TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/18/2018
Department:	Core Lab	**Due Date:**	8/7/2018
		Implementation:	**8/7/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Sysmex XN Series Operation for CBC and Reticulocytes SGAH.H963 v4

Delta Check SGAH.QA25 v5

Description of change(s):

Sysmex SOP *(only addendum 7 is included with SOP, other removed because no changes to them)*

Section	Reason
10.6, Addenda 7	Added action for plt between 50-100; Added scan if retic >6.0% for ages >30 days
10.6	Slide review process changed to release tech results and order manual diff for path review

Delta SOP:

Section 9: Changed platelets time frame from 24hr to 72hr

These revised SOPs will be implemented on August 7, 2018

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

Technical SOP

Title	**Sysmex XN Series Operation for CBC and Reticulocytes**	
Prepared by	Ashkan Chini	Date: 5/17/2017
Owner	Robert SanLuis	Date: 5/17/2017

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**

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Hemogram *(WBC, RBC, HGB, HCT, MCV, MCH, MCHC ,RDW PLT, MPV)*	Sysmex XN Series (1000 or 3000)	CBCND
Hemogram & diff (*WBC,RBC,HGB,HCT,MCV,MCH,MCHC,RDW, PLT, MPV, differential)*		CBC
Differential count only		DIFF
Platelet Count		PLTC
Reticulocyte (*Percent, Absolute, RET-He)*		RCOUNT

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Abbreviation	Term	Abbreviation	Term
WBC	White Blood Cell	MCHC	Mean Corpuscular Hemoglobin Concentration
RBC	Red Blood Cell		
HGB	Hemoglobin	RDW	Red Cell distribution Width
HCT	Hematocrit	DIFF	Differential Count
MCV	Mean Cell Volume	PLT	Platelet
MCH	Mean Corpuscular Hgb	MPV	Mean Platelet Volume
RETIC	Reticulocyte Count	IPF	Immature Platelet Fraction
RET-He	Reticulocyte Hgb Equivalent	IG	Immature Granulocytes

Department
Hematology

2. ANALYTICAL PRINCIPLE

The RBC detector counts the RBC and PLT via the Hydro Dynamic Focusing. At the same time, the hematocrit is calculated via the RBC pulse height detection method.
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.
The PLT count is calculated as a particle count between lower and upper discriminator, which are automatically set up in the ranges of 2 – 6 fL and 12 – 30 fL. PLT particular size distributions are checked for abnormalities, including abnormal relative frequencies at the lower discriminator, abnormal distribution widths, and existence of more than one peak.
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 and nucleated RBC. This scatter gram displays groups of nucleated RBC, basophil, non-basophil WBC, hemolyzed RBC and platelets.
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.
Sysmex XN does not use the formula HCT = (RBC x MCV)/10; instead it directly measures hematocrit by adding up the cumulative number and heights of the pulses determined during the RBC counting process.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	N/A
Special Collection Procedures	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred	K_3EDTA or K_2EDTA Whole Blood	
-Other Acceptable	Sodium Citrate – for platelet count only	
Collection Container	Lavender Top Tube or Microtainer Blue Top Tube (Sodium Citrate)	
Volume - Optimum	Full Tube	
- Minimum	Adult: 1.0 mL, Microtainer: 0.5 mL	
Transport Container and Temperature	Collection container at room temperature	
Stability & Storage Requirements	Room Temperature:	48 Hours
	Refrigerated:	48 Hours
	Frozen:	N/A
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Notify the attending nurse or physician and request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Example Quantity no sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS. Refer to section 13.11 for Icterus & Lipemic specimens	
Compromising Physical Characteristics	Gross hemolysis: Refer to section 13.11	
Other Considerations	Cancel clotted specimens, notify the attending nurse or physician and request a redraw.	

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 Clean Auto	Sysmex Corporation, Cat. No. CF579595
Cell Pack DCL	Sysmex Corporation, Cat. No. DCL-300A
Cell Pack DFL	Sysmex Corporation, Cat. No. BT965910
Fluorocell PLT	Sysmex Corporation, Cat. No. CD994563
Fluorocell RET	Sysmex Corporation, Cat. No. BN337547
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
Wrigh-Giemsa Stain	Sysmex Corporation, Cat. No. ACC-SP5741
Phosphate Buffer Solution, pH6.8	Sysmex Corporation, Cat. No. ACC-SP5548
Methyl Alcohol Absolute	Medical Chemical corporation, Cat. No. 107B
NERL Reagent Grade Water	Thermo Fisher Scientific, Cat. No. 9800-4

4.2 Reagent Preparation and Storage

Reagent	Cell Clean Auto
Storage	Store at 1 - 30°C. Avoid exposing to direct sunlight
Stability	This reagent is for single use only. Once the product stopper is punctured, the remaining reagent must be thrown away after each use.
Preparation	None

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

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

Reagent	Lysercell WNR
Storage	Store at 2 - 35°C. Avoid exposing to direct sunlight

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Stability	Once in use, this reagent remains 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, this reagent remains stable for 60 days.
Preparation	None

Reagent	Wright – Giemsa Stain
Storage	Store at 15 - 30°C
Stability	Reagent is stable unopened and opened until the expiration date on the container.
Preparation	None

Reagent	Phosphate Buffer Solution, pH 6.8
Storage	Store at 15 - 30°C
Stability	Reagent is stable unopened and opened until the expiration date on the container.
Preparation	None

Reagent	Methyl Alcohol Absolute
Storage	Store at 15 - 35°C
Stability	Reagent is stable unopened and opened until the expiration date on the container.
Preparation	None

Reagent	NERL Reagent Grade Water
Storage	Store at room temperature
Stability	Reagent will remain stable for 30 days after opening
Preparation	None

Auto Rinse needs to be run after every reagent change; to run an Auto Rinse:

- Click the **Analyzer Menu** button
- Select **Auto Rinse**
- Once complete, [Auto Rinse] disappears and the background check begins
- Background check performs analysis without aspirating the sample to verify the effects of the auto rinse
- When Background check is finished, from the **Main Menu**
- Select **Sample Explorer**
- High light the background check which was just run
- Click **Validate**
- Report prints

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Note: There should be no values on the report; only zeros and dashes should appear. If any value other than zero appears on the report, that means the background check has failed and the instrument will flag the failure.

- Review and sign the printed report and place in the Sysmex Maintenance binder.

To get reagent details, such as when it was placed onboard, lot number, expiration date and volume; From **Main Menu** select **History**, then click on **Reagent Replacement Log** tab.

To scan a reagent:

- From **Main Menu** either click on the reagent picture or click on **Analyzer Manu** then select **Reagent Replacement**.
- Select the desired reagent
- Select **Replace the Reagent**
- Click on the blank space below **Reagent Code**, make sure the cursor is blinking, then scan the barcode of the reagent
- Click on **Execute**

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier& Catalog Number
XN CAL™	Sysmex 213527
XN CAL™ PF	Sysmex 213536

5.2 Calibrator Preparation and Storage

Calibrator	**XN CAL™, XN CAL™ PF**
Storage	Store at 2-8°C in a dark refrigerator.
Stability	Unopened: Manufacturer's Expiration Date Opened: 4 hours
Preparation	Calibrator is supplied ready to use. Bring to room temperature prior to testing. Mix per manufacturer's guidelines.

5.3 Calibration Criteria and Procedure

Criteria	Special Notations
Frequency	• Assay calibration must be performed when the instrument is first placed in service and at least every 6 months thereafter. This process is managed by Sysmex Customer Support Center.

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Criteria	Special Notations
	1) First half of the year: Field Service Engineer (FSE) will perform the calibration. 2) Second half of the year: Customer Support Center will ship the calibrator ahead of the time. They will contact the Insight account holders prior to the calibration due date to inform them of the date and time for the calibration. • In addition, calibration verification is required (regardless of the length of time since last performed) immediately if any of the following occurs: 1) When control data indicates a significant shift in assay results and cannot be corrected by maintenance or troubleshooting. 2) After major maintenance, service or replacement of critical parts. 3) When advised by Sysmex Field Service Representative.
Tolerance Limits	Sysmex will provide a calibration report: 1) Review Reagents Information and Calibration Materials to verify all products used for calibration are in-date. 2) On the Background Counts chart, the Count for each parameter must be less than the Limit. 3) On the Precision Open Mode chart, the CV% of each parameter must not exceed the % Limit. 4) On the Sensitivity Verification, each parameter's Mean must fall between Lower and Upper Limit. 5) On the Calibration of Directly Measured Parameters – a. The first run is always eliminated. b. The Mean of each parameter must fall between Lower and Upper Limit. c. If the current coefficient of variation is not the same as the new one, 10 points of QC must be run and reviewed and the QC ranges adjusted if necessary.
Procedure	• Calibration is performed by Sysmex FSE or • Calibration is performed by Sysmex through remote access. Customer must contact Sysmex to order calibration material, for any calibrations that are done outside of major maintenance by FSE or the Sysmex calibration schedule. • Refer to Chapter 12 of the Instructions for Use manual – Performing Calibration – The Customer will be guided by the Sysmex representative to run the calibrators and the values will be updated by the Sysmex representative. • If calibration factors (compensations rates) have been changed, calibration verification must be performed by running all levels of commercial control. • At the completion of the calibration, a certificate of calibration

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Criteria	Special Notations
	will be printed by the Sysmex FSE that must be reviewed by a Group Lead/ Supervisor or designee.

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
XN CHECK, Levels 1, 2 & 3	Sysmex Corporation, Cat. No. 213499

6.2 Control Preparation and Storage

Control	XN CHECK
Preparation	None
Storage	Store at 2 - 8°C
Stability	Unopened: manufacturer's expiration date Opened: 7 days when stored at 2 - 8° C after each use.

6.3 Frequency

All three levels of control must be run on all Sysmex XN instruments every 4 hours of patient testing. QC must also be performed after shutdown, maintenance or instrument repairs.

Refer to addenda 4 for instructions 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.

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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 Program

- 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. Refer to addenda 4 and 5
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Sysmex XN Series 1000/3000

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Sysmex Automated Slide Preparation Unit SP – 10 (SG/WAH only)

7.2 Equipment

Microscope
Refrigerator

7.3 Supplies

Immersion Oil
Applicator sticks
Glass Slides
Lens Paper
Sysmex Glass Slides for Stainer (SG/WAH only)
Ribbon for Stainer (SG/WAH only)
Glass Plate Spreader (SG/WAH only)

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	Maintenance
1	Perform required instrument maintenance. Refer to addendum 2 for details.
2	Perform required stainer maintenance (SG/WAH). Refer to addendum 3 for details.

8.2	Test Run
1	Place the racks in the right side feed conveyor. Pre- mixing of samples is not required.
2	Racks will automatically feed to the analyzer. Tubes are rotated to read barcode.
3	On-board IPU rules will determine repeat or reflex testing. Rack will run in reverse to perform the repeat or reflex test.
4	When load is completed, remove racks from left side feed conveyor.

8.3	Special Handling
1	To load a STAT specimen while the instrument is analyzing other samples: Press the mode switch button, the tube holder (for manual/pediatric samples) slides out forward; then run the STAT specimen in manual mode.
2	Aspiration sensor must remain ON all the time. The only times that Aspiration Sensor is turn off are: • When hemoglobin is < 4.0 • When Platelet Poor Plasma study is in progress

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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

The following calculations are performed automatically by the instrument. The formulas used to calculate MCV, MCH and MCHC are:

- MCV: (HCT/RBC) x 10
- MCH: (HGB/RBC) x 10
- MCHC: (HGB/HCT) x 100

The following calculations are performed when screening a slide and/or performing a differential (refer to Sections 10.6 and 13 for details)

WBC Estimate:
Calculate the average WBC in 10 fields using the 50X objective and multiply by 3,000. If WBC estimate does not agree with what the instrument has reported within ± 20%, repeat the estimate focusing on the feathered edge of the smear. If counts still do not agree, consult with the supervisor or tech in charge.

Platelet Estimate:
Calculate the average PLT in 10 fields using the 100X objective and multiply by 20,000. If PLT estimate does not agree with what the instrument has reported within ± 20%, repeat the estimate focusing on the feathered edge of the smear. If counts still do not agree, consult with the supervisor or tech in charge.

Megakaryocytes could potentially interfere with the WBC count.
If the WBC estimate does not correlate with the automated WBC count in the presence of five or more megakaryocytes, then correct the WBC count use the formula below. To get the uncorrected WBC, **Main Menu** – **Data Browser** – select **Service** tab – select **WNR**.
TNC – N has the uncorrected WBC count.

Corrected WBC = (Uncorrected WBC x 100) / (100 + # of megakaryocytes)

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The relationship of the RBC, HGB and HCT to MCV, MCH and MCHC			
Parameter Affected	**MCV**	**MCH**	**MCHC**
RBC ↓	↑	↑	No change
RBC ↑	↓	↓	No change
HGB ↓	No change	↓	↓
HGB ↑	No change	↑	↑

The relationship of the RBC, HGB and HCT to MCV, MCH and MCHC			
Parameter Affected	**MCV**	**MCH**	**MCHC**
HCT ↓	↓	No change	↑
HCT ↑	↑	No change	↓

10.2 Rounding

Any result rounding is performed at the interface level.

10.3 Units of Measure

Parameter	Units	Decimal	Parameter	Units	Decimal	Parameter	Units	Decimal
WBC	x10(3)/mcL	1	RBC	10^6/µL	1	HGB	g/dL	1
HCT	%	1	MCV	fL	1	MCH	pg	1
MCHC	g/dL	1	PLT	x10(3)/mcL	0	MPV	fL	1
RDW	%	1	Diff, auto	%	1	Retic	%	1
RET-He	pg	0	Diff manual	%	0	IPF	%	0
Retic absol	x10(6)/mcL	4	Diff absol	x10(3)/mcL	2	IG	%	1

10.4 Analytical Measurement Range (AMR)

Parameter	Sysmex XN Series
WBC	0 - 440 x 10^3
RBC	0.00 - 8.60 x 10^6
HGB	0 - 25 g/dL
HCT	0 - 75%
PLT, PLT-F	0 - 5,000 x 10^3
RET%	0 - 30.0%

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

Dilution:

Sysmex XN is not capable of doing any dilutions. Refer to WBC and RBC sections for dilution details, and then follow these steps to program them on the instrument:

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- Manually program the accession number by typing the corresponding alpha character equivalent of the day of the week then followed by the number. **Verify the characters are set in a way that the DI will not auto verify the result**.
- Run the sample in manual mode.
- When the sample is resulted, multiply the value by the dilution factor used to make the dilution.

WBC		
Condition	**Action 1**	**Action 2**
< 0.5	Check for a clot, re-analyze sample in LW (Low WBC) mode.	SCAN
≤ 2.0	• Check Sample for a clot • If unable to evaluate 100 cells, do a 50 cell Diff and multiply results by 2. • Re-analyze and verify the count is within ± 15%. Add comment code RVT (reviewed by Technologist)	DIFF
≥ 30.0	Scan to verify count and rule out the increase due to presence of Giant platelets or abnormal protein/cryoglobulin	SCAN
≥ 440.0	Re-analyze using dilution factor 2 (use DCL Cell Pack as diluent); if the diluted result is still > 440.0, then report as > 880.0 , refer to ≥30.0, add comment code REP (results confirmed, test repeated)	SCAN

RBC		
Condition	**Action 1**	**Action 2**
≥ 8.60	Re-analyze using dilution factor 2 (use DCL Cell Pack as diluent); if the diluted result is still > 8.60 then report as > 17.2, scan to verify morphology and add comment code REP	SCAN

HGB		
Condition	**Action 1**	**Action 2**
< 4.0	Refer to section 8.3	N/A
≤ 6.0	Check for a clot	N/A
≥ 20.0 Excludes Neonates	Check coagulation sample if HCT ≥ 55, add REP comment.	N/A
≥ 25.0	Re-analyze using dilution, check coagulation sample if HCT ≥ 55, add comment	N/A

MCV		
Condition	**Action 1**	**Action 2**
≤ 50.0	Check for a clot, re-analyze and verify morphology, add RVT comment.	SCAN
≥ 130.0	Warm specimen to 37°C for 30 minutes then re-analyze, verify morphology, denote any rouleaux or RBC agglutinins	SCAN

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Platelet		
Condition	**Action 1**	**Action 2**
< 50	Check for a clot, re-analyze using optical mode if not already performed.	N/A
50-100	When patient is <30 days: Check for a clot, perform platelet estimate, and add RVT comment.	SCAN
> 5000	Re-analyze using dilution, perform platelet estimate, add REP comment.	SCAN

Lymphocyte		
Condition	**Action 1**	**Action 2**
≥ 70	If differential agrees with auto count, Pathologist review is required	DIFF
Note: For patients <12 years old perform DIFF if the Lymphocyte count is greater than Neutrophil		

Neutrophil		
Condition	**Action 1**	**Action 2**
≥ 90 No flags	Scan for any bands, hyper segmentation or toxic granulation	SCAN
≥ 90 With flags	Rule out immature Neutrophils	DIFF

Monocyte		
Condition	**Action 1**	**Action 2**
> 25	Rule out immature Monocytes	DIFF

Eosinophil		
Condition	**Action 1**	**Action 2**
≥ 35	Scan to verify Eosinophils. Rule out presence of parasites.	SCAN

Basophil		
Condition	**Action 1**	**Action 2**
≥ 3.5	Mix for 5 minutes then re-analyze, if still elevated scan to verify cells	SCAN

Reticulocyte		
Condition	**Action 1**	**Action 2**
> 30.0%	• Check Sample for a clot, Vortex the sample for 1 – 2 minutes and reanalyze • If same result is obtained with no flag - check patient's history, check with the attending physician/nurse to confirm the situation and result, inform the supervisor/tech in charge and with their permission report as > 30.0 %. • If same result is obtained with a flag, refer to section 13.9	Repeat
> 6.0%	• When patient is greater than 30 days old, hold for scan	SCAN

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Differential Timing
If a patient had a differential done in the past 48 hours while remaining admitted, there is no need to do another differential if CBC parameters are improving (moving toward normal). Exceptions are: • If blasts flag • Physician request • If Asterisk appears next to results

H and H Mismatch
On samples where hemoglobin and hematocrit results differ significantly (for example HGB value of 12.5 and HCT value of 1.6), do the following: • Check for a clot • Incubate the sample for 30 minutes at 37 °C and reanalyze. If the H and H mismatch remains proceed to next step • Spin the sample and check for hemolysis, lipemia or icteric. If either one is detected, refer to section 13.11 • Contact attending physician / nurse and ask for patient history, medication and a redraw if the current result seems questionable.

Supervisor (or designee) / Pathologist slide review		
Abnormality	**Supervisor**	**Pathologist**
Prolymphs > 5%	X	
Reactive and/or atypical lymphocytes >20%	X	
Bands > 25%	X	
Meta/Myelos/Promyelo >10%	X	
Any blast cell	X	X
Any unidentifiable cell	X	X
Any parasite or microorganism (reviewed by microbiology also)	X	
Lymphocyte > 75% in patients < 17 years of age	X	
Lymphocyte > 70% in patients > 17 years of age	X	X

NOTE: The above guidelines are for new and recurring patients performed initially and over each subsequent hospital encounter (ED visit, OP visit or admission).

Handling and Resulting Pathologist Reviewed Slides

A. Technician/Technologist will release / report results of their differential

B. Technician/Technologist will submit slides for pathologist review as follows:

1. Create a new order (accession number) for manual differential (DIFF) using same collected date and time as the sample.
2. Ensure slide is of acceptable quality for pathology review; appropriate smear, adequate staining, and properly labeled.
3. Cover-slip the slide
4. Complete Pathologist Slide Review Request form

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5. Attach analyzer print-out

C. Technician/Technologist will enter Pathologist differential results under the accession number created in step B.1.

Physician Request for Manual Differential
If a physician requests a manual differential, then a new order (accession number) must be created. Utilize the same collect date and time as the sample and order test code DIFF.

11. EXPECTED VALUES

11.1 Reference Ranges

See Addendum 1.

11.2 Critical Values

Parameter	Age	Critical Low	Critical High
HGB	1 month and older	< 6.1	> 19.9
HGB	0-29 days	< 6.1	> 23.9
WBC	all ages	< 2.1	> 29.9
Platelet	all ages	< 31	> 899

11.3 Standard Required Messages

SGMC only: If patient is in NICU (3C), then call platelet count ≤ 75 x10(3)/mcL

12. CLINICAL SIGNIFICANCE

- **CBC –** The quantitative and qualitative analysis of the cellular elements of blood will identify imbalance between cell production, cell release, cell survival, or cell loss. This information increases the accuracy and specificity of diagnosis based on pathogenesis and is also used to monitor the effectiveness of therapy.
- **Automated Differential –** The Differential distribution of white blood cells will, when correlated with absolute white cell count, identify imbalances between cell production, cell release, cell survival and/or cell loss. This information increases the accuracy and specificity of diagnosis based on pathogenesis and is also used to monitor the effectiveness of therapy.
- **Platelet Count –** Platelets must be present in adequate numbers and have proper function to aid in hemostasis. A normal bleeding time is dependent on adequate platelet number and function.
- **Reticulocyte Count -** The enumeration of reticulocytes provides an effective means of determining red cell production and regeneration. Elevation is seen in patients with

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hemolytic anemia, hemorrhage (acute and chronic), treatment of iron-deficiency anemia and megaloblastic anemias and uremia. Decreased counts may be seen in aplastic anemia, aplastic crisis of hemolytic anemias and ineffective erythropoiesis as seen in thalassemia, pernicious anemia and sideroblastic anemia.
- **IPF – Immature Platelet Fraction:** Platelets are produced in the bone marrow and are normally not released into the bloodstream until they have matured. When platelet numbers in the blood are low (thrombocytopenia), it stimulates the bone marrow to produce platelets faster. When the need is great and when production cannot keep up with demand, then an increased number of immature platelets will be released into the blood stream. The IPF may be used to help a healthcare provider determine the likely cause of a person's thrombocytopenia, that is, decrease in production by the bone marrow (IPF is low) versus increased loss of platelets in the blood (IPF is higher).
- **RET-He – Reticulocyte Hemoglobin Equivalent:** It is one way to measure the hemoglobin inside of reticulocyte. Reticulocytes are "young" red blood cells that are released by the bone marrow before they become fully mature. The amount of hemoglobin inside of reticulocytes can help determine if there has been enough iron available, to be incorporated into hemoglobin production and then into red blood cell production in the bone marrow. This makes the test useful in identifying functional iron deficiency.
- **IRF – Immature Reticulocyte Fraction:** It is the ratio of immature reticulocytes to the total number of reticulocytes. This parameter provides a very early and sensitive index of marrow erythropoietic (RBC production) activity.
- **Immature Granulocytes (IG):** This instrument has a 6-part differential that is comprised of Neutrophil, Lymphocyte, Monocyte, Eosinophil, Basophil and Immature Granulocyte. The Immature Granulocyte results include metamyelocyte, myelocyte and promyelocyte.
- **Platelet Fluorescent:** The platelet measurement is done using a nucleic acid stain specific for platelet organelles and flow cytometry. The PLT-F result will have “&F” to the left of the result indicating the result was obtained in the PLT-F channel.

13. PROCEDURE NOTES

- **FDA Status:** FDA Exempt/Cleared or Approved with modification(s).
- **Validated Test Modifications:** Sample room temperature stability extended. Quest Corporate Validation on file, see the Technical document index.

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

13.1	WBC Abn Scattergram
Cause: Clustering in the WNR or WDF scattergrams is abnormal; meaning analyzer cannot separate the cell population with confidence.	
Corrective Action: 1. If dashes appear in place of data: a. Repeat the sample b. If dashes still remain, perform a manual differential count 2. If Asterisk appears next to data: a. Scan the slide for abnormal cells and NRBC	

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13.1	WBC Abn Scattergram

b. Perform a manual differential if abnormal cells are observed
c. If no abnormal cells are found, then report the result

13.2	NRBC Present

The analyzer identifies and counts NRBCs simultaneously while counting WBCs (both are counted separately). **No further correction of the WBC count is required.**

If NRBCs are greater than 0.01/100 WBC, the lymphocyte count is automatically corrected.

13.3	IG Present (>5% flag)

Cause: Presence of cells (metamyelocyte, myelocyte and promyelocyte) accurately quantitated by the analyzer

Corrective Action:
For IG >5%, this flag appears in red. Perform a manual differential count and scan the peripheral smear for the presence of the following:

- Promyelocytes, myelocytes and metamyelocytes
- Band cells in increased numbers
- Toxic granulation or vacuolation of neutrophils
- Other abnormal cells

13.4	Blast/Abn Lymph

Cause: The analyzer has detected abnormal clustering in the region for blasts and abnormal lymphocytes in the WDF (differential) scattergram.

Corrective Action:
1. If dashes appear in place of data:
   a. Repeat the sample
   b. If dashes still remain, perform a manual differential count
2. If Asterisk appears next to data, perform a manual differential count and scan the peripheral smear for the presence of the following:
   a. Blasts – lymphoblasts, myeloblasts, and myelomonoblasts
   b. Immature Granulocytes – promyelocytes, myelocytes, and metamyelocytes
   c. Atypical or immature lymphocytes
   d. Other abnormal cells

13.5	Left Shift

Cause: The analyzer has detected abnormal clustering in the region for the left shift (bands) in the WDF (differential) scattergram.

Corrective Action:
1. If dashes appear in place of data:
   a. Repeat the sample
   b. If dashes still remain, perform a manual differential count
2. Perform a manual differential count and scan the peripheral smear for the presence of the following:
   a. Band cells in increased numbers
   b. Toxic granulation, hyper-segmentation or vacuolation of neutrophils
   c. Other abnormal cells

13.6	Atypical Lymph

Cause: The analyzer has detected significant clustering in the region for atypical lymphocytes that is located in the upper left lymphocyte region on the WDF (differential) scattergram. An asterisk appears next to the Neutrophil, Lymphocyte, Monocyte, Eosinophil and Immature Granulocyte % and #.

Corrective Action:
Perform a manual differential count and scan the peripheral smear for the presence of the following:

- Atypical or variant lymphocytes
- Abnormal or atypical monocytes
- Immature lymphocytes
- Immature monocytes
- Smudge cells
- Other abnormal cells

13.7	RBC Abn. Distribution

Cause: When the histogram pattern from the RBC channel is abnormal or when RBC is < 0.50 x 10^6/µL. Dashes may appear in place of results for the RDW-CV. This message may cause certain RBC parameters to be marked with an asterisk.

Corrective Action:
Scan the peripheral smear for the presence of abnormal RBC morphology such as those listed. (**Only note if findings are ≥ 2+)**:

- Increased anisocytosis
- Multiple RBC population
- Fragmented RBC
- Poikilocytosis
- Rouleaux or RBC agglutination

If the RBC morphology is normal and MCHC is abnormal (<30 or >37.5 g/dL) refer to guidelines for the HGB/Turbidity Interference? IP Message, section 13.11

If RDW remains uncalculated, result as UNC (unable to calculate)

Note: For consistent morphological reporting, the following criteria are recommended. Review 10 fields using the 100X objective to calculate this mean range.

Variation	Normal	1+	2+	3+
Poikilocytosis	0	1 – 5	6 – 15	> 15
Microcytosis or Macrocytosis	0	1 – 5	6 – 15	> 15
Anisocytosis	0 – 5	6 – 15	15 – 30	> 30
Polychromasia	0 – 2	3 – 4	5 – 6	> 6
Hypochromia	0 – 5	6 – 15	16 – 30	> 30

Cell Type	Normal	1+	2+	3+
Spherocyte, Acanthocyte, Sickle cell, Rouleaux	0	1 – 5	6 – 15	> 15
Helmet cell	0 – 1	1 – 5	6 – 15	> 15
Tear drop, Target cell, Schistocyte, Ovalocyte, Elliptocyte, Burr cell, Stomatocyte, Blister cell	0 – 2	3 – 4	5 – 6	> 6

13.8	Dimorphic Population
Cause: When there are multiple peaks in the RBC histogram pattern. Refer to section 13.7 for corrective action.	

13.9	RET Abn Scattergram
Cause: The analyzer cannot separate the cell population with confidence. There is a possibility of cell overlap. Asterisks appear next to the RET%, RET#, IRF and RET-H*e* parameters.	
Corrective Action: 1. Vortex 1-2 minutes and repeat. 2. If the flag is not eliminated, or the RBC count is <0.50 x 106/µL review the peripheral smear for the presence of polychromasia, parasites, NRBCs, Howell-Jolly Bodies, Heinz bodies or basophilic stippling. If any of those abnormal cells are present, report the results with comment "results may be affected by the presence of interfering substances".	

13.10	RBC Agglutination
Corrective Action: 1. Warm the sample at 37º C for 15 - 30 minutes. Reanalyze the warmed sample in the manual mode after mixing by manual inversion 10 times. Make a new peripheral smear from the warmed sample if agglutination is severe and WBCs and PLTs cannot be accurately measured. See section 9 for WBC and PLT estimate calculations. 2. Sometimes agglutination can be so severe that warming the sample does not enable accurate analysis. In this case perform a plasma replacement: a. Centrifuge an aliquot of blood from the primary tube to separate the cells from the plasma. b. Using a pipette, remove a measured amount of plasma removing as much plasma as possible without disturbing the buffy coat. c. Add back the same amount of CELLPACK DCL as the volume of plasma removed in step "b". d. Cap the tube and mix the sample by manual inversion until the cells are fully re-suspended in the CELLPACK DCL. e. Reanalyze the sample in the manual mode.	

13.11	Turbidity/HGB Interference
If the MCHC is ≤ 30.0 or ≥ 37.5, repeat to rule out random error. • If MCHC is ≤ 30.0 a slide should be made and scanned to look for potential causes of spuriously low MCHC, example: marked sickle cells or target cells. • If the MCHC is greater than 37.5, a slide should be made and examined as well as visual inspection of the sample to determine the integrity of the specimen. The smear review / visual inspection should indicate to the technologist which category the specimen falls into – cold agglutinin, lipemia, hemolysis, icterus or the situation where the results are accurate due to the presence of spherocytes.	
Corrective Action: 1. If Spherocytes are noted on the slide: a. Report the MCHC with a comment reflecting the presence of spherocytes as 1+, 2+ or 3+ 2. If significant RBC agglutination is noted on the slide, warm specimen in a 37°C heat block for 30 minutes and rerun. If not resolved, continue warming and rerun every 15 minutes continuing incubation after each run, not to exceed one hour. If necessary, make a warmed slide for	

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Quest Diagnostics
Site: Shady Grove Medical Center, Washington Adventist Hospital, Germantown Emergency Center
Title: **Sysmex XN Series Operation for CBC and Reticulocytes**

13.11	Turbidity/HGB Interference
morphology evaluation. a. If MCHC is within normal range, Report results with the LIS code SWCG which translates to "Specimen was prewarmed to 37ºC to obtain results. Cold agglutinin/cryoglobulin suspected." b. If MCHC is still greater than 37.5 after one hour of incubation, perform plasma replacement. Refer to section 13.10 3. If hemolysis is suspected, examine the specimen for visual hemolysis. If gross hemolysis is observed, cancel the specimen with the appropriate comment: -HMT 4. If lipemia or icterus is suspected, perform plasma replacement. Refer to section 13.10	

13.12	Fragments
Cause: Due to size comparison of certain RBC or Platelet population, the analyzer cannot separate the cell population with confident. There is a possibility of cell overlap.	
Corrective Action: Scan the peripheral smear for the presence of fragmented RBCs and other poikilocytosis	

13.13	PLT Abn Distribution
Cause: Indicates that the analyzer has detected abnormal size and population of platelets. Dashes may appear in place of data for the MPV or the MPV may be marked with an asterisk.	
Corrective Action: **GEC:** Vortex the specimen for 1 – 2 minutes and repeat. If the same flag appears, then scan the peripheral smear to estimate the platelet count and review for the presence of abnormal RBC or PLT morphology such as: a. Giant platelets b. Platelet clumps c. Fragmented RBCs d. Microcytic RBCs e. Parasites If platelet estimate confirms accuracy of analyzer count, report the result. If MPV remains uncalculated, result as UNC (unable to calculate) **SGMC & WAH:** Vortex the specimen for 1 – 2 minutes and reanalyze in PLT-F mode. If the same flag appears, then scan the peripheral smear to estimate the platelet count and review for the presence of abnormal RBC or PLT morphology such as: a. Giant platelets b. Platelet clumps c. Fragmented RBCs d. Microcytic RBCs e. Parasites If platelet estimate confirms accuracy of analyzer count, report the result. If MPV remains uncalculated, result as UNC (unable to calculate)	

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13.14	PLT Abn Scattergram (SGMC & WAH Only)
Cause: When clustering in the platelet and IPF area on the PLT – F Scattergram is abnormal. The PLT – F, IPF %, and sometimes MPV are reported with an asterisk. Dashes may appear in place of data for the MPV.	
Corrective Action: Follow the steps in section 13.13 under SGMC and WAH.	

13.15	PLT Clumps
Cause: Abnormal clustering of platelets in the WNR, WDF or PLT – F scattergrams.	
Corrective Action: 1. Check the sample for the presence of clots: • If a clot is detected, cancel the current specimen and request a redraw. • If no clot is detected, **SGMC & WAH:** vortex the specimen for 1 – 2 minutes and repeat in PLT – F mode. **GEC:** vortex the specimen for 1 – 2 minutes and repeat. 2. If the flag appears again, then scan the peripheral smear for the presence of abnormal morphology including: • Fibrin strands • Platelet clumps **Note:** If either fibrin or clumps are present, verify the WBC and PLT by a manual slide estimate (see section 9). If the WBC and PLT estimates match the analyzer counts, report the results. If the estimates do not match the analyzer counts, proceed to next step. 3. Recollect a new sample in sodium citrate. The platelet and/or WBC count obtained from the sodium citrate tube must be multiplied by 1.1 to account for the different blood to anticoagulant ratio in the citrate tube. The MPV from the citrate tube is also reported, but no correction factor is applied because the MPV is not affected by dilution. 4. If the platelet clumps still remain and the platelet count is ≤130, remove the platelet count number and result with these two comments: • Unable to report due to significant platelet clumping • Platelet estimate comment (decreased, increased or normal)	

13.16	Giant Platelets – GEC only
Corrective Action: Refer to section 13.15 steps 1 and 2 If PLT count is ≤130 with significant giant platelets found during morphology review, then release the result and append the LIS code GPINF which translates to "The WBC count and platelet count may be altered due to interferences caused by the presence of significant numbers of large giant platelets". Note: Fluorescent platelet functionality will resolve this at SGMC and WAH.	

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14. LIMITATIONS OF METHOD

14.1 Precision

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

14.2 Interfering Substances

Parameter	Causes of Spurious Increase	Causes of Spurious Decrease
WBC	PLT clumps, Cryoprotein, Cryoglobulin, Fibrin, Giant platelets (Platelets > 1,000,000/µL)	Leukocyte aggregation
RBC	Leukocytosis (>100,000µL) Giant platelets (Platelets > 1,000,000/µL)	Erythrocyte aggregation Microerythrocytes Fragmented RBCs
HGB	Leukocytosis (>100,000µL) Lipemia, Abnormal protein	
HCT	Leukocytosis (>100,000µL) Severe diabetes, Uremia, Spherocytosis	Erythrocyte aggregation, Microerythrocytes, Fragmented RBCs
MCV	Spuriously increased HCT Spuriously decreased RBC	Spuriously decreased HCT Spuriously increased RBC
MCH	Spuriously increased HGB Spuriously decreased RBC	Spuriously decreased HGB Spuriously increased RBC
MCHC	Spuriously increased HGB Spuriously decreased HCT	Spuriously decreased HGB Spuriously increased HCT
Platelets	Cryoglobulin, Cryoprotein, Fragmented WBCs, Fragmented RBCs, Microerythrocytes	Giant PLT, PLT Clumping PLT Satellitosis
Retic	Erythrocyte aggregation, giant platelets, clumped platelets, fragmented leukocytes, malaria, Howell –Jolly bodies	None specified

14.3 Clinical Sensitivity/Specificity/Predictive Values

Patient results may vary with sample condition and setting of instrument to review criteria established by the laboratory. Results may also vary due to disease abnormalities, overall patient population and institutional review criteria.

15. SAFETY

Cell Clean Auto reagent causes severe skin burns and eye damage.

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

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- Laboratory Safety Manual
- Data Innovations Instrument Manager, Laboratory Policy
- Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
- Pathologist Slide Review Request (AG.F127)
- Sysmex XN Maintenance Log (AG.F377)
- Sysmex Stainer SP–10 Maintenance Log (AG.F378)
- Automated Stainer Differential Comparison and Stain Quality Log (AG.F379)

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 Reticulocytes SOP, revised 01/09/2017
3. Sysmex Hematology Analyzer XN Series Instruction for use, revised 07/2015
4. Sysmex Stainer SP – 10 Series Instruction for use, revised 02/2013
5. Sysmex XN – 3000 Automated Hematology System Quick Guide, revised 01/2013
6. Sysmex XN Check Quality Control Package Insert, revised 12/2014
7. Roehrl, M.H., et al. Age-Dependent Reference Ranges for Automated Assessment of Immature Granulocytes and Clinical Significance in an Outpatient Setting. Arch Pathol Lab Med. 2011, 135(4):471-7.
8. Kickle, T.S., et al. A Clinical Evaluation of High Florescent Platelet Fraction Percentage in Thrombocytopenia. Am J Clin Pathol 2006;125:282-287
9. Reticulocyte hemoglobin content. Alan Mast, Morey Blinder, Dennis Dietzen. Blood: Vol 83, Issue 4, 307-310

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
0	8/25/17	8.2	Add stainer maintenance	L Barrett	R SanLuis
0	8/25/17	10.3	Add missing parameters	L Barrett	R SanLuis
0	8/25/17	10.4	Correct upper limit for Hgb	A Chini	R SanLuis
0	8/25/17	10.6	Update repeat criteria	R SanLuis	R SanLuis
0	8/25/17	13.7	Add micro & macrocytosis criteria	R SanLuis	R SanLuis
0	8/25/17	13.9.13.11	Delete dilution	R SanLuis	R SanLuis
0	8/25/17	19	Add addenda 6 and 7	L Barrett	R SanLuis
0	8/25/17	Add 1	Standardize decimal places	L Barrett	R SanLuis
0	8/25/17	Add 3	Add QC requirements	L Barrett	R SanLuis
0	8/25/17	Add 4	Add QC outlier documentation steps	Z Morrow	R SanLuis
0	8/25/17	Add 5	Add detail to data management	Z Morrow	R SanLuis

Version	Date	Section	Reason	Reviser	Approval
0	8/25/17	Footer	Corrected pages 28-36	L Barrett	R SanLuis
1	3/13/18	10.6	Add physician request for manual diff	L Barrett	R SanLuis
1	3/13/18	19	Add addendum 8	A Chini	R SanLuis
1	3/13/18	Add 1	Add peds values for IG %, extend adult age to include 13-18 yrs.	L Barrett	R SanLuis
2	5/2/18	10.3	Add decimal places for each analyte	L Barrett	R SanLuis
2	5/2/18	Add 1	Change IG% value to one decimal place	M Sabonis	R SanLuis
3	7/9/18	10.6, Add 7	Add action for plt between 50-100; add scan if retic >6.0% for ages >30 days	L Barrett	R SanLuis
3	7/9/18	10.6	Slide review process changed to release tech results and order manual diff for path review	L Barrett	R SanLuis

19. ADDENDA

Addendum	Title
1	Reference Ranges
2	Sysmex XN Maintenance and Quality Control
3	Sysmex Stainer SP–10 Maintenance
4	QC Instructions on the Sysmex XN
5	QC Instructions on Insight
6	Smear Review and Manual Differential
7	CBC DIFF/SCAN Action and Repeat Criteria
8	Sysmex Rules Management

Addendum 7:

CBC DIFF/SCAN Action and Repeat Criteria

Criteria	Criteria Action Limit	Action 1	Action 2
WBC	< 0.5	Check for a clot, re-analyze sample in LW mode	SCAN
WBC	≤ 2.0	Check for a clot	DIFF
WBC	≥ 30.0	Check for Giant Platelets	SCAN
WBC	≥ 440.0	Re-analyze using dilution	SCAN
RBC	≥ 8.60	Re-analyze using dilution	SCAN
HGB	< 4.0	Re-analyze with the Aspiration Sensor OFF	None
HGB	≤ 6.0	Check for a clot	None
HGB	≥ 20.0	Re-analyze, check Coag sample if HCT ≥ 55	None
HGB	≥ 25.0	Re-analyze using dilution, check Coag sample if HCT ≥ 55	None
MCV	≤ 50.0	Check for a clot, re-analyze and verify morphology	SCAN
MCV	≥ 130.0	Warm sample for 30 min, re-analyze, verify morphology	SCAN
PLT	< 50	Check for a clot, re-analyze	None
PLT	50-100	If patient <30 days/old - Check for a clot, perform PLT estimate, and add RVT comment.	SCAN
PLT	> 5000	Re-analyze using dilution, perform PLT estimate	SCAN

Criteria	Criteria Action Limit	Action 1	Action 2
Lymph	≥ 70	Pathologist review for patient >17 y/old	DIFF
Neutro	≥ 90 no flags	Scan for bands, hyper-segmentation, toxic granulation	SCAN
Neutro	≥ 90 & flags	Rule out immature Neutrophils	DIFF
Mono	> 25	Rule out immature Monocytes	DIFF
Eos	≥ 35	Scan to verify Eosinophils. Check for parasites	SCAN
Baso	≥ 3.5	Mix for 5 min, re-run. If still elevated SCAN	SCAN
Retic	>30.0%	Check for a clot, Vortex 1 -2 min, re-analyze	Repeat
Retic	>6.0%	Scan for patient >30 days/old	SCAN

Criteria	Action
WBC Abn Scattergram	If dashes appear: re-analyze, if dashes still remain perform a DIFF If asterisk appears: scan, perform a DIFF if abnormal cells observed
NRBC Present	Release the result. No further correction of WBC is required
IG Present >5%	Perform a DIFF and check for the presence of: Promyelocytes, Metamyelocytes and Myelocytes
Blast/Abn Lymph	If dashes appear: re-analyze, if dashes still remain perform a DIFF If asterisk appears: perform a DIFF, check for blasts & immature granulocytes
Left Shift	If dashes appear: re-analyze, if dashes still remain perform a DIFF and check for bands, toxic granulation, hyper-segmentation, vacuolation of neutrophils
Atypical Lymph	Perform a DIFF
RBC Abn Distribution	SCAN, Perform a morphology (only note if findings are ≥2+)
Dimorphic Population	SCAN, Perform a morphology

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Site: Shady Grove Medical Center, Washington Adventist Hospital, Germantown Emergency Center
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Criteria	Action
RET Abn Scattergram	Vortex 1 -2 min, re-analyze. If flag remains, scan smear for abnormal cells
RBC Agglutination	Warm & re-analyze. If flag still remains perform plasma replacement
Turbidity/HGB interference	Re-analyze, if flag remains SCAN. Check for the presence of Spherocytes. If RBC agglutination is noted warm sample and re-analyze. If lipemic or Icteric, perform a plasma replacement.
Fragments	SCAN for fragmented RBCs & other poikilocytosis
PLT Abn Distribution & PLT Abn Scattergram	GEC: Vortex 1 – 2 min, then re-analyze WAH & SG: Vortex 1 – 2 min, re-analyze in PLT-F mode All sites: If flag remains, SCAN and perform a morphology
PLT Clumps	Check for clots. If present, cancel and request re-draw. If no clots, then GEC: Vortex 1 – 2 min, then re-analyze WAH & SG: Vortex 1 – 2 min, re-analyze in PLT-F mode All sites: If flag remains, SCAN and perform a morphology If fibrin or clumps are present, recollect a new sample in sodium citrate

Non-Technical SOP

Title	Delta Check	
Prepared by	Leslie Barrett	Date: 8/20/2009
Owner	Robert SanLuis	Date: 2/20/2015

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

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

Form revised 3/31/00

Quest Diagnostics
Site: Shady Grove Medical Center, Washington Adventist Hospital,
Germantown Emergency Center
Title: Delta Check

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1. PURPOSE

Delta checking is employed by the laboratory to check for unexpected changes in patient test results that may indicate a significant change in the patient's clinical status. Delta checking also serves as a quality assurance tool to check for analytical errors, and to ensure that the specimen tested, and results obtained, are consistent with patient clinical condition.

2. SCOPE

Delta check parameters are set up in the test files in the Laboratory Information System (LIS). During delta checking, the LIS compares the current result to the previous result. If the difference in results exceeds predetermined limits (%D and absolute D), the LIS alerts the technologist to the delta check failure.

3. RESPONSIBILITY

The Laboratory Medical Director approves the delta check parameters.

Technologists verify the validity of any result that fails delta checking. This validity check is documented as a comment in the LIS.

The Supervisor or designee prints a failed delta check report each working day and checks that delta failures are investigated and documented by the technologist.
The reviewer checks the report for trends such as an unusual number of delta failures for an analyte that may not be seen by a single technologist and takes appropriate corrective action as needed. Delta check reports are retained for two years.

Form revised 3/31/00

4. DEFINITIONS

Delta check - a comparison of consecutive values for a given test in a patient's laboratory file used to detect abrupt changes, usually generated as a part of a computer-based quality control program.

LIS - Laboratory Information System

5. PROCEDURE

A. Delta checking is automatically performed by the LIS on all qualifying results before verification.

B. The "fail delta" flag will alert the technologist.

C. The technologist will take appropriate action to resolve the delta check before releasing the result. Items to consider:

1. An unexpected number of delta failures for the same analyte may indicate an assay problem. The analyst will troubleshoot the instrument for problems including running additional quality control samples as needed to ensure expected assay performance.

2. Specimen quality will be checked. Hemolysis is a reasonable explanation for an elevated potassium result that fails delta checking. Check the assay SOP or instrument operations manual for assays that are affected by specimen quality. **Note**: an improperly handled specimen may also fall into this group.

3. Patient information will be checked for an explanation. Patient treatment or change in status can affect results. Where possible check laboratory patient status reports or patient history for information on transfusions or anticoagulant therapy. Contact the patient's nurse or physician to gather more clinical history.

4. If there is no known reason for the change in the result, suggest to the nurse or physician that the patient be redrawn to verify the result. Hold the result in the LIS until redraw is tested and result is confirmed.

5. If the nurse or physician does not want the patient redrawn, accept the results and document this information via free text in the LIS.

D. If it is determined that the specimen has been misidentified (misdrawn or mislabeled), the results may not be released. Notify the patient's nurse or physician and complete a Quality Variance form.

6. RELATED DOCUMENTS

Delta Value - LIS Investigation, LIS procedure
Failed Delta Value Report, LIS procedure

Quest Diagnostics
Site: Shady Grove Medical Center, Washington Adventist Hospital,
Germantown Emergency Center
Title: Delta Check

7. REFERENCES

Stedman's Medical Dictionary, 26th edition, 1995.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L014.002		
000	11/17/10	Section 9: Update addenda	L Barrett	C Bowman
001	2/4/13	Section 5: Revise PI form to Quality Variance Section 9: Remove TBIL, DBIL, CBIL, PHOS, revise SOD and CL	L Barrett	C Bowman
002	2/20/15	Update owner Section 9: Remove CL, CREAT, FIBR, LI, GENP, GENT, PHENB, PTA, PTT, THEO, TOBP, TOBT, VANT, VANP. Revise INR to 60% Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
3	2/23/17	Header: add other sites	L Barrett	C Bowman
4	5/23/18	Section 9: Change platelets time frame from 24hr to 72hr	L Barrett R SanLuis	C Bowman

9. ADDENDA AND APPENDICES

LIS Delta Values

LIS DELTA VALUES

Test code	Test Name	Time Search	Delta %	Absolute
CA	Calcium	24hr	25	
CKMB	CKMB	12hr	100	
DIG	Digoxin	24hr	40	
GLUC	Glucose	24hr	100	
HGB	HGB	24hr		3
INR	INR	24hr	50	
MG	Magnesium	24hr	60	
MCV	MCV	24hr		3
SOD	Sodium	24hr		8
PLTC	Platelets	72hr	80	
K	Potassium	24hr	45	
RBC	RBC	24hr	35	
OSMO	Serum Osmo	24hr	50	
TROPI	Troponin I	12 hr	150	

Form revised 3/31/00