TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	1/2/2018
Department:	Core	**Due Date:**	1/31/2018
		Implementation:	**2/1/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Sysmex Pochi-100 Analyzer for Complete Blood Count GEC.H235 v2

Sysmex Pochi - 100 Maintenance Log AG.F329.1

Description of change(s):

SOP:

Section	Reason
4,5,6	Remove individual section labeling instructions and add general one
5.3	Change from monthly to every 6 months (per manufacturer)
8.2	Update mixing steps
8.5, 8.6	Change tube type to lavender top
10.5	Move patient review from section 6
15	Update to new standard wording

LOG:

- Change calibration frequency from monthly to semi-annual
- Add space to indicate that quarterly & semi-annual items are not due that month

This revised SOP & Form will be implemented on February 1, 2018

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

Technical SOP

Title	**Sysmex Pochi-100 Analyzer for Complete Blood Count**
Prepared by	Ashkan Chini Date: 7/15/2015
Owner	Robert SanLuis Date: 7/15/2015

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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TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Hemogram (*WBC, RBC, HGB, HCT, MCV, MCH, MCH, PLT)*	Sysmex Pochi-100	CBC, CBCND
Platelet Count	Sysmex Pochi-100	PLTC

Note: The Pochi-100 does not perform a differential. During its use, all differentials must be performed manually.

Abbreviation	Term	Abbreviation	Term
WBC	White Blood Cell	MCHC	Mean Corpuscular Hemoglobin Concentration
RBC	Red Blood Cell		
HGB	Hemoglobin	HCT	Hematocrit
HCT	Hematocrit	MCH	Mean Corpuscular Hemoglobin
MCV	Mean Cell Volume		

Department
Hematology

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2. ANALYTICAL PRINCIPLE

DC detection method: Blood sample is aspirated, measured to a predetermined volume, diluted at the specified ratio, then fed into each transducer. The transducer chamber has a minute hole called the aperture. On both side of the aperture, there are the electrodes between which flows direct current. Blood cells suspended in the diluted sample pass through the aperture, causing direct current resistance to change between the electrodes. As direct current resistance changes, the blood cell volume is detected as electric pulses. Blood cell count is calculated by counting the pulses, and a histogram of blood cell volume is plotted by determining the pulse heights. Also, analyzing a histogram makes it possible to obtain various analysis data.

Hydrodynamic focusing DC detection method: Inside the detector, the sample nozzle is positioned in front of the aperture and in line with the center. After diluted sample is forced from the sample nozzle into the conical chamber, it is surrounded by front sheath reagent and passes through the aperture center. The Hydro Dynamic Focusing DC detection method improves blood count accuracy and reproducibility. And because the blood cells pass through the aperture in a line, it also prevents the generation of abnormal blood cell pulses.

Non-cyanide hemoglobin analysis method: rapidly converts blood hemoglobin as the Oxyhemoglobin method and contains no poisonous substance, making it suitable for automated method. Being capable of analyzing methemoglobin, this method can accurately analyze control blood, etc. which contain methemoglobin.

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	Not applicable
Other	Not applicable

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	K_3EDTA or K_2EDTA Whole Blood
-Other Acceptable	Sodium Citrate – for platelet counts only
Collection Container	Lavender Top Tube Tri-Potassium or Di-Potassium EDTA Anticoagulant

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Volume	**Tube**	**Minimum**	**Optimum**
	K_3EDTA or K_2EDTA (non-pediatric)	1.0mL	Full tube
	Pediatric K_3EDTA or K_2EDTA tube	0.5mL	Full tube
	Microtainer tube	0.5mL	n/a
Transport Container and Temperature	Collection tube transported at room temperature.		
Stability & Storage Requirements	Room Temperature: 24 hours Refrigerated: Not recommended Frozen: Not recommended		
Timing Considerations	N/A		

Specimen Quality Table	**Condition**	**Slight**	**Moderate**	**Marked**
	Icterus	OK	OK	Orange-Brown
	Hemolysis	Slight pink OK	Pink OK	Cherry Red Unacceptable
	Lipemia	OK	OK	Milky

Other Interfering Specimens Factors	**CBC** Indicated by CBC results Fibrin, bacterial contamination, platelet clumps, abnormal proteins, cold agglutinins, extreme temperature conditions, resistant hemoglobin, abnormal chemistries and specimens older than 48 hours.

Actions to Take for Rejected Specimens Message Codes & Notes	**Condition**	**Code**	**Comment**
	QNS *(< minimum volume above)*	QNS	Quantity not sufficient to perform test. **Notify caregiver**. *(Document in the LIS)*
	Clotted	CLT	Specimen is clotted, unable to perform test. **Notify caregiver.** *(Document in the LIS)*
	Spurious results that will not duplicate	INT *or* UNSAT	Possible interfering substance. *or* Unsatisfactory specimen. **Notify caregiver.** *(Document in the LIS)*
	Gross hemolysis	HMT	Markedly hemolyzed. **Notify caregiver.** *(Document in the LIS)*

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.

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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
Poch-Pack D	Sysmex America, Cat. No. PPD-300A
Poch-Pack L	Sysmex America, Cat. No. PPL-200A

4.2 Reagent Preparation and Storage

Reagent	Poch-Pack D
Container	Plastic bottle
Storage	Store at 1 - 30°C
Stability	Unopened reagent is stable until the expiration date printed on the bottle. Opened reagent is only stable for 60 days. Use at 15 - 30°C
Preparation	None

Reagent	Poch-Pack L
Container	Plastic bottle
Storage	Store at 2 - 35°C
Stability	Unopened reagent is stable until the expiration date printed on the bottle. Opened reagent is only stable for 90 days. Use at 15 - 30°C
Preparation	None

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
SCS-1000 Hematology Calibrator	Sysmex America, Cat. No. 217685

5.2 Calibrator Preparation and Storage

Calibrator	SCS-1000 Hematology Calibrator
Preparation	None
Storage/Stability	Store at 2 - 8°C **Unopened**: stable until the expiration date printed on the vial **Opened**: stable for 4 hours

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5.3 Calibration Frequency

- When major maintenance is performed on the analyzer
- When control data indicates a significant shift in assay
- Every 6 months ~~Once per month~~

5.4 Calibration Procedure

1. Let the calibrator to come to room temperature for at least 30 minutes.
2. Insert the Control/Calibrator vial adapter (green) in the sample position.
3. From the main page press **Menu**
4. Press **Calib**.
5. Press **Calibrator (WB)**
6. Mix the vial by end to end inversion until all red blood cells are completely re-suspended (approximately 20 inversions).
7. **Remove the cap** and insert the vial into the sample adapter and close the sample door.
8. From the precision check screen, press **Run.** Analysis of the sample begins in the WB mode. The sample currently being analyzed is indicated by an underline cursor.
9. After analysis is complete, the first analysis results are displayed, and the underline cursor moves to the next line.
10. Remove the vial, replace the cap and remix by gently inverting the vial twice.
11. Repeat steps 8, 9 and 10, ten more times.
12. After analysis has been completed 11 times, press **Next**.
13. The Mean, SD and CV% will be automatically calculated and displayed in the Mean, SD and CV% columns. If any of the obtained values exceeds the limit value, the message **Pre. Chk Error** appears. In this case, press **Quit** and repeat steps 8, 9, 10 & 11. If there are no errors, then proceed to the next step.
14. Press **Quit** to return to the calibrator target value setting screen.
15. Press the Target Value icon for the target parameter. The numeric keys dialog will be displayed.
16. Enter the target value from the calibrator package insert by pressing the numerical values on the keypad, then press **Ent.** The entered value is saved and displayed.

    Note: The values for any setting must have value and may not be blank.
17. After setting the remaining target values, press **Next**. The calibrator target value setting confirmation dialog appears.
18. Pressing the **OK** button updates the target values and displays the calibrator analysis screen. Pressing the **Cancel** button closes the dialog and returns to the calibrator target value setting screen.
19. Remove the vial, replace the cap and remix by gently inverting the vial at least 12 times.

20. **Remove the cap** and insert the vial into the sample adapter and close the sample door.
21. Press **Run**.
22. Continue by pressing the **Run** button, and repeat sample analysis 6 times. Mix sample between runs.
23. After analysis has been completed, press **Next**. The analysis calibrator screen will appear.
24. If the instrument determines values are outside of the specifications (values will appear in red), it will not allow the values to be updated. In this case repeat the calibration. If the calibration fails again, contact the Sysmex Pochi-100 Technical Assistant Center.
25. If the values are within acceptable limits, press **Quit** to update the values and calibration history. The instrument will return to the Main screen.

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
EIGHTCHECK-3WP X-TRA	Sysmex America, Cat. No. 140 – 3004 – 0

6.2 Control Preparation and Storage

Control	EIGHTCHECK-3WP X-TRA
Preparation	None
Storage/Stability	Store at 2 - 8°C **Unopened**: stable until expiration date printed on the vial **Opened**: stable for 14 days when promptly refrigerated after each use.

6.3 Frequency

- When the primary hematology analyzer is in operation, analyze all levels of QC material after every calibration, any major maintenance and once per day.

- When the primary hematology analyzer is not in operation and this analyzer is used to run patient samples, then run all levels of QC material every 4 hours.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; 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.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Sysmex Pochi-100 analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2 - 8°C

7.3 Supplies

- Sample tube adapter (white)
- Thermal paper
- Control/Calibrator vial adapter (green)
- Pre-diluted (1:10) Bleach
- Disposable Glass 12 x 75 mm tubes

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	Set up Control Files
1.	Press the QC button on the touch screen.
2.	The QC file screen list is displayed, choose the appropriate file.
3.	Press the setting button.
4.	Scan the Lot ID barcode from the QC package Insert
5.	Press the Expire button and enter the expiration date.
6.	Press the right arrow button to proceed through each QC screen.
7.	In each screen, scan the appropriate barcode for Target and Limit for that parameter from the package insert until all six QC screens have been updated.

8.1	Set up Control Files
8.	When settings are complete, press Save and OK to store the ranges.
9.	Repeat the process for the remaining QC levels.

8.2	QC Procedure
1.	Allow the QC vials to sit at room temperature for 15 minutes.
2.	Press **QC** on the Main Screen.
3.	Press the display column of the correct file.
4.	Check that the status display reads "**Ready**".
5.	Press the top of sample position to open.
6.	Set the Control/Calibrator vial (**Green**) adapter in position.
7.	Verify cap is secure and mix the vial by end to end inversion until all red blood cells are completely re-suspended ~~(approximately 20 inversions~~).
8.	~~**Remove the cap** and~~ Insert the vial into the sample adapter and close the sample door.
9.	Press **Run**.
10.	After results are displayed, press **Print** to print the results.
11.	All results are entered in Unity Real Time.

8.3	Test Run
1.	Press **Sample ID**
2.	Enter the ID and press **Ent.**
3.	Open sample position
4.	Insert sample tube adapter
5.	Mix the sample at least 8 times
6.	Insert the sample tube and close the door
7.	Press **RUN**
8.	The analysis starts. Analysis results are automatically printed.

8.4	Review Patient Results
1.	Using function MEM in the LIS system, review each patient result before it is released.
2.	Check for delta checks and critical values.
3.	Call and document all critical values
4.	Release all values that do not need to be repeated for delta values, critical values, or are not flagged for review.
5.	Make a stained smear for the differential if there is one ordered. Follow the procedure for manual differential found in the main CBC analyzer procedure.

8.5	Clean Transducer (Bi Weekly)

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8.5	Clean Transducer (Bi Weekly)
1.	Add at least 3 mL of pre-diluted bleach into a clean lavender top ~~disposable glass 12 x 75 mm~~ tube
2.	Open sample position, insert sample tube adapter and then place the bleach solution in it, close the door.
3.	From the main page, press **Menu**
4.	Press **Maint.** (Maintenance)
5.	Press **Clean W. Chamber**
6.	Remove the tube when cleaning is completed

8.6	Clean Waste Chamber (Quarterly)
1.	Add at least 3 mL of pre-diluted bleach into a clean lavender top ~~disposable glass 12 x 75 mm~~ tube
2.	Open sample position, insert sample tube adapter and then place the bleach solution in it, close the door.
3.	From the main page, press **Menu**
4.	Press **Maint.** (Maintenance)
5.	Press **Clean Transducer**
6.	Remove the tube when cleaning is completed

8.7	Shut down (Daily)
1.	Removes deposits in the instrument tubing.
2.	From the main page, press **Shutdown**
3.	Press **Execute**
4.	Process begins
5.	Follow the instructions on the screen, then turn off

9. CALCULATIONS

MCV, MCH and MCHC results are released from the analyzer.

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

$$\text{Corrected WBC} = \frac{\textbf{Uncorrected WBC} \times 100}{100 + \#\text{NRBC's}}$$ and/or megakaryocytes

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

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None required

10.2 Rounding

Parameter	Number of decimals
WBC	1
RBC	2
HGB	1
HCT	0
MCV	0
MCH	1
MCHC	1
PLT	0

10.3 Units of Measure

Parameter	Units
WBC	x10(3)/mcL or K/µL
RBC	10^6 / µL or M/µL
HGB	g/dL
HCT	%
MCV	fL
MCH	pg
MCHC	g/dL
PLT	x10(3)/mcL or K/µL

10.4 Clinically Reportable Range (CRR)

Parameter	CRR
WBC	1.0 – 99.99 x 10^3 / µL
RBC	0.3 – 9.99 x 10^6 / µL
HGB	0.1 – 25.0 g/dL
HCT	10 – 60
PLT	10 – 999 x 10^3 / µL

10.5 Review Patient Data

Technologist must review each result for error messages. Refer to the Sysmex Pochi-100 manual "Error messages" section for troubleshooting. Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

Refer to Addendum 2 for CBC Diff/Scan action and repeat criteria.

Parameter	Repeat Tolerance Limits
WBC	± 0.8
RBC	± 0.25
HGB	± 0.6
HCT	± 1.7
MCV	± 3.0
MCH	± 1.2
MCHC	± 1.2
PLT	± 10%

Pattern of an upward or downward drift:

IF …	THEN …
a characteristic pattern of an upward or downward drift	• Check patient population to eliminate the possibility of an increased number of patients with a specific disease state. If this is found, then continue to run instrument. • Check patient population, if an increased number of patients with a specific disease state is not found, run the QC and check for similar trends/shifts.
If QC is in acceptable ranges	The instrument can continue to be operated.
If the QC shows a similar trend/shift	Troubleshoot the instrument and calibrate if necessary.

Pattern of an upward or downward drift			
When Measurement	**Then …**		
	MCV	**MCH**	**MCHC**
HGB Decreased	No change	Decreased	Decreased
HGB Increased	No change	Increased	Increased
RBC Decreased	Increased	Increased	No change
RBC Increased	Decreased	Decreased	No change
HCT Decreased	Decreased	No change	Increased
HCT Increased	Increased	No change	Decreased

LIS Resulting for Patients

Function: **MEM**
Worksheet: **GHMAX**
Test: **CBCND**
Accept or Modify: **M**
WBC: HMXG
GP100

Change the method code on each analyte to **GP100** with the exception of RDW and MPV. Skip past those using the enter key.

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Enter the Accession number and enter the patient results.
For RDW and MPV type **HIDE**.

Review all results for clerical errors before accepting them.

11. EXPECTED VALUES

11.1 Reference Ranges

Refer to Addendum 1

11.2 Critical Values

Parameter	Age	Critical Low	Critical High	Reference Units
HGB	1 month and older	< 6.1	> 19.9	g/dL
HGB	0-29 days	< 6.1	> 23.9	g/dL
WBC	all ages	< 2.1	> 29.9	x10(3)/mcL
Platelet	all ages	< 31	> 899	x10(3)/mcL

11.3 Standard Required Messages

None established

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.
- **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.

13. PROCEDURE NOTES

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

13.1 Potential Causes of Erroneous Results with Automated Cell Counter

Parameter	Causes of Spurious Increase	Causes of Spurious Decrease
WBC	Cryoglobulin, Cryofibrinogen, Heparin, Monoclonal Proteins, Nucleated RBC, PLT Clumps, Lyse-	Clotting, Smudge Cells, Uremia, Immunosuppressants

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Parameter	Causes of Spurious Increase	Causes of Spurious Decrease
	resistant RBC	
RBC	Cryoglobulin, Cryofibrinogen, Giant PLTs, High WBC *(>50,000/μL)*	Auto-agglutination, Clotting, *in vitro* Hemolysis, Microcytic RBC
Hemoglobin	Carboxyhemoglobin *(>10%),* Cryoglobulin, Cryofibrinogen, *in vitro* Hemolysis, Heparin, High WBC *(>50,000/μL),* Hyperbilirubinemia, Lipemia, Monoclonal Proteins	Clotting, Sulfhemoglobin
Hematocrit *(Automated)*	Cryoglobulin, Cryofibrinogen, Giant PLTs, High WBC *(>50,000/μL),* Hyperglycemia *(Glucose >600 mg/dL)*	Autoagglutination, Clotting, *in vitro* Hemolysis, Microcytic RBC
MCV	Cryofibrinogen, Autoagglutination, High WBC (>50,000/μL), Hyperglycemia, Reduced RBC Deformability	Cryoglobulin, Giant Platelets, *in vitro* Hemolysis, Microcytic RBC, Swollen RBC
MCH	High WBC *(>50,000/μL),* Spuriously High HGB, Spuriously Low RBC	Spuriously Low HGB, Spuriously High RBC
MCHC	Auto-agglutination, Clotting, Lipemia, *in vitro* Hemolysis, Spuriously High HGB, Spuriously Low HCT	High WBC *(>50,000/μL),* Spuriously Low HGB, Spuriously High HCT
Platelets	Cryoglobulin, Cryofibrinogen, Hemolysis *(in vitro and in vivo),* Microcytic RBC, RBC Inclusions, WBC Fragments	Clotting, Giant PLT, Heparin, PLT Clumping, PLT Satellitosis

13.2 Platelet Clumps

Platelet clumping represents agglutination rather than aggregation, as it is not prevented by inhibitors of the platelet release reaction. In addition to pseudo- thrombocytopenia, platelet agglutination may cause pseudoleukocytosis due to the counting of platelet clumps as leukocytes by automated analyzers. Thus, resolving the PLT clumping when possible improves the quality of result provided to the clinician.
When the platelet clump flag is noted check the specimen for a clots and fibrin.
Vortex the EDTA specimen for 1-2 minutes, then rerun the specimen.
If no clumps are seen following vortexing and the platelet count has increased, the count may be reported. However, exercise caution in the situation when only partial resolution of clumping is observed, even if the platelet count increases substantially.
If the post-vortex PLT count is normal, enter a comment that platelet clumping is present but the platelet count is adequate.

If	Then
If PLT count ≤ 130 with significant PLT clumps found during slide scan.	Remove the PLT count number and result with the comment CLMP = *Clumped platelet*

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13.3 Sodium Citrate for Platelet Count

Collection of a platelet count with Sodium Citrate anticoagulant is usually reserved for patients who are known to have a platelet clumping phenomena associated with EDTA anticoagulant. The specimen of choice is both an EDTA and a sodium citrate tube. The EDTA is used for the CBC results. The sodium citrate tube is used for the citrate Platelet count. Multiply the Na citrate platelet count by 1.1 to correct for dilution effects.

13.4 MCHCs greater than 36.5 or less than 29.0

If the MCHC is ≤ 29.0 or ≥ 36.5, it should be repeated to rule out random error. If MCHC is ≤ 29.0 a slide should be made and scanned to look for potential causes of spuriously low MCHC, i.e. marked sickle cells or target cells. If the MCHC is greater than 36.5, 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.

<table>
<tr><th>IF</th><th colspan="2">Then</th></tr>
<tr><td>Spherocytes are noted on the slide scan</td><td colspan="2">Report the MCHC with a comment reflecting the presence of spherocytes as 1+, 2+ or 3+.</td></tr>
<tr><td>Resistant hemoglobin, marked sickle cells or target cells noted on the slide scan</td><td colspan="2">Specimens with lyse resistant RBCs should be repeated on dilution using bottled, distilled water. Prepare a 1:2 dilution with equal parts of blood and water. Allow to sit three minutes. Resuspend and process through the analyzer. Using the HGB result, multiply the results by 2 to determine the corrected hemoglobin result. Use the corrected HGB to recalculate the MCH and the MCHC.</td></tr>
<tr><td rowspan="4">If significant RBC clumping is noted on the slide scan.</td><td colspan="2">Warm specimen in a 37°C water bath or 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 morphology evaluation</td></tr>
<tr><td>IF After Incubation</td><td>Then</td></tr>
<tr><td>The MCHC is within normal range</td><td>Report results with the appropriate comment: Specimen was prewarmed to 37ºC to obtain results; Cold agglutinin/cryoglobulin suspected.</td></tr>
<tr><td>The MCHC is still outside 36.5 after 1 hour incubation: (irreversible cold agglutinins)</td><td>Perform Plasma Replacement Procedure: See Addendum 3.</td></tr>
<tr><td>If hemolysis is suspected on the slide scan, i.e. schistocytes</td><td colspan="2">Examine the specimen for visual hemolysis. If gross hemolysis is observed, cancel the specimen with the appropriate comment: -HMT</td></tr>
<tr><td>If lipemia or icterus is</td><td colspan="2">Examine the specimen for visual lipemia /icterus. If observed</td></tr>
</table>

IF	Then
suspected on the slide scan.	perform a plasma hemoglobin blank. If there is sufficient specimen, mix well and pour off a portion into a plastic specimen tube. Spin the tube for 5-10 minutes at 2000 rpm. If the specimen is short, spin the lavender tube for 5-10 minutes at 2000 rpm. Run the instrument Diluent as a blank. Verify a "0" hemoglobin value. In the secondary mode, aspirate plasma portion of spun specimen to determine the plasma hemoglobin blank value. Using the following formula: Correct Hgb = OH – [PB x (1 – HCT/100)] Where OH = original hemoglobin PB = plasma hemoglobin blank HCT = original hematocrit Calculate corrected HGB. Enter the corrected HGB on the report and recalculate the indices (Refer to section 9 for formula) and enter the correct results with the comment**:** *"Results were obtained by repeat analysis to include running a plasma blank to eliminate interferences caused by either WBCs, lipemia, or protein entities."*

13.5 Slide Preparation

When making a smear always check the specimen for clots. This can be done by visual inspection or by the use of an applicator stick when appropriate. Refer to Addendum 4 for smear preparation.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

Parameter	AMR
WBC	$1.0 – 99.99 \times 10^3$
RBC	$0.3 – 9.99 \times 10^6$
HGB	0.1 – 25.0
HCT	10 – 60
PLT	$10 – 999 \times 10^3$

14.2 Precision

Performed by the manufacturer and all data is acceptable.

14.3 Interfering Substances

See 13.1

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not applicable.

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 (SDS)
- Laboratory Safety Manual
- Sysmex Pochi-100 Reference Manual
- Critical Values (Lab policy)
- Quality Control Program policy
- Quest Diagnostics Records Management Program
- Pathologist Slide Review Request (AG.F127)
- Sysmex Pochi - 100 Maintenance Log (AG.F329)

17. REFERENCES

1. Coulter AcT10 Operation for Complete Blood Count GEC.H11 Version 001
2. Pochi-100 User guide manual, Sysmex America, revised 06/2008.
3. SCS-1000 Hematology Calibrator, Sysmex America, revised 06/2014.
4. EIGHTCHECK-3WP X-TRA Quality Control, Sysmex America, revised 02/2013.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
0	11/17/17	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
0	11/17/17	8.2	Update mixing steps	R Bridges	R SanLuis
0	11/17/17	8.5, 8.6	Change tube type to lavender top	R Bridges	R SanLuis
0	11/17/17	10.5	Move patient review from section 6	L Barrett	R SanLuis
0	11/17/17	15	Update to new standard wording	L Barrett	R SanLuis
1	11/22/17	5.3	Change from monthly to every 6 months (per manufacturer)	L Barrett	R SanLuis

19. ADDENDA

Addendum	Title
1	Reference Ranges
2	CBC Scan Action and Repeat Criteria
3	Plasma Replacement
4	Smear Review and Manual Differential

ADDENDUM 1

ADULT CBC REFERENCE RANGES

	Male Reference Ranges		Female Reference Ranges	
Parameter/Units of measurement	**13y- 19y**	**> 19 years**	**13y – 19y**	**> 19 years**
WBC/ x10(3)/mcL	4.5 – 13.0	4.5 – 11.0	4.5 – 13.0	4.5 – 11.0
RBC/ 10^6/µL	4.5 – 5.3	4.5 – 6.3	4.1 – 5.1	3.9 – 5.6
HGB/ g/dL	13.0 – 16.0	13.5 – 18.0	12.0 – 16.0	11.5 – 16.0
HCT/ %	37.0 – 49.0	39.0 – 52.0	36.0 – 46.0	33.0 – 47.0
MCV/ fL	78 - 102	80 - 100	78 - 102	76 – 101
MCH/ pg	25.0 – 35.0	26.0 – 36.0	25.0 – 35.0	26.0 – 36.0
MCHC/ g/dL	32.0 – 37.0	32.0 – 37.0	32.0 – 37.0	32.0 – 37.0
PLT/ x10(3)/mcL	150 - 450	150 - 450	150 - 450	150 - 450

PEDIATRIC CBC REFERENCE RANGES

Parameter	0d	2d	3d	2w	1m	2m	3m	6m	1y	2y	6y – 12y
WBC/ x10(3)/mcL	19.0–25.0	9.0-30.0	9.0-30.0	9.0-30.0	5.0-19.5	5.0-19.5	5.0-19.5	6.0-17.5	6.0-17.5	6.0-17.0	5.0-16.0
RBC/ 10^6/µL	4.00-6.60	3.90-5.90	3.90-5.90	3.90-5.90	3.10-5.30	3.10-5.30	2.70-4.50	3.10-5.10	3.90-5.50	3.90-5.50	3.90-5.50
HGB/ g/dL	14.5-22.0	13.4-19.9	13.4-19.9	13.4-19.9	10.7-17.1	9.1-14.0	9.1-14.1	9.5-14.1	11.3-14.1	11.3-14.1	11.5-14.0
HCT/ %	45.0-65.0	42.0-65.0	42.0-65.0	42.0-65.0	33.0-55.0	28.0-42.0	29.0-41.0	29.0-41.0	31.0-41.0	31.0-41.0	34.0-42.0
MCV/ fL	95.0-121.0	88.0-123.0	88.0-123.0	88.0-123.0	88.0-123.0	91.0-112.0	74.0-108.0	74.0-108.0	70.0-86.0	70.0-86.0	73.0-87.0
MCH/ pg	31.0-37.0	31.0-37.0	31.0-37.0	31.0-37.0	27.0-36.0	27.0-36.0	25.0-35.0	25.0-35.0	23.0-31.0	23.0-31.0	24.0-30.0
MCHC/ g/dL	29.0-37.0	28.0-36.0	28.0-36.0	28.0-36.0	28.0-36.0	28.0-36.0	28.0-36.0	30.0-36.0	30.0-36.0	30.0-36.0	31.0-36.0
PLT/ x10(3)/mcL	150-450	150-450	150-450	150-400	150-400	150-400	150-400	150-400	140-400	140-400	140-400

ADDENDUM 2

CBC SCAN ACTION AND REPEAT CRITERIA

KEY	
RPT –	repeat CBC
SCAN –	microscopically scan smear & manual differential if required

Parameter	Condition		Action Needed
WBC	≤ 2.0	DIFF	• Re-analyze, verify count within ± 15% Add the comment that the result was checked. • Check sample for clots. If clotted, cancel the test and notify the ordering doctor or unit. • If unable to evaluate 100 cells, do a 50 cell diff and multiply the results by 2. • Re-analyze, scan to verify count verify count within ± 15%. Add the comment that the result was checked .
	≥ 30.0	SCAN	Scan to verify count. Rule out erroneous increase due to: • 2-3+ presence of large/giant platelets. Add appropriate message code. • Presence of abnormal protein/cryoglobulin *(blue streaks in smear).* • Presence of NRBC. Correct WBC. Add appropriate message code.
	≥ 99.99		• Do not result in the LIS. Notify the caregiver that this specimen will need to go to Shady Grove Medical Center for further testing and dilution. • Refer to WBC ≥ 30.0
	NRBC flag	SCAN	• Scan to verify WBC estimate. • Rule out erroneous results due to the presence of NRBC, PLT clumps or giant PLTs.
RBC	≥ 9.99		• Do not result in the LIS. Notify the caregiver that this specimen will need to go to Shady Grove Medical Center for further testing and dilution. • Scan to verify morphology. Report morphology.
HGB	≤ 6.0		• Re-analyze, verify count. Add comment. • Check for good H&H match. • Check sample for clots.
	≥ 20.0 (excludes neonates)		• Re-analyze. Add comment. • Rule out hemoconcentration. (pour off) • Check age of patient. • Check coagulation sample if HCT ≥ 55.0
	≥ 25.0		Note: Another quick check is to view the clot tubes on the patient for visibly high HCT level.
MCV	≤ 50.0	RPT MORPH	• Verify by repeat analysis. Add comment. • Verify value consistent with morphology review. See Action Needed on <70.0 MCV.
	< 70.0	MORPH	• Verify value consistent with morphology review. Denote any Target Cells, Sickle Cells, Schistocytes or Spherocytes. For 2+ or greater RBCs below threshold, evaluate accuracy of RBC count, consult supervisor if necessary.

Parameter	Condition		Action Needed
	> 110	MORPH	• Verify that value is consistent with morphology review.
	≥ 130.0	MORPH	• Verify that value is consistent with morphology review. • Denote any rouleaux or RBC agglutinins, apply message codes, and consider holding quantitative values. If necessary, consult supervisor. • Pathologic conditions include macrocytic anemias such as pernicious anemia *(oval macrocytes with hypersegmented neutrophils)* and other megaloblastic anemia. • Check for presence of cold agglutinins or cryoglobulins. Usually see elevation of MCHC also. Warm specimen to 37°C, 30 minutes and retest. • Apply message codes.
MCHC	≥ 36.5 ≤ 29.0	RPT *(warmed)* SCAN	Refer to Section 13.4.
Platelet	< 50	RPT, Check for clot, Perform PLT EST	• Verify by repeat analysis. Add comment • Be suspicious if occasional fields on morphology review have 2-3 platelets/hpf. Check closely for fibrin, >2+ large/giant platelets, platelet satellitism or platelet clumps. Check tube for clot. Scan the feather edge of the smear.
	> 50 and < 100 No flags & No History	Perform PLT EST	• *Review smear for large PLTs to ensure there is not a PLT gating (size classification) error with no previous history.*
	Platelet Clumped suspect flag	Check for clot, Vortex, WBC EST	• *Vortex specimen for 1-2 min and repeat.* • Perform scan to rule out interferences caused by ≥ 2+ large or giant platelets, plt clumps, platelet satellitism, fibrin, NRBCs, RBC fragments, or old blood/ excessive degeneration, WBC fragments or clumps. • Re-result as in section 13.2 if significant platelet clumping is noted. *Remove the PLT count before the hemogram is released*
	≥ 999	RPT SCAN	• Verify that the value is consistent with morphology review. Add comment: REP
	Other Platelet Flags	PLT EST	Scan diff to verify flag. Report noted observation.
Pediatric Rules	Special "No flag" DIFF Rule	DIFF	• DIFF all patients <12years old.
Differential Timing	≤ 48 Hours, No change in parameters or improvement	No DIFF, If	• No repeat differential if CBC parameters are improving (moving toward normal) and last differential was performed within 48 hours. • Exception 1- Physician request. • Exception 2- Patients < 1 year of age.

ADDENDUM 3

PLASMA REPLACEMENT WITH WARM DILUENT

Dispense 5 ml of instrument Diluent into a plastic tube with a tight fitting lid. Place the tube in a sealed plastic bag and place in the 37°C water bath in blood bank for a minimum of 15 minutes.

Meanwhile, spin a 2 mL aliquot of the patients sample for 10 minutes at 2700 rpm. After spinning, mark the level of the plasma on the outside of the tube. Take off the plasma as far down to the red cells as possible without removing any RBCs.

Fill the tube to the mark with the warmed Diluent, mix thoroughly and run IMMEDIATELY.

Examine the results. If the RBC is within ±0.02 of the original RBC result, the HGB and HCT agree and the MCHC is below 36.5 the results may be reported.

Append the following comment to the RBC result:

37 degree C results due to the presence of a cold agglutinin. Warm diluent replacement performed

ADDENDUM 4

SMEAR REVIEW AND MANUAL DIFFERENTIAL

The Sysmex Pochi-100 Analyzer does not report differentials. Refer to the main CBC analyzer procedure for smear review, staining and differential reporting.

Sysmex Pochi - 100 Maintenance Log

Month: _____ Year: _____ Instrument Serial Number: _____

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily																															
Quality Control is performed																															
Performed a Shut down																															
Tech																															

Bi Weekly		
Clean Transducer	Tech: Date:	Tech: Date:

Quarterly Check □ (√) if quarterly maintenance not due during current month.	
Clean Waste Chamber	Tech: Date:

Semi-Annual □ (√) if calibration not due during current month.	
Performed Calibration	Tech: Date:

Action / Comment:

_____

_____

_____

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: