/µL	Report the result as <3 cells/µL
>10.000 x 10^3/µL	>10,000 cells/µL	Make a 1:10 dilution with Cellpack DCL to obtain a number within the reportable range. The dilution factor is entered in DI. If the result remains >10.000 x 10^3/µL after dilution, report as >10,000 cells/µL.

IF the RBC-BF# result is …		THEN…
From Sysmex	**From DI/LIS**	
<0.002 x 10^6/µL	<2,000 cells/µL	Report the result as <2,000 cells/µL
>5.000 x 10^6/µL	>5,000,000 cells/µL	Report as >5,000,000 cells/µL

IF the MN# and/or PMN# result is …		THEN…
From Sysmex	**From DI/LIS**	
<0.003 x 10^3/µL	<3 cells/µL	Report the result as <3 cells/µL

Manual Differential:
A manual differential must be performed if difference between TC-BF and WBC-BF exceeds the TEa of 20%. Refer to the procedure *CSF Cell Count and Differential, Manual Method* for detailed instructions.

11. EXPECTED VALUES

11.1 Reference Ranges

Parameter / Units of Measurement	Both Male and Female	
	Neonate	**Adult**
Color	Colorless	
Appearance	Clear	
RBC - BF cells/µL	None	None
WBC - BF cells/µL	0 - 30	0 - 5
TC - BF cells/µL	None established	
PMN # cells/µL	0 – 0.08	0 – 0.06
MN # cells/µL	0.6 – 1.0	0.6 – 1.0
PMN %	0 - 8%	0 - 6%
MN %	60 - 100%	60 - 100%

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Cerebrospinal fluid analysis is utilized to diagnose meningitis, intracranial hemorrhage, leukemia, malignancies and central nervous system disorders. Cell count determination is part of the analysis.

13. PROCEDURE NOTES

- **FDA Status:** Approved/Cleared
- **Validated Test Modifications:** None

This section explains the Interpretive Program (IP) message generated by the Sysmex XN analyzer and the corrective action.

13.1	WBC Abn Scattergram
Cause: Clustering in the WDF scattergrams is abnormal; meaning analyzer cannot separate the cell population with confidence.	
Corrective Action: 1. If dashes or asterisk appear in place of data: a. Repeat the sample b. If dashes or asterisk still remain, perform a manual differential and cell count	

14. LIMITATIONS OF METHOD

14.2 Precision

Precision is assessed by analysis of body fluid. The data appears consistent and all parameters have a low CV%.

14.3 Interfering Substances

None

14.4 Clinical Sensitivity/Specificity/Predictive Values

None

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

- Safety Data Sheets
- Sysmex XN Reference Manual
- Critical Values (Lab policy)
- Quality Control Program policy
- Quest Diagnostics Records Management Program
- Laboratory Safety Manual
- Data Innovations Instrument Manager; Laboratory Policy
- CSF Cell Count and Differential, Manual Method; Hematology procedure
- Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls

17. REFERENCES

1. Quest Diagnostics Best Practice Sysmex XN Series Operation for CBC SOP, revised 04/03/2017
2. Quest Diagnostics Best Practice Sysmex XN Series Operation for Automated Nucleated Cell Counts in Body Fluid, revised 12/2017
3. Sysmex Hematology Analyzer XN Series Instruction for use, revised 07/2015
4. Sysmex XN – 3000 Automated Hematology System Quick Guide, revised 01/2013
5. Sysmex XN Check BF Quality Control Package Insert, revised 10/2016

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
0	10/12/18	6.2, 8.1, 8.2	Additional QC information and test run instructions added during SOP validation	L Barrett	R SanLuis
1	11/7/18	Add A	Added comment codes and path review process	L Barrett	R SanLuis
2	1/28/19	3.1	Added reference to Add A to report diff	L Barrett	R SanLuis
2	1/28/19	Add A	Added one tube rule	L Barrett	R SanLuis
3	5/16/19	2	Modified local test codes	D Concepcion	R SanLuis
3	5/16/19	8.3	Added color and appearance instructions	L Barrett	R SanLuis
3	5/16/19	Add A	Added DTYPE and CSF grouping; updated color choices. Added examples of various resulting scenarios and order of release. Added manual RBC for peds	D Concepcion	R SanLuis
4	5/22/19	10.6	Corrected instruction for TC >10,000	H Genser	R SanLuis

19. ADDENDA

A. DI (Data Innovations) Information and Actions

Addendum A

DI (Data Innovations) Information and Actions

A. Instrument and DI/SQ CSF Test Code Translation

Description	Instrument Code	DI/SQ Codes			
		CSF Tube 1	CSF Tube 2	CSF Tube 3	CSF Tube 4
Color	N/A	CCOL1	CCOL2	CCOL3	CCOL4
Appearance	N/A	CAPP1	CAPP2	CAPP3	CAPP4
White Blood Cells	WBC-BF	CWBC1	CWBC2	CWBC3	CWBC4
Red Blood Cells	RBC-BF	CRBC1	CRBC2	CRBC3	CRBC4
Mononuclear Cells Absolute	MN#	CMN1	CMN2	CMN3	CMN4
Mononuclear Cells Absolute	MN%	CMNP1	CMNP2	CMNP3	CMNP4
Polymorphonuclear Cells Percent	PMN#	CPMN1	CPMN2	CPMN3	CPMN4
Polymorphonuclear Cells Percent	PMN%	CPMNP1	CPMNP2	CPMNP3	CPMNP4
Total Nucleated Cell Count Absolute	TC-BF#	CTC1	CTC2	CTC3	CTC4
CSF Comment	N/A	CCOM1	CCOM2	CCOM3	CCOM4
CSF Manual RBC Count	N/A	CFR1	CFR2	CFR3	CFR4
Differential Type (ADIFF Group)	N/A	CDTYP1	CDTYP2	CDTYP3	CDTYP4
Differential Type (MDIFF Group)	N/A	CDTYM1	CDTYM2	CDTYM3	CDTYM4

B. Available Cell Counters

CSF Cell Counters
SGMC CSF Cell Counter
WAH CSF Cell Counter
GEC CSF Cell Counter

C. CSF Grouping

The Hematology Run Worksheet displays the CSF results in three groups. The groups are CSF Tube # (Tube 1 to 4), CSF ADIFF, and CSF MDIFF. See the description of each group below.

CSF Tube # group displays the automated count

CSF ADIFF group displays the automated differential

CSF MDIFF group displays the manual differential. The MDIFF groups is on a different run than the automated groups

Run Worksheet

Test Name	Test St...	Result (1)	Units (1)	Error Code(s) (1)	Error Name(s) (1)	Test St...	Result (2)	Uni
CSF Tube 3								
CCOL3	Held fo...			HOLD	HOLD			
CAPP3	Held fo...			HOLD	HOLD			
CWBC3	Held fo...	500	cells/uL	TEA,HOLD	Exceeds TEA. Perform DIFF			
CRBC3	Held fo...	400000	cells/uL	HOLD	HOLD			
CTC3	Held fo...	700	cells/uL	HOLD	HOLD			
CFR3	Held fo...	HIDE		HOLD	HOLD			
CSF Auto DIFF								
CDTYP3	Held fo...	ADIFF		HOLD	HOLD			
CMN3	Held fo...	5100	cells/uL	HOLD	HOLD			
CMNP3	Held fo...	60.0	%	HOLD	HOLD			
CPMN3	Held fo...	5200	cells/uL	HOLD	HOLD			
CPMNP3	Held fo...	40.0	%	HOLD	HOLD			
CSF Manual DIFF								
CDTYM3						Held fo...	MDIFF	
DilutionFactor						Held fo...	NONE	
CCOM3						Held fo...	PATHR	
CPOL3%						Held fo...	40	%
CLYMP3%						Held fo...	30	%
CMM3%						Held fo...	20	%
CEOS3%						Held fo...	10	%

D. Only One Tube Rule

1. DI will add a test called "Only_Tube_One" to the CT1 order. Tech must result this as **YES** or **NO**, which triggers DI to control the outcome:
   - If **YES** is selected, then do not hide autodiff (it will be reported).
   - If **NO** is selected, then hide auto-diff.

Test Name	Test St...	Result (1)	Units (1)	Error Code(s) (1)	Error Name(s) (1)
CSF Tube 1					
Only Tube One?	Held fo...	YES		HOLD	Report Auto-DIFF when only one CSF Tube is submitted
CCOL1	Held fo...			HOLD	HOLD
CAPP1	Held fo...			HOLD	HOLD
CWBC1	Held fo...	50	cells/uL	HOLD	HOLD
CRBC1	Held fo...	4900	cells/uL	HOLD	HOLD
CTC1	Held fo...	50	cells/uL	HOLD	HOLD
CFR1	Held fo...	HIDE		HOLD	HOLD
CSF Auto DIFF					
CDTYP1	Held fo...	ADIFF		HOLD	HOLD
CMN1	Held fo...	30	cells/uL	HOLD	HOLD
CMNP1	Held fo...	93.2		HOLD	HOLD
CPMN1	Held fo...	30	cells/uL	HOLD	HOLD
CPMNP1	Held fo...	6.8		HOLD	HOLD

2. If a physician requests a hidden autodiff be reported, then use function MEM to result:
   - Worksheet: enter appropriate code (WHE, SHE or GHE)
   - Accession number: enter M- accession number (*example*: M-T1234)
   - Press enter through all prompts until you see the auto-diff tests with HIDE.
   - Re-key the numeric value under the HIDE-value. Accept changes

E. To adjust the diluted result by the dilution factor:

Dilution **with** Manual Diff

1. Access the CSF Cell Counter and Select the **Dilution Factor** used to **"10x"** from the drop down menu.
2. Perform the differential. .
3. Select the **CDTYM** (CSF Diff Type) to "**MDIFF**" from the drop down menu
4. Send the data through the System. DI will apply the dilution factor
5. **The manual diff results and the adjusted CSF automated count results (CSF Tube #) will be displayed on the Run Worksheet as a new run**. The CSF automated differential count group (CSF ADIFF) will not be displayed. DI will add an error code of "Check Dilution" and "Dilution Factor Applied" to the WBC.

Dilution **without** Manual Diff

1. Access the CSF Cell Counter and Select the **Dilution Factor** used to **"10x"** from the drop down menu.
2. Select the **CDTYM** (CSF Diff Type) to "**ADIFF**" from the drop down menu
3. Send the data through the System. DI will apply the dilution factor
4. **The adjusted results from the CSF automated count group and the CSF ADIFF group will be displayed on the Run Worksheet as a new run.** The color and appearance will need to be resulted. DI will add an error code of "Check Dilution" and "Dilution Factor Applied" to the WBC. See example below

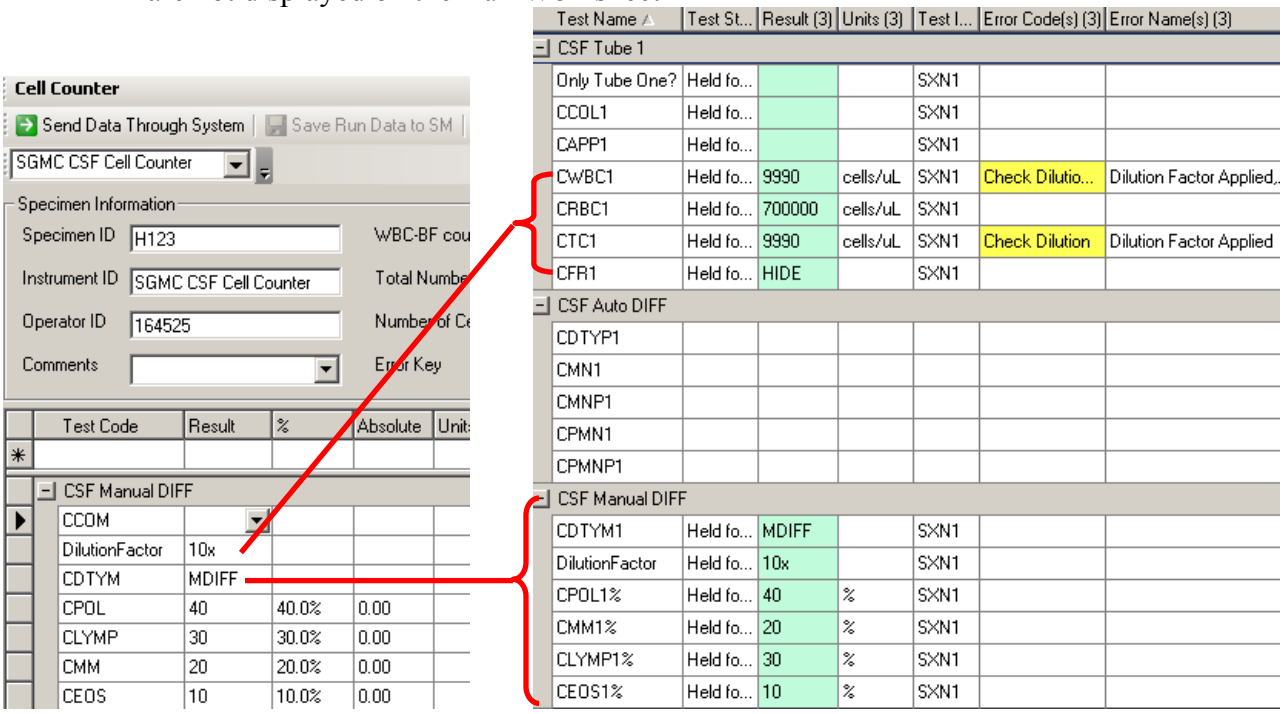
Examples:

1. Diluted results before the dilution factor is applied

Test Name	Test St...	Result (1)	Units (1)	Test I...	Error Code(s) (1)	Error Name(s) (1)
CSF Tube 1						
Only Tube One?	Held fo...			SXN1	HOLD	Report Auto-DIFF when...
CCOL1	Held fo...			SXN1	HOLD	HOLD
CAPP1	Held fo...			SXN1	HOLD	HOLD
CWBC1	Held fo...	> 10000	cells/uL	SXN1	TEA,HOLD	Exceeds TEA. Perform ...
CRBC1	Held fo...	700000	cells/uL	SXN1	HOLD	HOLD
CTC1	Held fo...	9990	cells/uL	SXN1	HOLD	HOLD
CFR1	Held fo...	HIDE		SXN1	HOLD	HOLD
CSF Auto DIFF						
CDTYP1	Held fo...	ADIFF		SXN1	HOLD	HOLD
CMN1	Held fo...	3000	cells/uL	SXN1	HOLD	HOLD
CMNP1	Held fo...	93.2		SXN1	HOLD	HOLD
CPMN1	Held fo...	3000	cells/uL	SXN1	HOLD	HOLD
CPMNP1	Held fo...	6.8		SXN1	HOLD	HOLD

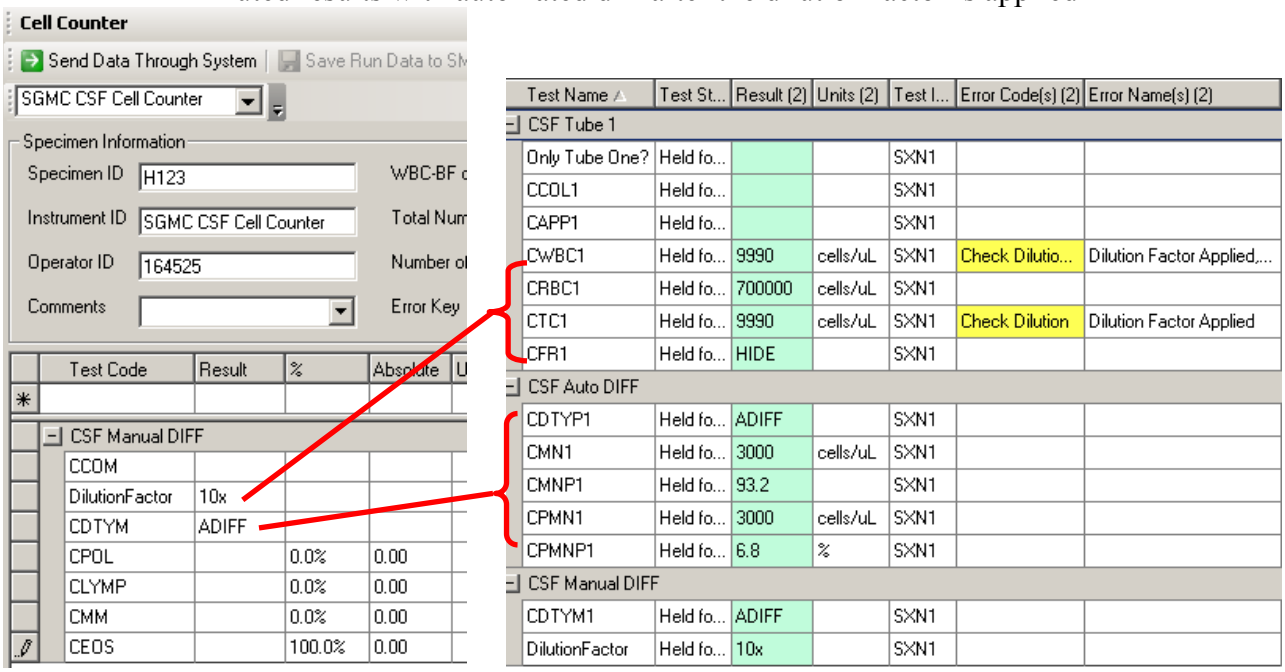
a) For Dilution with Manual Diff

Diluted results with manual diff after the dilution factor is applied. The results for ADIFF are not displayed on the Run Worksheet



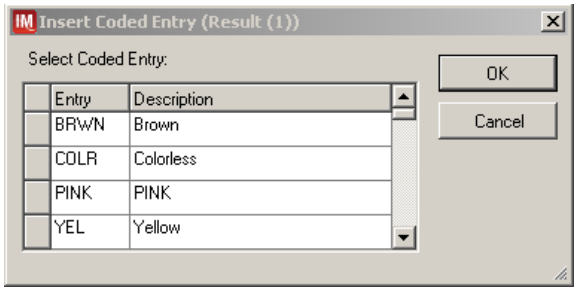
b. For Dilution with Automated Diff

Diluted results with automated diff after the dilution factor is applied

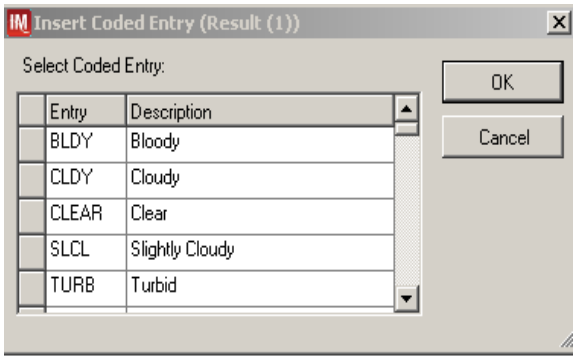


E. Resulting Color and Appearance

1. Select the CCOL# to match the tube tested, and right click. Select the **Insert Coded Entry**.
2. Select the appropriate color and press **OK**.



3. Select the CAPP# to match the tube tested, and right click. Select the **Insert Coded Entry**.
4. Select the appropriate appearance and press **OK**.



F. TEa and Manual Differential

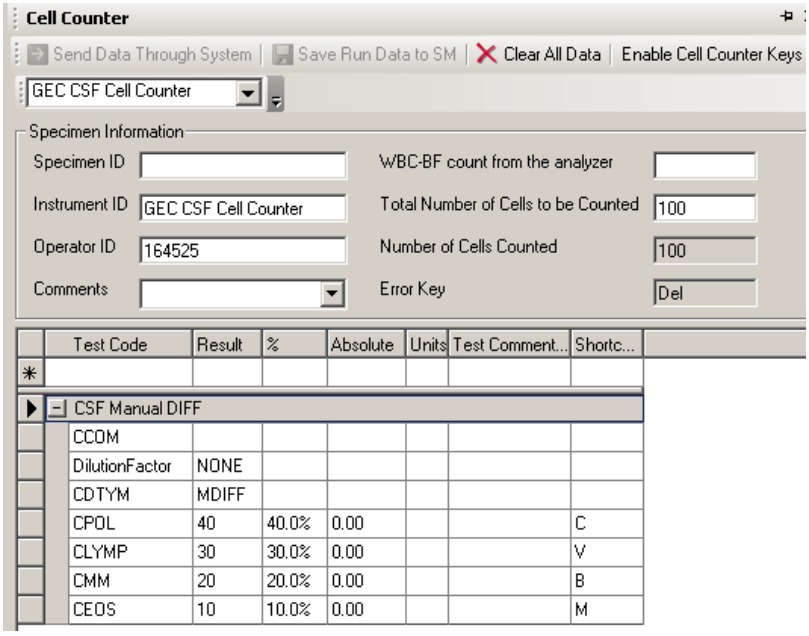
DI will display an error of "Exceeds TEa, Perform DIFF" whenever the difference between TC-BF and WBC-BF exceeds the TEa. A manual differential count is required whenever error code "TEA HOLD" is seen.

Test Name	Test St...	Result (1)	Units (1)	Error Code(s) (1)	Error Name(s) (1)	Test St...	Result (2)	Units (2)
CSF Tube 3								
CCOL3	Held fo...			HOLD	HOLD			
CAPP3	Held fo...			HOLD	HOLD			
CWBC3	Held fo...	500	cells/uL	TEA,HOLD	Exceeds TEA. Perform DIFF			
CRBC3	Held fo...	400000	cells/uL	HOLD	HOLD			
CTC3	Held fo...	700	cells/uL	HOLD	HOLD			
CFR3	Held fo...	HIDE		HOLD	HOLD			
CSF Auto DIFF								
CDTYP3	Held fo...	ADIFF		HOLD	HOLD			
CMN3	Held fo...	5100	cells/uL	HOLD	HOLD			
CMNP3	Held fo...	60.0	%	HOLD	HOLD			
CPMN3	Held fo...	5200	cells/uL	HOLD	HOLD			
CPMNP3	Held fo...	40.0	%	HOLD	HOLD			

G. CSF Cell Counter

The CSF Cell Counter works for all CSF tubes. The test codes that are displayed on the cell counter get translated to their corresponding test codes for that tube. The translation occurs when the "Send Data Through System" is selected. The test codes are updated to reflect the tube number that testing was performed on. *Example*: when you are working on tube 3, CPOL on the Cell Counter will be translated to CPOL3 on the run workspace.

Cell Counter Test Code	Description	Tube #1 Test Code	Tube #2 Test Code	Tube #2 Test Code	Tube #4 Test Code
CCOM	Comment	CCOM1	CCOM2	CCOM3	CCOM4
CDTYM	Cell Counter CSF Diff Type	CDTYM1	CDTYM2	CDTYM3	CDTYM4
CPOL	CSF Poly	CPOL1	CPOL2	CPOL3	CPOL4
CLYMP	CSF Lymph	CLYMP1	CLYMP2	CLYMP2	CLYMP2
CMM	CSF Mono	CMM1	CMM2	CMM2	CMM2
CEOS	CSF EOS	CEOS1	CEOS2	CEOS2	CEOS2



The following coded entries are available for CDTYM (Cell Counter CSF Diff Type). CDTYPM is only defined in DI and not in SQ. It serves as a place holder for the type of differential performed for the cell counter.

Code	Interpretation	Explanation
ADIFF	Automated Diff	If dilution is performed but no manual diff, the differential type is ADIFF since you want to use the auto-diff from the instrument.
MDIFF	Manual Diff	If you want to do dilution and a manual diff, then the diff type is MDIFF since you want to use the diff from the cell counter.

The following coded entries are available for CCOM (Comment) field:

Code	Interpretation
SAGE	Counts may not be accurate due to specimen age
SFPR	Submitted for Path Review
SCLOT	Specimen contains clots, counts may not be accurate
SCYT	See Cytology Report

H. Order of Release

CSF Cell Count and diff reporting consists of three (3) groups in DI. Below is the order in which they need to be released in DI to ensure proper filing into Sunquest.

Diluted Results with Automated Diff (doesn't need Manual Diff)

- Release the CSF Tube #group
- Release the CSF ADIFF group
- Release the CSF MDIFF group (Note. This group has the CDTYM#, Dilution factor and CCOM# results)

Diluted Results with Manual Diff

- Release the CSF Tube #group
- Release the CSF MDIFF group
- Reject the CSF ADIFF group from the previous run

Undiluted Results with Automated Diff

- Release the CSF Tube #group
- Release the CSF ADIFF group
- Release the CSF MDIFF group

Undiluted Results with Manual Diff

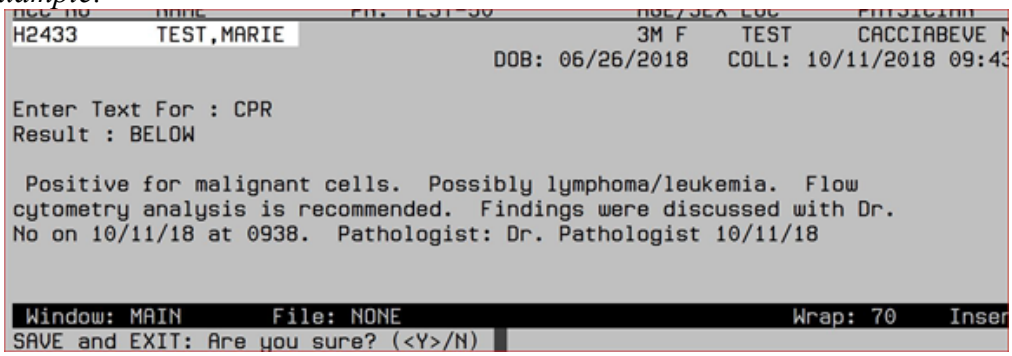
- Release the CSF Tube #group
- Release the CSF MDIFF group
- Release the CSF ADIFF group from the previous run

I. Pathologist Review Process

1. To submit slides for path review -
   - Add order code CPATH to the Accession via REI or GUI Order Entry.
   - Complete Pathologist Slide Review Request form.
   - Give slide(s) and review form to the pathologist.

2. When the Pathologist Slide Review form and slide(s) are returned to the lab, enter results into the LIS via SmartTerm. Note: This should also include the pathologist's comments or assessment regarding the diff count which has already been reported in SmartTerm. The original reported diff does NOT need to be corrected.

   Example:



Example of display in Sunquest Inquiry:

H2433 COLL: 10/11/2018 09:43 REC: 10/11/2018 09:53 PHYS: CACCIABEVE MD, Req. No.:

CSF Path Review
CSF Path Review See below
(See Below)
Positive for malignant cells. Possibly lymphoma/leukemia. Flow cytometry analysis is recommended. Findings were discussed with Dr. No on 10/11/18 at 0938. Pathologist: Dr. Pathologist 10/11/18

CSF Tube 3

Apperance tube 3	Cloudy	[CLEAR]	
Color tube 3	Colorless	[COLR]	
CSF WBC Tube 3	2	[0-5]	cell/mcL
CSF RBC Tube 3	12		cells/mcL
CSF Polys tube 3	20	%	
CSF Lymph tube 3	54	%	
Submitted for path review			
CSF Macro/Mono tube 3	16	%	
CSF EOS tube 3	10	%	

J. Manual RBC Count on Pediatric Patient

IF……	THEN……
If the automated RBC count is less than 2,000 cells/µL **AND** the patient age is < 18 years old	DI will display an error code of "Manual Count, Perform Manual RBC Count". • The automated RBC count (CRBC#)* will be replaced by HIDE • The manual RBC count (CFR#)* will be added • Perform manual count and record results on Cell Count worksheet • In DI, enter count result in CFR# field. See example below
If the automated RBC count is less than 2,000 cells/µL and patient age is 18 years old and over	Automated RBC count will be reported as <2,000 cells/µL (see note below)
If the automated RBC count is greater than or equal to 2,000 cells/µL (any age)	Automated count will be reported

* The # will display to indicate the actual tube order (ie, tube 1 = CRBC1 and CFR1; tube 2 = CRBC2 and CFR2, etc.)

Example of a patient result who is less than 18 yrs. old with RBC count less than 2,000 cells/µL

Result of CRBC# was <2000 cells/uL. The result got replaced with HIDE

Enter result of Manual RBC Count from the Manual Worksheet

Run Worksheet

Test Name	Test St...	Result (1)	Units ...	Test I...	Error Code(s) (1)	Error Name(s) (1)
CSF Tube 2						
CAPP2	Held fo...			SXN1	HOLD	HOLD
CCOL2	Held fo...			SXN1	HOLD	HOLD
CWBC2	Held fo...	500	cells/...	SXN1	HOLD	HOLD
CRBC2	Held fo...	HIDE		SXN1	Manual Count,HO...	Perform Manual RBC Count
CTC2	Held fo...	500	cells/...	SXN1	HOLD	HOLD
CFR2	Held fo			SXN1	HOLD	HOLD
CSF Auto Diff						
CDTYP2	Held fo...	ADIFF		SXN1	HOLD	HOLD
CMN2	Held fo...	3000	cells/...	SXN1	HOLD	HOLD
CMNP2	Held fo...	93.2	%	SXN1	HOLD	HOLD
CPMN2	Held fo...	3000	cells/...	SXN1	HOLD	HOLD
CPMNP2	Held fo...	6.8	%	SXN1	HOLD	HOLD

Note: If a physician requests a manual RBC after an automated count is reported, then

1. Perform manual count and record on Cell Count worksheet
2. Use function MEM to replace HIDE result for code CFR# with actual count