Procedure for Calibration and Equipment Maintenance

1.0 Purpose - To specify the required elements for the performance check, verification and/or maintenance of equipment used by the DNA Database Section as performed by the DNA Database Quality Control Officer or designee(s).

2.0 Scope – This procedure applies to equipment used by the DNA Database Section.

3.0 Definitions

- **ABI -** Applied Biosystems (Life Technologies).
- **Critical equipment –** Equipment that requires validation, performance check or verification. This is required prior to initial use by the DNA Database Section or as specified in this procedure. Critical equipment includes the ABI 3130XL, ABI 9700, bulb thermometers, bead sterilizers, balances, pipettors, temperature chart recorders (or equivalent), biosafety cabinets, chemical fume hoods, laminar flow benches, Qiagen BioRobot, heat blocks, and refrigerators/freezers that contain critical reagents.
- **FA -** Forensic Advantage.
- **Purified dH_2O -** Water that has been deionized and then filtered to the extent that no particle larger than a nanometer is present in the water.
- **NIST Traceable -** Sample, equipment or material(s) that has been verified against a National Institute of Standards and Technology certified sample, equipment or material(s).
- **QC Check -** Quality control assessment of materials or instrumentation prior to use within the DNA Database Section.
- **QCO -** Refers to the DNA Database Quality Control Officer or their designee(s).

4.0 Equipment, Materials and Reagents

- NIST traceable digital thermometer
- Ice Shaver/crusher
- Purified dH_2O
- dH_2O
- NIST traceable weight set
- Spectral calibration kits (for 3130XL, or equivalent)
- Microwave
- ~1000 mL beaker
- Syringe
- Septa
- 10x buffer
- Wipes (delicate task wipes)
- 50 mL conical tube
- 96 well reaction trays
- Pipettes
- Pipette tips
- Matrix standard set DS-33 to automatically analyze the five different colored fluorescent dye-labeled samples in a single capillary
- Eutechnics 4500 probe (or equivalent)

5.0 Procedure

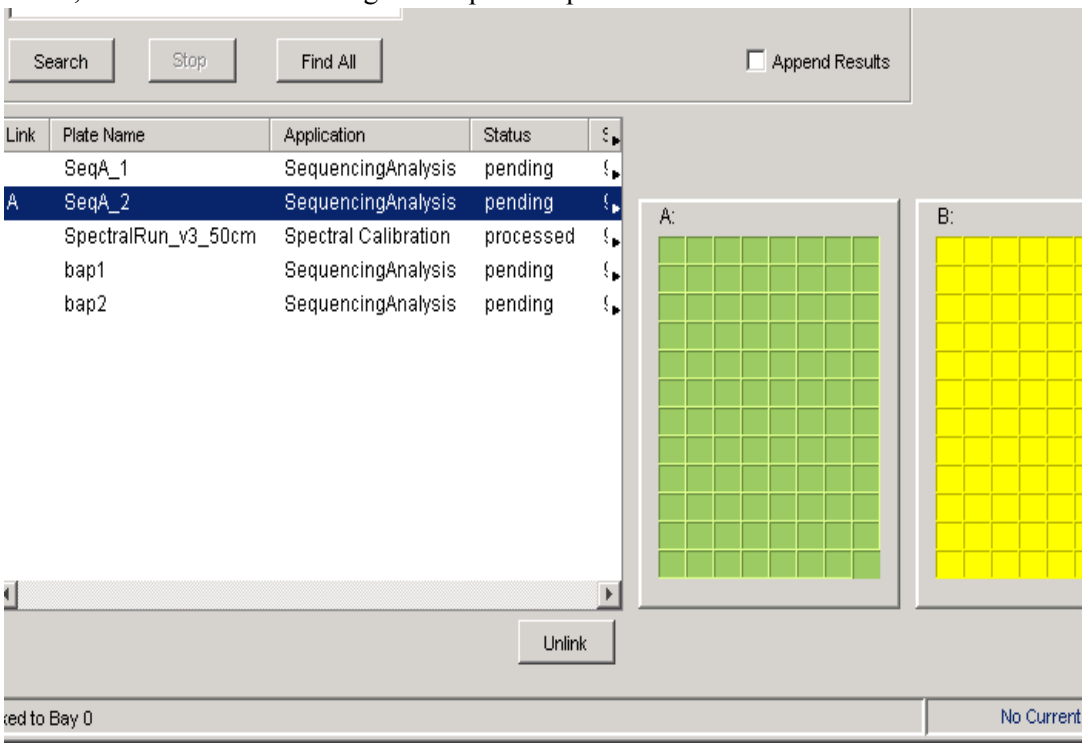
5.1 ABI 3130XL Genetic Analyzers

5.1.1 Maintenance to be Performed by First User of the Day: refer to the DNA Database Section Procedure for Use of the 3130XL Genetic Analyzer.

5.1.2 Weekly Maintenance

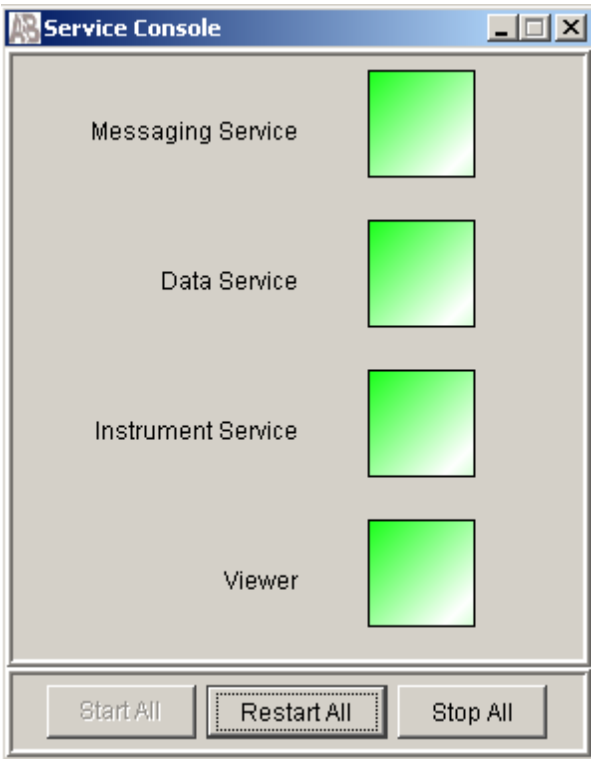
5.1.2.1 Weekly Maintenance shall be performed by the QCO. Documentation of such maintenance shall be noted on the 3130XL Monthly Maintenance Schedule chart. Such documentation shall be retained in the Section indefinitely and kept in the binder for each specific instrument which shall be located near that instrument.

5.1.2.2 At the 3130XL instrument, unlink any plates currently on the instrument. If a plate is linked, click on the green plate position and then click "unlink."



5.1.2.3 Restart the system. At the computer under service console, single click on "restart all."

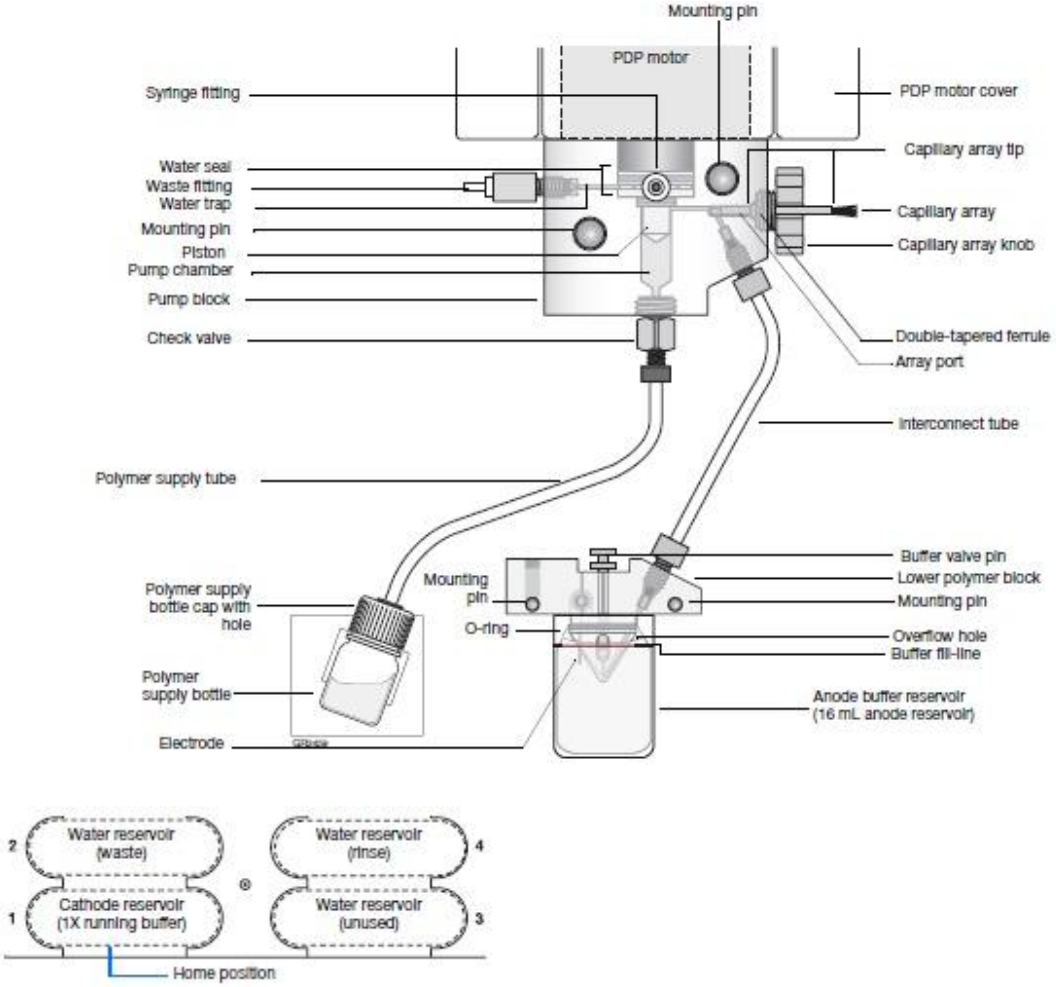
5.1.2.4 Once all areas appear as green squares, start the weekly maintenance.



5.1.2.5 Microwave ~500 mL of purified water in a beaker on high for approximately 2 minutes, until lukewarm and remove from microwave. Do NOT use boiling water.

5.1.2.6 At the 3130XL, push the tray button and wait for the autosampler tray to come to the front of the instrument. After it comes to a complete stop, and the status light is a steady green, open the doors.

5.1.2.7 Remove the anode and cathode buffer and water reservoirs and close the doors.



5.1.2.8 Discard septa in the biohazard box.

5.1.2.9 Pour contents of the reservoirs down the sink.

5.1.2.10 Using a 24 mL syringe, draw up at least 10 mL of warm purified water.

5.1.2.11 Loosen the syringe fitting and waste fitting knobs.

5.1.2.12 Place the filled (24 mL) syringe in the loosened syringe fitting knob and place the anode buffer reservoir under the waste fitting and rinse by depressing the syringe plunger slowly and steadily.

5.1.2.13 Push on the syringe and dispense at least 10 mL of lukewarm water through the syringe fitting, but do not overflow the anode buffer reservoir.

5.1.2.14 If bubbles are present in the water seal and/or water trap, re-fill the syringe and push through additional purified water until no bubbles are present.

5.1.2.15 Tighten the syringe fitting and waste fitting knobs and discard contents from the anode buffer reservoir.

5.1.2.16 Place the anode and cathode buffer reservoirs and the two water reservoirs into the purified water that was placed in microwave.

5.1.2.17 Agitate the openings and remove items from water (removing all crystals that may have formed).

5.1.2.18 Place items on a wipe, and using an additional wipe, dry the anode and cathode buffer reservoirs along with the 2 water reservoirs. Pour water down sink.

5.1.2.19 Make 1X genetic analyzer buffer from 10X stock.

5.1.2.19.1 Add 5 mL of 10X stock to 50 mL conical tube.

5.1.2.19.2 Add 45 mL purified water.

5.1.2.19.3 Invert the conical tube by hand several times to mix contents.

5.1.2.19.4 Label with name, date prepared, DNA Database Forensic Scientist's initials, and expiration date (refer to the DNA Database Section Procedure for DNA Reagent Preparation and Quality Control for expiration date parameters).

5.1.2.20 Add 1X buffer to the fill line of the anode and cathode buffer reservoirs and cap with a new septa. Add purified water to the fill lines of the water reservoirs and cap with a new septa as well.

5.1.2.21 At the 3130XL, push the tray button and wait for the autosampler tray to come to the front of the instrument. After it comes to a complete stop, make sure the status light is a steady green. Open the doors to the 3130XL.

5.1.2.22 Secure the anode buffer reservoir onto the 3130XL.

5.1.2.23 Place the cathode buffer reservoir and water reservoirs in the designated positions.

5.1.2.24 Check for bubbles in the polymer supply tube, interconnect tube, and array port.

5.1.2.25 If there are bubbles, click on the wizard file on the top of the Foundation Data Collection Version 3.0 Software. Click on "Remove Bubbles Wizard" and follow the prompted instructions until no bubbles remain.

5.1.2.26 Once bubbles are no longer present, ensure there is polymer in the polymer supply bottle.

5.1.2.27 If there is not enough polymer, remove the polymer supply bottle, add more polymer from the refrigerator, and re-secure the polymer supply bottle back on the instrument.

5.1.2.28 Once complete, close the instrument doors and fill in the instrument cleaning log with QCO initials, date, array usage and maintenance performed.

5.1.2.29 Change temperature chart on temperature chart recorder and label the chart with the date of the current week.

5.1.3 Water Wash

5.1.3.1 On the first Monday (or first day of the week) of each month, a water wash shall be performed by the QCO and recorded on the 3130XL Monthly Maintenance Schedule chart. Documentation shall be retained indefinitely and stored in the binder associated with the specific instrument, located near the specific instrument.

5.1.3.2 At the 3130XL instrument, ensure the plate is unlinked. If a plate is linked, click on the green plate position and then click "unlink."

5.1.3.3 Restart the Collection software: at the computer, under "service console" single click on restart all.

5.1.3.4 When all areas are green squares, start with the water wash.

5.1.3.5 Microwave ~500 mL of purified water in a beaker on high for approximately 2 minutes, until lukewarm and remove from microwave. Do NOT use boiling water.

5.1.3.6 Add at least 8 mL of purified water to the extra bottle labeled dH_2O.

5.1.3.7 At the 3130XL, push the tray button and wait for the autosampler tray to come to the front of the instrument. After it comes to a complete stop, ensure the status light is a steady green and open the doors.

5.1.3.8 Remove the anode and cathode buffer reservoirs along with the water reservoirs.

5.1.3.8.1 Discard the septa in the biohazard box.

5.1.3.8.2 Pour the contents of the reservoirs down the sink.

5.1.3.8.3 Place the anode buffer reservoir under the lower block.

5.1.3.9 On the Foundation Data Collection Version 3.0 (data collection software), click on "Wizard," highlight water wash, and run the "Water Wash Wizard."

5.1.3.10 Once the window appears, replace the water bottle with the polymer supply bottle. Do not continue until the syringe fitting knob is washed.

5.1.3.11 Using a 24 mL syringe, draw up at least 10 mL of lukewarm water.

5.1.3.12 Loosen the syringe fitting and waste fitting knobs.

5.1.3.13 Place the filled syringe in the loosened syringe fitting knob and place the anode buffer reservoir under the waste fitting.

5.1.3.14 Push on the syringe and dispense at least 10 mL of lukewarm purified water through the syringe fitting, but do not overflow the anode buffer reservoir.

5.1.3.15 If bubbles are present in the water seal and/or water trap, re-fill the syringe and push purified water through until no bubbles are present when tightening the knobs.

5.1.3.16 Tighten the syringe fitting and waste fitting knobs.

5.1.3.17 Continue to follow the instructions on the water wash wizard. Once the "finish" button appears, click finish.

5.1.3.18 Place the anode and cathode buffer reservoirs and the two water reservoirs into the purified water (the following steps may be performed while the water wash wizard is running).

5.1.3.19 Agitate the opening and remove items from water (removing all crystals that may have formed).

5.1.3.20 Place items on a wipe. Using an additional wipe, dry the anode and cathode buffer reservoirs along with the two water reservoirs. Pour water down sink.

5.1.3.21 Add 1 X buffer to the fill line of the anode and cathode buffer reservoirs and cap with a new septa. Add purified water to the fill lines of the water reservoirs and cap with a new septa as well.

5.1.3.22 At the 3130XL, push the tray button and wait for the autosampler tray to come to the front of the instrument and come to a complete stop. Ensure the status light is a steady green. Open the doors to the 3130XL.

5.1.3.23 Secure the anode buffer reservoir on the 3130XL.

5.1.3.24 Place the cathode reservoirs and water reservoirs in the appropriate positions.

5.1.3.25 Check for bubbles in the polymer supply tube, interconnect tube, and array port.

5.1.3.26 If there are bubbles, click on the Wizard File on the top of the Foundation Data Collection Version 3.0 software. Then click on "Remove Bubbles Wizard" and follow the prompted instructions until no bubbles remain.

5.1.3.27 Once bubbles are no longer present, ensure there is polymer in the polymer supply bottle.

5.1.3.28 If there is not sufficient polymer, remove the polymer supply bottle and add more polymer from the refrigerator. Re-secure the polymer supply bottle on the instrument.

5.1.3.29 Once complete, close doors and document the maintenance as noted in **5.1.3.1**.

5.1.4 Changing the Capillary Array – when a capillary has repeated ILS (i.e., sizing standard) failure, or the bases of the alleles in samples broaden (monitor closely once the array usage approaches 200 injections), or the background noise in the electropherograms becomes repeated and excessive (based upon the training and experience of the DNA Database Forensic Scientists), the array shall be replaced. DNA Database Forensic Scientists shall notify the QCO and DNA Technical Leader if they observe any of the above-mentioned scenarios.

5.1.4.1 If the array is replaced at the start of the week (i.e., coinciding with weekly maintenance), the following procedure shall be followed:

5.1.4.1.1 At the 3130XL instrument, make sure the plate is unlinked. If a plate is linked, click on the green plate position and then click "unlink."

5.1.4.1.2 Restart the Collection software: at the computer under "service console," single click on "restart all."

5.1.4.1.3 When all areas are green squares, the array change may proceed.

5.1.4.1.4 Microwave ~500 mL of purified water in a beaker on high for 2 minutes until lukewarm and remove from microwave. Do NOT use boiling water.

5.1.4.1.5 Add at least 8 mL of purified water to the extra bottle labeled dH_2O.

5.1.4.1.6 At the 3130XL, push the tray button and wait for the autosampler tray to come to the front of the instrument. After it comes to a complete stop, make sure the status light is a steady green and open the doors.

5.1.4.1.7 Remove the anode and cathode buffer reservoirs along with the water reservoirs.

5.1.4.1.8 Discard of the septa in the biohazard box.

5.1.4.1.9 Pour the contents of the reservoirs down the sink.

5.1.4.1.10 Place the anode buffer reservoir under the lower block.

5.1.4.1.11 On the Foundation Data Collection Version 3.0 software, click on "Wizard." Highlight "Install Array Wizard" and follow the instructions on the software.

5.1.4.1.12 When the window appears, replace the water bottle with the polymer supply bottle stop until the syringe fitting knob is washed.

5.1.4.1.13 Using a 24 mL syringe, place it in the water and draw up at least 10 mL of lukewarm purified water.

5.1.4.1.14 Loosen the syringe fitting and waste fitting knobs.

5.1.4.1.15 Place the filled syringe in the loosened syringe fitting knob and place the anode buffer reservoir under the waste fitting.

5.1.4.1.16 Push on syringe and dispense at least 10 mL of lukewarm purified water through the syringe fitting. Do not overflow the anode buffer reservoir.

5.1.4.1.17 If bubbles are present in the water seal and/or water trap, re-fill the syringe and push purified water through until no bubbles are present when the knobs are tightened.

5.1.4.1.18 Tighten the syringe fitting and waste fitting knobs.

5.1.4.1.19 Continue to follow the instructions on "Install Array Wizard." Click on the "finish" button when it appears.

5.1.4.1.20 Place the anode and cathode buffer reservoirs and the two water reservoirs into the purified water.

5.1.4.1.21 Agitate the opening and remove items from water (removing all crystals that may have formed).

5.1.4.1.22 Place items on a wipe. Use an additional wipe to dry the anode and cathode buffer reservoirs along with the two water reservoirs. Pour water down the sink.

5.1.4.1.23 Prepare 1X buffer (see **5.1.2.19**).

5.1.4.1.24 Add 1 X buffer to the fill line of the anode and cathode buffer reservoirs and cap with new septa. Add purified water to the fill lines of the water reservoirs and cap with new septa.

5.1.4.1.25 Secure the septa on the cathode buffer reservoir along with the water reservoirs.

5.1.4.1.26 At the 3130XL, push the tray button. Wait for the autosampler tray to come to the front of the instrument and to a complete stop. Ensure the status light is a steady green.

5.1.4.1.27 Open the instrument door and place the cathode buffer reservoir and water reservoirs in their proper positions.

5.1.4.1.28 Secure the anode buffer reservoir onto the 3130XL.

5.1.4.1.29 Check for bubbles in the polymer supply tube, interconnect tube, and array port.

5.1.4.1.30 If there are bubbles, click on the Wizard File on the top of the Foundation Data Collection Version 3.0 software. Then click on "Remove Bubbles Wizard" and follow the instructions through the Wizard until no bubbles remain.

5.1.4.1.31 Once bubbles are no longer present, ensure there is polymer in the polymer supply bottle.

5.1.4.1.32 If polymer needs to be added, remove the polymer supply bottle and add more polymer from the refrigerator. Re-secure the polymer supply bottle back on the instrument.

5.1.4.1.33 Once complete, close doors. Fill out the 3130XL Monthly Cleaning Schedule chart with QCO initials, date, array use and maintenance performed. Any polymer or array information (e.g., changing lot numbers) shall be documented in FA.

5.1.4.1.34 Perform both a Spatial and Spectral Calibration (see **5.1.7 and 5.1.8**).

5.1.4.2 If the array is replaced at any other point (e.g., not coinciding with weekly maintenance), the following procedure shall be followed:

5.1.4.2.1 Push the tray button. Once the autosampler tray comes to the forward position and comes to a complete rest, ensure the status lights on the instrument are a steady green. Open the doors.

5.1.4.2.2 Click on the Wizard File on the top of the Foundation Data Collection Version 3.0 software that states "Update Cap Array Info" and follow the prompts.

5.1.4.2.3 Perform both a Spatial and Spectral Calibration (see **5.1.7 and 5.1.8**).

5.1.5 Service and/or Repair

5.1.5.1 Repair: If a 3130XL becomes inoperable due to a need for repair by the manufacturer, the QCO shall notify the Section via email as well as by placing a notice on the specific instrument that is not available for use. The QCO shall also notify the DNA Technical Leader and the manufacturer that repair is needed.

Performance QC Check: if a 3130XL instrument is removed from use due to repair, a post maintenance QC check on the instrument shall be performed by the QCO prior to its return to use in the Section.

5.1.5.2 Annual Preventative Maintenance: the ABI 3130XL Genetic Analyzers shall have preventative maintenance performed annually by the manufacturer.

5.1.5.2.1 Refer to the Planned Maintenance Protocol (record) provided by the manufacturer for specific calibrations, verifications, and tests performed during the annual preventative maintenance.

5.1.5.2.2 Performance QC Check: After preventative maintenance, each 3130XL shall have a post maintenance QC check performed by the QCO.

5.1.5.3 Argon-ion Laser Failure: the argon-ion laser inside the 3130XL instrument excites the dyes attached to the DNA fragments in the capillaries. When the laser fails, no fluorescent data is generated across all color channels.

5.1.5.3.1 If the argon-ion laser fails on a 3130XL instrument, the QCO shall proceed as described in **5.1.5.1**. Only the manufacturer (via field engineer) may replace the laser.

5.1.5.3.2 Once the laser has been replaced, the QCO shall perform both spatial and spectral calibrations (see **5.1.7** and **5.1.8**) if not already performed by the manufacturer during laser replacement.

5.1.5.3.3 The QCO shall then perform a Post Maintenance Performance QC Check on the instrument (see **5.1.6**).

5.1.5.3.4 Additionally, a sensitivity study shall be performed on the instrument by the QCO at the direction of the DNA Technical Leader.

5.1.5.3.5 After all conditions set in **5.1.5.3.1** through **5.1.5.3.4** are satisfied, the DNA Technical Leader shall release the instrument for use in the Database Section. The QCO shall notify the Section by email and by placing a notice on the specific instrument that it is again available for use.

5.1.5.3.6 All documentation pertaining to a laser failure shall be retained as described in **5.1.5.4**.

5.1.5.4 Documentation of any repair or annual preventative maintenance, as well as subsequent QC Checks shall be retained in the Section indefinitely and shall be maintained by the QCO in the binder associated with each specific instrument which shall be located near that specific instrument.

5.1.6 Post Maintenance Performance QC Check: Before any validated 3130XL shall be used by DNA Database Forensic Scientists in the DNA Database Section after repair or maintenance, a Performance QC check shall be performed by the QCO. Additionally, this check shall be performed after the instrument has been taken off-line due to temperature fluctuations in the room. This QC check shall be performed as follows:

5.1.6.1 A NIST-Traceable Standard (NIST-TS) and associated Negative Extraction Control (see DNA Database Section Procedure for DNA Reagent Preparation and Quality Control) shall be amplified (i.e., Identifiler™) with the appropriate amplification positive and negative control(s).

5.1.6.2 Items listed in **5.1.6.1** shall be electrophoresed on the 3130XL at the 10 second injection protocol.

5.1.6.3 The NIST-TS, positive amplification control(s), and allelic ladder shall provide the expected allele calls at all the loci tested.

5.1.6.4 All testing negatives (Negative Extraction Control, amplification negative control(s)) shall be free of any peaks above the analytical threshold used in the Database.

5.1.6.5 If either **5.1.6.3** or **5.1.6.4** are not satisfied (for reasons other than instrument failure, known artifacts), then the QCO may retest (re-electrophorese or re-amplify) the samples one more time.

5.1.6.6 The QCO shall notify the Section via email as well as by placing a notice on the specific instrument that it is again available for use once the QC check is completed.

5.1.6.7 The QCO shall document the testing performed and retain such information in the appropriate QC files with the specific 3130XL maintenance records.

5.1.7 Spatial Calibrations

5.1.7.1 Purpose: establish a relationship between the signal emitted by each capillary and the position where that signal falls and is detected by the CCD camera.

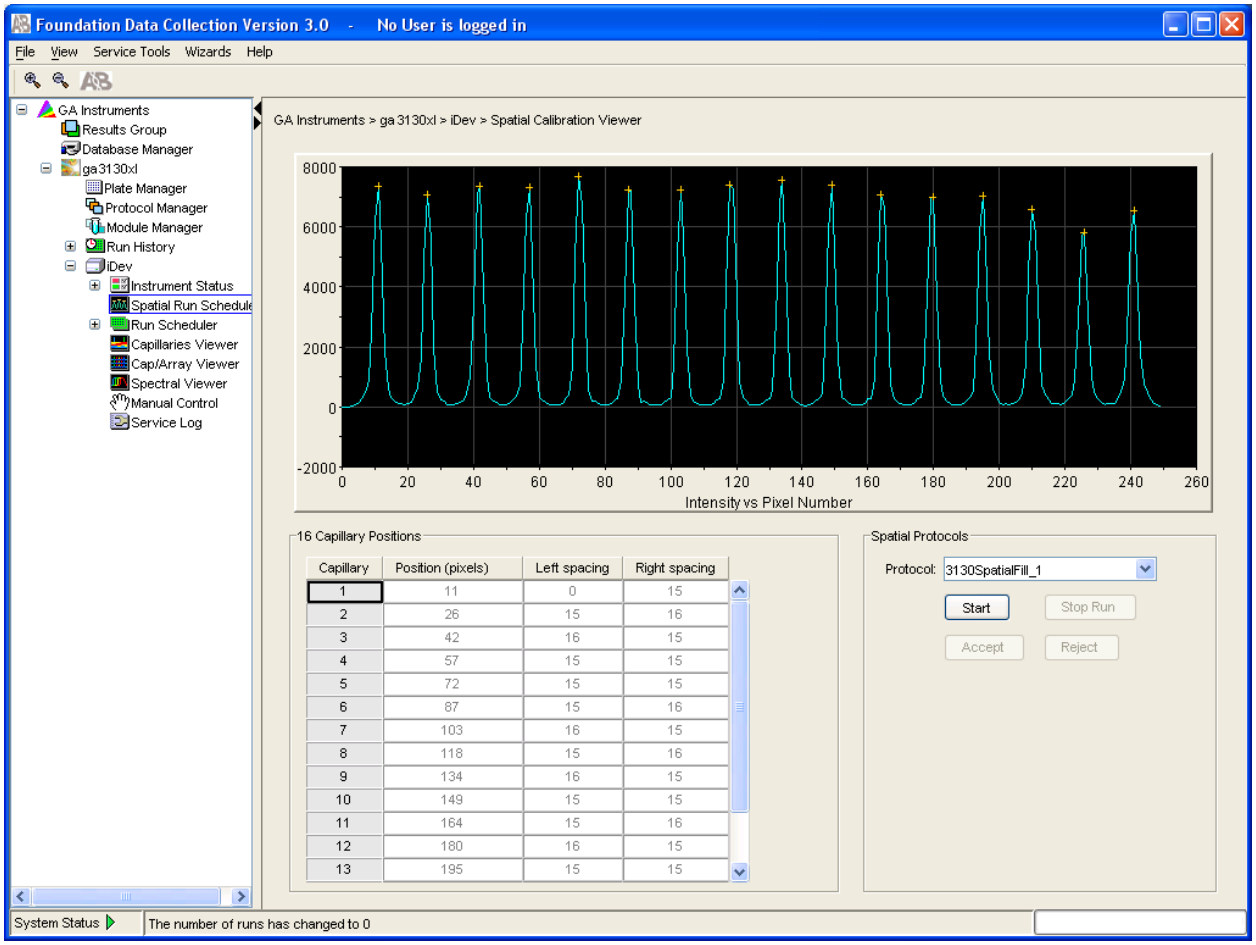
5.1.7.2 A spatial calibration shall be performed when a capillary array is installed/replaced, an instrument is moved, or when the capillary array is temporarily removed from the detection block. The spatial shall be performed by the QCO.

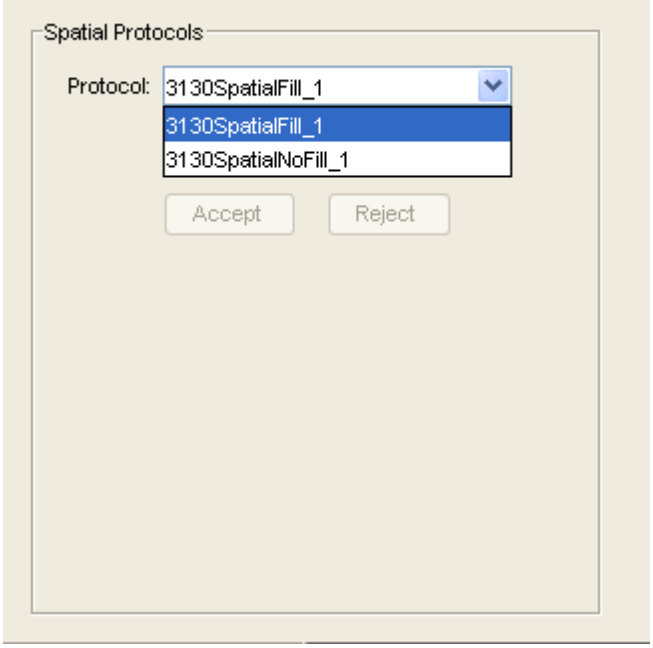
5.1.7.3 In the Data Collection software, click “ga” instruments.

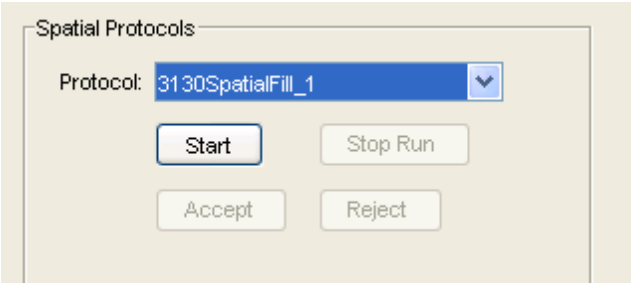
5.1.7.4 Select “ga3130” or “ga3130xl”, instrument name, and spatial run scheduler.

5.1.7.5 In the spatial protocol section, select one of the following: “3130SpatialNoFill_1” or “3130SpatialFill_1.” (Note: It is not necessary to fill the capillaries each time a spatial calibration is performed.)

5.1.7.6 Click start.





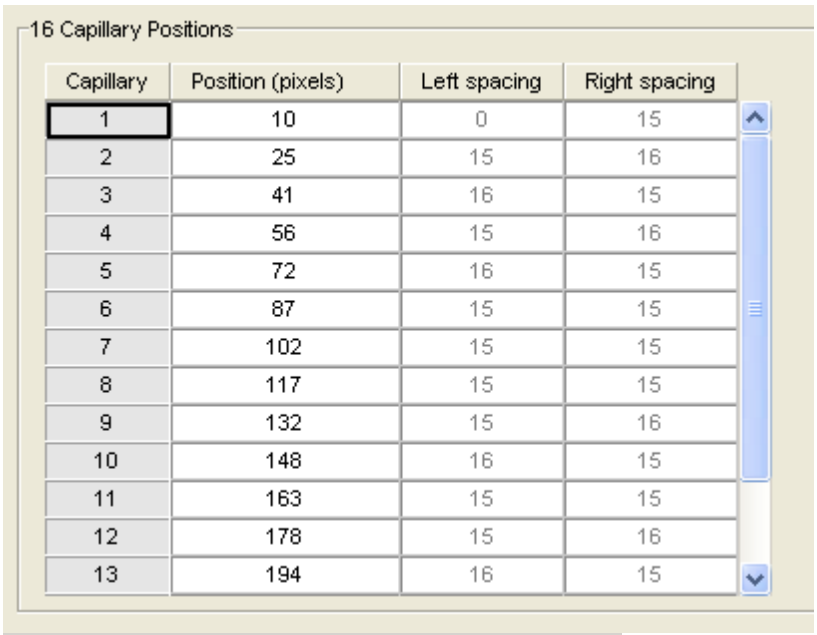


5.1.7.7 Evaluating a spatial calibration file

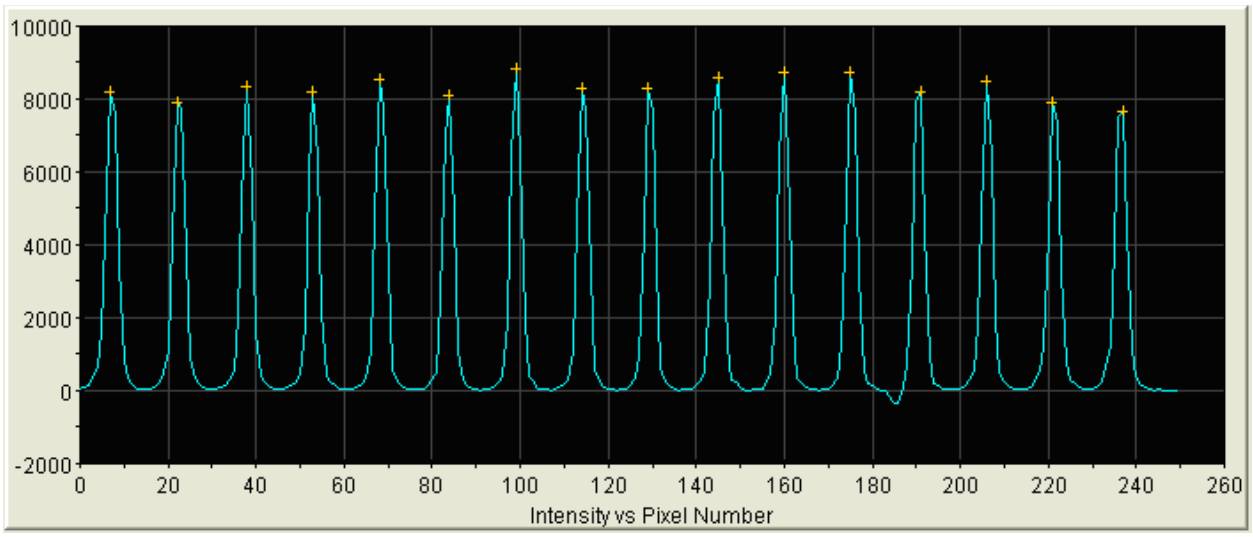
5.1.7.7.1 Ensure the following: peak heights are similar for all peaks, one orange cross marking the top of every peak (no misplaced crosses), single sharp peaks for each capillary are present with small shoulders, and the difference between adjacent positions is 13 to 16 pixels (theoretical spacing between capillaries is 15).

5.1.7.7.2 Examine each row in the 16 capillary positions table and verify that the values in both the left spacing and right spacing columns range from 13 to 16 pixels.

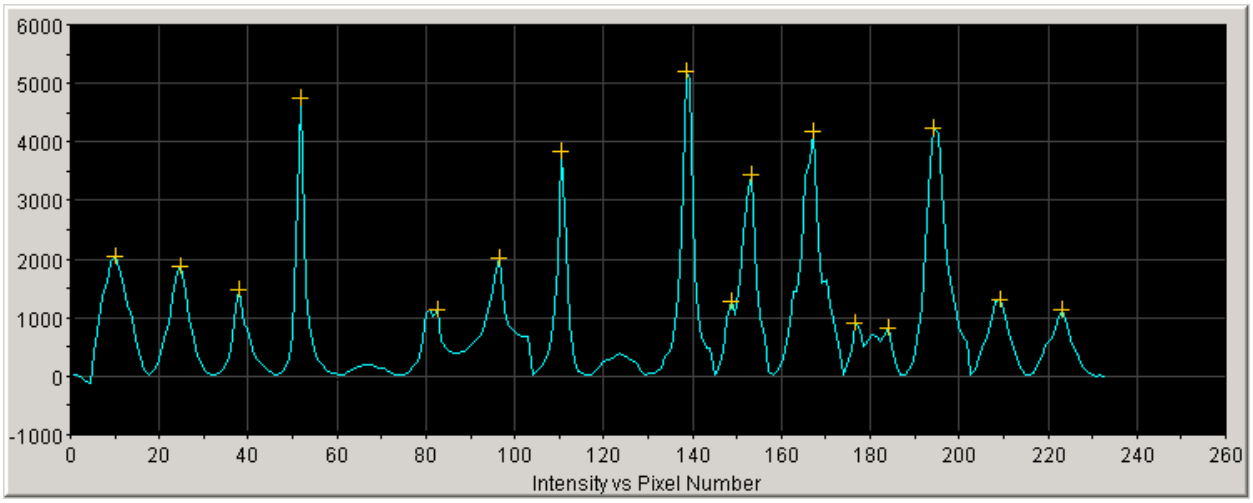
5.1.7.7.3 The spatial shall be accepted or rejected; if rejected, repeat the steps as prompted.



5.1.7.7.4 Pass:



5.1.7.7.5 Failed:



5.1.8 Spectral Calibrations

5.1.8.1 Spectral calibration creates a matrix that is used during a run to reduce raw data from the instrument to the 4-dye or 5-dye data stored in sample files.

5.1.8.2 A spectral calibration shall be performed if any of the following conditions occur: the capillary array is changed, new dye set is used, the capillary array length or polymer type for fragment analysis is changed, after the laser or CCD camera has been realigned/replaced by the service engineer, if a decrease in spectral separation is seen (pull up and/or pull down peaks become excessive) in the raw or analyzed data. Note: a previously run and accepted spectral or a spectral from another instrument can be imported and used.

5.1.8.3 Remove matrix kit from the refrigerator (4 °C) and vortex.

5.1.8.4 Remove two aliquots of formamide from the freezer (-20 °C) and allow to thaw.

5.1.8.5 Add 5 µL of the matrix standard to 195 µL of Hi_Di formamide (matrix standard may be increased or decreased based on the spectral calibration results).

5.1.8.6 Vortex and spin briefly in a microcentrifuge.

5.1.8.7 Using a 96 well plate in columns 1 and 2 and rows A-H, add 10 µL of the matrix/formamide mixture to each well.

5.1.8.8 Cover plate with a 96 well plate septa and spin in a centrifuge for ~ 1-2 minutes @ 2000 rpm.

5.1.8.9 Remove from centrifuge and place on a thermal cycler. Denature the plate on the thermal cycler.

5.1.8.10 Assemble the plate for electrophoresis (plate base, 96 well plate, plate retainer) and press the tray button on the 3130XL to move the autosampler tray forward. Once the light stays a constant green, open the doors and place the plate on the instrument and close the doors.

5.1.8.11 Under Data Collection software, "ga instrument," "ga3130xl," protocol manager, click "new" under the instrument protocols pane and the protocol editor dialog box opens.

5.1.8.12 Complete the protocol editor dialog box (name, type: spectral, dye set, select polymer, array length, chemistry file, run module). Then click "ok." (Note: chemistry file for fragment analysis dye set defaults to the matrix standard and modules list is filtered based on the polymer type and array length.)

5.1.8.13 Under the "Data Collection software," "ga instruments," "ga3130xl," "plate manager," click "new."

5.1.8.14 Complete the new plate dialog box by entering the "plate name," "application," "plate type," "owner" (SBI), and "operator name." Click "ok."

5.1.8.15 The spectral calibration plate editor appears.

5.1.8.16 In "sample name" type in matrix and under "instrument protocol 1," select spectral.

5.1.8.17 Once the entire 2 rows are filled, click "ok."

5.1.8.18 Under "ga instrument," "ga3130xl," "instrument name," "run scheduler," click "plate view."

5.1.8.19 Change search type to advanced, "plate status" select "=," change "value 1" to "pending" and click "search."

5.1.8.20 Select the record to "run," click the plate position indicator that matches the plate to link, and click the green arrow to begin. When prompted: you are about to start processing plates, click "ok."

5.1.8.21 Viewing the pass/fail status after the run:

5.1.8.21.1 Select "ga instrument," "ga3130xl," "instrument name," "instrument status," "event log."

5.1.8.21.2 In the event message section of the window, view the status of each capillary. Each capillary should have a Q-value above 0.95 (if spectral calibration failed, see troubleshooting and reference guide).

5.1.8.21.3 Under the data collection software, click "ga instruments," "ga3130xl," "instrument name," "spectral viewer."

5.1.8.21.4 In the dye set drop-down list, select the dye set.

5.1.8.21.5 In the plate diagram, select a well on the plate diagram to view the capillary spectral results (Note: a failing capillary is automatically assigned the spectral profile of its nearest passing capillary).

5.1.8.21.6 Evaluate the spectral profile and raw data for the selected capillary: verify that the order of the peaks in the spectral profile for Intensity vs. Pixel Number (from left to right) is blue, green, yellow, and red followed by orange for 5-dye chemistry.

5.1.8.21.7 Verify that the order of the peaks in the raw data profile for Intensity vs. Scan Number (from left to right) is orange, red, yellow, green, and blue.

5.1.8.21.8 Verify that the peaks in the spectral profile do not contain gross overlaps, dips, or other irregularities.

5.1.8.21.9 Repeat for each capillary in the array.

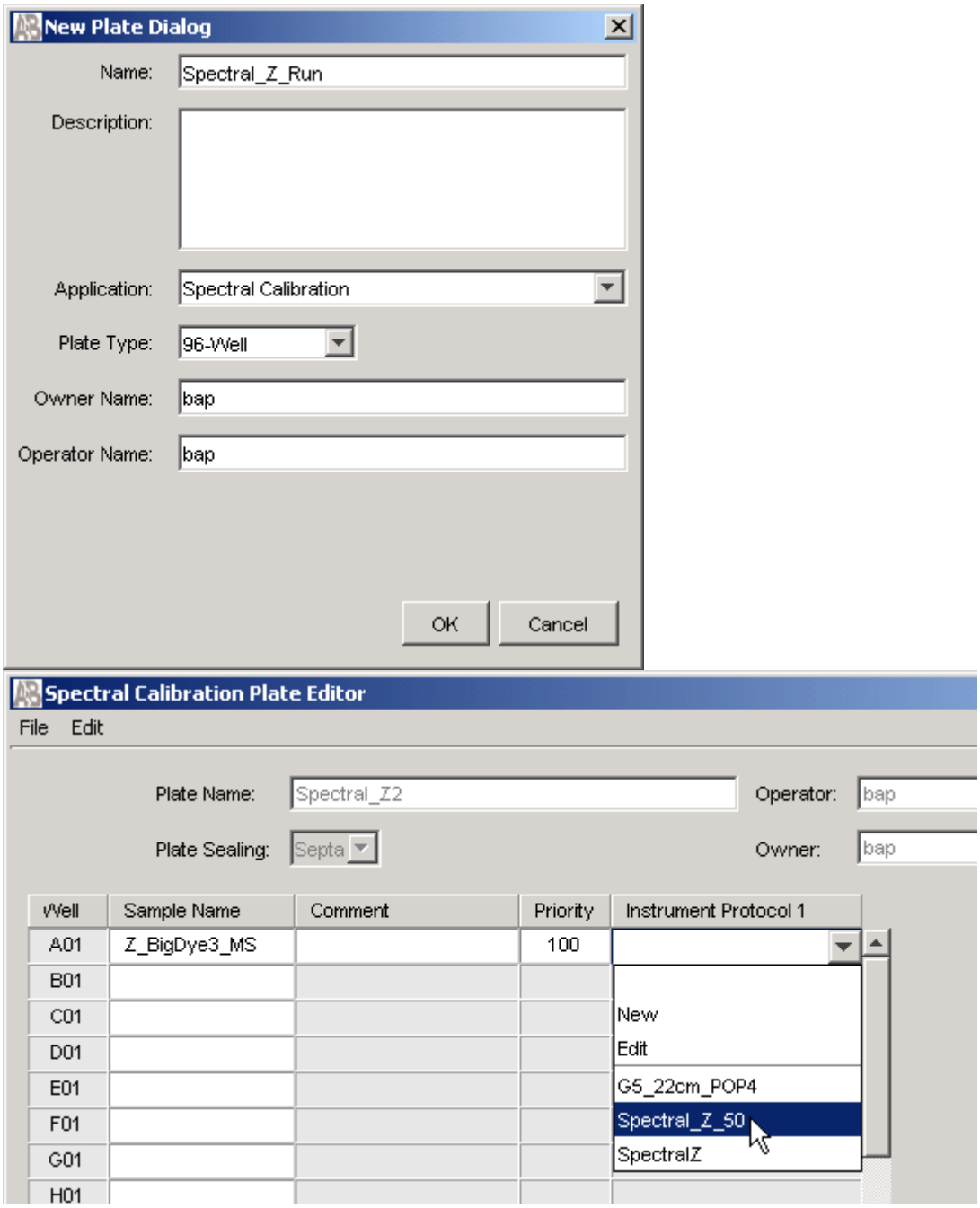
5.1.8.22 Setting an active spectral calibration:

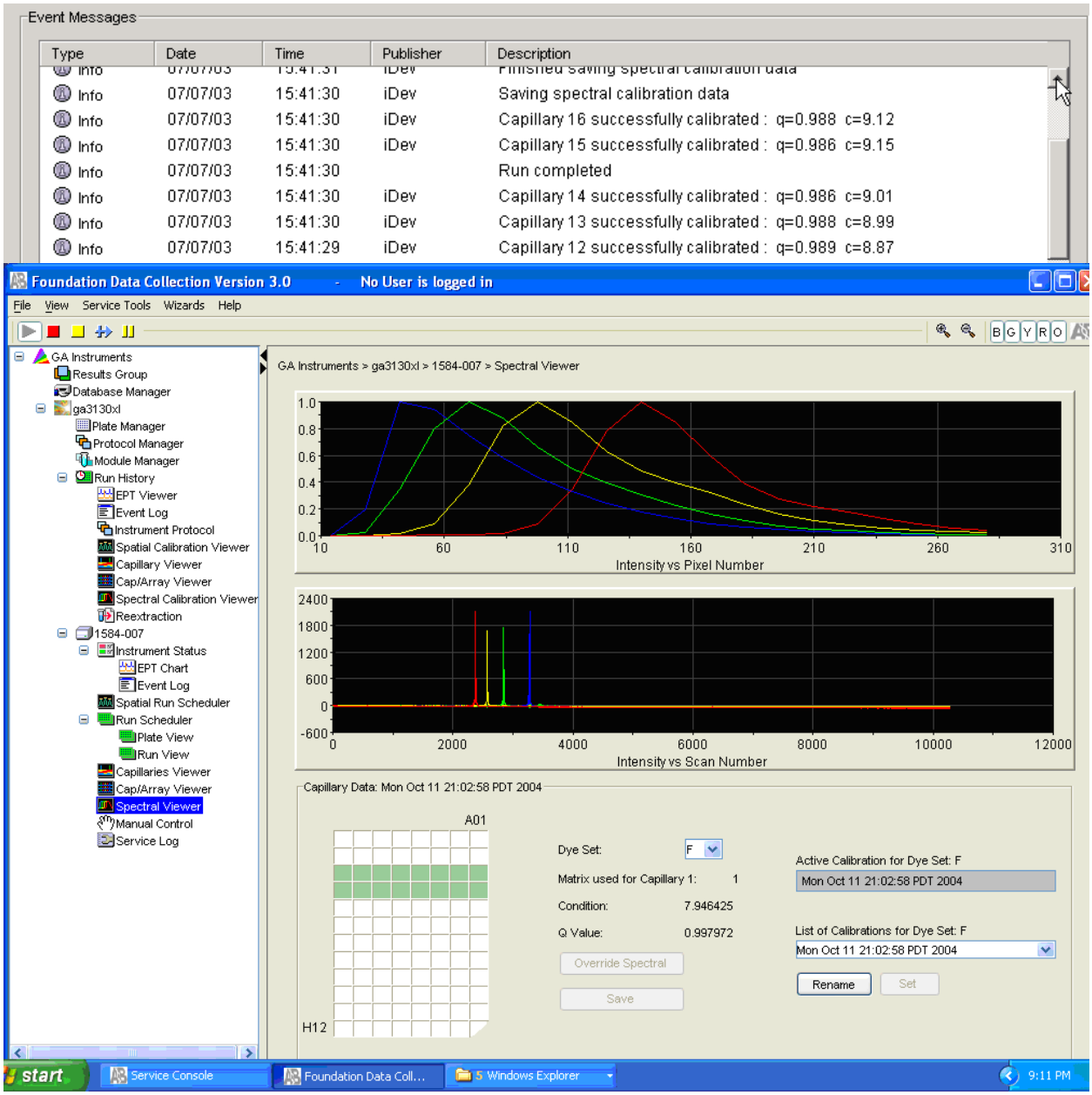
5.1.8.22.1 In the data collection software click, "ga instrument," "ga3130xl," "instrument name," "spectral viewer."

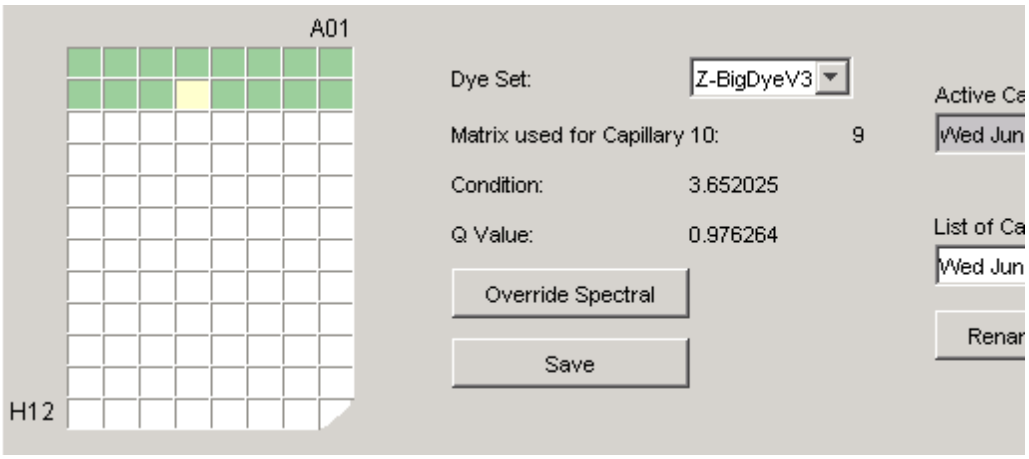
5.1.8.22.2 In the dye set drop-down list, select a dye set.

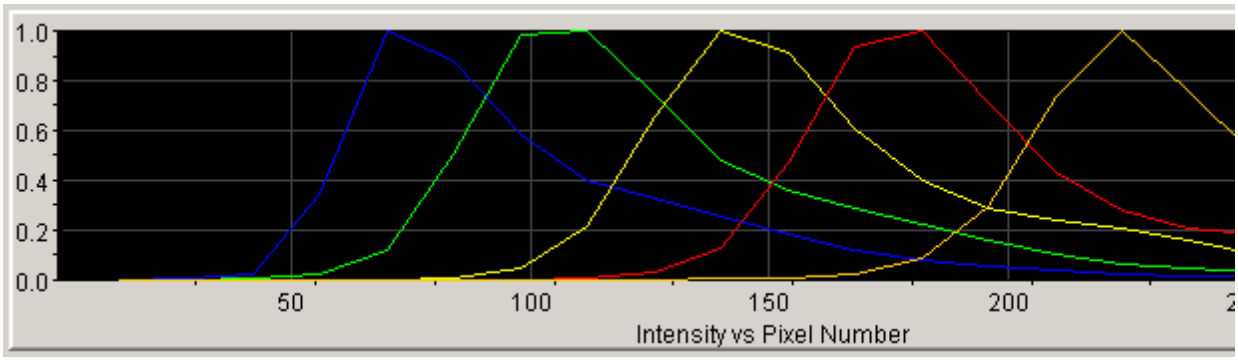
5.1.8.22.3 Select the spectral calibration to use from the dye set drop-down list.

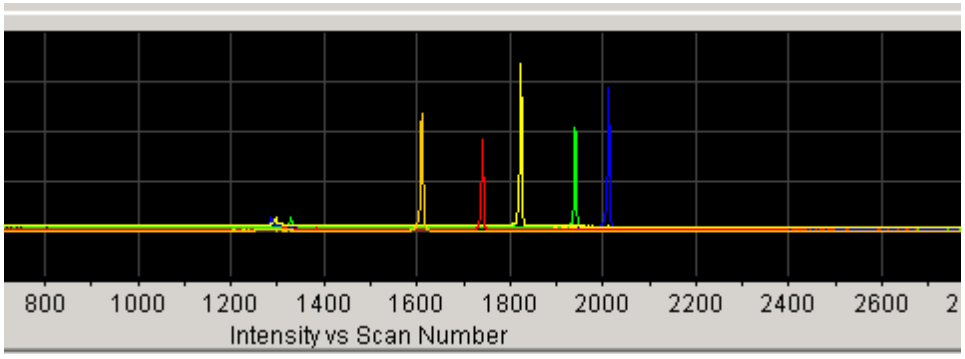
5.1.8.22.4 If the spectral calibration is acceptable, then click "set." Otherwise run a new spectral calibration.











5.1.9 Clearing Errors

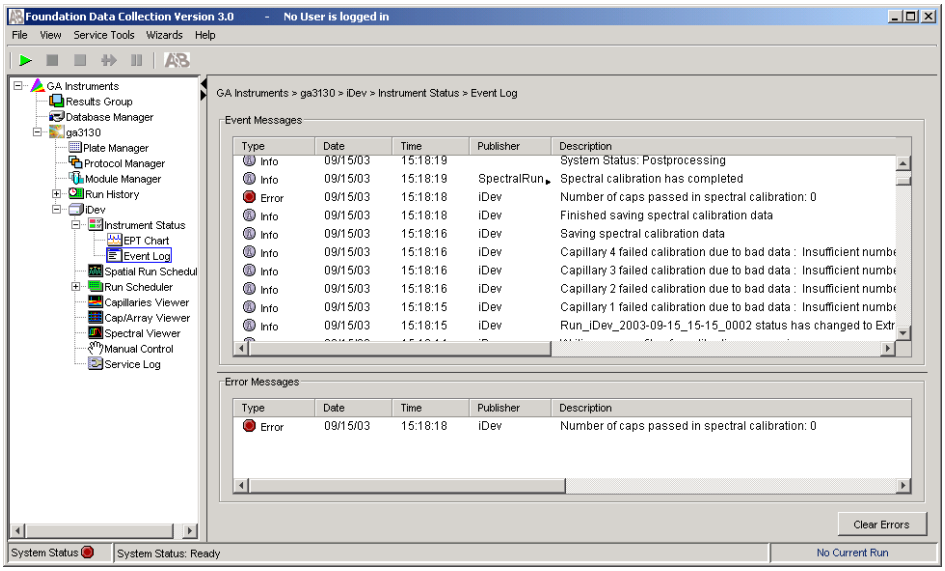
5.1.9.1 If the instrument status light is flashing red or the software System Status is flashing red, the error must be cleared before any further analysis can be completed. The QCO shall evaluate the situation and perform the following steps once notified by a DNA Database Forensic Scientist that an error is present.

5.1.9.2 To clear the error on the software, open the Foundation Data Collection Version 3.0 (data collection software), under the instrument's name there is a "+" to the left of "Instrument Status."

5.1.9.3 Click the "+" to the left of "Instrument Status" and another drop down menu appears on the screen.

5.1.9.4 Click on "Event Log."

5.1.9.5 Click on the button located at the lower right that states "Clear Errors."



"Clear Errors" changes the System Status from red to green.

5.1.9.6 If the software System Status does not change back to a green arrow, or if the instrument status light does not stop flashing red, Power Off/On the Instrument (refer to the DNA Database Section Procedure for Use of the 3130XL Genetic Analyzer).

5.2 ABI 9700 Thermal Cyclers

5.2.1 Internal Quarterly Verification: All thermal cyclers currently in service within the Section shall be subjected to a series of temperature verifications on a quarterly basis by the QCO. Gloves, masks and lab coats shall be worn at all times. Caution shall be exercised at all times as the thermal cyclers can reach temperatures in excess of 100 °C. Documentation of all verifications shall be noted on the Thermal Cycler Verification Record by the QCO performing the verification for each thermal cycler. This documentation shall be retained indefinitely by the QCO.

5.2.1.1 Temperature Uniformity: A set of twelve wells on each thermal cycler shall be tested for two temperature groups: 95 °C and 40 °C. For each temperature group, the range between the highest and lowest values shall not exceed +/- 1 °C. Additionally, each individual well, for each individual temperature, shall not deviate +/- 1 °C from the set temperature.

5.2.1.1.1 Turn on the thermal cycler, select "run" and "TNU" (or "Temp Uniformity"). Select a 25 µL reaction volume. Select "start."

5.2.1.1.2 When the thermal cycler reaches 95 °C as indicated on the display, select the "pause" button. Insert the digital Eutechnics 4500 probe (or equivalent) into the appropriate well (listed below) and shut the lid. Do not pinch the cord. Tested wells are as follows: A1, A6, A12, C4, C9, D7, E3, F2, F11, H1, H7, and H12.

5.2.1.1.3 Allow the probe to stabilize (may take a few minutes). Record the temperature to the nearest tenth of a degree for that well as indicated by the probe. Proceed to the next well until all twelve wells have been recorded on the Thermal Cycler Verification Record (TCVR) for the 95 °C temperature range. Note: QCO may have to continue selecting the "pause" mode to complete this step so as to keep the thermal cycler at 95 °C.

5.2.1.1.4 Select the "resume" button on the display or allow the "pause" mode to time out. The thermal cycler begins to cool down to 40 °C. Using the same wells as listed in **5.2.1.1.2**, test and record the 40 °C temperature results as described in **5.2.1.1.2** and **5.2.1.1.3**. Record the temperature for each well on the TCVR.

5.2.1.1.5 Calculate the range in temperature from **5.2.1.1.3** to **5.2.1.1.4**. These values shall not exceed +/-1 °C from the set temperature or from each other (compare highest recorded temperature for each range to the lowest recorded temperature for each range). Record the results on the TCVR.

5.2.1.1.6 If the calculated values exceed the criteria described in **5.2.1.1**, the QCO shall notify the DNA Technical Leader and the thermal cycler in question shall be removed from service. The QCO shall notify the Section via email, as well as by placing a "Do Not Use" sticker on the thermal cycler.

5.2.1.2 Heat and Cool Rate Test: the ability of the thermal cycler to heat and cool the block quickly is determined by the following steps:

5.2.1.2.1 Turn on the thermal cycler, select "Utilities," "Diag," "System," and "Rate."

5.2.1.2.2 The thermal cycler displays a warning. At this time, place an empty 3130XL 96-well tray, with septa, onto the thermal cycler, and close the lid. Select "Cont."

5.2.1.2.3 The thermal cycler runs the program. When the program is completed, the display indicates "pass" or "fail." It also provides the rate at which the thermal cycler both heats and cools. Rates, as well as "pass" or "fail," shall be recorded on the TCVR.

5.2.1.2.4 If a "fail" result is obtained, the QCO may retest the thermal cycler once more. If the particular thermal cycler indicates a second "fail", the QCO shall notify the DNA Technical Leader and the thermal cycler in question shall be removed from service. The QCO shall notify the Section via email, as well as by placing a "Do Not Use" sticker on the thermal cycler.

5.2.1.3 Temperature Verification: the digital probe is used to verify that the thermal cycler is producing a temperature within +/- 1 °C of the set temperature.

5.2.1.3.1 In the display window, select "Utilities," "Diag," "TempVer."

5.2.1.3.2 Place the digital probe into well A6 and close the lid. Do not pinch the cord. Select "Run."

5.2.1.3.3 The thermal cycler ramps up to 85 °C and prompt the user when complete. At this point, the QCO records the temperature on the digital probe on the TVCR and enter that value as prompted into the thermal cycler to the nearest tenth of a degree.

5.2.1.3.4 Continue the test by allowing the thermal cycler to ramp down to 45 °C ("stabilizing at setpoint") and record the resulting information as described in **5.2.1.3.3**. Select "accept" once both the 85 °C and 45 °C values are entered into the display window.

5.2.2 Notification for Use: If any thermal cycler fails any of the three tests, the QCO shall immediately notify the DNA Technical Leader, as well as the Section via email and an "Out of Use" sticker shall be placed on the affected instrument.

5.2.3 Performance QC Check: if a thermal cycler requires a QC check after repair, for validation, or before a new instrument is put on-line, a QC check shall be performed by the QCO, in addition to the three tests as described in **5.2.1**.

5.2.3.1 This QC check shall consist of the amplification of the following as a set:

5.2.3.1.1 Positive amplification control (9947A) and negative amplification control (Neg Amp), using the current amplification kit.

5.2.3.1.2 NIST-TS and associated Negative Extraction Control.

5.2.3.2 Five total sets shall be amplified at the following well locations and electrophoresed and analyzed per DNA procedures:

5.2.3.2.1 E1-H1, C4-F4, B7-E7, E10-H10, A12-D12

5.2.3.3 The expected results for the NIST-TS, positive amplification controls, and allelic ladders shall be obtained for all loci and the alleles shall be balanced within and between loci and peak heights generally between 1000 and 6000 RFU's. All Negative Extraction controls and negative amplification controls shall be free of any peaks or activity. If any of these conditions are not met (for reasons other than instrument failure, known artifacts), then the QCO may retest the affected wells in the thermal cyclers once. If the conditions are not met this second time, the QCO shall keep the thermal cycler offline and notify the DNA Technical Leader and manufacturer. If the thermal cycler is under a manufacturer warranty, the manufacturer shall be contacted for repair. If the thermal cycler is no longer under any warranty, it shall be placed in storage for eventual surplus.

5.2.4 External Calibrations/Verification: if the thermal cyclers are verified by an external vendor, the results shall be documented. The thermal cyclers that are passed by the external vendor shall be

accepted as calibrated/verified and noted as such until the next quarterly verification is due. This documentation shall be retained indefinitely by the QCO.

5.3 Digital Probes

5.3.1 Annual External Calibration: the digital probes (Eutechnics 4500 or equivalent) shall be calibrated annually by a contract vendor against an appropriate NIST traceable standard.

5.4 Bulb Thermometers

5.4.1 Purpose/Use: used to measure temperatures in heat blocks, incubators and select refrigeration storage units. Surplus calibrated bulb thermometers shall be retained by the QCO, unless broken and then they shall be disposed of in accordance with the DNA Database Administrative Policy and Procedure for Safety and Hazardous Waste Disposal.

5.4.2 Annual Internal Performance Check: all bulb thermometers in use within the DNA Database Section shall be checked on an annual basis internally against a NIST traceable thermometer (i.e., the "NIST lollipop") in an ice bath.

5.4.2.1 Freeze several trays of dH_2O into ice cubes; once frozen, grind or crush them in an ice shaver (or equivalent). Mix the ice shavings with dH_2O and place into an insulated container deep enough (thermos or equivalent) to contain the metal probe portion of the NIST Traceable Thermometer.

5.4.2.2 The QCO shall wipe down each bulb thermometer with fresh 10 % bleach followed by an ethanol rinse and allow it to dry (either through evaporation or wiping with a wipe) before inserting it into the ice bath.

5.4.2.3 Using clamps and foam (or equivalent) to hold both the NIST traceable thermometer and the bulb thermometer to be calibrated within an inch of each other in the ice bath, wait for the NIST traceable thermometer to register 0.0 °C. Align the bulb thermometer such that the bulb portion is submerged in the ice bath, but that the area marked for 0.0 °C can be visualized by the QCO.

5.4.2.4 Once the NIST traceable thermometer reads 0.0 °C, record the temperature to the nearest tenth of a degree on the bulb thermometer. If the bulb thermometer is greater than +/- 1 °C from the NIST traceable thermometer, it shall be destroyed and replaced with a calibrated bulb thermometer.

5.4.2.5 The QCO shall record both the NIST traceable thermometer and calibrated bulb thermometer readings on the Bulb Thermometer Temperature Performance Check Form. The QCO shall also create and place a sticker on each calibrated bulb thermometer that indicates the specific bulb thermometer number, the date the next performance check is due, the initials of the QCO performing the check, and whether the user of the bulb thermometer shall add or subtract tenths of a degree to the reading of that bulb thermometer to bring it to specifications as indicated by the NIST traceable thermometer (i.e., if the bulb thermometer reads 0.5 °C higher than the NIST traceable thermometer, the Forensic

Scientist shall subtract 0.5 °C from the bulb thermometer reading before recording a temperature).

5.4.2.6 This process shall be completed for all bulb thermometers, including those set aside for storage or future use (i.e., replacement).

5.4.2.7 Documentation of the performance checks shall be retained indefinitely by the QCO in the Section.

5.5 Digital Thermometers: Purchased from external vendor; shall be NIST traceable and replaced when NIST traceability expires. Digital thermometers shall be used to monitor temperatures on freezers and refrigerators in the Section as needed. Surplus digital thermometers shall be retained by the QCO.

5.6 NIST Traceable Thermometer (i.e., the "NIST lollipop"): Has an elongated metal probe which is used for testing against the bead sterilizers and bulb thermometers purchased from an external vendor; shall be NIST traceable and replaced when NIST traceability expires.

5.7 Bead Sterilizers: Used only for the purpose of sterilizing scissors used to cut Database blood samples for out-sourcing.

5.7.1 Prior to use, each bead sterilizer shall be verified against a NIST Traceable Thermometer by the person using it. This person shall insert the metal probe of the thermometer into the beads and visually confirm that the thermometer reaches a temperature of at least 250 °C.

5.7.2 A Temperature Record Form shall be filled out by the employee for each bead sterilizer in use.

5.7.3 The employee shall indicate that the bead sterilizer reached at least 250 °C by writing their initials in the box corresponding to the date the bead sterilizer was tested on the Temperature Record Form.

5.7.4 Bead sterilizers shall have temperatures verified only on days they are used.

5.7.5 If a bead sterilizer fails to reach the minimal temperature of 250 °C, it shall be removed from service and the QC Officer and DNA Technical Leader notified.

5.7.6 The QCO shall retain the Temperature Record Forms in the appropriate QC files.

5.8 Balances

5.8.1 Monthly Verification Check: Using a NIST traceable weight set, all balances in the DNA Database Section shall be verified monthly by the QCO with the following weights and limits:

5.8.1.1 Weight #1: 1 gram; Limit: 0.90 to 1.10 grams.

5.8.1.2 Weight #2: 25 grams; Limit: 24.90 to 25.10 grams.

5.8.1.3 Weight #3: 100 grams; Limit: 99.90 to 100.10 grams.

5.8.1.4 If any tested weight falls above or below the established limit criteria listed above, the QCO shall immediately notify the DNA Technical Leader and the balance shall be removed from service until or unless repaired and calibrated by an external vendor.

5.8.1.5 The performance checks shall be recorded to the nearest hundredth of a gram by the QCO on the Monthly Balance Verification Form.

5.8.2 Biannual External Calibrations: All balances in the DNA Database Section shall be calibrated biannually by a contract vendor.

5.9 Pipettors

5.9.1 Biannual External Calibrations: all pipettors in the DNA Database Section shall be calibrated biannually by a contract vendor.

5.9.2 Repair: if a pipettor breaks or a DNA Database Forensic Scientist based on their training and experience believes that the pipettor does not work properly, it shall be given to the QCO for storage until an external calibration vendor can repair and calibrate it. If the pipettor is not repairable, it shall be removed from the Section.

5.10 Temperature Chart Recorders/Data Loggers

5.10.1 Temperature Chart Recorders or Data Loggers may be used to monitor temperature in post amplification rooms where 3130XLs (or equivalent) are currently in use.

5.10.2 Temperature Chart Recorders:

5.10.2.1 Biannual External Calibrations: all temperature chart recorders in the DNA Database Section shall be calibrated biannually by a contract vendor.

5.10.2.2 Retention of data: paper temperature discs shall be changed weekly when in use by the QCO. Any circular discs shall be scanned into digital images. Both the original disc and the digital image shall be retained indefinitely by the QCO in the Section.

5.10.3 Data Loggers (USB)

5.10.3.1 Annual External Calibrations: all data loggers in the DNA Database Section shall be calibrated annually by a contract vendor.

5.10.3.2 Retention of data: the data loggers shall be set to record data every five minutes. The data shall be printed by the QCO every month (to coincide with monthly 3130xl maintenance) and retained indefinitely by the QCO in the Section. The data shall include the date range captured by the logger as well as the serial number of the logger. Once monthly data is captured and retained, the data logger shall be cleared to record data for the next month by the QCO.

5.11 Centrifuges

5.11.1 Annual Preventative Maintenance: the Beckman-Coulter Allegra X-12R and X-12 centrifuges shall have annual preventative maintenance performed by the manufacturer. The manufacturer shall place a maintenance sticker on the centrifuge documenting that the service was performed.

5.11.2 Repair: If repairs are necessary, the manufacturer shall be notified by the QCO and an "Out of Use" sticker placed on the affected centrifuge notifying the Section of its unavailability. Once the affected centrifuge is repaired, the QCO shall remove the "out of use" sticker.

5.12 Biosafety Cabinets/Chemical Fume Hoods/Laminar Flow Clean Air Benches

5.12.1 Annual External Calibrations: all Nuaire Biological Safety Cabinets, Chemical Fume Hoods, and Laminar Flow Clean Air Benches (amplification hoods) in the Section shall be calibrated annually by a contract vendor.

5.12.2 Any hood listed in **5.13.1** that does not pass certification shall not be used.

5.13 Qiagen BioRobot® Universal System

Refer to the Qiagen BioRobot® Universal Procedure

5.14 Heat Blocks

5.14.1 Heat blocks shall have stickers placed on them to indicate their specific purpose and associated temperature:

5.14.1.1 Knowns: 56 °C.

5.14.2 The heat block temperatures shall be monitored by a calibrated bulb thermometer (see **5.4**).

5.14.3 If a DNA Database Forensic Scientist uses a particular heat block for extraction, the temperature shall be recorded on the Temperature Record Form (TRF) associated with that specific heat block on the day(s) that it is used.

5.14.3.1 If the heat block is not used, the DNA Database Forensic Scientist shall strike through the box which corresponds to the day(s) not in use.

5.14.3.2 The DNA Database Forensic Scientist shall fill out all required information regarding equipment name and serial number, the location of the equipment, the set temperature of the equipment, and the associated bulb thermometer number.

5.14.3.3 If at any point during the calendar year a new bulb thermometer is needed, the DNA Database Forensic Scientist shall write at the bottom of the TRF the date on which a new thermometer was used and the number for the new thermometer.

5.14.4 If a heat block deviates more than +/- 5 °C from the set temperature for more than five consecutive readings, the DNA Database Forensic Scientist shall use the temperature knob controls on the heat block to readjust the temperature back into range (this may take several attempts). If all efforts with the temperature knobs fail, the DNA Database Forensic Scientist shall request a new bulb thermometer from the QCO to determine if the temperature issue is due to the heat block or the bulb thermometer. During this period of adjustment, the heat block shall not be used by the DNA Database Forensic Scientist for database purposes. If after both temperature knob adjustments and a new bulb thermometer are unsuccessful, the DNA Database Forensic Scientist shall notify the QCO immediately and that particular heat block shall be

removed from use. The DNA Database Forensic Scientist shall note on the bottom of the TRF for that particular heat block the date it ceased to be in use.

5.15 Freezers/Refrigerators

5.15.1 Recording Temperatures: The QCO shall make every effort to record temperatures for all common area refrigerators/freezers in the Section at the beginning of every business day; however, if the QCO has not yet recorded the temperature and a DNA Database Forensic Scientist uses a common area refrigerator/freezer, the DNA Database Forensic Scientist shall record the temperatures prior to opening the door(s). Refrigerators/freezers which are in limited access areas (such as between suites) shall have their temperatures recorded weekly by the DNA Database Forensic Scientist who has access to such refrigerators/freezers.

5.15.2 -20 °C Freezers: These freezers shall not vary more than + 5 °C from the set temperature. The temperature for these freezers shall be recorded by personnel using the TRF as described in **5.15.1**.

5.15.2.1 The QCO shall fill out all required information regarding freezer serial number, the location of the freezer, the set temperature of the freezer, and the associated digital thermometer serial number at the beginning of every calendar year on a TRF for each common area -20 °C freezer.

5.15.2.2 If at any point during the calendar year a new digital thermometer is needed, the QCO or designee shall write at the bottom of the TRF the date on which a new thermometer was used and the serial number for the new thermometer.

5.15.2.3 If a -20 °C freezer must be thawed, the contents shall immediately be moved to another -20 °C freezer that is within range and the QCO shall note this, as well as the affected dates, on the TRF. The contents shall not be returned to the original -20 °C until the temperature is within range.

5.15.2.4 If the temperature for a -20 °C freezer exceeds the + 5 °C range for more than 5 consecutive business days, QCO shall immediately move the contents to another -20 °C freezer that is within range and note this, as well as the affected dates, on the TRF. The contents shall not be returned to the original -20 °C freezer until the temperature is within range.

5.15.3 -10 °C/4 °C Freezer/Refrigerator Units: These units shall not vary more than +5 °C from the set temperature(s) for the freezer portion; the refrigerator portion shall not fall below 0 °C or exceed 9 °C. The temperature for these freezers shall be recorded using the TRF by personnel as described in **5.15.3.1**, **5.15.3.2, 5.15.3.3,** and **5.15.3.4**.

5.15.3.1 The QCO shall fill out all required information for common area -10 °C/4 °C freezer/refrigerator units regarding the unit serial number, location, set temperatures, and the associated digital thermometer serial number on the TRF. For limited access -10°C/4°C freezer/refrigerator units, the DNA Database Forensic Scientist(s) that have access to such units shall fill out the information on a TRF.

5.15.3.2 If a DNA Database Forensic Scientist is out of the office unexpectedly (sick day), the Manager or designee for that DNA Database Forensic Scientist shall record the temperature for that day. If a DNA Database Forensic Scientist has planned days out of the office (court or vacation), it is the responsibility of the DNA Database Forensic Scientist to arrange for a suitemate or Manager/designee to perform temperature recordings.

5.15.3.3 If at any point during the calendar year a new digital thermometer is needed, the QCO shall be notified and the new thermometer serial number shall be recorded on the TRF associated with the refrigerator/freezer.

5.15.3.4 If the QCO or DNA Database Forensic Scientist observes temperatures out of the range specified in **5.15.3** for more than five consecutive business days, then the QCO (for common area units) or the DNA Database Forensic Scientist (limited access units), shall attempt to adjust the temperature back in range using the thermostat for the unit. If the temperature does not come within range within an 24 hour period, the QCO (or DNA Database Forensic Scientist) shall transfer the contents of the unit to another unit with the same temperature parameters and note on the TRF the unit to which the contents were transferred and the date of transfer. If additional adjustments of the thermostat are unsuccessful, the unit shall be removed from service and clearly marked as being out of service. If additional adjustments are successful at restoring the unit to the temperatures specified in **5.15.3**, then the contents may be returned to the unit.

5.16 Incubators: temperatures shall be recorded on the day(s) the incubator is in use. If the incubator is in a common area, the QCO shall record the temperature. If the incubator is in a shared suite, the DNA Database Forensic Scientist shall record the temperature. Temperatures shall be recorded on a TRF specific for the incubator.

5.16.1 The QCO or DNA Database Forensic Scientist shall fill out all required information regarding the unit serial number, location, set temperatures, and the associated bulb thermometer number on the TRF.

5.16.2 If the incubator is not used, the QCO or DNA Database Forensic Scientist shall strike through the box which corresponds to the day(s) not in use.

5.16.3 The incubators shall be +/- 5 °C degrees within the set temperature. If an incubator deviates more than this over a period of five consecutive readings, then the QCO or DNA Database Forensic Scientist shall attempt to adjust the temperature back into the acceptable range over a period of 24 hours. If all attempts at obtaining a set temperature within range fail, the QCO shall be notified and the incubator removed from service and marked as such.

5.17 All verification, calibration, maintenance, and QC documentation shall be retained within the Forensic Biology and DNA Database Sections.

5.18 When any of the following instruments/equipment need repair and are taken out of use from the Section, the QCO shall notify the DNA Technical Leader, and if necessary, the manufacturer. The QCO shall also notify the DNA Technical Leader when the instruments/equipment are suitable for use by the Section again.

- 3130XL, ABI 9700, Centrifuges, Hoods, Freezers/Refrigerators, Balances.

6.0 Limitations - Once a plate has been set up, it may be used for up to, but shall not exceed, 72 hours. Plates are stored at room temperature. After this time, the samples must be set up again either on another plate or in different wells if another injection is performed.

Temperature: The results from the 3130XL instrumentation can be affected by temperature changes. If the temperature in the room where the instrument is located is outside the range of 60 to 85, the results may be affected and should be taken into account during analysis. If the results are affected (i.e., the data is incomplete), the DNA QC officer (or designee) shall take the affected instrument(s) off-line until the temperature is within range and the instrument has passed a QC check.

7.0 Safety

7.1 Thermal cyclers can exceed temperatures of 100 °C; use with caution to avoid burns.

7.2 Gloves, masks, and lab coats shall be worn when performing any verifications, calibrations, or QC checks described in Section 5.

7.3 If the ice shaver (or equivalent) used as described in **5.4.2.1** is not self contained, safety glasses shall be worn during operation.

7.4 Formamide is a known chemical hazard; causes eye, skin and respiratory tract irritation. It is a possible reproductive and birth defect hazard. Wear appropriate eyewear, masks, gloves and clothing when in use.

8.0 References

DNA Database Section Administrative Policy and Procedure for Safety and Hazardous Waste Disposal

DNA Database Section Procedure for Use of the 3130XL Genetic Analyzer

DNA Database Section Procedure for DNA Reagent Preparation and Quality Control

DNA Database Section Procedure for PCR Amplification with Identifiler™

DNA Database Section Procedure for Aseptic Technique and Contamination Control

DNA Database Section Procedure for Qiagen BioRobot® Universal
Instrument manuals.

Applied Biosystems 3130/3130xl Genetic Analyzers. User Bulletin. 2005 Applied Biosystems. Part Number 4363787. Rev A. (or most recent revision)

Eutechnics 4500 Manual.

NIST Special Publication 819.

9.0 Records

- Temperature logs for freezers, refrigerators, heat blocks (Daily and Weekly).
- Thermal Cycler Temperature Performance Check Forms.
- Bulb Thermometer Calibration Forms.
- Biosafety Cabinets/Chemical Fume Hoods/Laminar Flow Clean Air Benches Certificates.
- Certificates of Calibration for NIST Traceable Digital Thermometer, Digital Thermometers, Balances, Pipettes, Digital Probes, Data Loggers, and Temperature Chart Recorders.
- Manufacturer documentation of preventative maintenance and/or repair for 3130XL's, and centrifuges.

10.0 Attachments - N/A.

Revision History		
Effective Date	Version Number	Reason
12/18/2013	1	Original Document
04/18/2014	2	5.1.4.1.34 and 5.1.4.2.3 - added requirement for spectral calibration; 5.1.8.2 - added spectral calibration requirement when capillary array changed; added volume of matrix standard can be increased or decreased based on spectral calibration results; 5.8.1 - added reference to Forensic Biology Procedure for Calibration and Equipment Maintenance; 5.10 - updated to included procedure for use of data loggers; Data Loggers added to 9.0 Records