**Purpose:** To define in detail the daily, weekly, monthly, and as needed maintenance to be performed specifically by a supervisor and/or trained designee.

**Procedure:**

**Daily Maintenance: all techs to perform**

1. Check commercial QC & Moving Averages (X-B and WBC map)
2. Check problem log
3. Auto clean
4. Visually inspect syringes, lines for any leaks or crystallization

**Weekly Maintenance: supervisor or trained designee only to perform**

1. Check daily maintenance log signed –off (completed, if not resolve with operators)
2. Check mean limits on QC 11 & 12 library
3. Delete out unused libraries i.e. QC file used for precision or whole blood comparison
4. Clean Autoloader tray
5. Clean racks
6. Clean Rack completion Indicator Cleaning (turkey timer)
7. Replace 1,2,3 peri-pump tubing
8. Every 5,000 cycles or 1-1.5 weeks replace vent cone and aspiration needle and perform zero park

**Monthly Maintenance: supervisor or trained designee only to perform**

1. Whole Blood Correlation for Sapphire 1,2,3 & 4, Fluid Sapphire
2. Every **2 months** **or 120 sample runs** for current QC lot print and purge current QC file
3. Sign-off on monthly maintenance and problem log
4. Clean HGB Syringe, check if needed to be changed (if changing also replace leur fitting)
5. Flush T-fitting with distilled water above valve # 345 “vent cleaning waste”
6. Flush T-fitting to the right of valve #317 “flush cup drain”
7. Visually inspect fittings and lines above and below #345 and #317 for pieces of cap cork (flush lines and fittings if cork pieces observed)
8. Click on Remove and install aperture plate (Do not take off)
9. Clean the waste line port with hot water to flush the top fittings on the vacuum accumulator”(waste port to right of waste chamber #1)

**Whole blood Comparisons: supervisor or trained designee only to perform**

**To be performed on all Sapphires (1st week of the month) or as needed**

* 1. Review commercial QC and X-B and WBC map files
  2. Check all Reagents are within expiration date, and are at least ½ full
  3. Check all instrument maintenance ( i.e. auto-clean) is up to date (according to problem/maintenance log)
  4. Check Background counts are within specifications
     + WBC<0.10 x103
     + RBC < 0.02 x103
     + HGB < 0.10 x103
     + PLT< 5.0 x103
  5. Check Precision results – run a single normal blood (always check for clots before running) with ¾ or greater volume 10 times in closed mode in a QC library review for acceptable CV%
     + WBC <2.7
     + RBC< 1.5
     + HGB <1.0
     + MCV <1.0
     + RDW < 2.5
     + PLTo <4.0
     + MPV <5.0
  6. Gather 10 normal bloods about ¾ full with blood, use QC 11 normal criteria for CBC, (no starred or error flagged results or clots)
  7. Cover barcodes (not order #s) for 10 normal bloods with blank label. Program the rack of 10 bloods into the designated Whole Blood comparison QC file. (Use match rack and tube option)
  8. Tolerance Ranges for whole blood comparisons

|  |  |
| --- | --- |
| Wbc | ±0.5 |
| Rbc | ±0.15 |
| Hgb | ±0.2 |
| Hct | ±1.5 |
| MCV | ±2.0 |
| MCHC | ±1.0 |
| Plt | ±10 |

* 1. Print out Whole Blood Comparison QC file from each instrument.
  2. Log the file mean of each whole blood comparison QC file per instrument on the Whole blood comparison worksheet (stored in whole blood comparison notebook).
  3. Also include the actual QC library print out of the whole blood comparison from each instrument
  4. Note how instruments performing on commercial control recovery. Instrument recovering closest to established control mean is the one you review the others against for tolerance checks.
  5. Review Whole Blood comparison results with a supervisor

**Control Overlap: supervisor only to perform**

1. Make sure instruments are maintained and running well before control overlap is started, if not do maintenance and check if calibration needed. Patient X-B should be running well within moving average range, check Levey Jennings
2. Run control overlap 2 weeks prior to expiration of old lot, need a minimum of 5 days of overlap runs
3. Load new lot of QC ranges into each Sapphire computer
4. Run all commercial controls on 1,2,3,4 Sapphires on all shifts
5. Review QC results, remove any obvious “bad” runs from libraries
6. Print out control overlap after 5 days
7. Check file means for each parameter, compare with manufacturer assay and instrument to instrument recovery
8. File mean should be close to target mean
9. CVs should be within manufacturers specifications
10. Note on overlap assay sheets if file mean used, or if any “in lab “assay results used and sign-off
11. File all paper work in control overlap notebook

**Calibration : supervisor only to perform**

*Pre-calibration procedure*

* 1. Review commercial QC results
  2. Print and review X-B files
  3. Identify parameters which may require re-calibration based on peer group data, X-B, and moving average program
  4. Print current calibration factors
  5. Check that all instrument maintenance is up to date
  6. Check Background counts are within specifications
     1. WBC<0.10 x103
     2. RBC < 0.02 x103
     3. HGB < 0.10 x103
     4. PLT< 5.0 x103
  7. Check Precision results – run a normal blood with good volume 10 times in a QC library review for acceptable CV%
     1. WBC <2.7
     2. RBC< 1.5
     3. HGB <1.0
     4. MCV <1.0
     5. RDW < 2.5
     6. PLTo <4.0
     7. MPV <5.0
  8. Check all Reagents are within expiration date, and are at least ½ full
     1. If using a commercial calibrator, make sure it has been stored, handled, and mixed per the package insert and has not expired or if using open vial run within 7days of open

*Calibration procedure*

1. Verify Pre-calibration complete
2. Run commercial Calibrator in empty QC file closed mode a minimum of 5 times, maximum of 10
3. Print QC calibration file and compare with manufacture reference values, refer to instrument calibration specifications in Sapphire manual (access via F1 on keyboard)

*Perform manual calibration*

1. Review printed QC calibration file and ensure that the results are within tolerance limits
2. Calculate new calibration factors for each parameter to 3 decimal places
3. New calibration factor = Reference value (what you want)/ Cell-Dyn Sapphire Mean value (what you have) x Current calibration factor
4. Review calibration factors are correct and enter in the new factors entry window, new factors must be in the allowable range of 0.750-1.250, download/activate new factors
5. Print new cal factors and put in Specified Sapphire notebook.

*Post Calibration Verification*

1. Confirm the new calibration factors by running calibrator and verifying the results agree with the reference values
2. Run at least 3 levels of controls and verify they are in range
3. All calibration materials, pre, cal and post cal are printed and attached to calibrator assay sheet and filled in Calibration manual.

**As-Needed Cleaning Maintenance : supervisor of trained designee to perform**

1. If resulting issues present: visually check syringes for crystallization. ---Only take off syringe and feel movement for RETIC, DIL SHEATH, IMPEDANCE, OPTICAL, WBC A, WBC B, HGB. Syringe assessment is only done on syringes that would affect specific poor resulting.
2. Dilution cup area cleaning
3. Vent Needle Cleaning
4. Aspiration probe cleaning
5. Syringe cleaning (besides HGB)
6. Bar Code window Reader window cleaning
7. Impedance Aperture Plate cleaning
8. Pinch valve Plunger/Spring unit cleaning (this should be only an FSR function)
9. Printer Cleaning

**As needed Component Replacement: supervisor of trained designee to perform**

1. Vent cone assembly
2. Aspiration Probe
3. Change Syringe
4. Pinch valve Plunger/Spring Unit (only an FSR function)
5. Reagent Container Replacement
6. Impedance Aperture Replacement (only FSR function, changing aperture plate requires gains, etc. checks and adjustments)