**Purpose:** This procedure details the sample preparation, sample analysis for Complete Blood Counts and Result Reporting. All testing is to be performed on the Advia 560 hematology analyzer. Complete blood counts at Bioreach Laboratory include:

1. WBC count
2. RBC count
3. Hemoglobin determination
4. Hematocrit determination
5. Platelet count
6. Mean Platelet count
7. RBC indices: MCV, MCH, MCHC
8. Red Cell distribution width (%)

**Principle:** Thorough, knowledgeable and precise operations in hematology is critical in ensuring accurate results. Diagnostic information addressing conditions such as Anemias, Leukemias, Infections, Thalassemias etc can only be diagnosed through strict attention to details, certified references, and comprehensive knowledge of Hematology. Operation knowledge and documented training on the Siemens Advia 560 (see operators manual) are required.

**Equipment:**

1. Siemens Advia 560 Hematology analyzer and all related equipment.
2. STRATUSDX LIS
3. 1-2% hypochlorite solution
4. Transfer Pipets
5. Dacron swabs
6. Alcohol wipes
7. Disposable tubes

**Specimen Collection and Preparation:**

1. Samples should be well mixed EDTA specimens with the proper proportion of blood to anticoagulant.
2. Any sample tubes not filled Half way should be rejected.
3. Samples should be visually checked for clots before placing them on the analyzer.
4. Bioreach Specimen stability guide should be used to ensure proper specimen requirements.
5. EDTA samples are acceptable up to 48 hour refrigerated or 7 hours room temperature.
	1. Samples not adhering to sample time guidelines should be rejected.
	2. Document rejected specimens on the “Tests not Performed” log in the Bioreach Drive. Designated individuals on log will contact the provider to inform of the test not performed and work on recollection.

**Siemens Advia 560 Procedure:** The complete procedural instructions for the Advia 560 are included in the most updated package inserts/IFU’s and current analyzer onboard help guide. These include detailed test specific instructions which include limitations, calibration requirements, and specifications. Please refer to these documents for complete procedural guidelines and troubleshooting help.

**Routine Procedures (Daily Procedures):**

**Routine Preventative Maintenance:**

1. **Daily Maintenance**
	1. Perform Daily shutdown/Cleaning
		1. The shutdown procedure will be done at the end of shift. navigate to the home screen, then select exit. This will prompt a pop up box, select shut down. Then the Advia will ask for you to insert a cleaning solution with a 1:1 ratio of DI H2O and 1-2% hypochlorite solution. select okay and the system will begin cleaning itself before shut down.
	2. Perform Blank measurement
		1. A Blank measurement must be done at the beginning of the work day. To do this navigate to the measure Icon (top right), ensure that the mode says blank. Then select start, if it needs to be cleaned it will ask you to insert a cleaning solution before running a Blank. (refer to previous step for cleaning solution).
	3. Empty waste
		1. To empty the waste, remove the screw cap from the waste pouch, then discard liquid waste in the laboratory's designated area. Then place the cap back onto the waste pouch.
		2. Now, the Waste needs to be reset on the instrument. Navigate to the menu, then select diagnostics, reagent status. Select reset waste.
	4. Run QC
		1. To run QC, Navigate to Menu, select QC.
		2. Select the appropriate QC level by locating the QC measure option with a box with arrows on each side.
		3. Select the appropriate Lot and level of QC that will be ran.
		4. Click on QC measure. Then place QC material on the front rotor and select start next, this will start the measurement.
		5. Once done the results will appear on the screen. repeat with other levels of QC.
		6. Any out of control values for reportable tests must be repeated.
			1. Repeat out of control issues must be addressed.
		7. No Differential analysis QC is required.
2. **Weekly**
	1. Perform wash head cleaning
		1. To perform the wash head cleaning, the instrument needs to be powered off. Once off, open the front cover and secure it in position. Then locate the sample rotor. There are two ways to get to the wash head:
			1. unlock the sample rotor by pressing the latch in the hole on the left side of the rotor.
			2. Turn the rotor door clockwise, using a cotton tipped applicator, moisten with distilled water and clean the bottom of the wash head.
			3. Turn the sample rotor door back to default position and close the cover.
			4. If you are able to access the wash head through the gap between the rotor and the instrument, you can swab the washer head with a moisten cotton tip applicator to clean it.
			5. Power on instrument when done.
3. **Monthly/as needed maintenance**
	1. Clean shear valve
		1. Navigate to the menu, select maintenance, select shear valve cleaning.
		2. Open up the instrument and secure it into position.
		3. locate the shear valve (its white disk with a screw on top). Unscrew and remove the axis screw.
		4. Rinse the access screw with water and wipe dry. Then separate the surfaces of the shear valve by sliding the upper disc towards you.
		5. Gently clean the surfaces of the shear valve, then resemble it and place the access screw back in place.
		6. lower the cover and select OK and complete the process.

**Calibration:** The Advia 560 requires semi-annual calibration to ensure accurate results. Calibrators are stable, whole blood preparations that are used to verify and adjust calibrations on the Advia 560.

1. Samples are to be ordered upon notification from the analyzer that the calibration date is pending.
2. Calibrator handling instructions are detailed in the calibrator package insert.
	1. Bring to room temperature.
	2. As per package insert, mix by hand. Do not mix on a mechanical mixer.
	3. Prime the analyzer once by aspirating the calibrator sample, deleting results.
	4. Continue with Multiple repeats of calibration.
	5. Analyzed mean values are compared to calibrator definitions. If difference in within manufacturer limits, calibration adjustment is not needed.
	6. If the analyzed mean differs from calibrator definitions, calibration is required. See the Advia 560 Operator’s Guide for complete instructions. Siemens technical support also can be utilized for any troubleshooting issues.

**Routine Daily Management of Patient Samples**:

 Basic operation of the Siemens Advia 560 at Bioreach Laboratories involves communication between STRATUSDX LIS and the Advia 560.

1. Samples are received into the lab using the Results Reporting menu. Once samples are received into the lab, patient and test information is downloaded to the Analyzer.
2. The Siemens Advia 560 will perform a complete blood count with a six part differential.
3. The values are then uploaded to STRATUSDX and the technologist can then verify/send the results to the ordering clinician.
4. While Laboratory personnel have general discretion as to bench workflow certain topics need to be addressed at all time:
	1. Critical Values should be repeated on the analyzer.
	2. Document all critical value actions in the STRATUSDX database and the Bioreach Critical value log.
	3. Proper Specimen stability requirements must be adhered to.
	4. QC and Proficiency testing samples are to be ran in the manual mode only.

**Interpretation of Results:** Testing personnel are to review the analyzer printout and determine whether the sample needs to be repeated. The Coulter report is then initialized and dated and placed in the daily report pile.

**Limitations/Interference:**

1. WBC count: > 5 NRBC/100 WBC’s, PLT clumps, Large Platelets
2. RBC count: WBC count > 75.0 x 10^3/uL
3. MCV/HCT: WBC count > 75.0 x 10^3/uL
4. Platelet count: PLT clumps/Large Platelets
5. Hemoglobin: WBC count > 75.0 x 10^3/uL, Lipids > 280 mg/dL, moderate to grossly lipemic specimens.

**Proficiency Testing:**

* Proficiency test material will be obtained from an approved source
* Proficiency test material will be handled and documented in the same manner as a patient specimen
* The Laboratory Director and Laboratory Manager will review all proficiency test results

**QA Measurements:** All quality control data is reviewed monthly for shifts, trends and other quality issues. All data will be reviewed at regular Lab meetings.

**Quality Improvement Plan/Performance Improvement**: Repeat Chemistry/Immunoassay problems/issues should be considered as a potential Quality Improvement/Performance Improvement item. Please refer to the Bioreach Quality Assurance Policy for Performance Improvement guidelines for additional information.

* **Reference:** Wallace, Bobbie F. and Windlont, Gay McCutchen, *Hematology Procedure Manual*, American Society For Medical Technology, Bellarie, Texas, pp. 123-124
* Miale, John B., *Laboratory Medicine Hematology*, 4th Edition, The C.V. Mosby Co., St. Louis, pp. 1209-1210
* Siemens Advia 560 Operators Manual
* STRATUSDX LIS operation procedure