HealthPartners/GHI

Hemogram **ABX Pentra 60 C+ with Automated Differential**	**Attachments** ☒ Yes ☐ No
Key words CBC, blood count, indices, Hemoglobin, White count, Red count, Platelets	**Number** **GHP-PC-CLINIC LAB-Procedures-Hemogram 60C+ v. 05-2012**
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Review Responsibility Laboratory Technical Consultants	**Contact** Laboratory Technical Consultants
APPROVAL(S) Laboratory Medical Director	

Hemogram ABX Pentra 60 C+
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ABX Troubleshooting (ABX folder – Lab on Enterprise)

I. PURPOSE/PRINCIPLE

The ABX Pentra 60 C+ is a closed-tube, automated hematology analyzer that determines 9 parameters (WBC, RBC, HGB, HCT, PLT, MCV, MCH, MCHC, & RDW) in CBC mode.

In CBC + 5DIFF mode an additional 10 parameters CAN be reported (LYM, NEU, EOS, BASO, MONO in % and #). WBC, RBC, PLT and BASO are determined by focused flow impedance. HGB is measured by photometry. LYM, MONO, NEU, and EOS are determined by cytochemistry, impedance and light scattering. HCT, MCV, MCH, MCHC, and RDW are based on computation from directly measured data.

II. POLICY

Laboratory Staff will follow the approved techniques outlined in this procedure.

Specimen:

- Specimens are good for 24 hours if refrigerated.
- K^+ EDTA whole blood. Tube must be at least 1/3 full. **Hand mix IMMEDIATELY.**
    - **Immediately after blood drawing, thoroughly mix the EDTA sample with 8-10 inversions. This will facilitate the chelating of calcium and EDTA in the sample to prevent clotting.**
    - **Place on the mechanical tipper for a minimum of 5 minutes.**
    - **Analyze the sample. If there are no flags, result and report.**
    - **If specimen has a delta failure make sure specimen is remixed prior to repeating.**
    - **If there continues to be flags, place on the tipper for an additional 5-10 minutes.**
    - **If the flags go away, report. If they remain, do a manual differential or send to Central Lab.**
    - **If tube has been standing, this requires at least 60 inversions, or 2 minutes on a mixer.**
- For fingersticks, collect in a capiject EDTA microtainer. Fill capiject to the first line (250ul).
    - Capiject specimens must be mixed well by hand, in addition to mechanical mixing.
- Specimens cannot be tested if tube is not adequately filled, a clot is present, or grossly hemolyzed and will need to be redrawn.
- **Slides for differentials or slide review must be made the same day as collected (8 hr stability)**
- Volume aspirated is 30ul in CBC mode and 53ul for CBC + 5DIFF mode.
- Upon completion of tests, store specimens in refrigerator.

NOTE: For patients who have been identified as having a platelet clumping condition, please see the information on page 12.

Reagents/Materials:

- ABX reagents
  ABX Diluent (Expiration date on box). If the diluent container is placed below the instrument, the maximum distance below is 2 feet.
  ABX LyseBio (Expiration date on box)
  ABX Cleaner (Expiration date on box)
  ABX Eosinofix (Expiration date on container)
  ABX Basolyse II (Expiration date on container)
  ABX Minoclair (Expriation date on container)
- Chlorox Bleach: Undiluted, high quality, fragrance free bleach (use only for troubleshooting)

Store all reagents away from light at 18-25^{O}C (64-77^{O}F)

Calibration:

Calibration is not a routine procedure. The ABX systems are calibrated to a commercial calibration product. Calibration is performed, at a minimum, twice yearly or after a major repair or maintenance. Refer to page 15 for instructions on calibration procedures.

Correlation is evaluated monthly between the ABX at the clinic and the primary Hematology instrument at Central Lab. Each clinic runs a CBC & Diff on at least one sample, and then sends it to Central Lab to be run on their primary instrument.

Correlation is also continually evaluated between the Pentra 60 and the primary Hematology instrument at Central Lab. This is accomplished each time a patient sample is referred to Central Lab for final analysis. Recommendations for adjustments are communicated to the lab technical consultants.

If concerns regarding proper calibration arise at any time, contact a lab technical consultant. Whenever recalibration is necessary, refer to the ABX Penta 60 C+ manual.

Quality Control:

1. **Commercial Controls: ABX Pentra Diff Hematology Reference Control**
   Three levels; Low, Normal and High
   a. Store opened and unopened vials upright at 2-8^{O} C. Unopened vials are stable until the expiration date. Opened vials are stable for 14 days. Always date the vials when you open them. For further information, refer to package insert.

   b. When new controls arrive, verify the ranges from the package insert by running each level approximately 10 times over a period of time in parallel with current month's controls, as directed by a Technical Consultant. Record results and enter each value into the computer using the appropriate QC codes, C-PDL,V, C-PDN,V and C-PDH,V.

   c. **QC frequency:**

	ALL CLINICS
Start-up	Normal and High
5 PM	Normal and low

   d. If any parameter of a control is out of limits or violates a Westgard rule, refer to the QC Information at the end of procedure (page14) and notify your Laboratory Technical Consultant via mailbox with what parameter and level is out. Patient samples cannot be run until all QC parameters are within acceptable limits.

   e. At the end of the month, the technical consultant should mail edited control results to R&D for computation of means, CVs, SDs, etc. Review data thoroughly upon its return, sign and date.

   f. Run all three levels of controls after bleaching, maintenance or troubleshooting.

2. **QC Review**
   - Techs should review QC daily and provide ongoing communication to their lab technical consultant concerning observed QC shifts, trends and problems.
   - On a weekly basis, or when a problem arises, the technical consultant should review Heme QC.

3: **QC Data entry via diskette**
Put the disk into the silver "Lacie" disk drive
Click on the QC/Calibration tab on the top menu list
Click on the CONTROL tab on the bottom menu list
Using the drop down list of available lot #s, select the PDL of the lot
NOT currently in use (the oldest lot)
Once selected, click on the "Modify Target" tab
Click on “Import Targets”
A "QC target level" menu will pop up
Select the LOW, and click on "OK"
A box will open up with several options….select “QCget60” and click “open”
Click on "Accept". Verify that results have changed.
Go back to the drop down menu for the PDN of the old lot and repeat for the PDN and the PDH
Remove disc

III. PROCEDURE

1. Power up work station
   a. The ABX universal power supply (UPS) should remain “on” at all time. Everything except the OKIDATA printer should be hooked to this power supply.
   b. Turn on the printer if it has been turned off.
      NOTE: *The printer may be left in the ON position*
   c. Press the ON/OFF switch of the ABX Workstation computer.

d. Turn on the ABX monitor
e. Click on ABX icon which will appear on the ABX monitor desktop
f. Select your tech code (or initials if you have a 4 digit tech code).
    If you are a new user, you must enter your tech code/initials
        i. Select ABX as temporary user code
        ii. Select "Settings" from the top of the menu bar
        iii. Select "System settings"
        iv. Select "Users"
        v. Click on "Create new"
        vi. Type in tech code (or initials if you have a 4 digit code)
        vii. Do NOT create a password
        viii. Click on "Validate" and close out of the system settings
g. Turn on the ABX by pressing the ON/OFF switch on the left side of the instrument.

2. Reagent Status

    a. The reagent status is displayed. The Analyzer system indicator will turn green if the connection is successful and reagent levels are adequate. The instrument computer monitors level and expiration dates of reagents.
    b. See ABX Users' manual section 5-2 for reagent replacement.

3. Click Start-up button

    a. A rinse cycle and background check will be performed. The computer will log the information into the data bank. The instrument will not operate until a background check is acceptable. If the background counts are not within acceptable limits, the message <<Startup Failed>> is displayed.
    b. If necessary, refer to the ABX Users' manual section 5-11 for direction on concentrated cleaning cycle.

4. Run Controls (Normal and High at start-up, Normal and low at 5 pm)

    a. Click on the QC & Calibration tab from the main menu.
    b. Click on the Controls tab from the QC & Calibration menu.
    c. Open the "current target" scrolling list and select the control to be run.
    d. Place the well-mixed control into the correct position of the tube holder (6 o'clock position). The cap does not need to be removed.
    e. Close the tube holder to start sampling.
    f. Remove the tube when the holder opens. When the analysis cycle ends, the result is displayed on the result chart table.
    g. Verify that the control results are within the acceptable values. Outliers will be displayed in blue if out of range low, and red if out of range high.
    h. Follow the Supplemental Troubleshooting Procedure for QC failures on pages 16-17.

5. Running patient samples

    a. Click on the RUN tab from the main menu at the top of the screen.
    b. Use the barcode scanner to input the specimen information.
    c. Place a well-mixed tube into the correct position of the tube holder Place a well-mixed tube into the correct position of the tube holder**.**
        Be sure to remove the cap on fingerstick specimens!!!
    d. When the green LED light is lit, close the tube holder to begin sampling.
    e. When the tube holder opens, remove the tube. When the LED light returns to green, the next sample can be scanned and put into the tube holder.

6. Printouts show the following information

    a. Patient information

b. Histogram
c. Pathology codes if applicable
d. Designated morphology documentation area
e. Designated manual differential documentation area

7. Prior to releasing results in the Misys system verify patient identification. Verify results by repeating the sample if values are within repeat range or if any parameter has flags or error codes. Refer to the Hematology Verification Guidelines for linearity, critical values, flag and/or error codes.

8. Delta Checks have been set up on the following parameters:

WBC +/- 10.0 %
HGB +/- 2.0 %
MCV +/- 3.0 %
PLTS +/- 25 % (for counts <100)

Evaluating Failed Deltas:

a. Identify which parameter(s) has failed delta check. **Always rerun patient sample to verify results of failed delta on any parameter. Add –pckd to the repeated value. If there is more than one parameter, attach the pckd code to only one of the paramters.**
b. Use Function I or IQ in Misys or EPIC to check the patient's previous lab history BEFORE YOU ACCEPT THE RESULTS.
c. Decide if the history correlates with the change that you are seeing (e.g. Pt. pregnant? Oncology? All platelet values normal but jumping around a little?)
d. If the results do not make sense and you are not comfortable accepting them, make sure to retest the sample and verify correct tube/patient.
e. See if anyone in the lab knows patient history (e.g. Just out of hospital? Recent blood transfusions? Suspected infection? etc.) **If needed, (especially if big changes in WBC or HGB values) discuss results with provider.** You may alert provider to new patient information.

Automatic Cleaning

1. When the instrument has performed a designated number of specimens from the time of the date change, an automatic cleaning procedure is performed.
2. The 75 specimens is a default set by the manufacturer. This can be adjusted at the time of installation or anytime thereafter. See Section 3, page 48 in the Technical Manual.
    - After sitting for 2 hours, the instrument requires a cleaning cycle
    - After sitting for 4 hours, the instrument requires a "start up" and a cleaning

Shutdown

1. After completion of the workload for the day, it is necessary to perform a complete cleaning of the instrument by putting the instrument in shutdown.
2. The system then goes into a standby mode. Press the OFF button on the side of the instrument to shut off the instrument.

Interpretation of Results

Also refer to Hematology verification guidelines

When the analysis is completed, results are displayed and printed according to the setup of the instrument during initial configuration. This printout will include flags defined to alert for panic/critical results, problems with possible morphology of cell populations and any flags linked to instrument operation or "default analysis."

"H" indicates a result above **panic** limit
"L" indicates a result below **panic** limit

RESULTS EXCEEDING INSTRUMENT CAPABILITY

ANALYTE	READING WILL BE "0" if RESULT:
WBC	$<0.01 \times 10^3$ cells/ul
HCT	<0.7%
HGB	<0.7 g/dl
PLT	$<0.5 \times 10^3$ cells/ul
RDW	<10
No DIFF Results	WBC $\leq 0.7 \times 10^3$ cells/ul

"DIL" indicates that the result is above the **UPPER** limit capability of the instrument. The specimen must be diluted and rerun. Refer to page 11 for instructions.

"REJECTION" flags indicated by either **(-.- or *)** indicates a parameter not within 2 SD of replicate counts. If this occurs, rerun the sample. If this continues to occur, clean the instrument; first perform a chamber and cytometer rinse and then perform a concentrated cleaning if necessary.

"NO" flags indicate a background noise constituted by platelet aggregates, non-lyse of RBCs, nucleated RBCs or excessive number of platelets.

"REJECT" on the LMNE channel **(-.- or *)** indicates a poor correlation between the resistive and optical measurement on the matrix and the specimen should be rerun.

"SUSPISCION" indicated by **(!)** on the differential analytes is associated with clotted samples, plasma cells or a pathology consideration for review.

Maintenance:

1. **Changing Reagents**
   a. The instrument calculates each reagent bottle capacity according to the number of cycles run. The instrument performs a reagent capacity check on each cycle. If a reagent low level is expected, an alarm is triggered. Example for ABX Eosinofix: <<REAGENT LOW LEVEL (EOSINOFIX)>> will appear on the screen.
   b. The operator can click on the "OK" button and continue to run until the message reappears, at which time the reagent **must** be replaced.
   c. To change a reagent, open the front door of the reagent compartment.
      1. Remove the stopper and reagent straw assembly and place into the new reagent.
      2. Never pour reagent from old container into the new container.
      3. Confirm the replacement by clicking on the ANALYZER tab in the software.
         i. Double-click on the reagent bottle icon you are replacing
         ii. The REAGENT REPLACEMENT dialog box opens.
         iii. Double click in the LOT NUMBER field and enter new reagent lot number.
         iv. Open EXPIRATION scrolling list to select expiration date with a calendar. Select expiration date by click on the calendar.
         v. Click the OK button to close the window. There isa comment field if needed, then click OK.
         vi. The software will show the replacement and update the quantity.
   d. Run all three levels of controls.

2. **Hydraulics systems**
   - Access thru MENU\SERVICE\HYDRAULICS\CLEANING CYCLES system window

a. Backflush: delivers pressure through the aperture of the counting chambers to clean them in case of blockages.

b. Rinse: diluent is sent to either chambers or cytometer to rinse out these parts separately.

c. Concentrated cleaning: clean the chambers with Minoclair.

- This process should be done weekly at a minimum. With continued use, more frequent cleaning may be necessary.
- Press the ENTER button. A rinse cycle will run. Wait for the message "POUR 3ML OF MINOCLAIR INTO CHAMBERS PRESS ESC KEY TO CONTINUE" to be displayed. Open the instrument pneumatic door. Using a disposable pipette, dispense approximately 3 cc undiluted bleach into each chamber and press ESC. Close the door and wait for the instrument to complete the cleaning procedures. This process should be done weekly at a minimum.
- Run all three levels of controls.

d. Extended Concentrated cleaning:

- This procedure is done upon direction from service. Fill the chambers with 3 ml of minoclair. Run the BACKFLUSH option 10 times. Proceed to the usual concentrated cleaning procedure outlined above.
- Run all three levels of controls.

e. Autocontrol: This cycle is required after an emergency stop of the instrument or when a faulty operation has been detected.

3. **Filter cleaning**

a. When system is in standby, open the panel on the right side of the instrument.

b. The filter is located behind valve position 1. Disconnect tubing and rinse filter with distilled water until particulates are rinsed away. Reattach tubing. Maintain correct orientation. A toothbrush may be used to clean the filter.

- This process should be done monthly at a minimum. With continued use, more frequent cleaning may be necessary.

Reference Ranges:

WBC* k/ul	16+ yr.	4.0-11.0
	8-15 yr.	4.5-13.5
	5-7 yr.	5.0-14.5
	2-4 yr.	6.0-17.0
	1-23 mos.	5.0-19.5
	7-30 days	5.0-21.0
	0-6 days	9.0-30.0
RBC M/ul	18+ male	4.5-5.9
	18+ female	4.0-5.2
	12-17 male	4.5-5.3
	12-17 female	4.1-5.1
	6-11 yr.	4.0-5.2
	2-5 yr.	3.9-5.3
	1-23 mo.	3.0-5.4
	0-30 days	4.0-6.6

MCH pg	18+	26-34
	12-17 yr.	25-35
	6-11 yr.	25-33
	2-5 yr.	24-30
	2-23 mos.	26-34
	0-<2 mos.	31-37
MCHC %	all	32-36

HGB g/dl	18+ male	13.5-17.5
	12+ female	12.0-16.0
	12-17 male	13.0-16.0
	6-11 yr.	11.5-15.5
	2-5 yr.	11.5-13.5
	1-23 mos.	10.0-18.0
	7-30 days	13.5-21.5
	0-6 days	14.5-22.5
HCT %	18+ male	41.0-53.0
	12+ female	36.0-46.0
	12-17 male	37.0-49.0
	6-11 yr.	35.0-45.0
	2-5 yr.	34.0-40.0
	1-23 mos.	31.0-55.0
	0-30 days	45.0-67.0
MCV fL	18+	80-100
	12-17 yr.	78-98
	6-11 yr.	77-95
	2-5 yr.	75-87
	2-23 mos.	77-104
	0-<2 mos.	98-118

PLTS k/ul	all	150-450
RDW %	17+	11.5-14.5
	12-16 yr.	11.5-14.0
	2-11 yr.	11.5-15.0
	1-23 mos.	11.5-16.0
	0-<1 mo.	13.0-18.0

*If WBC is outside of normal range make and fix “just in case” slides when no differential has been ordered.

Differential Reference Ranges

NEUT %	16-Adult	43-72%
	12-16 yrs	35-71
	8-12 yrs	32-70
	5-8 yrs	32-64
	2-5 yrs	23-55
	10 days-2 yrs	14-45
	4-10 days	19-59
	0-4 days	32-72
LYMPH %	12-Adult	17-43%
	5-12 yrs	23-48
	2-5 yrs	35-65
	6 mo.-2 yrs	45-76
	1-6 mos.	41-71
	14 days-1 mo.	43-53
	10-14 days	36-45
	4-10 days	26-36
	0-4 days	19-29
MONOS %	All ages	4-12%
EOS %	All ages	0-8%
BASOS %	All ages	0-1%
ABS NEUT	21-Adult	1.8-7.7 k/ul
	16-21 yrs	1.8-8.0
	6-16 yrs	1.5-8.0
	1-6 yrs	1.5-8.5
ABS NEUTs	6 mo.-1 yr	1.0-8.5

	7 days - 6 mos.	1.5-10.0
	0-7 days	6.0-26.0
ABS LYMPHs	21-Adult	1.0-4.8 k/ul
	16-21 yrs	1.2-5.2
	6-16 yrs	1.5-7.0
	4-6 yrs	2.0-8.0
	1-4 yrs	4.0-10.5
	1 mo.-1 yr	2.5-16.5
	7 days-1 mo.	2.0-17.0
	0-7 days	2.0-11.0
ABS MONOs	18-Adult	0.1-0.7 k/ul
	0-18 yrs	0.0-1.0
ABS EOS	All Ages	0.0-0.5 k/ul
ABS BASOS	All Ages	0.0-0.2 k/ul

Critical Values:

The following critical values must be reported to the physician immediately:

TEST CRITICAL LIMITS

- WBC ≤ 1.0 or ≥ 50.0 (x 10^3 cells/ul)
  Blasts Present on new patient
- Hemoglobin ≤ 7.0 g/dl
- Platelets ≤40 or ≥ 1,000 (x 10^3 cells/ul)

Reporting of Hematology Preliminary Results:

1. **Preliminary reports should be given only when the provider needs a result, but a final result cannot be reported at the clinic.** Preliminary results must be documented in the computer since the provider may be providing treatment based on these results.
2. If the ABX results on a hemogram parameter or differential are considered unreportable because of linearity limits, flags or codes, it **may** be appropriate to give the provider some of the sample results. Refer to the Hematology verification guidelines and procedural flowsheets and/or call a lab technical consultant if you are unsure as to whether a preliminary result should be given out.
   Order the test code HEDP (Hematology Preliminary) and result on worksheet HCON. Refer to the computer test procedure (page 18).
3. Pack specimen tube (and slides if held overnight), ABX copy of results and manual diff results if applicable in ziplock bag, track and send to Central lab.

Here are some possible scenarios when a preliminary report may be appropriate:

1. WBC < 0.4 or PLTS <4.
2. WBC value is underlined but is verified by a slide check and WBC estimate. Prelim WBC value could be given. Central Lab to result final.
3. Platelet values fluctuating. Other hemogram parameters could be given as prelim. Platelet estimate (low, normal, high) could be given as prelim after slide is checked.
4. WBC and platelets fluctuating or underlined but hemoglobin is stable. Prelim hemoglobin may be given out.
5. Differential shows immature or unidentifiable cells. Result HEDP with "unidentifiable cells seen."

Special Procedures:

1. **Cold Agglutinins:**
   If the RBC appears too low in relation to the HGB and HCT, and the MCV, MCH, and MCHC are moderately elevated, the specimen may contain cold agglutinins. At temperatures less than body temperature, cold agglutinin antibodies bind the RBCs together so that the "particles" counted by the instrument are clumps rather than individual cells. This results in falsely low RBC values. Red cell indices in a cold agglutinin patient will usually show an MCV of > 105, MCH of > 40 and MCHC of > 36. The following pre-warming technique will dissociate the RBC-antibody complex so those cells will pass through the aperture individually, resulting in "true" counts:
   a. Place the blood sample in an incubator (in a beaker of warm water) for at least 30 minutes.
   b. Mix specimen in warm hand (or with warm gel pack wrapped around tube) and run immediately.
   c. If, after prewarming, the patient results change in a manner consistent with the presence of cold agglutinins, report out the results from the warmed specimen.
   d. Append the code PW (Pre-warmed) to the RBC value.

Note:
- Blood smears may be helpful in determining the presence of cold agglutinins. Red cell agglutination occurs when red blood cells cluster or clump together in an irregular mass in a thin area of the blood film. One must distinguish this abnormality from rouleaux formation (clumping vs. stacked coins).
- WBC and HGB are not affected by cold agglutinins, so these values should remain the same after warming the specimen.
- Moderately Complex Labs should send their slides to Central Lab for interpretation.

2. **Lipemia - Moderately Complex sites:**
   If a specimen is lipemic, write “lipemic” on the ABX report and send to Central Lab or to Regions.

   Highly Complex sites:
   Heme specimens are good for 24 hours. When possible, if lipemic, write "lipemic" on the ABX report and send to Central Lab. On Friday evenings or Saturdays the specimen must be run at the clinic.

   When run at the clinics:
   a. Obtain an initial whole blood CBC result. Rule out that specimen does not contain cold agglutinins before proceeding to the next step.
   b. If lipemia is present, spin down a portion of the blood. Perform a hgb on the non-hemolyzed plasma, or on serum (from other tests ordered) in duplicate.
   c. Correct the Hgb result as follows:
      Whole blood HGB - {Plasma HGB X (1.00 - HCT} = True HGB

      Example: Whole blood HGB = 15.0
      Plasma HGB = 2.0
      ABX HCT = 38.0% (=.38)

      True HGB = 15.0 - {2.0 x (1.00 - .38)}
      = 15.0 - {2.0 x .62}
      = 15.0 - 1.2
      = 13.8

      If the difference between ABX HGB and True HGB is > 0.5, enter the True HGB value into the computer. If ≤ 0.5, correction is not needed.

d. If the HGB is corrected, the MCH and MCHC must be recalculated using the true HGB value.

$$MCH = \frac{\text{True HGB}}{\text{RBC}} \times 10$$

$$MCHC = \frac{\text{True HGB}}{\text{HCT}} \times 100$$

e. Append the code CGRL (corrected for gross lipemia) to the HGB result.

e. If non-hemolyzed plasma or serum is not available, consult with a Technical Consultant. Options include resulting HGB, MCH and MCHC with LUP (Lipemic Specimen, Unable to Perform) or attach LE (Lipemia May Falsely Elevate Result) to the HGB, MCH and MCHC results.

f. Send a copy of the calculations to your Technical Consultant.

3. **Dilutions for High Values:**

The upper limits of linearity of the instrument is as follows:

- WBC 118 x 10^3 cells/ul
- RBC 7.5 x 10^6 cells/ul
- HGB 23 g/dl
- HCT 67%
- PLT 2500 x 10^3 cells/ul

Moderately Complex sites: If linearity values are exceeded, send the specimen to Central Lab or Regions for testing.

Highly Complex sites: If linearity values are exceeded, the specimen must be diluted and retested using the following procedure:

a. Dilute specimens 1:2 using ABX diluent or saline.

b. Make dilution by pipetting equal volumes of blood sample and diluent into a small tube using a calibrated pipette.

c. Mix gently and analyze in duplicate.

d. Multiply the results by 2. Make higher dilutions as needed.

4. Flags on the Histograms

Mix specimens on a tipper for 15 minutes to reduce the number of flags and flipped diffs. For **Moderately Complex sites, if unable to resolve, send specimen to Central Lab.**

Highly Complex sites: Refer to Hematology Verification Guidelines

Flags on WBC/BASO histogram (L1 flag)

L1 indicates the possible presence of platelet aggregates and NRBCs, which may be counted as leukocytes.

a. Flags on RBC histogram (MIC and MAC)
MIC and MAC flags are triggered when the percentages of cells counted in the microcytic area (MIC) and macrocytic area (MAC) in relation to the total number of RBCs are above the limits set by the user.

b. Flags on PLT histogram

1) Excessive presence of microcytes on the right side of the threshold area will trigger the MIC flag. The PLT result is reliable.

2) When the ABX is unable to establish a standard area, a *MIC flag will trigger. The PLT result is not reliable.

3) If there is no PLT and RBC separation, the SCH (schistocyte) flag is triggered. Check a slide for schistocytes or platelet clumps. If platelet clumping is found, consider patient redraw or result PLT with CLUMP.

Patients known to have a platelet clumping condition:

- There is usually a standing order in EPIC to draw both an EDTA and Citrate tube for every heme order and to make slides immediately.

a) If patient is drawn again using venipuncture:

(1) Draw EDTA **and** Citrate tube (citrate must be full).
(2) **Make slides STAT from needle.**
(3) Run citrate tube immediately in triplicate (look for decreasing or low platelet counts and increasing WBC counts).
(4) After running Citrate tube make another set of slides from tube to check for platelet clumping and correlation with count
(5) Repeat (3) and (4) using EDTA tube.
(6) If the EDTA tube still exhibits platelet clumping, but there appears to be no clumping with citrate, multiply the citrate PLTS result (and WBC if needed) by 1.1 to correct for citrate anticoagulant dilution.
(7) Append corrected result(s) with CIT (count performed on citrated blood due to platelet clumping in EDTA).
(8) Red cell values should be reported using EDTA values.
(9) High complexity labs may report out the platelet from Citrate plasma following the instructions listed in a-6 & a-7.
(10) Moderate complexity labs must send a copy of the analyzer printouts and the slides made STAT from the needle to Central Lab to result.

REPORTING RESULTS
Clinic Labs: see the Computer Entry section of this procedure

Well@Work Clinics - Wilson:

1. enter results on test log sheet
2. fax test log sheet to Central Lab for result entry into the Laboratory Computer System

REFERENCE(S)

ABX Pentra 60 C+ User Manual.
Koepke, JA: Lipemia and Hemoglobin Determinations. MLO, Jan 1983.
Davisohn and Henry: Clinical Diagnosis by Laboratory Methods.
Cornbleet J: Spurious Results from Automated Hematology Cell Counters.
Lab Med. vol. 14 #8, Aug. 1983, pages 509-514.

RELATED DOCUMENTS

Hemogram - Computer Entry for Hematology for ABX Clinics
Hemogram: Manual Differential, Cell Morphology, and Platelet Estimate Procedure (Wright Stain)

APPENDIXES

Pediatric minimum volume chart
Blood Transfer Device Highlight Sheet
ABX 60 C+ for high complexity labs – Heme Verification guidelines
ABX 60 C+ for moderate complexity labs – Heme Verification guidelines

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IV. DEFINITIONS

V. COMPLIANCE

Failure to comply with this policy or procedure may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS

High complexity ABX Pentra 60 C+ Heme verification guidelines
Moderate complexity ABX Pentra 60 C+ Heme verification guildelines

VII. OTHER RESOURCES

VIII. ENDORSEMENT

Laboratory Administration

QUALITY CONTROL INFORMATION

Process quality control in the following manner:

1. **Run ABX Pentra Diff controls** as per the manufacturer's instructions.
   ALL CLINICS:
   At start-up: **Run Normal and High control**
   At 5 PM: Run Normal and Low control
   Run all three levels of controls after bleaching, maintenance or troubleshooting.

2. **Enter ALL ABX Pentra Diff control values into the computer** (refer to the Computer Test procedure (page 19) or General Computer Manual QC Data Entry Procedure for value input). The computer will indicate on the screen at the time of value input when a quality control error has occurred.

   Proceed in the following manner for each type of situation:
   a. **No errors indicated** – this indicates that the QC results are within the limits. Proceed with the QC evaluation in step #3.
   b. **R12S Failure (1 2SD failure)** – this indicates that the QC results are outside the 2 SD but within 3 SD. Answer with the QC modifier SN (Supervisor Notified). **Notify a Technical Consultant of the error**. Statistically this error should occur about 5% of the time (one out of 20 values). Proceed with QC evaluation, step #3.
   c. **R13S Failure (1 3SD failure)** – this indicates that the QC results are out of limits. **STOP ANALYSIS. DO NOT REPORT ANY PATIENT RESULTS.** Proceed with the QC evaluation in step #3.

3. **Evaluate the quality control results** based on the following conditions:
   a. If ABX Pentra Diff control values are within limits, or control values exhibit R12S failure **no more than twice in the month**– continue with normal operation.
   b. If the ABX Pentra Diff control values are out of limit R12S more than twice in the month or R13S at all, perform troubleshooting procedures (pages 16-17)

QC Modifier Codes:

SN – 1 2SD Supervisor Notified.
Notify supervisor. No need to repeat control.

RS – To be Repeated, Same Vial
Use when value exceeds limits on the first run.
Your next step will be to re-run the control using the same vial.

RN – To be Repeated, New Vial
Use when value exceeds limits on the first or second run.
Your next step will be to re-run the control using a new vial.

RSOK – Repeated Control (Same vial) Now OK
Enter when the control is okay after re-running

RNOK – Repeated Control (New vial) Now OK
Enter when the control is okay after running with new vial.

References:

Misys Information Systems, Inc. Department Workbook, 10/17/91.
Westgard, JO, et all: A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry. Clinical Chemistry, March 1981, pp 493-501.

CALIBRATION and CONCENTRATED CLEANING PROCEDURE

- Calibration is a procedure to standardize the instrument by determining its deviation, if any, from calibration references and to apply any necessary correction factors.
- A minimum of three analyses cycles must be performed with a known sample (target) to calibrate the instrument. Results are averaged and new calibration coefficient values are calculated so as to generate results conforming to those supplied by the target.

1. Prior to a calibration, a concentrated cleaning should be performed
    a. Open “Menu/Service/Hydraulics systems” window on the menu bar
    b. Open “Cleaning cycles”
    c. Select “Concentrated cleaning” and confirm by clicking on the “OK” button
    d. A rinse cycle will start; enter comments to update log
    e. Open the side door and using a 5 ml syringe, add 3 ml of MINOCLAIR to each chamber. Click OK
    f. Using an alcohol wipe, clean the inside of the chamber area.
    g. Close the instrument door and wait for the cleaning cycle to finish.
    h. Exit “Concentrated cleaning” by clicking on the OK button.
    i. Perform 2 blank cycles
2. Select the Repeatability tab and run one specimen between 5 and 10 times to ensure that the instrument is reproducing results. Parameters which have failed the CV limits will be flagged. If there is a repeatability problem the issue must be resolved prior to calilbration.
3. On the menu bar, select “QC/Calibration” and then select the “Calibration” tab
4. In the lot# section, select the calibrator you will be using, or click on the Modify Target button to enter new values. If modifying:
    a. Select a previously used Calibrator lot#
    b. Click on “Modify Target”
    c. Enter the new lot number of the calibrator and the new expiration date
    d. Enter the target values and click on the “Accept” button to save changes
5. Place the calibrator into the specimen holder and close the door to begin the sampling process
    a. Run the calibrator a minimum of 4 times, deleting the first one. 3 to 11 values may be used to complete a calibration.
    b. If the coefficient of variation is within the acceptable limits, the calibration is possible.
    c. Click on “Calibrate” to update the coefficients.
    d. Click on “OK” to confirm the calibration.
6. Run all three levels of controls to ensure performance. All levels must be in range before proceeding with patient testing.

SUPPLEMENTARY TROUBLESHOOTING PROCEDURES

- **When the ABX Controls are out of limits:**

1. Check the expiration date of the control material and verify that it is the current lot number of control. Check the date that the vial was opened. The stability for an open vial of control is 14 days.

2. Make sure that the QC data is being entered into the correct QC file in the computer. If the data is entered into the incorrect file (ie: normal control in the high control files), the computer will flag all results as out of range.

3. Check the flow of reagents, sample and dilutions. Look for leaks, bubbles, crimped lines, adequate reagents or expired reagents. If problems noted, try to fix. Then notify Technical Consultant and/or call the ABX Hotline at 1 888 903-5001 to help resolve these types of problems. Otherwise continue.

4. Depending on the parameter, perform the cytometer rinse and the chamber rinse and/or concentrated cleaning. See ABX seminar summary for suggestions.

5. If problems are still not resolved, consult the Supplemental Troubleshooting Guide for more problem solving ideas.

6. Verify that the calibration factors are correctly entered in the ABX. Current coefficient factors should be written on a log sheet in your heme book or posted on your instrument.

7. Document ALL actions taken on the heme problem log. Be sure to enter control values in the computer.

- **Verification and follow-up of problem resolution**

Verify problem resolution by running all 3 levels of the ABX Pentra Diff controls.

1. When **all** controls are within established limits:
   a. Continue with normal operation.
   b. Document all control values in the computer in the sequence in which they were analyzed.
   c. Repeat a few patients since the last valid control to verify that patient values are maintained. Consult with a Technical Consultant as to whether previous patient needs to be repeated and/or corrected.
   d. Document problem and corrective actions taken on the Instrument Problem Log.
2. If **any** of the controls are not within established limits:
   a. Consult ABX Seminar Summary (next page).
   b. Consult with the Supplementary Troubleshooting.
   c. Call the ABX Hotline and/or notify a Technical Consultant.

- **Examples:**

Problem Situation #1:
The ABX Pentra Diff controls are out of range. The patient results duplicate with previous results.
The problem appears to be with the commercial controls rather than the instrument. Depending on the parameters involved, options include the following:

1. Get a control from another clinic lab or Central Lab to try.
2. Call a Technical Consultant to discuss and troubleshoot. It may be necessary to check the calibration of the instrument.
3. Call ABX for assistance.

Problem Situation #2:
The ABX Pentra Diff controls are out of range and the patient results do not duplicate with previous results.
The problem appears to be with the instrument. Patient values resulted since the last control was within limits may not be accurate. Assess whether samples need to be repeated/corrected after resolution of the problem. Options for reporting results until the ABX Pentra 60 is operable are:

1. Send samples to Central Lab for analysis.
2. Send samples to another clinic for analysis. Definitely consider this option for waiting samples if the ABX may be down for more than 3 hours. Patient samples with questionable results may also be sent to another lab for verification of results.

Problem Situation #3:

One or more parameter values have taken a giant increase or decrease in results when running the specimen in duplicate, and other specimens now exhibit this significant change from previous results.

1. See notes in #2 above regarding reporting patient results.
2. Look for leaks, bubbles, crimped lines, adequate reagents or expired reagents. If problems are noted, try to fix, consult supervisor and/or call ABX hotline.

References
Belvedere, Dale: Hematology Quality Control. American Dade.
ABX Seminar Summary

Hematology Preliminary Results
(Clinic prelim results – final testing at Central Lab)
Order code: HEDP-W

ORDERING:
Order only if provider insists on a result before the final comes back from Central Lab and the hemogram and/or diff results cannot be reported.

NOTE: Keep HEMPL and/or HEDF pending so that Central Lab can result.

RESULTING:
WORKSHEET:
Function MEM, worksheet HCON

RESPONSE:

Code	Name	Response
HEDFP	Prelim Results	Free text results. Examples: **;**WBC <0.4 **;** Unidentified Cells seen. **;** 25% Neutrophils, 65% Lymphs * **;**Hemoglobin 12.3
HCALL	Result called to	Free text who received the results. Enter first and last names, date and time. Examples: **;** Diff given to Dr XXX at 1050,050804 **;**WBC called to Jane Smith, RI OB,12N,030104
HEDP2	Will be automatically answered with VTF: "Verification to Follow".	

ADDITIONAL INFORMATION:
***** Differential percentages may not add up to 100%. Enter appropriate partial results, according to preliminary procedure.

HEMOGRAM

Order Codes: HEMPL, HEHGB, HEHCT, HEPLT, HEWBC

ORDERING:

HEMPL	Hemogram, includes platelets	Also see package HEMD below.
HEHGB	Hemoglobin only	
HEHCT	Hematocrit only	
HEPLT	Platelet only	
HEWBC	WBC only	

Note: Package HEMD includes a (HEMPL) and diff (HEDF).

HEMD-W	(waiting – perform at clinic)
HEMD	(routine or same day - perform at Central Lab)

RESULTING:

WORKSHEET: Function MEM Worksheet HM1_ _ (Hemogram)
Function OEM (see OEM/OFC procedures pages 3-5)

To enter controls:	Function MEM	Worksheet HM1_ _ (Hemogram)
	At Acc. No. prompts:	Enter C-PDL (Abnormal Low)
		Enter C-PDN (Normal)
		Enter C-PDH (Abnormal High)

If QC (R & D Low, Normal, or High) is out of range, rerun sample. Evaluate the Quality Control results based on the information provided in the QC/Troubleshooting guide. The following QC modifier codes may be used:

RS	To Be Repeated, Same Vial
RN	To Be Repeated, New Vial
SN	2SD Failure, Supervisor Notified
RSOK	Repeated Control (Same Vial) Now OK
RNOK	Repeated Control (New Vial) Now OK
OUT	Control Exceeds Limits, Proceed to Troubleshoot
OKNOW	OK after Troubleshooting

TEST CODES:

WBC
RBC
HGB
HCTC
MCV Enter results to 1 decimal place. If entering in MEM, manually add .0 Example: 86.0
MCH
MCHC
RDW
PLTS

ADDITIONAL INFORMATION; Clinics:

1. **-PCKD** (All Parameters Rechecked) Append to WBC result

   -SCKD (Slide Checked) Append to MCV or PLTS results

   -QNR (QNS to Repeat) Append to WBC

   -PW (Specimen Exhibits Characteristics Suggestive of an Elevated Level of Cold Agglutinins) Append to RBC

   -CGRL (Corrected for Gross Lipemia) Append to RBC

   -CIT Append to PLTS
   (Count Performed on Citrated Blood Due to Platelet Clumping in EDTA)

CLUMP Replace PLTS with this code (Unable to Perform Due to Platelet Clumping)

And Append **–CPLT** to the WBC
(WBC May be Falsely Elevated Due to Platelet Clumping)

2. See OEM and OFC procedures for information on running Hemograms on-line through the instrument interface.

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On Line Instruments: (Function OEM)

Function: Enter OEM

Tech Code: <Return> accepts tech code from password data

Shift: <Return> for current shift or enter 1, 2, or 3

Device: Defines the instrument and which lab is performing tests
ABX Pentra 60s are all ABX_ _ (clinic abbreviation)
Examples: ABXAV, ABXRI, etc.

Test: <Return> assumes all tests to be reviewed

Workload Data for: <Return>

Then screen will display:
"Last Cup Received: "B" Last Cup Processed: "A"

B = last cup received from instrument by lab system
A = last cup processed by tech at computer

Example: Last cup received: 22 Last cup processed: 20
Cup 20 has been processed, looked at, or accepted. Cups 21 and 22 (and maybe other cups before 20) have been run but may not have reviewed on computer screen.

Start Cup: <Return> to start at cup following "A"
Or enter specific cup number
Or enter string of numbers to display several results (Example 18-22)

Screen Displays:
"Cup B Acc. No.: W12345 (for example)
<Return>

Hemogram results will display along with any failures in QA checks.

Note: Options at "Cup B Acc. No: W12345" (for example) include:

a) **/**Cup C skips from displayed cup to new cup.
Example: /57 will take you to cup 57
/# of "last cup received plus 1" will put you into "waiting" mode
Example: If last cup received is 23, enter /24 to go to "waiting"

b) **[**Acc. No.: scans for specific Acc. No in all the cups since the last OFC
Example: [W12345 will take you first cup where W12345 is and ask if you want to choose that cup. If W12345 has been run more than once and you do not want that cup to display, answer B and the system will take you to the next cup that W12345 resides and ask if you want to choose that cup.

Note: The ABX Pentra 60 allows for positive specimen identification meaning that the patient barcode can be scanned or the accession number can be manually entered into the ABX. When the barcode is scanned you will notice that accession number displays as a 9-digit number. For example, M12345 displays as 020012345. For manual entry of the accession number, the tech can enter either the all-numeric value or the alphanumeric (M12345) accession number**. Either way, the correct accession number must be entered into the ABX for OEM to work properly.**

Here is a translation for all-numeric accession numbers:

	Alpha	Numeric	Example: Nine digits are required
Sunday	X	1	**X**123: **0100**00123 (extra two zeroes are required)
Monday	M	2	**M**12345 **0200**12345
Tuesday	T	3	**T**1234 **0300**01234 (extra zero is required)
Wednesday	W	4	**W**12341 **0400**12341
Thursday	H	5	**H**12344 **0500**12344
Friday	F	6	**F**12346 **0600**12346
Saturday	S	7	**S**12347 **0700**12347

Waiting (enter * to exit OE)
Displayed whenever last cup filed is equal to the last cup received. System will wait for a maximum of 15 minutes for additional specimens received from the instrument. As values are received, prompting will resume, beginning with the Acc. No.: prompt.

Options at Waiting:
a) * exits to Function prompt
b) /Cup B moves to that cup number to get out of waiting and go into a cup with results

Accept (A), Modify (M), or Reject (R)?

A: Accepts all data

M: Allows for modification of all data or reviews all data again
DO NOT MODIFY in OEM **EXCEPT** to append a comment (-PCKD, etc).
Reject and start over. Otherwise calculations will not be performed.

M-Test Code: allows for modification of a specific result.
Example: M-WBC will call up WBC, then add "-PCKD" to this result only and DO NOT RETYPE THE RESULT. Add the comment to only one result.

R: Rejects all data entered during current entry session. Data will still be retrievable and can be accessed and resulted later.

R-Test Code: rejects result of a specific test. Then result may be entered in MEM. Example: WBC is 99.9 – so reject only the WBC. Then dilute and enter in MEM.

EXAMPLE: OEM Entry and Cup Search - Illustrates Positive Specimen ID

FUNCTION: OEM

ONLINE RESULT ENTRY

TECH: 244 SMITH,ROBIN HP

SHIFT: 1

ONLINE RESULT ENTRY

DEVICE: ABXRI METHOD FOR CAP = ABXRI

TEST-1:

WORKLOAD DATA ENTRY

NO. OF SPECIMENS FOR OTHER WORKLOAD, METHOD ABXRI:

WORKLOAD DATA FOR:

LAST CUP RECEIVED = 215 LAST CUP PROCESSED = 195

START AT CUP **204-210**

Print on this terminal? <Y>:

CUP ACC WBC RBC HGB HCTC MCV MCH MCHC RDW PLTS dmethabneuablymabmonabeo abbasneut lymt monoseosinbasosdcom SEQ ACC

204 **W33602** 5.6 3.84 12.1 35.2 91.6 31.6 34.5 16.3 312 2.4 2.2 0.4
0.4 0.1 44 40 8 8 1 204 **W33602**
205 **W34776** 8.6 5.75 14.9 43.7 76.0 25.9 34.0 17.5 230 5.0 2.1 0.9
0.4 0.2 58 25 10 4 2 205 **W34776**
206 **W32397** 5.8 3.76 11.5 33.1 88.0 30.6 34.8 19.3 235 2.6 2.1 0.9
0.2 0.0 45 37 15 3 1 206 **W32397**
207 **W33012** 1.6 4.15 13.9 39.9 96.1 33.5 34.9 19.4 76 0.6 0.9 0.1
0.0 0.0 38 54 5 3 1 207 **W33012**
208 **W34999** 8.1 4.47 13.8 40.4 90.2 30.8 34.1 15.5 106 6.5 0.8 0.7
0.1 0.1 79 10 8 1 1 208 **W34999**
209 **W33182** 5.1 3.79 11.8 34.0 89.7 31.1 34.7 17.3 253 3.3 1.1 0.5
0.1 0.0 66 21 11 2 1 209 **W33182**
210 **W32801** 3.0 4.80 14.5 41.5 86.4 30.1 34.8 17.3 136 2.2 0.6 0.1
0.1 0.0 72 21 4 2 1 210 **W32801**

LAST CUP RECEIVED = 215 LAST CUP PROCESSED = 195
START AT CUP

On Line File Cleanup: Function OFC

DO NOT perform OFC if you have results that you still want to retrieve and attach to a patient's access number. OFC will wipe out **ALL** results that have come over from the instrument. Then the only way to enter results is to search through the instrument printouts and enter results in MEM.

On Line File Cleanup: Function OFC

Function: OFC

Device Code: Enter instrument code. Example: ABXRI for ABX at RI.

Start at cup number: 1

Stop with cup number: <Return> defaults to last active cup (clears the system)

System will display the following messages:

CLEANUP OF DEVICE (DEVICE CODE) STARTED

CLEANUP OF DEVICE (DEVICE CODE) COMPLETED

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