TITLE: Sysmex pocH – 100i™ Hematology Analyzer Procedure

General Principle

The Sysmex pocH-100*i*™ is a compact automated hematology analyzer for in vitro diagnostic use. It provides both analytical results and histograms that can be printed on the built in thermal printer or displayed on the color LCD screen. Values outside the specified upper and lower limits are marked for further analysis and review.

The sample is aspirated with the aspirating piercer. An exact volume is sent into the mixing chamber and the transducer, together with a measured volume of the diluent.

All parameters are analyzed in the order of: (1) WBC/HGB and (2) RBC/PLT using the same transducer.

For WBC/HGB analysis, the WBC/HGB lyse is added to the measuring chamber for further dilution and hemolysing. The sample RBC's lyse in the chamber for about ten seconds.

During this reaction period, the erythrocytes are dissolved under the influence of the lysis, hemoglobin emerges and is converted into red methemoglobin. The leukocytes remain intact

The volume and number of the leukocytes (WBC) are determined by the DC (direct current) detection method. In the HGB detector, the hemoglobin concentration is photometrically measured.

For RBC/PLT analysis, the diluted sample is transferred from the mixing chamber to the transducer, and the volume and blood cell count for erythrocytes and platelets are analyzed by the DC detection method.

Based on the measured values, the microprocessor calculates the remaining parameters: HCT, MCV, MCH, MCHC, RDW-CV. (MPV not reported).

A three-part WBC differential is reported using neutrophils, lymphocytes and middle leukocytes that are equivalent to monocytes, eosinophils, and basophils. Absolute counts of these parameters are also available.

Technology Principles:

A. *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.

B. *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.

C. *Non-Cyanide Hemoglobin analysis me Indices (MCV, MCH, MCHC)*

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

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

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

$$\text{MCV (fL)} = \frac{\text{HCT}}{\text{RBC}} \times 10$$

$$\text{MCH (pg)} = \frac{\text{HGB}}{\text{RBC}} \times 10$$

$$\text{MCHC (g/dL)} = \frac{\text{HGB}}{\text{HCT}} \times 100$$

E. *Analysis of WBC Differential*

The WBC is discriminated into small, middle, and large WBC by 3-part differential method using 4 discriminators (LD, T1, T2, UD). Approximately: 30 – 300fL.

LD (LOWER Discriminator)
T1 (TROUGH Discriminator 1)
T2 (TROUGH Discriminator 2)
UD (UPPER Discriminator)
LYM # [W-SCC (WBC-Small Cell Count)]
Lymphocytes between discriminator (LD) and (T1), which is considered highly correlated with lymphocyte count.

1. MXD# [W-MCC (WBC-Middle Cell Count)]
   Mixed cells between discriminator (T1) and (T2), which is considered highly correlated with the sum of monocytes, basophils, and eosinophils.
2. NEUT# [W-LCC (WBC-Large Cell Count)]
   Neutrophils more than discriminator (T2), which is considered highly correlated with neutrophils.

F. *Electrical 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 is photoelectrically converted, A/D converted, and then sent to the HGB counting circuit for calculation of the absorbance.

Specimen Collection, Handling and Storage

- All body fluids and, when stated by manufacturer, controls, should be handled as if capable of transmitting infectious diseases. Always use standard precautions when in contact with such materials. Refer to Laboratory Infection Control Policy.

1. Whole blood drawn into lavender top tubes (K3 or K2EDTA as the anticoagulant) is required. **Use of other anticoagulants can yield misleading results.** Perform specimen collection on venous blood by means of vacuum collection tube or by syringe. A minimum of one (1) ml is required.
2. There are no special considerations for patient preparation. Pre-analytic variables are limited to:
    - Sufficient amount of blood in collection tubes so as not to introduce erroneous dilution factors.
    - A "clean" venipuncture to eliminate hemolysis.
    - Complete mixing of tubes to eliminate any microclots.
    - Not drawn above an IV.
3. Gently invert the specimen collection tube at least ten (10) times to ensure that the specimen is completely mixed prior to sampling on the analyzer.
4. The specimen is stable for four (4) hours after collection when stored at room temperature. Specimen is not to be analyzed on the Sysmex pocH – 100i beyond the 4 hours stability time. If the specimen requires further testing, place the specimen in the refrigerator (2 – 8^{o} C), and transport the specimen to the Main Concord Hospital Laboratory within 8 hours of collection.
5. Specimen collection tubes analyzed on the **Sysmex pocH – 100i** can be checked for clots prior to analysis. Two wooden applicator sticks are inserted into the tube and swirled. Clots will adhere to the wooden applicator sticks. **When clots are found, testing CANNOT be done on the specimen.** A new order is placed and specimen drawn. Contact a Point of Care Specialist to cancel the order for the clotted specimen. Flags and messages on the pocH-100i print out may also be an indication that the specimen has clots or microclots.
6. Criteria for specimen rejection: unlabeled specimen, information on specimen label does not match information on test requisition, specimen collection time beyond four (4) hour stability at room temperature, time of collection unknown, clotted specimen, QNS for analysis, abnormal results not consistent with previous results, if known.
7. Cancel any ordered test unsuitable for testing. Document reason for cancellation on the Laboratory Tests/Results Form, and reason annotated. Notify the physician. Collect a new sample if still requested.

Reagents

- The pocH-pack D**,** is a ready-to-use diluent for DC detection and absorbance analysis of whole blood. Store at 1°C-30°C. Unopened reagent stored at this temperature remains usable for 12 months after manufacture. Once opened (connected to instrument) reagent stability is 60 days.

  PocH pack D composition:

Sodium chloride	6.38 g/L
Boric acid	1.0 g/L
Sodium Tetraborate	0.2 g/L
EDTA-2K	0.2 g/L

- The pocH-pack L, reagent that lyses RBC's for accurate WBC count and Hemoglobin determination. Store at 2^{o}C- 35^{o}C. Unopened reagent stored at this temperature remains usable for 12 months after manufacture. Once opened (connected to instrument) reagent stability is 90 days. Do not use the pocH-pack L if it has been frozen.

  pocH-pack L composition:

Sodium Chloride	0.6g/L
Org. quart. Ammonium salt	8.5g/L

- A 5% solution of Clorox®bleach is recommended for use in cleaning of the pocH-100*i* whenever CELLCLEAN is indicated as the cleaning agent. Scented or splashless varieties of Clorox bleach must not be used at any time. Refer to the label of the product in use for the sodium hypochlorite concentration.

  Clorox Ingredients

  Sodium Hypochlorite

  Clorox Storage

  Stable under normal use and storage conditions

  When using Clorox bleach, avoid acidification or contact with ammonia containing products that can generate hazardous chlorine gas.

Handling of Reagents

- Read the note documentation and labeling on all reagents.
- Avoid direct contact with reagents. Reagents can cause irritation of the eyes, skin and mucous membranes.
- Should you inadvertently come in contact with a reagent, rinse skin immediately with plenty of water.
- At eye contact, rinse at once with plenty of water. See a physician immediately.
- If reagent was swallowed, obtain immediate medical advice.
- Leave the reagent at room temperature (15^{0} –30^{O}C) for at least 24 hours before using.
- Avoid contact of dust, dirt or bacteria with the reagent tubing when installing new reagent bottles.
- Reagents must not be used after their expiration date.
- Handle reagents gently to avoid bubbling. Do not shake. Do not use directly after transportation.
- If reagent is spilt, wipe up with damp cloth.
- Ensure reagents used with the instruments are kept level or below the main unit of the instrument. Do not put reagents on top of the instrument.

Labeling

- Date all reagent containers/boxes when received.
- When reagents are placed in service, date the reagent container/bottle with open date and expiration date.
- DO NOT use any reagent that has reached its open or closed expiration date. Discard partially used reagent container. Rinse container thoroughly, and flush with copious amounts of water.

Calibration

Calibration is performed at least every six (6) months, and sooner if applicable to conditions below:

- upon instrument installation
- after major maintenance or service
- after any major constituents (parts) in the instrument are repaired or changed
- at complete changes of reagents, if quality control values are affected by reagent lot changes
- when controls have reflected an unusual trend or shift, or are outside acceptable ranges, and other means of assessing and correcting control values have failed
- when recommended by the manufacturer

PROCEDURE: (Calibration procedure is performed by Technical Consultant or designee)

- Use ***SCS-1000 Calibrator (Ordered through Sysmex Corp)***
  Prepare the calibrator according to the specific instructions indicated in the manufacturer's package insert regarding temperature, handling and mixing. Improper handling and mixing will affect results. Allow approximately 2 hours to complete this procedure. This includes time to prepare the material according to the manufacturer's insert.
- **Execute Calibrator Calibration Program**
  1. Press [MENU] at the Ready status. The Menu screen will appear.
  2. Press [CALIB]. The Calibration Menu screen will appear.
  3. Press [CALIBRATOR CAL]. The Precision Check screen will appear.
- **Precision Check**

  Use the pocH-100i Precision Work Sheet to record results. Be sure to record results before you move on to the next screen. You cannot retrieve information once you leave a screen.
  1. Insert the green (control) sample adapter in the sample position.
  2. Remove the cap from the SCS-1000, insert the vial into the sample adaptor and close the sample door. **NOTE:** Failure to remove cap will cause serious damage to the instrument.
  3. 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.
  4. After analysis is complete, the first analysis results are displayed, and the underline cursor moves to the next line.
  5. Remove the vial, replace the cap and handle per manufacture's instructions.
  6. Repeat analysis of the SCS-1000 by removing the cap from the SCS-1000, insert the vial into the sample adapter and close the sample door.
  7. Continue by pressing [RUN], and repeat the sample analysis 11 times remixing the sample between each run. This ensures dispersion of the cells in the vial. Record the

results of each run on the "Analyzer Precision Verification Worksheet", prior to sampling the next run.

8. After analysis has been completed 11 times, press [NEXT]. The average, the standard deviation (SD) and coefficient of variation (CV%) will be automatically calculated and displayed in the "Mean", "SD" and "CV(%)" columns, respectively.
   Precision CV(%) limit:
   WBC $\leq$ 3.0
   RBC $\leq$ 1.5
   HGB $\leq$ 1.0
   HCT $\leq$ 1.5
   PLT $\leq$ 4.0
9. Press [QUIT] to return to the calibrator target value setting screen.
   If any of the obtained CV (%) values exceeds the LMT (Limit) (%) value, then the CV (%) for that analysis parameter is displayed in reverse video, and the message "Pre. Chk. Error" appears. Press [QUIT] and perform the precision check again. If the problem persists, contact the Sysmex Technical Assistance Center at 1-866-879-7639.

NOTE: Calibrator material for precision check can be replaced with patient whole blood. Prior to precision run, test patient sample on CH lab Hematology instrument to confirm the results are in the "normal" reference range for all parameters. Patient sample cap needs to be removed for each run. Piercing of the vacutainer cap more than twice may result in pieces of rubber interfering with analysis. Calibration should not be performed if the precision CV(%) exceeds the limit values.

- **Entering target values for calibrator**
  1. Press the target value icon for the target parameter. The numeric keys dialog will be displayed.
  2. Enter the target value from the SCS-1000 Assay Sheet by pressing the numerical values on the keypad, and press [ENTER]. The entered value is saved and displayed.
     NOTE: The values for any setting must have a value and may not be blank.
  3. After setting remaining target values, press [NEXT]. The calibrator target value setting confirmation dialog appears.
  4. 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.
- **Analysis for calibrator calibration**

Use the pocH-100i Calibration Work Sheet to record all results and calculations done by pocH-100i. Record results from each screen before moving onto the next screen. You cannot go back to retrieve the information that appears on each screen.

1. Press [OK] on the target value setting confirmation dialog. The analysis calibrator screen will appear.
   NOTE: Follow the SCS-1000 package insert for mixing instructions.
2. Press [RUN]. Calibrator analysis begins. The sample currently being analyzed is indicated by an underline cursor. After analysis is completed, the first analysis results are displayed, and the underline cursor moves to the next line.
3. Continue by pressing the 'RUN' button, and repeat sample analysis 6 times.

After analysis has been completed 6 times, press [NEXT]. The analysis calibrator screen will appear. A detailed description of the analysis results is contained in the table below.

Explanation of Calibration Program messages

ITEM	DESCRIPTION
Target	Assay Target values provided with calibrator are entered.
Range V.	The highest value minus the lowest value within five consecutive analysis is displayed.
MaxRange	The maximum Range Value allowed is automatically calculated from the Assay Target and displayed.
Mean V.	Mean value of five consecutive analysis results.
Delta%	Is automatically calculated and displayed.
ACPT LMT	Maximum Upper Limit of Delta Percent (%). Calibration is not necessary when the Delta Percent is within this limit.
SERV LMT	If the Delta Percent exceeds this limit, technical assistance may be necessary and instrument system needs service. Calibration will not be allowed.
Current	Current calibration value which was obtained in the previous calibration procedure.
New	New calibration value calculated from the calibrator analysis.

- **Printing Calibration History**
  An overview of the five most recent calibration histories can be printed out on the built-in thermal printer. Printed history of the calibrations will be attached to the calibration logs.
  1. Press [MENU] at the Ready status. The Menu screen will appear.
  2. Press [CALIB]. The Calibrating Menu screen will appear.
  3. Press [PRINT CAL HIS]. The built-in thermal printer will print the calibration history

Quality Control – Preparation, Storage and Stability

Quality Control is performed to monitor instrument performance. Control material with known values and charts with appropriate limits alert the operator to potential systematic problems. Analysis of three levels of control material (low, normal, and high) will be run once each day, per manufacturer recommendations, and according to regulatory agency standards of performance.

- Quality control utilized: EIGHTCHECK-3WP X-TRA- Three levels. The control material contains stabilized human erythrocytes, fixed mammalian and simulated white blood cells, and a platelet component in a plasma-like medium.
- Store upright at 2-8°C before and after opening. When handled in this manner, the unopened product is guaranteed stable until the expiration date stated on the package. After opening, the product is stable for 14 days if returned to the refrigerator promptly after use. Date QC box upon receipt. When placed in service, indicate the new expiration date on each vial.
- Tolerance limits: see package insert/instrument QC sheet for acceptable performance ranges.
- PROCEDURE NOTES**:** EIGHTCHECK-3WP X-TRA is shipped every 84 days, with a 100 day closed vial product life.

Daily QC Procedure

1. Allow controls to warm to room temperature (18 to 30 ° C or 65 to 86 ° F) for 15 minutes.
2. Set control vials on mechanical rocker for 10 minutes.
3. Examine the bottom of the vial and assure thoroughly mixing by confirming that there is no

pellet of cells adhering to the bottom of the vial before performing the analysis.

If there still is pellet of cells, manually invert vial until the pellet of cells has dispersed. **DO NOT SHAKE.** Verify open date stability. Opened vial is stable for 14 days provided proper handling has occurred. Discard and open new vial if over 14 days.

Level 1 (Low) and Level 3 (High) are run at morning set up. Level 2 (Normal) is run early afternoon.

1. Press **[QC]** on the Main Screen.
2. Press the display column of the correct file.
3. Check that the status display reads "Ready".
4. Press the top of sample position to open.
5. Set the control blood adaptor (green) in position.
6. Gently invert vial 8-10 times immediately before sampling.
7. Open control blood and set in the adapter.
8. Close position and press **[RUN].**
9. When instrument is finished analyzing sample and results are displayed on the screen press **[QUIT].** Results will automatically print.
10. Press **[QC]** to perform the next level of QC material. Repeat steps 2-9 for each level of QC material.
11. Review QC printout results for acceptability, place your initials on print out. The acceptable result ranges for controls in use is posted in the lab
12. Return QC vials to monitored refrigerator for storage.
13. All QC results are reviewed by the Point of Care Specialists via Telcor's Quick Multi Link
14. When QC results are out of range or do not meet Levy-Jennings criteria (L-J) built into the pocH-100i software, document the result that is out of control in the Quality Assurance Log Book, and repeat testing. The QC error must be resolved before any patient testing can be done.
    Failure to obtain proper values may indicate control or reagent deterioration; instrument malfunction or calibration drift

<u>Quality Control decisions</u>

1. Accept control results if:
   (a) all controls read within +/- 2 SD of established mean
   (b) one control reads within +/- 2 SD; the other level reads between +/- 3SD (only once)
2. Reject control results if:
   (a) one control is > than +/- 3 SD from the mean
   (b) two consecutive control observations are > +/- 2 SD from the mean
   (c) the range or difference between the largest and the smallest control observations within the run exceeds 4 SD
   (d) > 10 points above or below mean
3. When a control is rejected:
   (a) <u>Do not report patient results until QC is further investigated.</u>
   (b) Check lot #, expiration date, opened date stability, appearance of control, proper handling.
   (c) Rerun same QC vial.

(d) Clean the system and rerun the QC. Open new vial if needed.
(e) If (b) is acceptable, but control(s) still unacceptable after rerun, notify Technical Consultant or designee at main Concord Hospital lab.
(f) Review reagent history, calibration history, maintenance procedures due.
(g) Review cumulative QC data for trends or shifts.
(h) Recalibrate the analyzer if other means of assessing and correcting control values have failed
(i) Document QC value(s) out of range. Document corrective action taken on the QC corrective action log.
(j) If after troubleshooting, the problem cannot be isolated or corrected, contact the pocH-100i technical Assistance Center at 1-866-879-7639 for further assistance.
(k) Should the pocH-100i System become inoperable for any reason, specimens should be collected and submitted to the main Concord Hospital laboratory with appropriate test request requisition form, in accordance with the Laboratory Procedure Manual. Transport specimen with transport staff and/or courier.

Starting a New Lot of Controls

Compare the mean values and standard deviation on the bar code assay sheet to the assay sheet showing the printed ranges. If a discrepancy is discovered, call Sysmex pocH-100i Technical Support to resolve issue before scanning the barcodes and analyzing control for parallel testing. Scan the barcodes from the assay sheet. Review results to confirm all information was successfully entered into the pocH-100i.

Prior to the use of any new lot number of controls (low, normal & high), the new controls are tested in parallel with the current lot number of controls to assure the new lot number of controls are performing within the manufacturer's expected ranges.

The new control lot numbers are tested in QC mode. This allows the software in pocH-100i to flag results that are out of range or do not meet the Levy-Jennings (L-J)criteria.

Each level of the new lot number is run ten times (twice a day for 5 days) with the current lot number to verify manufacturer's recommended assay ranges. Target values must fall within the recovery range supplied by the manufacturer.

QC Management

The pocH-100i has six (6) QC folders. These folders allow for the storage of manufacturer's QC result ranges. The folders are rotated between the current lot number and the previous lot number. The QC lot numbers, expiration date, mean and ranges are bar coded or manually entered into pocH-100i

On going QC review of cumulative data points, and Levy-Jennings charts are seen in pocH-100i QC data manager and Telcor's Quick Multi Link (QML). Review documentation is recorded by the Technical Specialist or designee in QML .

All QC exceptions are recorded in the Quality Assurance log for pocH-100i along with any corrective action taken.

Quality Control points are submitted electronically into Sysmex's Insight QC program. Sysmex publishes the dates for submission.

The Technical Consultant or designee reviews and signs the completed reports**.** Investigation is made and documented when analyte(s) is flagged. Laboratory Medical Director is consulted.

DAILY OPERATION PROCEDURES

Startup Operator Checks

- 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/ Self 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 ($x10^3$/uL) or less
RBC……0.02 (x 10^6/uL) or less
HGB……0.1 x (g/dL) or less
PLT ……10 ($x10^3$/uL) or less

Record the background check on the daily QC sheet. To view/print background values:

1. Press **[Menu]**
2. Press **[Str.Data]**
3. Look for **Blank Check** with today's date (usually at the bottom of the list on the screen, usually highlighted)
4. Press **[⇨]** to view results
5. Press **[Top]** when ready to return to main screen

Shutdown (End of day)

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

When instrument has been idle for 2 hours or more after a sample analysis, perform an Auto Rinse.

The Auto Rinse cleans all the lines in the unit and drains the waste into the waste container. A background check is also performed. If the background counts are acceptable, the unit returns to normal status.

Background Check/ Auto Rinse

1. Press **[MENU]**
2. Press **[MAINT]**
3. Press **[AUTO RINSE]**
4. Press **[EXECUTE]**
5. After completion, the Main screen will appear
6. Verify that results are within acceptable background limits

PATIENT WHOLE BLOOD (WB) SAMPLE ANALYSIS

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 SoftLab patient bar code label into the pocH-100i.
4. Press **[Ent.]**
5. Press top of the sample position to open
6. Set the correct adapter in the position (tan)
7. Mix lavender (EDTA) top tube (minimum draw 1 mL) by gently inverting tube 10 times

8. Set sample in adapter and close door
9. Make sure that status screen display displays "Ready"
10. Press **[RUN]**
11. When status display displays "Running", remove the sample tube.
12. Initial the pochH-100i instrument print out.
13. When all test results are within acceptable parameters, patient results will automatically print on the laser printer at the desk.

COMPUTER DOWN TIME:

a. Write the patient's name, DOB or MRN and your initials on the pocH-10i print out.
b. Use the Walk In Urgent Care Laboratory Result From to record:
c. Patient Information (name, MRN or DOB)
d. Provider
e. Specimen Collection date
f. Person who collected specimen
g. Transcribe results on the Laboratory Down Time Result Form.
h. A second staff trained staff member will compare printout results to transcribe results on the tests result form for clerical error, before result form is released to the physician. Both staff members will initial, date and time the result information.

Repeat Analysis

Resample specimen on the pocH-100i whenever:

1. **WBC** <2.0 or > 40.0 (10^3 / uL)
2. **HCT** < 20.0 or > 54 %
3. **PLT** <50 or > 700 (10^3 / uL)
4. Flag follows any parameter (see error flags –Histogram flags for results below).
5. Indicate on the report that the sample was repeated (RPTD).

Reporting Results

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), Red Cell Distributuon Width (RDW), Absolute Neutrophil Count (ANC). The differential that pocH-100i performs is a three part differential. It will include the following parameters: lymphs (LYM%), neutrophils (NEUT%), mixed (MXD%) which includes monocytes, eosinophils, and basophils.

Error flags- Histogram flags for results

The following are System Limitation Interference flags that are know to affect test results.

Flag	Probable sample cause	Action
WL	Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids.	Check for clots. Clot present, do not report, redraw. No clot, Re-analyze. Flag still present, send to Main Concord Hospital Lab.
RL	Presence of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, presence of micro-erythrocytes.	Check for clots. Clot present, do not report, redraw. No clot, Re-analyze. Flag still present,

		send to Main Concord Hospital Lab.
PL	Effects of cryoglobulins, fragmented red blood cells, or cellular fragments of white blood cells.	Re-analyze. Flag still present, do not report, send to Main Concord Hospital Lab.
WU	Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc.	Re-analyze. Flag still present, do not report, send to Main Concord Hospital Lab.
RU	Effects of cold agglutinin, inclusion of white blood cells.	Re-analyze. Flag still present, do not report, send to Main Concord Hospital Lab.
DW (RBC)	Significant anisocytosis, etc	Send to Main Concord Hospital Lab.
DW (PLT)	Inclusion of fragmented red blood cells, non-uniformity in size of platelets, effects of cryoglobulins, etc	Send to Main Concord Hospital Lab.
MP (RBC)	Effects of anemia treatment or blood transfusion causing the presence of cells of multiple sizes.	Send to Main Concord Hospital Lab.
MP (PLT)	Platelet aggregation, low platelet count.	Re-analyze. Flag still present, do not report, send to Main Concord Hospital Lab.
T1	Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, etc., causing the first two WBC populations in the WBC-Histogram not to be separated.	Re-analyze. Flag still present, do not report, send to Main Concord Hospital Lab.
T2	Presence of CML or other immature granulocytes, aged sample, incomplete lysing of red blod cells, etc., causing the last two WBC populations in the WBC-Histogram not to be separated.	Re-analyze. Flag still present, do not report, send to Main Concord Hospital Lab.
F1, F2, F3	Presence of CML or other immature granulocytes, sample with high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc.	Re-analyze. Flag still present, do not report, send to Main Concord Hospital Lab.

AG	Presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids, etc.	Re-analyze. Flag still present, do not report, send to Main Concord Hospital Lab.

Linearity (Reportable Range)

Linearity is measured 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. This material may be ordered from Sysmex at 1-800-379-7639, order part number 130-4001-0.

Calibration Verification/ Linearity material from the College of American Pathologists (LN-9) is used every six months to confirm the calibration and linearity of the pocH-100i.

Sysmex pocH-100i Linearity Limits (Reportable Range)

Parameter	Range	Units
WBC	1.1 – 90.0	$x10^3$/uL
RBC	1.00 – 6.60	$x10^6$/uL
HGB	3.0 – 19.0	g/dL
HCT	10 – 60.0	%
PLT	10 – 850	$x10^3$/uL

Normal Reference Range

Specimens were obtained from adults of assumed good health. Samples were analyzed on the Sysmex pocH-100i upon 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).

For the infant and pediatric population, refer to Wintrobe's *Clinical Hematology*, 9th ed.

Reference Range

	Female	**Male**
WBC (10^3/uL)	**3.5 – 11.4**	**3.8 – 11.2**
RBC (10^6/uL)	**3.85 – 5.07**	**4.24 – 5.72**
Hgb (g/dl)	**12.3 – 15.1**	**12.8 – 16.8**
Hct (%)	**36.0 – 44.2**	**39.5 – 48.5**
MCV (fL)	**84.7 – 100.1**	**84.1 – 101.0**
MCH (pg)	**26.5 – 31.9**	**27.3 – 33.0**
MCHC (g/dl)	**31.3 – 36.0**	**31.9 – 36.2**
RDW (%)	**11.4 – 14.7**	**11.5 – 13.8**
PLT (10^3/uL)	**154 - 410**	**138 - 350**
ANC (10^3/uL)	**1.4 – 6.2**	**1.7 – 7.4**
%Neut	**42.1 – 80.8**	**42.1 – 80.8**
%Lymph	**14.4 – 40.8**	**14.4 – 40.8**
%MXD	**2.2 – 15.2**	**2.2 – 15.2**
(includes Monos, Eos, Basos)		

MAINTENANCE PROCEDURES

Replace Reagent

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 out (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 diluent.

8. Press **[pocHpack L]** to replace lysing agent.
9. The replacing reagent screen will appear.
10. To display the individual reagent replacement log, press **[Reag.Log]**
11. Read the barcode affixed on the new reagent.
12. Press **[Manual].** The numerical keys dialog appears and the barcode can be entered by using them. Press **[OK]**
13. When the incorrect reagent barcode is input, an error code appears.
14. Press **[Execute]**
15. Document the date opened and expiration date on the reagent container and document the lot number in the reagent log.

Disposing of Waste Fluid

1. Remove the cap from the full waste bottle. Pull the float switch straight out to remove it.
2. Dispose the waste fluid and clean the waste bottle out with water.
3. Insert the float switch into the empty waste bottle, and apply the cap. Check that the tube is not bent.
4. Press the [Execute] button on the error help screen. The waste processing screen will apprear, and the waste discharge operation will be performed.
   To return to the Main screen without performing the waste discharge operation, press the [Cancel] button. When the process is finished, the Main screen will appear
   a. The pocH-100i will alarm when the waste container is full (there is a float that detects the fluid level in the waste container). Follow the prompts on the screen.

Cleaning the sample tube adapter

If sample has been spilt into the sample tube adapter that is set in the sample position, remove and clean the adapter.

1. Check that the power switch is turned OFF.
2. Press the top of the sample position to open.
3. Remove the sample tube adapter.
4. Clean the sample tube adapter with 1:10 dilution of filtered bleach. Rinse with water after cleaning.
5. Set the cleaned adapter in the sample position.
6. When the adapter has been set, 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.

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.

This procedure can be accessed from the maintenance menu as **[Clog Removal]**

Scheduled Maintenance

- Daily Shutdown (see Daily Operation Procedures)
- Every Two-Weeks (or Every 150 Samples) CLEAN TRANSDUCER
  pocH-100i™ will alarm when the following needs to be done. Turn alarm off and perform maintenance at earliest convenience
    1. Press **[Maint.]** on the menu screen
    2. Press [**Clean Transducer]**
    3. Prepare an empty sample tube with at least 3 mL of CELLCLEAN (use a lavender top tube. Drain the liquid EDTA out of the tube and add the CELLCLEAN. Replace stopper on tube)
    4. Press the top of the sample position to open.
    5. Set the adapter(tan) in the sample position.
    6. Set the sample tube with CELLCLEAN in place and close the door.
    7. Press **[Execute]**
    8. After completion, the Main screen will appear.
    9. Remove the sample tube from the sample position
    10. Document the maintenance procedure in maintenance log.
- Every 3-Month (or every 1500 samples) Maintenance
  pocH-100i™ will alarm when the following needs to be done. Turn alarm off and perform maintenance at earliest convenience
- Waste Chamber Cleaning
    1. Press **[Maint.]** on menu screen
    2. Press **[Clean W. Chamber]**
    3. Prepare an empty sample tube with at least 3 mL of CELLCLEAN
    4. Press the top of the sample position to open.
    5. Set the adapter in the sample position.
    6. Set the sample in the sample position.
    7. Set the sample tube with 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 position.
    11. Document the maintenance procedure on Maintenance log.

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

REFERENCE — EIGHTCHECK-3WP X-TRA product circular of information rev.10,20-May-03.SYSMEX Corperation, Kobe, Japan, pocH-100i Instructions for Use Manual last rev. 10-31-2003 by SYSMEX Corperation 2002-2003©

DISTRIBUTION — Walk-In Urgent Care Center Lab at Horseshoe Pond

RESPONSIBLE DEPARTMENT/UNIT — Point-of Care Testing, Technical Operation

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Pathology Approval — Cristina E. Taylor, MD Date: