Procedure for Instrument and Equipment Quality Control

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 – See Section Definitions List

4.0 Equipment, Materials and Reagents

- NIST traceable digital thermometer
- Ice Shaver/crusher
- Purified dH_2O
- dH_2O
- NIST traceable weight set
- Autoclave
- Centrifuge
- Luer Lock Syringe
- Septa
- Conditioning Reagent
- POP-4
- Anode Buffer Container (ABC)
- Cathode Buffer Container (CBC)
- Wipes (delicate task wipes)
- 96 well reaction trays
- Pipettes
- Pipette tips
- Matrix standard set DG4850 to automatically analyze the five different colored fluorescent dye-labeled samples in a single capillary for the 3500xL
- PowerPlex® Fusion reagents
- PowerPlex® Y23 reagents
- Hi-Di Formamide
- Alpha Technics 4690 probe (or equivalent)
- Disinfecting solutions including 10% bleach, alcohol

5.0 Procedure

5.1 3500xL Genetic Analyzers

5.1.1 Maintenance to be Performed Prior to Each Run: Refer to the Checking Consumable Status and Replenishing Consumables section of the DNA Database Section Procedure for Use of the 3500xL Genetic Analyzer.

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5.1.2 Weekly Maintenance

5.1.2.1 Weekly Maintenance shall be performed by the QCO on the first day of the week that the instrument is used. Each item will be prompted in the **Maintenance Notifications** list in the **Dashboard**. As each item is completed, it shall be marked as complete by clicking on the green check mark that appears next to the notification. Documentation of such maintenance shall be retained as described in the Documentation of Weekly Maintenance, Monthly Maintenance, and POP-4 Changes section of this procedure.

5.1.2.2 At the 3500xL instrument, unlink any plates currently on the instrument. If plates need to be unlinked from the instrument, select **Library** from the menu bar. Select the yellow **Main Workflow** button on the left of the screen; select **Load Plates for Run** in the **Run Instrument** menu. Before selecting **Unlink** for a plate, ensure the plate is not currently in process. Select **Unlink** for each plate that is linked.

5.1.2.3 Restart the System

5.1.2.3.1 Close the 3500xL Data Collection Software.

5.1.2.3.2 Turn off the 3500xL.

5.1.2.3.3 Turn off the computer.

5.1.2.3.4 Turn on the computer. Log in to the Instr-User profile. A 3500 service monitor will appear in the lower right corner. Before proceeding to the next step, ensure each item in the service monitor is listed as Y and that the overall status is listed as "3500 Services Loaded: Y." When the associated icon has a green check mark, proceed to the next step.

5.1.2.3.5 Turn on the 3500xL. Do not proceed to the next step until the instrument's status light appears as a steady green.

5.1.2.3.6 Open the 3500xL Data Collection Software and log in with user name.

5.1.2.4 Water Wash

5.1.2.4.1 From the **Dashboard**, select **Maintain Instrument**.

5.1.2.4.2 Select the blue **Maintenance Wizards** button on the left of the screen.

5.1.2.4.3 From the **Maintenance Wizards** screen, select **Wash Pump Channels**.

5.1.2.4.4 Follow the Wash Wizard steps to complete a water wash.

5.1.2.4.5 When placing conditioning reagent on the instrument, check the expiration date on the label to make sure it is not expired prior to use.

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NOTE: The RFID label must be facing the instrument to ensure that the RFID information is read accurately by the instrument.

5.1.2.4.6 A partially used polymer may be returned to the instrument after a water wash is complete if the polymer has not been on the instrument for 7 calendar days and has not reached its expiration date.

5.1.2.5 Change the Anode Buffer Container

5.1.2.5.1 The use of an Anode Buffer Container (ABC) shall not extend beyond 7 calendar days.

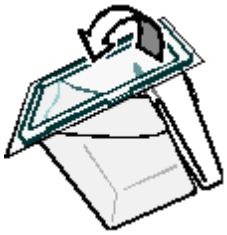
5.1.2.5.2 Remove an unopened ABC from storage.

5.1.2.5.3 Check the expiration date on the ABC label to make sure it is not expired prior to or during intended use.

5.1.2.5.4 Allow the refrigerated ABC to equilibrate to ambient temperature prior to first use. Do not remove the seal.

5.1.2.5.5 Verify that the seal is intact.

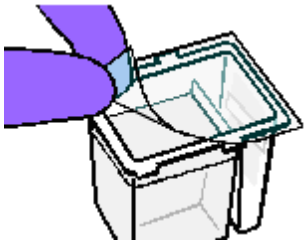
5.1.2.5.6 Tilt the ABC slightly (as shown in the figure below) to make sure most of 1X buffer is in the larger side of the container. There should be less than 1 mL of 1X buffer remaining in the smaller side of the container.



5.1.2.5.7 Verify that the buffer is at or above the fill line.

5.1.2.5.8 Remove the current ABC from the 3500xL. Pour contents of the reservoir down the sink. Discard the reservoir in the biohazard box.

5.1.2.5.9 Peel off the seal at the top of the ABC.



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5.1.2.5.10 Place the ABC into the Anode end of the instrument, below the pump. Ensure the electrode is in the larger side of the container.

NOTE: The RFID label must be facing the instrument to ensure that the RFID information is read accurately by the instrument.

5.1.2.6 Change the Cathode Buffer Container

5.1.2.6.1 The use of a Cathode Buffer Container (CBC) shall not extend beyond 7 calendar days.

5.1.2.6.2 Remove an unopened CBC from storage.

5.1.2.6.3 Check the expiration date on the CBC label to make sure it is not expired prior to or during intended use.

5.1.2.6.4 Allow the refrigerated CBC to equilibrate to ambient temperature before use.

5.1.2.6.5 Verify that the seal is intact.

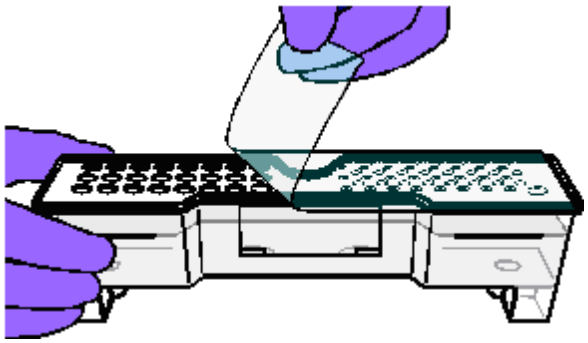
5.1.2.6.6 Tilt the CBC back and forth gently and carefully to ensure that the buffer is evenly distributed.

5.1.2.6.7 Verify that the buffer is at or above the fill line.

5.1.2.6.8 At the 3500xL, 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, open the door.

5.1.2.6.9 Remove the current CBC. Squeeze along the front tab of the CBC to allow the container to release from the autosampler tray. Remove septa. Pour contents of the reservoir down the sink. Discard the reservoir and septa in the biohazard box.

5.1.2.6.10 When ready to install the CBC, place the container on a flat surface and peel off the seal.



5.1.2.6.11 Wipe off any buffer on the top of the CBC with a lint-free cloth. Ensure that the top of the container is dry.

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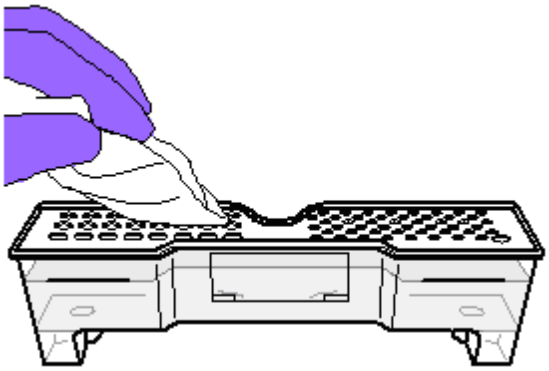
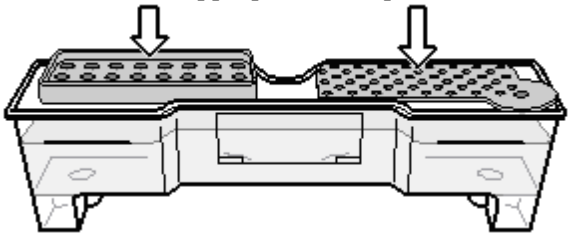


5.1.2.6.12 Place the appropriate septa on both sides of the CBC.

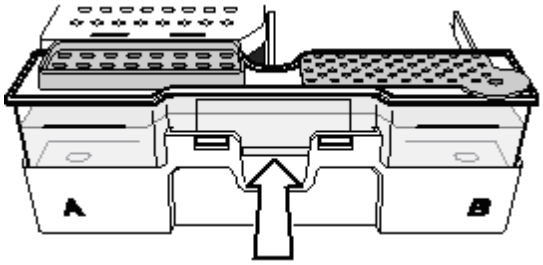


5.1.2.6.12.1 Align the buffer septa (the part that is symmetrical) over the 24 holes of the CBC.

5.1.2.6.12.2 Push the septa lightly into the holes to start and then push firmly to seat the septa.

5.1.2.6.13 Install the CBC on the autosampler.

NOTE: When properly installed, it will click on the autosampler as the tabs are snapped in place.



5.1.2.7 Clean Anode Buffer Cup Pin-Valve Assembly on Polymer Delivery Pump

5.1.2.7.1 Wipe off the anode buffer cup pin-valve assembly using a lint-free tissue that is dampened with water.

5.1.2.8 When all desired weekly maintenance is complete, close the instrument door to re-initialize.

5.1.2.9 Click **Refresh** from the **Dashboard** to update the screen.

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5.1.2.10 Check the **Consumables Information** section of the **Dashboard** for updated consumable statuses.

5.1.3 Monthly Maintenance

5.1.3.1 By the end of the first Monday (or first day of the first full week) of each month, monthly maintenance shall be performed by the QCO. Each item will be prompted in the **Maintenance Notifications** list in the **Dashboard**. As each item is completed, it shall be marked as complete by clicking on the green check mark that appears next to the notification. Documentation of such maintenance shall be retained as described in the Documentation of Weekly Maintenance, Monthly Maintenance, and POP-4 Changes section of this procedure.

5.1.3.2 Disk Space

5.1.3.2.1 To ensure available disk space on the 3500xL, run data shall be removed from the 3500xL computers at least quarterly.

5.1.3.2.2 Plate maps from the previous month shall be cleared from each 3500xL computer. From the **Dashboard**, select **Library**. Select **Plates** on the left of the screen. Double click the Run Date header to sort the plates by run date. Highlight the plates from the previous month. Right click and select **Delete**. When the dialog box pops up asking if you are sure you want to delete your selection, select **Yes**.

5.1.3.3 Defragment the Computer Hard Drive

5.1.3.3.1 Purpose: The fragmentation of files decreases the performance of both the Data Collection software and the computer operating system. Programs take a longer time to access files by performing multiple search operations of the fragments.

5.1.3.3.2 Go to the computer's Start menu.

5.1.3.3.3 Select **Programs**.

5.1.3.3.4 Select **Accessories**.

5.1.3.3.5 Select **System Tools**.

5.1.3.3.6 Select **Disk Defragmenter** and follow the prompts.

5.1.3.4 Flush the Water Trap (Pump Trap)

5.1.3.4.1 Fill the supplied 20 mL, plastic Luer lock syringe with distilled or deionized water. Expel any bubbles from the syringe.

5.1.3.4.2 Open the Luer fitting by grasping the body of the fitting and turning it counterclockwise approximately one half turn to loosen. Hold the fitting with

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one hand while threading the syringe onto the fitting in a clockwise direction with the other hand.

5.1.3.4.3 Take approximately 30 seconds to flush 5 mL of either distilled or deionized water through the trap.

5.1.3.4.4 Remove the syringe from the Luer fitting. Hold the fitting with one hand while turning the syringe counterclockwise with the other hand.

5.1.3.4.5 Close the Luer fitting by lightly turning clockwise until the fitting seals against the block.

5.1.3.4.6 Empty the waste trap container and the condensation container. The waste trap container is to the right of the pump block.

5.1.3.5 Clean Autosampler

5.1.3.5.1 Press the Tray button on the front of the instrument to move the autosampler to the forward position.

5.1.3.5.2 Wipe off any liquid on or around the autosampler using a lint-free tissue.

5.1.3.6 Clean Drip Tray

5.1.3.6.1 Clean out the drip tray with deionized water (or ethanol (absolute)) and lint-free tissue.

NOTE: The drip tray can be removed.

5.1.4 As Needed Maintenance

5.1.4.1 Replenish Polymer

5.1.4.1.1 The use of a POP-4 pouch shall not extend beyond 7 calendar days. When placing POP-4 on the instrument, check the expiration date on the label to ensure it has not expired prior to or during intended use.

5.1.4.1.2 From the **Dashboard**, select **Maintain Instrument**.

5.1.4.1.3 Select the blue **Maintenance Wizards** button on the left of the screen.

5.1.4.1.4 From the **Maintenance Wizards** screen, click **Replenish Polymer**.

5.1.4.1.5 Follow the Replenish Polymer Wizard steps to replenish the polymer.

5.1.4.1.6 Refresh the **Consumables Information** section of the **Dashboard** for an updated status of the polymer.

5.1.4.1.7 Add the POP-4 pouch change to the schedule.

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5.1.4.1.7.1 From the **Dashboard**, select **Maintain Instrument**.

5.1.4.1.7.2 Select **Schedule** on the left of the screen.

5.1.4.1.7.3 Select **Create** from the menu bar at the top of the screen.

5.1.4.1.7.4 Fill the fields as follows.

5.1.4.1.7.4.1 **Title**: POP-4 Change

5.1.4.1.7.4.2 **Schedule Starts On**: Date POP-4 change occurred

5.1.4.1.7.4.3 **Priority**: High

5.1.4.1.7.4.4 **Repeat**: Never

5.1.4.1.7.4.5 In the **Description** field, list the date the POP-4 was changed and the lot number of the POP-4 along with the date and initials of the analyst who completed the task. If any other notes are needed, they may also be added to the **Description** field.

5.1.4.1.7.5 Select **OK**.

5.1.4.1.8 The item will add to the **Maintenance Notifications** list in the **Dashboard**. When the notification appears, it shall be marked as complete by clicking on the green check mark that appears next to the notification. Documentation of such maintenance shall be retained as described in Documentation of Weekly Maintenance, Monthly Maintenance, and POP-4 Changes section of this procedure.

5.1.4.2 Remove Bubbles from the Polymer Pump

5.1.4.2.1 From the **Dashboard**, select **Maintain Instrument**.

5.1.4.2.2 Select the blue **Maintenance Wizards** button on the left of the screen.

5.1.4.2.3 From the **Maintenance Wizards** screen, click **Remove Bubbles**.

5.1.4.2.4 Follow the Bubble Remove Wizard steps to remove bubbles from the polymer pump fluid path.

5.1.4.2.5 Refresh the **Consumables Information** section of the **Dashboard** for an updated status of the polymer.

5.1.4.3 Shutdown the Instrument – This wizard prepares the instrument for an extensive period of disuse (greater than 2 weeks). In this procedure, the capillary array is removed and a conditioning reagent pouch is placed on the instrument.

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5.1.4.3.1 From the **Dashboard**, select **Maintain Instrument**.

5.1.4.3.2 Select the blue **Maintenance Wizards** button on the left of the screen.

5.1.4.3.3 From the **Maintenance Wizards** screen, click **Shutdown the Instrument**.

5.1.4.3.4 Follow the Instrument Shutdown Wizard steps.

5.1.4.3.5 Ensure that the Data Collection Software, computer, and instrument are all off.

5.1.5 Documentation of Weekly Maintenance, Monthly Maintenance, and POP-4 Changes

5.1.5.1 All maintenance actions are recorded in the **Notification Log**. For each month, a record of weekly maintenance, monthly maintenance, and as needed POP-4 changes shall be listed in a monthly **Notification Report** and maintained in the DNA Database Section. From the **Dashboard**, click the yellow **Maintain Instrument** button. Select **Notifications Log** in the **Planned Maintenance** menu on the left of the screen. Select **View Notification Log Report**. Enter the desired date range the report should cover. Select **OK**. At the top of the screen, select **Print** and then the **Print Report** option. In the printer dialog box, select **CutePDF Writer** and print the report as a .pdf file.

5.1.6 Changing the Capillary Array – When a capillary has repeated ILS (i.e., size standard) failure, the bases of the alleles in samples broaden (monitor closely once the array usage approaches 160 injections), the background noise in the electropherograms becomes repeated and excessive (based upon the training and experience of the DNA Database Forensic Scientists), the array has reached its maximum of 160 runs, or the array has reached its expiration date, the array shall be replaced. DNA Database Forensic Scientists shall notify the QCO and Technical Leader if they observe any of the above-mentioned scenarios.

5.1.6.1 From the **Dashboard**, select **Maintain Instrument**.

5.1.6.2 Select the blue **Maintenance Wizards** button on the left of the screen.

5.1.6.3 From the **Maintenance Wizards** screen, click **Install Capillary Array**.

5.1.6.4 Follow the Install Capillary Array Wizard steps to install a capillary.

5.1.6.5 Refresh the **Consumables Information** section of the **Dashboard** for an updated status of the capillary array.

5.1.6.6 Perform both a Spatial and Spectral Calibration as outlined in this procedure.

5.1.7 Service and/or Repair

5.1.7.1 Repair: If a 3500xL 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 it is not available for use. The QCO shall also notify the Technical Leader and the manufacturer that repair is needed.

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Performance QC Check: If a 3500xL 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.

5.1.7.2 Annual Preventative Maintenance: The 3500xL Genetic Analyzers shall have preventative maintenance performed annually by the manufacturer.

5.1.7.2.1 Refer to the maintenance reports provided by the vendor for specific calibrations, verifications, and tests performed during the annual preventative maintenance.

5.1.7.2.2 The QCO shall notify the Section via email as well as by placing a notice on the specific instrument that it is not available for use.

5.1.7.2.3 Performance QC Check: After preventative maintenance, each 3500xL shall have a post maintenance QC check performed by the QCO prior to its return to use in the Section.

5.1.7.3 Solid State Laser Failure: the solid state laser inside the 3500xL 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.

5.1.7.3.1 If the solid state laser fails on a 3500xL instrument, the QCO shall remove the instrument from service as previously described. Only the manufacturer (via field engineer) may replace the laser.

5.1.7.3.2 Once the laser has been replaced, the QCO shall perform both spatial and spectral calibrations (as described in this procedure) if not already performed by the manufacturer during laser replacement.

5.1.7.3.3 The QCO shall then perform a Post Maintenance Performance QC Check on the instrument as described in this procedure.

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

5.1.7.3.5 After all conditions are satisfied, the 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.

5.1.7.3.6 All documentation pertaining to a laser failure shall be retained.

5.1.7.4 Documentation of any repair or annual preventative maintenance, as well as subsequent QC checks shall be retained in the Section.

5.1.8 Post Maintenance Performance QC Check: Before any validated 3500xL shall be used by DNA Database Forensic Scientists in the DNA Database Section after repair or maintenance, a Performance

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QC check shall be performed by the QCO. Additionally, this check shall be performed after the instrument has been taken offline due to temperature fluctuations in the room. This QC check shall be performed as follows:

5.1.8.1 A NIST-Traceable Standard (NIST-TS) and associated controls shall be amplified using current amplification chemistries and electrophoresed on the 3500xL at the 18 second injection protocol.

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

5.1.8.3 All testing negatives (Reagent Blank(s), amplification negative control(s)) must be free of any true alleles above the analytical threshold used in the Section.

5.1.8.4 If either criteria are not satisfied (for reasons other than instrument failure, known artifacts), then the QCO may retest (reelectrophorese or reamplify) the samples one more time. If the criteria are not satisfied by the retest, the DNA TL shall be notified and shall determine the appropriate course of action.

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

5.1.8.6 The QCO shall document the testing performed and retain such information in the Section.

5.1.9 Spatial Calibrations: The purpose of a spatial calibration is to establish a relationship between the signal emitted by each capillary and the position where that signal falls and is detected by the CCD camera.

5.1.9.1 A spatial calibration shall be performed when the capillary array is removed or replaced, the detector cell door is opened or the detection cell is moved, or the instrument is moved. The spatial shall be performed by the QCO.

5.1.9.2 Access the **Spatial Calibration** screen. From the **Dashboard**, select **Maintenance** and then select **Spatial Calibration** in the navigation pane.

5.1.9.3 Select **No Fill**, or select **Fill** to fill the array with polymer before starting the calibration.

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5.1.9.4 Select **Perform QC Checks** for the system to check each capillary against the specified range for spacing and intensity. During the calibration, the software calculates:

Attribute	Calculation	Threshold
Average peak height	$\frac{\text{Sum of all peak heights}}{\text{Number of peaks}}$	24-cap: 3000 RFU
Uniformity (peak height similarity)	$\frac{\text{Standard deviation}}{\text{Average peak height}}$	0.2
Capillary spacing	Max spacing – Min spacing	2 pixels

5.1.9.5 Select **Start Calibration**. The display updates as the run progresses. If the average of any of the QC values exceeds the threshold, a Spatial QC Check error message is displayed. Click **OK** and rerun the spatial calibration.

5.1.9.6 Evaluate the spatial calibration profile to ensure that you see:

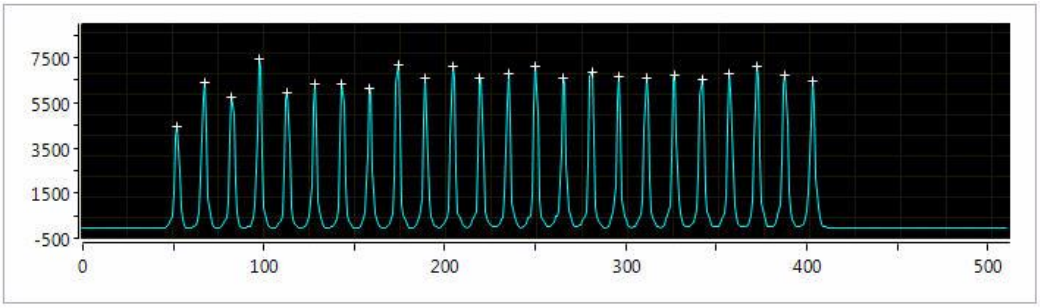
5.1.9.6.1 One sharp peak for each capillary. Small shoulders are acceptable.

5.1.9.6.2 One marker (+) at the apex of every peak. No off-apex markers.

5.1.9.6.3 An even peak profile (all peaks about the same height).

5.1.9.6.4 Spacing should be between 13 and 16.

NOTE: If any peaks are lower than usual for the instrument or the heights drastically slope up or down, repeat the calibration with a fill.



5.1.9.7 If the results meet the criteria above, click **Accept Results**. If the results do not meet the criteria above, click **Reject Results** and run a new spatial calibration or refer to the Applied Biosystems 3500/3500xL Genetic Analyzer User Guide for troubleshooting information.

5.1.9.8 View and print a spatial calibration report.

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5.1.9.8.1 Click **View Spatial Calibration Report**.

5.1.9.8.2 To print the report, click **Print**; then select **Print Report**.

5.1.9.8.3 In the printer dialog box, select **CutePDF Writer** and print the report as a .pdf file.

NOTE: After performing a calibration, the calibration report can be saved electronically for record keeping. The software does not save historical calibration results. Only the most recent spatial calibration is maintained in the software.

5.1.9.8.4 Close the report.

5.1.9.8.5 Spatial Calibration Reports shall be maintained in the Section.

5.1.10 Spectral Calibrations: Spectral calibration creates a matrix that corrects for the overlapping fluorescence emission spectra of the dyes. Although each of these dyes emits its maximum fluorescence at a different wavelength, there is some overlap in the emission spectra between the dyes. The goal of multicomponent analysis is to correct for spectral overlap and minimize the presence of artifacts, such as spectral pull-up, in the data.

5.1.10.1 A spectral calibration shall be performed if any of the following conditions occur: the capillary array is changed, the instrument is moved, the laser or CCD camera has been realigned/replaced by a service engineer, an increase in pull-up and/or pull-down peaks is observed, or the capillary array length or polymer type is changed.

5.1.10.2 Prepare the instrument.

5.1.10.2.1 If you have not already done so, perform a spatial calibration.

5.1.10.2.2 In the **Dashboard**, check the **Consumables Information**. Ensure that consumables have not expired and that adequate injections remain for consumables.

5.1.10.2.3 Ensure that the buffer levels are at the fill lines.

5.1.10.2.4 Set the oven temperature to 60°C; then select **Start Pre-Heat**.

5.1.10.2.5 Check the pump assembly for bubbles and run the Remove Bubble wizard if needed.

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5.1.10.3 Remove the 5C matrix mix from the freezer (-30°C to -10°C) and allow to thaw for the first use. If previously opened, remove the 5C matrix mix from the refrigerator (2°C to 10°C). Remove one tube of Matrix Dilution Buffer from the freezer (-30°C to -10°C) and allow to thaw.

5.1.10.4 Remove at least 500 µL of Hi-Di Formamide from the freezer (-20˚C) and allow to thaw.

5.1.10.5 Vortex the 5C Matrix Mix for 10-15 seconds prior to use. Add 10 µL of the 5C Matrix Mix to one tube of the Matrix Dilution Buffer. Vortex for 10-15 seconds. Note the date of dilution on the tube. The diluted 5C Matrix Mix may be stored for up to one week at 2°C to 10°C.

5.1.10.6 Add 10 µL of the 5C Matrix Mix/Matrix Dilution Buffer mixture to 500 µL of Hi-Di formamide. Vortex for 10-15 seconds.

5.1.10.7 Using a 96-well reaction plate in columns 1-3 and rows A-H, add 15 µL of the matrix/formamide mixture to each well.

5.1.10.8 Cover plate with a 96-well plate septa and briefly centrifuge the plate to remove bubbles. Do not heat denature.

5.1.10.9 Place the plate in the 3500 series 96-well standard plate base and cover with the plate retainer. Place the plate assembly in Position A on the autosampler, positioned correctly with the notch in the lower right corner.

5.1.10.10 Close the instrument door to re-initialize the instrument.

5.1.10.11 Once the temperature of the oven has stabilized at 60°C, access the **Spectral Calibration** screen. From the **Dashboard**, select **Maintenance** and then select **Spectral Calibration** in the navigation pane.

5.1.10.12 Choose “96” for number of wells and specify the plate location on the instrument.

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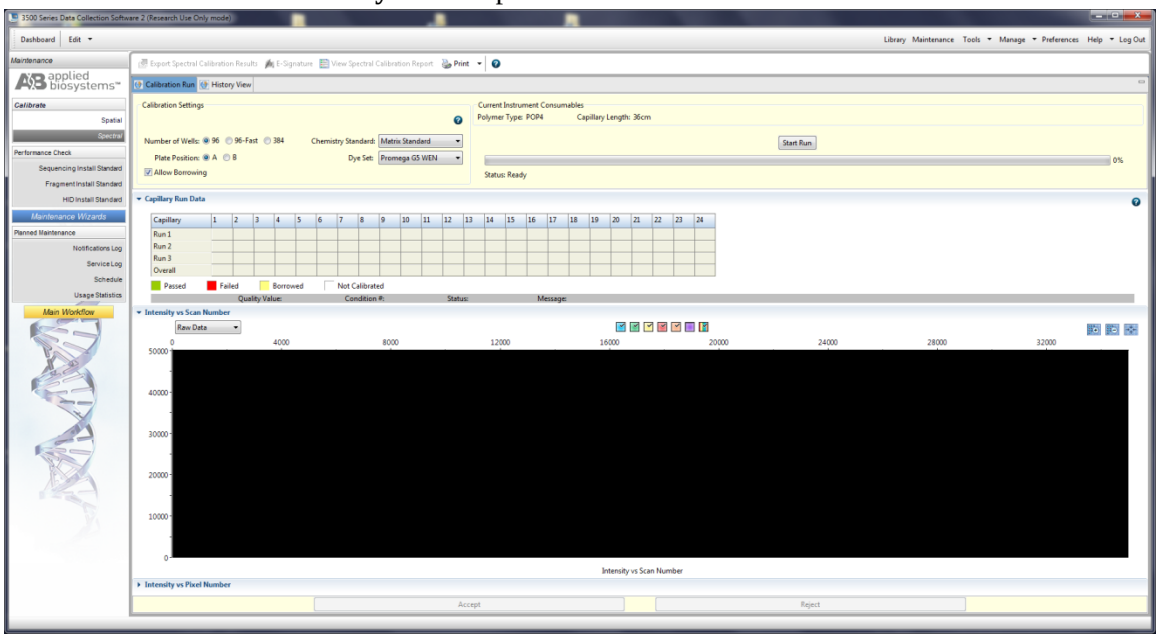
5.1.10.13 Choose **Matrix Standard** from the **Chemistry Standard** drop-down menu and **Promega G5 WEN** from the **Dye Set** drop-down menu.



5.1.10.14 Select **Allow Borrowing**. Selecting this option instructs the software to automatically replace information from failed capillaries with information from an adjacent passing capillary with the highest Quality Value.

5.1.10.15 Select **Start Run**.

5.1.10.16 If fewer than the recommended number of capillaries pass, the spectral calibration run will be repeated automatically up to three times. When borrowing is enabled, all capillaries must pass within the borrowing limits.

5.1.10.17 Upon completion of the spectral calibration, check the quality in the Capillary Run Data display. Passing and failing capillaries are shown in green and red respectively. Borrowed capillaries are shown in yellow with an arrow indicating the adjacent capillary from which results were borrowed. To display the results for each capillary (spectral data, Quality Value, and Condition Number) below the run results table, click a capillary in the table. The ranges that the software uses to determine if a capillary passes or fails with a G5 dye set are a Quality Value minimum of 0.95 and a Condition Number maximum of 13.5.

NOTE: The results displayed when you click a borrowed capillary are the passing results borrowed from the adjacent capillary. To determine the reason that a capillary fails, view the spectral calibration report.

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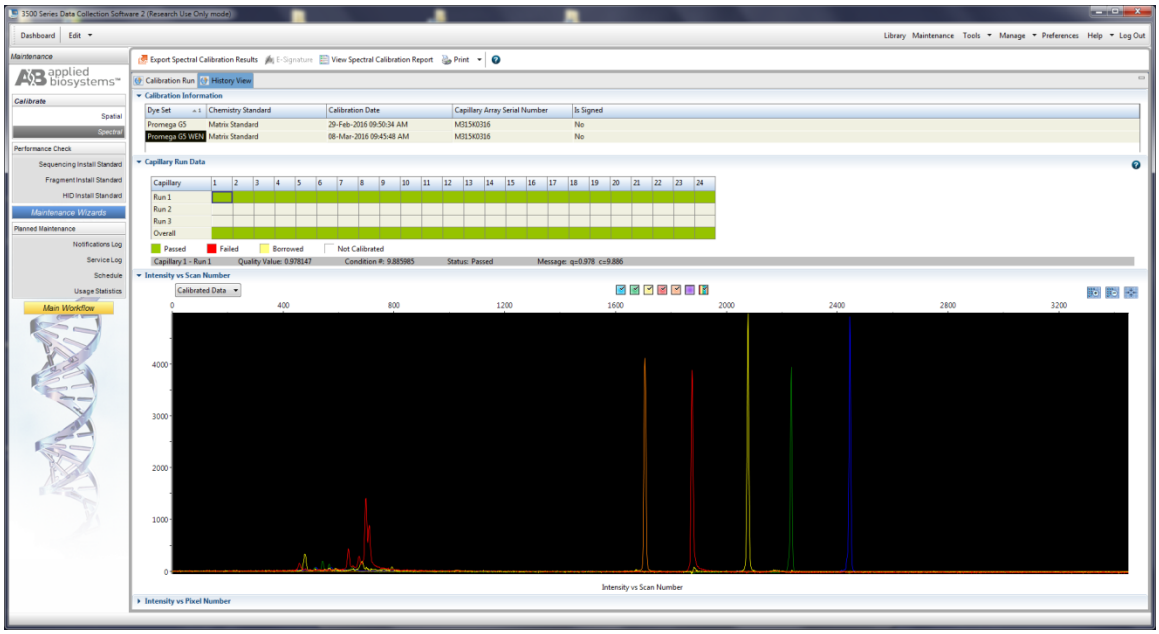
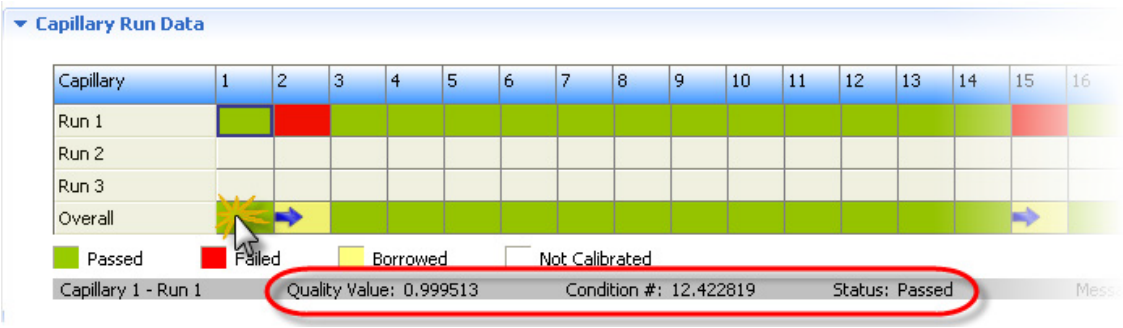
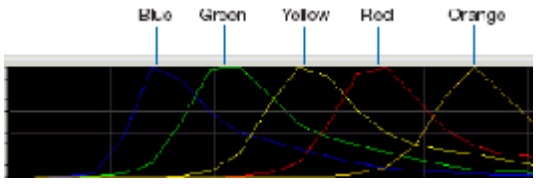




5.1.10.18 Viewing the pass/fail status after the run:

5.1.10.18.1 View the status of each capillary. Each capillary should have a Quality Value above 0.95 (if spectral calibration failed, see the troubleshooting and reference guide in the 3500/3500xL Genetic Analyzer User Guide).

5.1.10.18.2 Evaluate the spectral profile and raw data for each 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.



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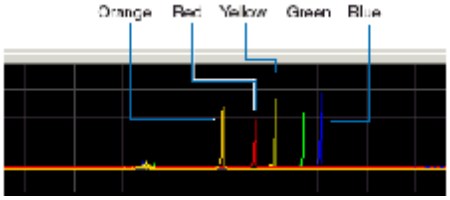
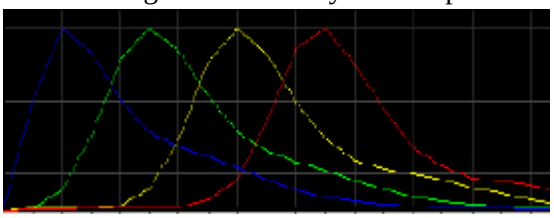
5.1.10.18.3 Verify that the order of the peaks in the raw data profile for Intensity vs. Scan Number (from left to right) is orange, red, yellow, green, and blue.



5.1.10.18.4 Verify that the peaks in the spectral profile do not contain gross overlaps, dips, or other irregularities. Verify that the peaks are separate and distinct.



5.1.10.19 If the spectral calibration is acceptable, then click **Accept Results**. If the spectral calibration is not acceptable, click **Reject Results** and run a new spectral calibration or refer to the Applied Biosystems 3500/3500xL Genetic Analyzer User Guide for troubleshooting information.

5.1.10.20 View and print a spectral calibration report.

5.1.10.20.1 Click **View Spectral Calibration Report**.

5.1.10.20.2 To print the report, click **Print**; then select **Print Report**.

5.1.10.20.3 In the printer dialog box, select **CutePDF Writer** and print the report as a .pdf file.

NOTE: After performing a calibration, the calibration report can be saved electronically for record keeping. The software does not save historical calibration results. Only the most recent spectral calibration is maintained in the software.

5.1.10.20.4 Close the report.

5.1.10.20.5 Spectral Calibration Reports shall be maintained in the Section.

5.1.11 Errors

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5.1.11.1 Error messages in the 3500 Series Data Collection Software include a **Details** button. Click **Details** to display more information about an error message.

5.1.11.2 For error help, see the Troubleshoot section of the 3500/3500xL Genetic Analyzer User Guide.

5.2 ProFlex PCR System Thermal Cyclers

5.2.1 Quarterly Maintenance

5.2.1.1 Disconnect the power supply to the instrument and allow the instrument to equilibrate to room temperature.

5.2.1.1.1 Clean the touch screen with any commercially available LCD cleaning product.

5.2.1.1.2 Clean the Sample Wells

5.2.1.1.2.1 Open the heated cover.

5.2.1.1.2.2 Use a cotton swab soaked in isopropanol to clean the sample wells thoroughly.

5.2.1.1.2.3 Ensure the isopropanol has evaporated completely before reloading a sample tray.

5.2.1.1.3 Clean the Heated Cover

5.2.1.1.3.1 Open the heated cover.

5.2.1.1.3.2 Soak a lab wipe with isopropanol and gently wipe the heated plate.

5.2.1.1.3.3 Remove any remaining isopropanol from the cover.

5.2.1.2 Quarterly maintenance shall be logged on the DNA Database Thermal Cycler Quarterly Maintenance Log by the QCO performing the maintenance. This documentation shall be retained indefinitely by the QCO.

5.2.2 Yearly Internal Verification: All thermal cyclers currently in service within the Section shall be subjected to a series of temperature verifications once per calendar year by the QCO.

5.2.2.1 Gloves, masks, and lab coats shall be worn at all times.

5.2.2.2 Caution shall be exercised at all times as the thermal cyclers can reach temperatures in excess of 100°C.

5.2.2.3 Reports of all yearly internal verifications shall be imported into the Thermal Cycler Verification Record by the QCO performing the verification for each thermal cycler. This documentation shall be signed by the QCO and approved and signed by the Technical Leader. This documentation shall be retained indefinitely by the QCO.

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5.2.2.4 All yearly internal verification tests can be accessed from the Block Verification Test screen. From the **Home** screen, select **Settings**, then select **Maintenance and Services**. Choose **Block Verification Test**. The Block Verification screen presents two buttons, **Verify Cycle Performance** and **Block Verification**. Yearly internal verification tests are accessed through the **Block Verification** selection.

5.2.2.5 Block verification tests require the use of a Thermal Verification Kit (TVK). Assemble the TVK by attaching the free end of the ribbon cable to the input connector port on the thermometer. Connect the round end of the communication cable to the communication port on the thermometer. Connect the 9-pin end of the of the communication cable to the USB adaptor. The adaptor is used to communicate to the thermal cycler USB port.

5.2.2.6 **Heated Cover Test** – Verifies the heated cover holds temperature at 105 ±3°C.

5.2.2.6.1 Connect the TVK to the USB port on the thermal cycler.

5.2.2.6.2 Insert the probe into Zones 3 and 4 by placing the probe in well A5.

5.2.2.6.3 Close and lock the thermal cycler cover.

5.2.2.6.4 Power on the digital thermometer.

5.2.2.6.5 On the thermal cycler, select the **Heated Cover Test**.

5.2.2.6.6 Select **Start Test**.

5.2.2.6.7 The thermal cycler will run the test and display the Heated Cover Test Results when complete.

5.2.2.6.8 Insert a USB into the thermal cycler.

5.2.2.6.9 Choose **Export** to save the report to the USB.

5.2.2.6.10 Click **Okay** to return to the results screen, then **Close**.

5.2.2.6.11 Click the back arrow button to return to the Block Verification Test Window

5.2.2.7 **Temperature Verification** – Verifies the temperature accuracy of the thermal cycler by measuring sample well temperatures at two set points, 45°C and 85°C. To pass the test, the six sample zones must be within ±0.25 degrees Celsius of the set points.

5.2.2.7.1 Connect the TVK to the USB port on the thermal cycler.

5.2.2.7.2 Insert the probe into Zones 1 and 2 by placing the probe in well A1.

5.2.2.7.3 On the thermal cycler, select the **Temperature Verification Test**.

5.2.2.7.4 Select **Start Test**.

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5.2.2.7.5 After the thermal cycler prompts the first reading is complete, move the probes into Zones 3 and 4 by placing the probe in well A5.

5.2.2.7.6 Close the cover and choose **Next**.

5.2.2.7.7 After Zones 3 and 4 are complete, move the probe into Zones 5 and 6 by placing the probe in well A11.

5.2.2.7.8 Close the cover and choose **Next**.

5.2.2.7.9 When all testing is complete, choose **Export** to save the report to the USB.

5.2.2.7.10 Click the back arrow button to return to the Block Verification Test Window.

5.2.2.8 Temperature Non-Uniformity – Verifies the temperature uniformity of the instrument. To pass the test, all six sample zones must be within ±0.5 degrees Celsius of each set point temperature (95°C and 60°C) no later than 30 seconds after the set point temperature is changed.

5.2.2.8.1 Connect the TVK to the USB port on the thermal cycler.

5.2.2.8.2 Insert the probe into Zones 1 and 2 by placing the probe in well A1.

5.2.2.8.3 Close the thermal cycler cover.

5.2.2.8.4 On the thermal cycler, select the **Temperature Non-Uniformity Test**.

5.2.2.8.5 Select **Start Test**.

5.2.2.8.6 After the thermal cycler prompts the first reading is complete, move the probes into Zones 3 and 4 by placing the probe in well A5.

5.2.2.8.7 Close the cover and choose **Next**.

5.2.2.8.8 After Zones 3 and 4 are complete, move the probe into Zones 5 and 6 by placing the probe in well A11.

5.2.2.8.9 Close the cover and choose **Next**.

5.2.2.8.10 When all testing is complete, choose **Export** to save the report to the USB.

5.2.2.8.11 Click the back arrow button to return to the Block Verification Test Window.

5.2.2.9 Block Verification Test Failures

5.2.2.9.1 If any of the block verification tests fail, they may be repeated one time.

5.2.2.9.2 Prior to the second run of the test,

5.2.2.9.2.1 Verify that the probe tips are not cracked or damaged.

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5.2.2.9.2.2 Ensure all cables are connected securely to the ports.

5.2.2.9.2.3 Ensure the probes are seated securely in the test wells.

5.2.2.9.2.4 Ensure the ribbon cable lies flat and is not crimped.

5.2.2.9.2.5 Ensure the heated cover is closed and locked down.

5.2.2.9.3 The test wells may be coated with mineral oil using a cotton swab. After completion of testing, ensure the test wells and the probe are cleaned.

5.2.2.9.4 If the test fails a second time, the QCO shall notify the Technical Leader, and the thermal cycler in question shall be removed from service. The QCO shall notify the section via email, and an "Out of Service" sticker shall be placed on the thermal cycler.

5.2.3 As Needed Maintenance

5.2.3.1 Decontaminate Sample Wells

5.2.3.1.1 Clean the wells thoroughly with a cotton swab soaked in a 10% bleach solution.

5.2.3.1.2 Follow by wiping the wells thoroughly with a cotton swab soaked in deionized water.

5.2.3.2 Decontaminate the Heated Cover

5.2.3.2.1 Soak a lab wipe with a 10% bleach solution and wipe the heated plate.

5.2.3.2.2 Soak a lab wipe with deionized water and wipe the heated plate.

5.2.3.3 Self Verification Test – Run the Self Verification Test when there is an intermittent instrument error. This test initiates the instrument to conduct a check on the instrument hardware. The check includes testing the block, heated cover, and other components.

5.2.3.3.1 From the **Home** screen, select **Settings**.

5.2.3.3.2 Select **Maintenance and Services**.

5.2.3.3.3 Select **Self Verification Test**.

5.2.3.3.4 Select **Start Test**.

5.2.3.3.5 The thermal cycler will run the test and display Self Verification Test Results when complete.

5.2.3.3.6 Insert a USB into the thermal cycler.

5.2.3.3.7 Choose **Export** to save the report to the USB. This documentation shall be retained indefinitely by the QCO.

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5.2.3.3.8 The test may be run twice.

5.2.3.3.9 If the test fails a second time, the QCO shall notify the Technical Leader, and the thermal cycler in question shall be removed from service. The QCO shall notify the section via email, and an "Out of Service" sticker shall be placed on the thermal cycler.

5.2.4 Performance QC Check

5.2.4.1 If a thermal cycler requires a QC check after repair, for validation, or before a new instrument is put online, a QC check shall be performed by the QCO. QC checks after repair or before a new instrument is put online shall include all current amplification chemistries. The QCO shall also perform the block verification tests.

5.2.4.1.1 The QC check shall consist of the amplification of the following as a set:

5.2.4.1.1.1 Positive amplification control (2800M)

5.2.4.1.1.2 Negative amplification control (NegAmp)

5.2.4.1.1.3 Reagent blank

5.2.4.1.1.4 NIST-TS

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

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

5.2.4.1.3 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 with peak heights generally below 12,000 RFU's. All Reagent Blanks and negative amplification controls shall be free of any peaks. 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 Technical Leader.

5.2.5 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 yearly verification is due. This documentation shall be retained indefinitely by the QCO.

5.3 Thermal Verification Kits (TVK)

5.3.1 Annual External Calibration: The thermal verification kits (Alpha Technics 4690 or equivalent) shall be calibrated annually by a contract vendor against an appropriate NIST traceable standard. TVKs that do not meet calibration standards shall not be used in the DNA Database Section.

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5.4 Bulb Thermometers

5.4.1 Purpose/Use: Used to measure temperatures in heat blocks and select refrigeration storage units. Surplus calibrated bulb thermometers shall be retained by the QCO, unless broken, and 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. Bulb thermometers that do not meet calibration standards shall not be used in the DNA Database Section.

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 of 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 Verification 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.

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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 in 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 bulb thermometers purchased from an external vendor; shall be NIST traceable and replaced when NIST traceability expires.

5.7 Balances

5.7.1 There is no balance maintained within the DNA Database section. A balance may be used from another section within the North Carolina State Crime Laboratory. That balance shall be calibrated as designated in that section's procedures.

5.8 Pipettors

5.8.1 Annual External Calibrations: All pipettors in the DNA Database Section shall be calibrated annually by a contract vendor. Pipettors that do not meet calibration standards shall not be used in the DNA Database Section.

5.8.2 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.

5.9 Centrifuges

5.9.1 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.

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

5.10.1 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.

5.10.2 Any hood that does not pass certification shall not be used.

5.11

5.12 BSD600 Ascent Puncher

5.12.1 As Needed: Dust the external surfaces (punch hood and card platform cover) using soft damp cloth.

5.12.2 Preventative Maintenance: Recommended – instrument serviced at 6 month intervals by an authorized field service personnel.

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5.12.3 Repair, Service, and Calibration Performed by Manufacturer – A post maintenance performance check is required after repair, service, or calibration performed by the manufacturer. The performance check shall meet the following requirements:

5.12.3.1 Completion of pre-run maintenance

5.12.3.2 A NIST-Traceable Standard (NIST-TS) and associated controls shall be amplified using current amplification chemistries and electrophoresed on the 3500xL.

5.12.3.3 All testing negatives (Reagent Blank(s), amplification negative control(s)) must be free of any true alleles above the analytical threshold used in the Section.

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

5.12.3.5 The QCO shall document the testing performed and retain such information in the Section.

5.13 Heat Blocks

5.13.1 Heat blocks shall have stickers placed on them to indicate their associated temperature:

5.13.1.1 70°C

5.13.1.2 95°C

5.13.2 The heat block temperatures shall be monitored by a calibrated bulb thermometer.

5.13.3 If a DNA Database Forensic Scientist uses a designated heat block, 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.

5.13.3.1 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.

5.13.3.2 The QCO 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.

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

5.13.4 If a heat block deviates more than +/-5°C from the set temperature for more than five consecutive readings, the QCO shall be notified. The QCO 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, a new bulb thermometer shall be used 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. If after both temperature knob adjustments and a new bulb thermometer are

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unsuccessful, the QCO shall remove that particular heat block from use. The QCO shall note the date the heat block ceased to be in use on the bottom of the TRF for that particular heat block.

5.14 Freezers/Refrigerators

5.14.1 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).

5.14.2 -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.

5.14.2.1 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.

5.14.2.2 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.

5.14.2.3 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.

5.14.2.4 If the temperature for a -20°C freezer exceeds the +5°C range for more than 5 consecutive business days, the 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.

5.14.3 -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.

5.14.3.1 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.

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

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5.14.3.3 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.

5.14.3.4 If the QCO or DNA Database Forensic Scientist observes temperatures out of the specified range for more than five consecutive business days, then the QCO 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 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 specified temperatures, then the contents may be returned to the unit.

5.15 All verification, calibration, maintenance, and QC documentation shall be retained within the - DNA Database Section.

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

- 3500xL, ProFlex PCR System thermal cyclers, BioRobot®, Centrifuges, Hoods, Freezers/Refrigerators, Balances.

6.0 Limitations

6.1 Once a 3500xL 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.

6.2 Temperature: The results from the 3500xL instrumentation can be affected by temperature changes. If the temperature in the room where the instrument is located is outside of the range of 60°F to 85°F, this shall be taken into account during analysis. If the results are affected, then the QCO (or designee) shall take the affected instrument(s) offline until the temperature is within range and the instrument has passed a QC check.

6.3 Items requiring yearly calibration by an external vendor shall be calibrated once per calendar year. Due dates listed on equipment stickers serve as courtesy reminders for the next external calibration and do not reflect an expiration of calibration.

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 maintenance, verifications, calibrations, or QC checks.

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7.3 If the ice shaver (or equivalent) used for bulb thermometer calibration 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 also a possible teratogen. Wear appropriate eyewear, masks, gloves and clothing when using.

7.5 Bleach shall not be used to clean or disinfect the Qiagen BioRobot® or its components.

7.6 Refer to Appendix 1 for Chemical Hygiene and Safety Precautions for extremely hazardous and particularly hazardous substances.

7.6.1 Hi-Di Formamide

8.0 References

3500xL Data Collection Software

Applied Biosystems 3500/3500xL Genetic Analyzer. User Bulletin. 2011 Life Technologies Corporation. Part Number 4469192 Rev. A. (or most recent revision)

Applied Biosystems 3500/3500xL Genetic Analyzer User Guide. 2010 Life Technologies Corporation. Part Number 4401661 Rev. C. (or most recent revision)

BSD Studio Software

DNA Database Administrative Policy and Procedure

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

DNA Database Procedure for BSD600 Ascent Puncher

DNA Database Section Procedure for DNA Reagent Quality Control

DNA Database Section Procedure for GeneMapper® ID-X and STR Interpretation with PowerPlex® Fusion

DNA Database Section Procedure for GeneMapper® ID-X and STR Interpretation with PowerPlex® Y23

DNA Database Section Procedure for PCR Amplification with PowerPlex® Fusion

DNA Database Section Procedure for PCR Amplification with PowerPlex® Y23

DNA Database Section Procedure for Sample Processing

DNA Database Section Procedure for Sample Processing Quality Control

DNA Database Section Procedure for Use of the 3500xL Genetic Analyzer

Instrument manuals

NIST Special Publication 819

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North Carolina Department of Cultural Resources Record Retention Schedule

PowerPlex® 5C Matrix Standard: Instructions for Use of Product DG4850. 2015 Promega Corporation. Part Number TMD049 Rev. 10/15.

State Crime Laboratory Quality Manual

Laboratory Safety Manual- Chemical Hygiene Plan and Hazardous Communication Program

9.0 Records

- BSD Log Notebook
- Bulb Thermometer Temperature Verification 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, and Data Loggers
- DNA Database Quarterly Maintenance Log
- Manufacturer documentation of preventative maintenance and/or repair for 3500xLs and centrifuges
- Temperature logs for freezers, refrigerators, heat blocks
- Thermal Cycler Verification Records

10.0 Attachments – Appendix 1 – Chemical Hygiene and Safety Precautions for Extremely Hazardous and Particularly Hazardous Substances

Revision History		
Effective Date	Version Number	Reason
06/09/2023	8	4.0-Removal of Qiagen BioRobot materials; 5.1.9-Removal of Yearly NIST Requirement, Subsequent renumbering; 5.9-Removal of Data Loggers section, Subsequent renumbering; 5.11-Removal of Qiagen BioRobot information and addition of BSD600 Ascent information; Updated References; Updated Records

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Appendix 1: Chemical Hygiene and Safety Precautions for Extremely Hazardous and Particularly Hazardous Substances

Hi-Di Formamide (Fischer) **DANGER: PARTICULARLY HAZARDOUS SUBSTANCE**	
	**HEALTH 2** **FLAMMABILITY 1** **REACTIVITY 0**
Detection of Release	Clear odorless liquid.
Signs/Symptoms of Exposure	May cause skin and eye irritation
PEL	NIOSH Recommended Exposure Limits (TWA) 10 ppm USA
Associated Hazards	Suspected of causing cancer. May damage fertility or the unborn child. Danger of cutaneous absorption. May cause damage to organs (Blood) through prolonged or repeated exposure if swallowed. May cause liver and kidney damage.
Controls	Use under fume hood. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. Use tight sealing safety goggles. Handle with gloves. Wear lab coat. Gloves: nitrile (break through time > 1 hour).
Safe handling, storage, disposal	Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Keep in a tightly closed container. Store in a cool, dry, corrosion-proof, ventilated area away from moisture, sources of heat or ignition, combustibles and oxidizers. Protect against physical damage. Dispose of in Hazardous Chemical Waste.
Emergency Procedures	**Eye Contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Immediate medical attention is required. **Inhalation Exposure:** Remove to fresh air. If not breathing, give artificial respiration. If symptoms persist, call a physician. **Ingestion:** Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice. If swallowed, rinse mouth with water (only if the person is conscious). Risk of serious damage to the lungs (by aspiration). Get medical attention if symptoms occur. **Skin Contact:** Wash off immediately with plenty of water for at least 15 minutes. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Immediate medical attention is required. **Spills:** Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Small contained spill: wearing appropriate PPE, soak up with inert absorbent material, and place in container. Dispose in Hazardous Waste. Large spills: Evacuate area and call 911 (Haz Mat).

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