POCT 340

**TITLE: Sysmex Poch- 100i Hematology Analyzer**

**PRINCIPLE**: The Sysmex pocH-100*i* is a quantitative automated hematology analyzer for *in vitro* diagnostic use. It is used to determine 17 hematological parameters which include a complete blood count (CBC). Examinations of the numerical and/or morphologic findings of the CBC are useful in diagnosis of such disease states as anemias, leukemias, allergic reactions, and viral, bacterial and parasitic infections. The Sysmex pocH-100*i* measures WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-CV and RDW-CV, as well as absolute numbers and percents of neutrophils, lymphocytes and mixed cell populations. The only results reported are WBC, RBC, HBG, HCT, MCV, MCH, MCHC, and PLT.

The pocH-100*i* counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection and hydrodynamically focused technology. Hematocrit (HCT) is measured as the ratio of the total RBC volume to whole blood using cumulative pulse height detection. Hemoglobin (HGB) is a non-cyanide-based method read photometrically at 555nm.

**TEHCNICAL PRINCIPLES**

***DC Detection Method***

The blood sample is aspirated, measured to a predetermined volume, diluted at the specified ratio, and then fed into each transducer. The transducer chamber has a minute hole called the aperture. On both sides 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. 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***

Non-cyanide hemoglobin analysis method rapidly converts blood hemoglobin into methemoglobin. This method contains no poisonous substance.

***Indices (MCV, MCH, MCHC)***

RBC constant (mean RBC volume, mean RBC hemoglobin, mean RBC hemoglobin concentration) is calculated from RBC, HGB, and HCT.

MCV (fL) = HCT X10

RBC

MCH (pg)= HGB X 10

RBC

MCHC (g/dL) =HGB X 100

HCT

***Electric system***

The microprocessor in the main unit controls the hydraulic system’s solenoid valves and syringe, thus regulating the flow of samples, reagents, and waste in the hydraulic system.

Electric signals received from various transducers go through the analogue circuit for electrical waveform-processing, and to the microcomputer. The microcomputer converts the analogue signals into digital signals for the calculation.

The WBC, RBC, and PLT cell signals are sent to the respective waveform-processing circuits in the analogue circuit, where the noise in signals is eliminated to acquire the required cell signals only. The microcomputer converts the A/D-converted cell signals into particle distribution data, and outputs them to the built-in thermal printer.

To calculate HGB, absorbance of only the diluent (background) is deducted from samples’ absorbance. The beam that has passed through the fluid is detected by the photo diode. The signals are photoelectrically converted, A/D converted, and then sent to the HGB counting circuit for calculation of the absorbance.

**SPECIMEN:**

*Patient Preparation:*

* None.

*Specimen requirements:*

* A minimum of 1 ml of whole blood collected in a 2ml or 4ml EDTA tube is required for testing. Specimens are to be run within 4 hours of collection and must be well mixed and free of clots. **Use of other anticoagulants can yield misleading results.**
* Unacceptable specimens include: unlabeled specimen, information on specimen label does not match information on test requisition, collection in tube with wrong anticoagulant, specimen collection time beyond four (4) hour stability at room temperature, clotted specimen, QNS for analysis, abnormal results not consistent with previous results, if known.

*Specimen Stability:*

* EDTA specimens can be stored at 2-8˚ C for 24 hours and at room temperature for 4 hours.
* Samples stored at room temperature may exhibit an increase in the MCV, and Hematocrit and a decrease in the MCHC after 16 hours.
* Samples removed from the refrigerator need to come completely to room temperature and be well mixed before they can be analyzed.
* Samples should not be placed on a mechanical rocker. The constant mixing can cause platelet activation and clumping, while altering white blood cell membranes causing inappropriate flagging on the Sysmex Poch- 100i Hematology Analyzer.

 All body fluids should be handled as if capable of transmitting infectious diseases. Use universal precautions when in contact with such materials.

**REAGENTS AND MATERIALS:**

* **PocH-pack D:** Is a ready-to-use diluent for Direct Current (DC) detection and absorbance analysis. It is stored at room temperature (20 to 25° C) and supplied by Sysmex America, Inc.

Active Ingredients:

Sodium Chloride 6.38 g/L

Boric Acid 1.0 g/L

Sodium Tetraborate 0.2 g/L

K2EDTA 0.2 g/L

Storage and Stability:

The expiration date is shown on the outer packaging. If stored unopened at 1° to 30° C, it remains usable for 12 months from date of manufacture. Once opened, product stability is 60 days. Write the opened date and the new 60 day expiration date on the bottle. If signs of instability, such as cloudiness or color change are displayed, the reagent should be replaced.

**Reagent is not to be used past its opened or closed expiration date.**

* **PocH-pack L:** This reagent lyses RBC for accurate WBC count, hemoglobin determination, and allows WBC count and volume distribution analysis by the DC detection method. Reagent is stored at room temperature (20-25° C) and supplied by Sysmex America, Inc.

Active ingredients:

Sodium Chloride 0.6 g/L

Org. quart. ammonium salt 8.5 g/L

Storage and Stability:

Use pocH-pack L at 20° to 25° C. If analysis is performed outside of these temperatures, incorrect results may be obtained. The expiration date is shown on outer packaging. If unopened and stored at 20° to 25° C, reagent remains stable for 12 months from date of manufacture. Once opened, product stability expires after 90 days. Write open date and new 90 day expiration date on bottle. pocH-pack L reagent displaying any signs of contamination or instability, as indicated by cloudiness or color change, should be replaced. Do not use pocH-pack L once frozen.

**Reagent is not to be used past its opened or closed expiration date.**

* + **Hazard listing:**

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. pocH-pack D and pocH-pack L do not have ingredients with those characteristics.

* **5% solution of Clorox® Ultra bleach:** This is used in the cleaning of the Sysmex Poch- 100i Hematology Analyzer.

Clorox Ultra Ingredients

Sodium Hypochlorite 6.0%

Clorox Ultra Storage

Stable under normal use and storage conditions

Clorox Ultra Health Risk

Can be a respiratory irritant if mist or vapor is inhaled, nausea and vomiting if ingested. May irritate skin; contact with eyes can cause severe, but temporary injury to the eye.

* **EIGHTCHECK-3WP X-TRA:** This quality control is a tri-level whole blood commercial control for use with the Sysmex pocH-100*i* hematology analyzer.

EIGHTCHECK-3WP X-TRA Ingredients (formulation)

EIGHTCHECK-3WP X-TRA consists of stabilized human erythrocytes, human and simulated leukocytes and a platelet component in plasma-like fluid. Each vial contains 2.0 mL of control material.

EIGHTCHECK-3WP X-TRA Storage:

Vials should be stored at 2 o to 8o C. **DO NOT** freeze or expose to excessive heat.

EIGHTCHECK-3WP X-TRA Stability:

* Unopened and properly stored, EIGHTCHECK-3WP X-TRA is stable until the expiration date stated on the vial.
* Open vial stability is 14 days when promptly refrigerated after each use.
* Record the date on each vial upon opening.
* Heat or freezing can damage EIGHTCHECK-3WP X-TRA without gross visible changes. Moderate hemolysis can be normal. Deterioration is suspected when the mean of the control results is not within the assay expected ranges after appropriate troubleshooting.
* **Reagent is not to be used past its opened or closed expiration date**

If deterioration is suspected, call the Sysmex Technical Assistance Center at 1-866-879-7639 (1-866-8SYSMEX).

* **SCS-1000 Calibrator™** is a secondary whole blood calibrator for use with the Sysmex pocH-100*i* hematology analyzer. Assay values for primary parameters are traceable to reference methods.

SCS-1000 Ingredients (formulation)

SCS-1000 consists of human red and white blood cells with a platelet component suspended in fluid medium. Each vial contains 2.0 mL of calibrator material.

SCS-1000 Storage

Store vials at 2 o to 8o C. **DO NOT** freeze or expose to excessive heat.

SCS-1000 Stability

* Unopened and properly stored, SCS-1000 is stable until the expiration date stated on the vial.
* Open vial stability is 4 hours.
* Storage outside of 2 o to 8o C can damage SCS-1000 causing deterioration that risks inaccurate calibration. If deterioration is suspected, call the Sysmex Technical Assistance Center at 1-866-879-7639 (1-866-8SYSMEX).
* Use of the product at environmental temperatures that exceed 30 o C (86 o F) can reduce calibration accuracy.

 All control and calibration materials should be handled as if capable of transmitting infectious diseases. Use universal precautions when in contact with such materials.

**CALIBRATION**

Initial calibration of all measured parameters is performed at Sysmex America, Inc. prior to shipment of analyzer. Calibration compensates for any bias inherent to the pneumatic, hydraulic, and electrical system that may affect the accuracy of results. Calibrators traceable to reference methods are used in the calibration of the instrument.

Calibration verification is performed at implementation and approximately every 6 months to ensure accuracy of the system. Calibration is also required if one or more of the following occur:

* Critical parts are replaced such as manometers, apertures or detector circuit boards.
* Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting.
* When advised by pocH-100*i* Technical Assistance Center (1-866-8SYSMEX).

Calibration verification may be accomplished by review and documentation of at least two (2) levels of commercial control each day patient specimens are run, and proficiency testing results. The operator may calibrate HGB and HCT with normal fresh whole blood, or use SCS-1000 calibrator to calibrate WBC, RBC, HGB, HCT, and PLT. The calibration verification includes a precision check prior to the WB Calibration.

***WB CALBIRATION AND PRECISION CHECK PROCEDURE***

1. Press the **[MENU]** button from the main Pochi screen.
2. Press **[CALIB.]**
3. Choose **[CALIBRATOR WB]**
4. After allowing the SCS-1000 calibration material to come to room temperature, mix it well; remove the cap and place in the green sample adaptor. Press **[RUN]** to start the precision check.
5. You will repeat this 11 times, in between each time replace the cap and mix well prior to starting the next run.
6. Once you have the 11 runs completed, the Pochi will automatically calculate the mean, Standard Deviation (SD) ,the Coefficient of Variation (%CV) and the Limit (LMT%).
   * You will want to record these results because once you quit from this screen you will be unable to retrieve them.
7. Press **[QUIT]** to exit the precision check portion of the calibration.
8. On the next screen enter the target values of the SCS-1000 calibration material from the assay sheet by using the key pad, and press **[Next]** when you are done.
9. Verify that the target values have been entered correctly and at “Set target value” press **[OK]**.
10. You will now have to run the SCS-1000 six times to validate the calibration. Mix the sample well, remove the cap, place in the green samples adaptor and press **[RUN].**
    * Only five of your runs will appear on the screen, the first run serves as a primer.
11. When the last analysis is complete press **[NEXT]**
12. The Pochi will automatically perform calculations for the Range V., MaxRange, Mean V., Delta%, ACPT LMT, SERV LMT, Current, and New.
    * You will want to record these results because once you quit from this screen you will be unable to retrieve them.
13. Press **[Quit]** accepting your new calibration.

**QUALITY CONTROL**

***Setup of Quality Control Files***

1. Before performing QC analysis for the first time or at change of lot number set up the 3 QC files.
2. Input information on the control blood, i.e. Lot ID, Expiration date, Target value and Limit value.
3. Press the display column of the file to be used. The quality control analysis starting screen will appear.
4. Press **[SETTINGS]**. The QC file [1] setting screen will appear. When the display column for the parameter to be set is pressed, the numerical key pad will be displayed and the setting value can be entered.
5. Press ‘Lot ID’ column. The numeric value input dialog will appear. Enter or scan the Lot ID. Up to 10 digits can be entered.
6. Press ‘Expire’ column. The data input window will appear.
7. Enter the expiration date. Up to 10 digits can be entered.
8. Press [→] or [←]. There are six (6) QC file setting screens. When the right arrow button is pressed, the display changes from the first QC file screen to the second screen. After the sixth screen, pressing the right arrow button returns the display to the first screen. When the left arrow button is pressed, it changes the display in reverse order.
9. Press each of the parameter display columns. The numeric input message will appear.
10. Scan barcodes from assay sheet or enter the Target values and the limit values for each parameter using the right arrow or left arrow to switch from screen to screen. There are 21 control parameters.
11. When the entering of control values is completed, press **[SAVE]**. The quality control setting storing confirmation message will appear
12. Press **[OK]** to store the settings and the L-J analysis start screen will appear.
13. Press **[CANCEL]**, **[OK]** to close the control settings menu and return to Main menu. If you press **[TOP]**, **[OK]**, the quality control setting will be aborted and no data will be stored.

***Running Quality Control***

The running of the Low, Normal and High EIGHTCHECK will take place immediately after the start up of the Sysmex Poch- 100i Hematology Analyzer. It is the responsibility of the testing personnel to run and review the EIGHTCHECK making sure it is within acceptable limits before patient testing takes place. **IT IS NEVER ACCPETABLE TO RUN PATIENTS IF THE QUALITY CONTROL IS NOT WITHIN EXPECTED RANGE.**

1. Remove EIGHTCHECK-3WP X-TRA vials from refrigerator and allow them to come to room temperature (18o to 25o C), for approximately 15 minutes.
2. Mix vials by rolling between your palms and gentle end-to-end inversion until the cell button in the bottom of the vial is completely suspended. Do not use a mechanical rocker.
3. Wait until analyzer displays the ‘Ready’ message and press **[QC]** on Main screen.
4. Press the correct lot number for QC sample to be analyzed. The analyzing start screen will be displayed.
5. Press the top of the sample position to open it automatically. Do not force it to open or the analyzer may be damaged.
6. Make sure the green sample adaptor is in place.
7. Open the control blood cap carefully to avoid splashing of blood. Set the control blood into the green sample adapter and close the sample position.
8. Press **[RUN]**. The analysis starts. The status display reads ‘Aspirating’. When sample aspiration is completed, status display ‘Aspirating’ changes to ‘Running’. When ‘Running’ is displayed, the sample position door can be opened and the control blood can be removed safely. Do not open the sample position while ‘Aspirating’ is displayed. If the sample position is opened while displaying ‘Aspirating’ an incorrect analysis result will be displayed.
9. The analyzing screen will appear.
10. After completion of a single analysis, these analysis results will be displayed on the LCD screen. Use [↓] or [↑] to scroll the screen page. The analysis values are compared to the target range.
11. If no error codes are displayed, the values are acceptable.
12. Press **[QUIT]** to accept the QC and print the results.
13. Repeat with the remaining 2 levels of QC. All analytes on all levels must be acceptable in order to proceed with patient testing.
14. If QC **DOES NOT** pass, acknowledge the error by pressing the blinking error button and then pressing **[OK].**
15. Any analyte that is not acceptable is highlighted in red with a (+) or (-) sign.
16. When the QC does not pass and the unacceptable results are displayed, press **[TOP]** to quit the QC program. At the “Quit QC Analysis?” prompt, press **[OK].**
17. Remove that vial of QC from the sample adapter. Replace the cap and gently remix the specimen. Select the correct lot number of QC from the list on the menus screen. Remove the cap from the vial, place the vial in the sample adapter, and run that level of QC again.
18. If unable to obtain acceptable QC values, open a new vial of QC and run this sample.
19. All analytes on all levels must be acceptable in order to proceed with patient testing.
20. If necessary, call the Point of Care department for assistance.

***Quality Control Decisions***

1. Accept control results if:

* all controls read within the programmed manufacturer’s acceptable ranges and there are no error messages

1. Reject control results if:

* an error message is displayed on the screen

1. When a control is rejected:

* **Do not report patient results until QC is further investigated.**
* Check lot #, expiration date, opened date stability, appearance of control, proper handling.
* Gently mix and rerun same QC vial.
* Clean the system and rerun the QC. Open new vial if needed and run this vial.
* If control(s) still unacceptable after rerun, notify the Point of Care (POC) department at Catholic Medical Center
* The POC will review reagent history, calibration history, maintenance procedures due.
* Review cumulative QC data for trends or shifts.
* Recalibrate the analyzer if other means of assessing and correcting control values have failed
* Document QC value(s) out of range. Document corrective action taken on the QC corrective action log.
* If the POC Department cannot troubleshoot the problem they will contact pocH-100i technical Assistance Center at 1-866-879-7639 for further assistance.
* Should the pocH-100i System become inoperable for any reason, specimens should be collected and submitted to the Laboratory at Catholic Medical Center with an appropriate test requisition, in accordance with the Laboratory Procedure Manual. Transport specimen with transport staff and/or courier.

***Starting a New Lot of Controls***

Scan the barcodes from the assay sheet accompanying the shipment of QC samples in order to load the target values of the new lots. Perform parallel testing with the new controls by analyzing the three (3) levels of control for a period of 3-5 days prior to expiration of the previous lot. The data is reviewed by the POC to determine that the manufacturer’s target values are reproduceable.

***Insight***

Insight is an online Quality Management tool provided by Sysmex to help monitor the quality control values that are obtained from the Sysmex Poch- 100i Hematology Analyzer. The CMC Point of Care Department/Designee will be responsible for gathering the QC Data, reviewing it, and entering it into the insight website on a cumulative weekly basis.

**DAILY OPERATION PROCEDURES**

Verify the following before turning instrument on:

* Check that the power cable is connected.
* Check that there is sufficient printer paper.
* If needed, discard any waste fluid in waste container.

***Power On/ Background Check***

* Turn instrument on using switch located on right side of the instrument.
* Three automatic rinse cycles are performed and then a background check. Should any values be out of the acceptable limit, a maximum of two extra background checks will be performed.

ACCEPTABLE BACKGROUND LIMITS

WBC………….. 0.3 (x103/µL) or less

RBC……………0.02 (x 106/µL) or less

HGB……………0.1 x (g/dL) or less

PLT ……………10 (x103/µL) or less

Record the daily background check on the daily maintenance log sheet.

If the background check results are unacceptable, perform another background check using the following steps:

1. Press **[MENU]**
2. Press **[MAINT]**]
3. Press **[AUTO RINSE]**
4. Press **[EXECUTE]**
5. After completion, verify that results are within acceptable background limits
6. If still unacceptable, contact the Point of Care department for assistance. Do not run QC or perform any patient testing.

***Quality Control Analysis***

See running Quality Control

***Shut Down***

1. Press **[SHUTDOWN]** at Ready screen
2. Press **[Execute].** It takes approximately 2 minutes.
3. When completed, switch power OFF by pressing the power switch located on the right side of the instrument.

**PATIENT TESTING**

***Running a Patient Sample***

1. The whole blood mode is the default setting when the instrument is turned ON.
2. Press **[Sample ID].** The numeric keys will appear.
3. Scan the patient demographic barcode on the specimen. This is the patient’s account number. Verify the number scanned is correct.
4. Press **[Ent.]**
5. Press the top of the sample position to open.
6. Set the tan adapter in the sample position.
7. Gently mix the lavender (EDTA) top tube (minimum draw 1 mL) by inverting tube 10 times.
8. Set the sample in the adapter and close the door.
9. Make sure that status screen displays “Ready”.
10. Press **[RUN].**
11. Remove the sample when processing is complete and results are displayed on the screen.
12. The results will automatically transmit into Centricity provided that
    * + The patient’s account number was entered accurately as the sample ID
      + There are no error codes or flags on the results
      + All results are within the determined linearity for each analyte
13. When testing is complete, store the specimen in the rack in the refrigerator.

**Result Reporting**

After each analysis, the test results are displayed on the LCD screen and automatically print with the built-in thermal printer. Reportable parameters will be White Blood Count (WBC), Red Blood Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelets (PLT), MCH, MCHC, AND MCV.

***Linearity (Reportable Range)***

Linearity is determined by testing levels of an analyte that are known relative to each other. Understanding the linear relationship of the instrument method and the analyte concentration defines the usable assay range. Commercially available linearity material, “RANGE CHECK”, is used for this study.

|  |  |
| --- | --- |
|  | **Linearity**  **(Reportable Range)** |
|
| **WBC** | 2.1-29.9 x 103/µL |
| **RBC** | 2.2-6.2 x 106 µL |
| **HGB** | 7.1-19.9 g/dL |
| **HCT** | 21-60% |
| **MCV** | 70-110 fL |
| **MCH** | 23.0-36 pg |
| **MCHC** | 28.0-36.5 g/dL |
| **PLT** | 31-999 x 103/µL |

##### Repeat Analysis Criteria

1. Repeat specimen testing on the pocH-100i when an analyte result is lower or higher than the defined reportable range.
2. Repeat specimen testing when a flag follows any analyte result (see error flags cheat sheet)
3. Remember, to rerun a specimen, ensure that the correct patient barcode is scanned as the patient ID, gently remix the specimen, and run as stated above.
4. If any repeated patient test result is still outside the determined reportable range, the specimen and test requisition is to be sent to the CMC main laboratory for testing.

***Normal Reference Range***

Adult normal reference ranges were validated by obtaining specimens from adults of assumed good health. Samples were analyzed on the Sysmex pocH-100iupon completion of installation, calibration, linearity and quality control checks. Normal reference range was determined for female (minimum 20 samples collected) and male (minimum 20 samples collected). Pediatric reference ranges are determined per literature recommendations.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **CBC Normal Ranges by Age** | | | | | |
|
| **WBC** | | | **RBC** | | |
|  | Male | Female |  | Male | Female |
| 0-14 days | 8.0-15.4 | 8.1-14.5 | 0-14 days | 4.1-5.5 | 4.12-5.74 |
| 14-30 days | 7.8-15.9 | 8.3-14.4 | 14-30 days | 3.16-4.63 | 3.32-4.8 |
| 30-60 days | 8.1-14.9 | 7.0-14.6 | 30-60 days | 3.02-4.22 | 2.93-3.87 |
| 60 days-6 months | 6.51-13.32 | 6.0-13.2 | 60 days-6 months | 3.43-4.80 | 3.45-4.75 |
| 6 months -2 years | 5.98-13.51 | 6.48-13.02 | 6 months -2 years | 4.03-5.07 | 3.97-5.01 |
| 2-6 Years | 5.14-13.38 | 4.86-13.18 | 2-6 Years | 3.89-4.97 | 3.84-4.92 |
| 6-12 Years | 4.31-11.0 | 4.27-11.4 | 6-12 Years | 3.96-5.03 | 3.9-4.96 |
| 12-18 Years | 3.84-9.84 | 4.19-9.43 | 12-18 Years | 4.03-5.29 | 3.93-4.90 |
| Over 18 | 4.5-11.5 | 4.5-11.5 | Over 18 | 4.63-6.08 | 3.93-5.22 |
| **Hgb** | | | **HCT** | | |
|  | Male | Female |  | Male | Female |
| 0-14 days | 13.9-19.1 | 13.4-20 | 0-14 days | 39.8-53.6 | 39.6-57.2 |
| 14-30 days | 10.0-15.3 | 10.8-14.6 | 14-30 days | 30.5-45 | 32.0-44.5 |
| 30-60 days | 8.9-12.7 | 9.2-11.4 | 30-60 days | 26.8-37.5 | 27.7-35.1 |
| 60 days-6 months | 9.6-12.4 | 9.9-12.4 | 60 days-6 months | 28.6-37.2 | 29.5-37.1 |
| 6 months -2 years | 10.1-12.5 | 10.2-12.7 | 6 months -2 years | 30.8-37.8 | 30.9-37.9 |
| 2-6 Years | 10.2-12.7 | 10.2-12.7 | 2-6 Years | 31.0-37.7 | 31.2-37.8 |
| 6-12 Years | 10.7-13.4 | 10.6-13.2 | 6-12 Years | 32.2-39.8 | 32.4-39.5 |
| 12-18 Years | 11.0-14.5 | 10.8-13.3 | 12-18 Years | 33.9-43.5 | 33.4-40.4 |
| Over 18 | 13.7-17.5 | 11.2-15.7 | Over 18 | 40.0-54.0 | 35.0-49.0 |
| **MCV** | | | **MCH** | | |
|  | Male | Female |  | Male | Female |
| 0-14 days | 91.3-103.1 | 92.7-106.4 | 0-14 days | 31.3-35.6 | 31.1-35.9 |
| 14-30 days | 89.4-99.7 | 90.1-103.0 | 14-30 days | 29.9-34.1 | 30.4-35.3 |
| 30-60 days | 84.3-94.2 | 83.4-96.4 | 30-60 days | 27.8-32 | 28.0-32.5 |
| 60 days-6 months | 74.1-87.5 | 74.8-88.3 | 60 days-6 months | 24.4-28.9 | 24.4-29.5 |
| 6 months -2 years | 69.5-81.7 | 71.3-82.6 | 6 months -2 years | 22.7-27.2 | 23.2-27.5 |
| 2-6 Years | 71.3-84.0 | 72.3-85.0 | 2-6 Years | 23.7-28.3 | 23.7-28.6 |
| 6-12 Years | 74.4-86.1 | 75.9-87.6 | 6-12 Years | 24.9-29.2 | 24.8-29.5 |
| 12-18 Years | 76.7-89.2 | 76.9-90.6 | 12-18 Years | 25.2-30.2 | 24.8-30.2 |
| Over 18 | 80-100 | 80-100 | Over 18 | 25.7-32.2 | 25.6-32.2 |
| **MCHC** | | | **PLT** | | |
|  | Male | Female |  | Male | Female |
| 0-14 days | 33.0-35.7 | 33.4-35.4 | 0-14 days | 218-419 | 144-449 |
| 14-30 days | 32.7-35.1 | 33.2-35.0 | 14-30 days | 248-586 | 279-571 |
| 30-60 days | 32.3-34.8 | 32.5-34.9 | 30-60 days | 229-562 | 331-597 |
| 60 days-6 months | 31.9-34.4 | 32.1-34.4 | 60 days-6 months | 244-529 | 247-580 |
| 6 months -2 years | 31.6-34.4 | 31.9-34.2 | 6 months -2 years | 206-445 | 214-459 |
| 2-6 Years | 32.0-34.7 | 31.8-34.6 | 2-6 Years | 202-403 | 189-394 |
| 6-12 Years | 32.2-34.9 | 31.8-34.6 | 6-12 Years | 206-369 | 199-367 |
| 12-18 Years | 31.8-34.8 | 31.5-34.2 | 12-18 Years | 175-332 | 194-345 |
| Over 18 | 32.3-36.5 | 32.2-35.5 | Over 18 | 150-440 | 150-440 |

***Critical Results***

Critical patient results from this analyzer are not reported. These critical results are outside the determined reportable range. Therefore, the patient sample would be sent to the CMC Lab with a test requisition for analysis.

|  |  |  |
| --- | --- | --- |
| **Analyte** | **Critical Results** | |
|
| **Low** | **High** |
| **WBC** | ≤2.0 K/µL | ≥30.0 K/µL |
|
| **WBC Neonatal (0-1 month)** | ≤5.0 K/µL | ≥35.0 K/µL |
|
|
| **Hemoglobin** | ≤7.0 g/dL | ≥20.0 g/dL |
|
| **Hemoglobin Neonatal (0-1 month)** | ≤7.0 g/dL | ≥23.0 g/dL |
|
| **PLT** | <30 K/µL | >1000 K/µL |
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***Sysmex Poch- 100i Hematology Analyzer Error Flags***System Limitation Interference flags that are known to affect test results.

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| **Pochi Flags and Corrective Actions** | | |
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| Error Flag | Possible Cause of Problem | Corrective Action |
| WL | Unlysed Red Cells, Nucleated Red Blood Cells, Large Platelets, Platelet Clumps, and Clotted Specimens | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| WU | Unlysed Red Cells, Abnormal White cell forms, and Elevated White Cell Count | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| AG | Presence of Nucleated Red Blood Cells, Platelet aggregation, Giant Platelets or Fibrin Strands | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| DW (PLT) | Fragmented Red Blood Cells, Giant Platelets, or Poor Platelet distribution | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| MP (PLT) | Platelet aggregation or Low Platelet Counts | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| PL | Fragmented Red Blood Cells, Cellular Fragments, or Platelet abnormalities | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| PU | Increase of large platelet forms, Red Blood Cell inclusions, Platelet aggregates, Microcytic Red Blood Cells or Fragmented Red Blood Cells | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| RL | Fragmented Red Blood Cells, Large Platelet forms, Platelet aggregation or Microcytic Red Blood Cells | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| RU | Cold Agglutinin, White Blood Cell inclusions, or Nucleated Red Blood Cells | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| DW (RBC) | Significant anisocytosis | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| MP (RBC) | Blood Transfusions or Various Anemias | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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| ! | Outside of the Pochi Reportable Range | 1. Mix Specimen 2. Rerun Specimen 3. If flags are not resolved flagged indices **CANNOT** be reported will need to go to CMC Lab for testing |
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**MAINTENANCE PROCEDURES**

All maintenance procedures can be accessed by pressing **[MENU].** All maintenance procedures are to be documented on the maintenance log sheet.

***Reagent Replacement (pocH packD or pocH packL)***

1. Obtain new container of reagent and check the expiration date.
2. Remove the cap from the new reagent bottle.
3. Remove the cap from the empty reagent bottle. Pull the container spout kit straight up to remove.
4. Insert the container spout kit straight down into the new reagent bottle and tighten cap.
5. Press **[MENU]** on the Main screen.
6. Press **[Chg.Reag.]**
7. Press **[pocHpack D]** to replace diluents **OR**
8. Press **[pocHpack L]** to replace lysing agent.
9. The replacing reagent screen will appear.
10. Press **[Manual]**
11. Scan the barcode on the reagent bottle.
12. Press **[Execute]**
13. Document the date opened and reassigned expiration date on the reagent bottle.

***Disposing of Waste Fluid***

*The pocH-100i will alarm when the waste container is full (there is a float that detects the fluid level in the waste container).*

1. Remove the cap and the float switch assembly from the full waste bottle. Place the float switch on a clean paper towel.
2. Place a cap on the full waste bottle for transport to a designated dirty sink. Dispose the waste fluid and clean the waste bottle out with water. Replace the cap for return to the lab area.
3. Remove the cap and insert the float switch assembly into the empty waste bottle, and tighten the cap assembly. Check that the tube is not bent.
4. Press the **[Execute]** button on the error help screen. The waste processing screen will appear, and the waste discharge operation will be performed.

***Scheduled Maintenance***

* **Clean Transducer** – every two weeks (or every 150 samples)

*PocH-100i™ will alarm when this needs to be done. Turn alarm off and perform maintenance at earliest convenience*

* 1. Press **[Menu].**
  2. Press **[Maint].**
  3. Press [**Clean Transducer].**
  4. Prepare a 4.5ml EDTA (lavender top) tube by rinsing out the EDTA with water. Add about 3ml of 5% bleach and about 1ml of water to the tube. Replace stopper on tube.
  5. Press the top of the sample position to open.
  6. Set the adapter (tan) in the sample position.
  7. Set the sample tube with 5% bleach in place and close the door.
  8. Press **[Execute].**
  9. After completion, the Main screen will appear.
  10. Remove the sample tube from the sample position.
  11. Dispose of sample tube in appropriate waste container.
  12. Document the maintenance procedure in maintenance log.
* **Clean Waste Chamber** - every 3 months (or every 1500 samples)

*PocH-100i™ will alarm when this needs to be done. Turn alarm off and perform maintenance at earliest convenience*

* 1. Press **[Menu].**
  2. Press **[Maint.].**
  3. Press **[Clean W. Chamber]**
  4. Prepare a 4.5ml EDTA (lavender top) tube by rinsing out the EDTA with water. Add about 3ml of 5% bleach and about 1ml of water to the tube. Replace stopper on tube.
  5. Press the top of the sample position to open.
  6. Set the adapter (tan) in the sample position.
  7. Set the sample tube with 5% bleach in place and close the door.
  8. Press **[Execute].**
  9. After completion, the Main screen will appear.
  10. Remove the sample tube from the sample position.
  11. Dispose of sample tube in appropriate waste container.
  12. Document the maintenance procedure in maintenance log.

***As Needed Maintenance***

* **Cleaning the sample tube adapter**

1. Press the top of the sample position to open.
2. Remove the sample tube adapter.
3. Clean the sample tube adapter with 1:10 dilution of filtered bleach. Rinse with water after cleaning. Dry with a paper towel or allow to air dry.
4. Set the cleaned adapter in the sample position.
5. Close the sample position.

* **Replace Thermal Printer Paper**

1. Push the lever on the right side of the built-in printer down and then open the printer cover.
2. Remove any remaining paper. Insert new printer paper, and close the printer cover so that it catches the paper.
3. Cut the paper that is protruding from the top of the built-in printer.

* **Clog Removal from Transducer Aperture**

*When the instrument encounters difficulty aspirating a patient sample, the”Aperture Clog” error screen will display.*

1. Press **[Execute]** on the “Aperture Clog” error help screen.
2. When the cleaning process is finished, the main screen will appear.
3. Check specimen for clots. If there are no clots retest the sample.

**PROCEDURE NOTES**: For Troubleshooting specifics see Chapter 14 of the pocH-100*i* Instruction for Use Manual.

**REFERENCES:**

* PocH-100i CLSI/NCCLS Procedure by Sysmex September 2010
* Sysmex PocH – 100iTM Hematology Analyzer Procedure, by Suzanne Chute, BB(ASCP), Susan Krause, MT(ASCP) October 2004
* Sysmex Poch-100i implementation binder, October 2010

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