This action will bring up the first screen in the sample loading process. “Section 5.2 Perform Run” for sample loading and run procedures.

6.3.3 Manage data on the ANDE instrument

The **Manage Data** feature allows the Admin to access and manage data directly on the ANDE instrument. Data can also be managed using the ANDE Data Management Software by exporting it off the instrument via USB or Ethernet and importing to a computer with the ANDE Data Management Software installed. The data export instructions provided in this section are intended to instruct Admins on how to export data from the ANDE using a USB drive. See “Section 7.3.2 Manage Data on ADMS” for instructions on importing and managing ANDE data using the ANDE Data Management Software.

CAUTION
Do not attempt to export data to a USB drive or to import data directly via Ethernet while a run is in progress. Data should be exported to USB or imported via Ethernet only while the instrument is not performing a run.

The Admin can manage data on the ANDE instrument by touching the **Manage Data** button.

The **Manage Data** screen will open and allow the Admin to perform the following tasks:

1. View Lane Success Results
2. View Run Data
3. Export Encrypted Run Data
4. Export Encrypted Telemetry Data
5. Export Encrypted Optical Data
6. Generate Run Reports
7. Done (Close the **Manage Data Menu** screen to return to the **Admin Menu** screen)

To perform any of the above tasks, the Admin should touch the appropriate button.

6.3.3.1 View Lane Success Results

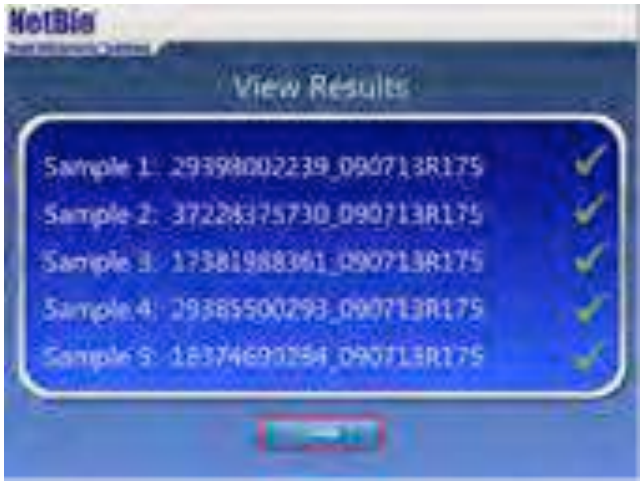
The **View Lane Success Results** feature allows the Admin to view the success results from a run, in the form of a green check, yellow check, or red X. The success results are displayed to ANDE system operator at the end of every run on the **Process Complete** screen (see "Section 5.2.5 Complete the Run"). The **View Lane Success Results** feature allows the Admin to view the results at a later time by accessing the **Manage Data Menu** screen and touching the **View Lane Success** button.

- Touch the **View Lane Success Results** button.

- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated. The runs performed within the designated date range will be displayed.

- Select the run to be viewed by touching the circle to the left of the run file, and then touch the **View Results** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

- The **View Results** screen will now be displayed.



- Touch the **Done** button to close the screen and return to the previous **Run Selection** screen.
- To view more run results, select the run of interest and touch the **View Results** button.
- When finished viewing results, touch the **Done** button to return to the **Manage Data Menu** screen.

6.3.3.2 View Run Data

The **View Run Data** feature allows Admin Users to view the STR profiles from each of the five samples and the run allele table. Only one run can be viewed at a time. Follow the instructions below to view run data:

- Touch the **View Run Data** button on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated.

- Select run data to be viewed by touching the circle to the left of the run file, and then touch the **View Run Data** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

- The STR profiles from all five samples will now be displayed. Touch the **Lane** tab at the top of the screen to view the each of the five profiles.

Note that STR profiles with ILS displayed can be viewed using the ANDE Data Management Software.

- Touch the **Allele Table** tab to view a table showing all allele calls at each locus for each sample.

- Touch the **Done** button to close the screen and return to the **View Run Data** screen. To view data from a different run, select the run of interest and touch the **View Results** button.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

6.3.3.3 Export run data

For every run performed, the instrument generates and can export a run file containing the following four data files:

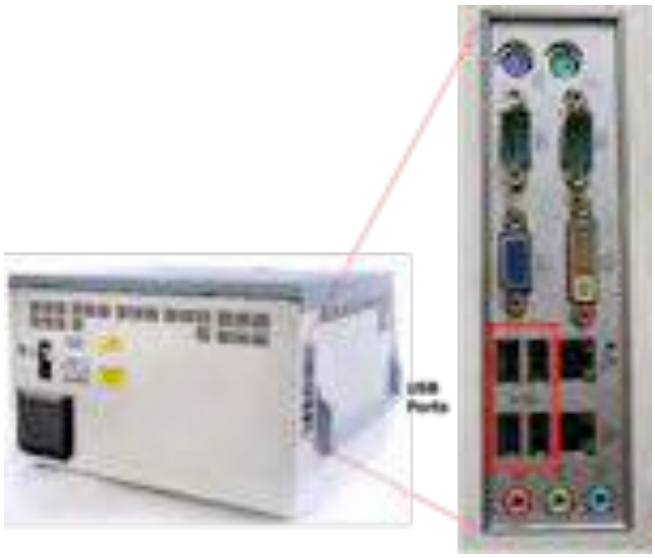
- A CODIS compatible .xml file for database searching. This file can be customized to be compatible with other international databases).
- A standard .fsa file containing the raw data that is compatible with other commercially available genotype analysis software programs
- A .png file that displays an image of the electropherograms and all designated alleles.
- An allele table in a .cvs file (Microsoft Excel™ compatible).

All data stored on the ANDE instrument are encrypted with a FIPS-140-2 compliant algorithm. The Admin is required to either export the encrypted data from the ANDE instrument onto a USB drive or

import it directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software. See “Section 7.3.2 Manage Data on ADMS” for instructions on data decryption using the ANDE Data Management Software.

To export data to a USB drive follow the instructions below:

- Before beginning the export process, insert a USB drive into any of the available USB ports located on the left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Run Data** button found on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.

- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the

Next Page/Previous Page arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed run files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all run files within the selected data range for export.

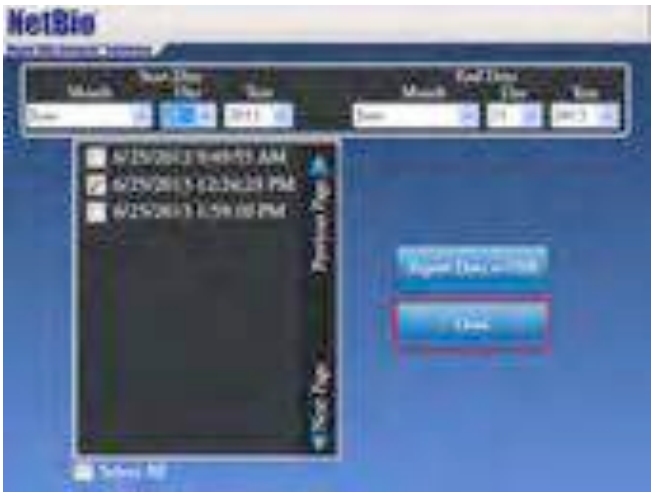
NOTICE. If the USB drive has not been properly inserted into the ANDE instruments USB port or if the USB drive has not properly read, a message will inform the Admin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

NOTICE. If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your NetBio representative for assistance.

- As data is being exported, a progress bar will be displayed to display export progress.

- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.

- Touch the **Done** button to return to the **Manage Data Menu** screen.



To export run data from the ANDE instrument directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see “Section 7.3.2 Manage Data on ADMS” for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.3.3.4 Export Telemetry Data

For every run performed, the instrument records all the telemetry associated with the subsystems within the instrument. The telemetry data contains only subsystem measurement information and does not contain any STR profile or sample identification information. The purpose of the telemetry data is to allow technical issues to be remotely diagnosed and triaged by a qualified NetBio service engineers. If the customer reports a problem, in certain cases a SuperAdmin or Admin will be asked to export the telemetry data for this purpose. Note that all telemetry data is encrypted and can only be decrypted by a NetBio service engineer.

To export data to a USB drive follow the instructions below:

- Before beginning the export process, insert a USB drive into the any of the available USB ports located on the left side of the instrument.

- To begin the export process to a USB drive, touch the **Export Telemetry Data** button found on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.

- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed telemetry files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all telemetry files within the selected data range for export.

NOTICE. If the USB drive has not been properly inserted into the ANDE instruments USB port or if the USB drive has not properly read, a message will inform the Admin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

NOTICE. If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your NetBio representative for assistance.

- As data is being exported, a progress bar will appear to display export progress.

- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

To import telemetry data directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see Section 7.3.2 Manage Data on ADMS for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.3.3.5 Export optical data

The instrument generates raw optical data associated with STR fragment detection for each run performed on the ANDE instrument. A qualified NetBio service engineer may require these data to diagnose and triage certain technical issues associated with the optical subsystem. The optical data does contain information that could be used to recreate an STR profile, and as such these data should be provided to NetBio only with approval from the customer. Note that all optical data is encrypted and can only be decrypted by a qualified NetBio service engineer.

To export data to a USB drive follow the instructions below:

- Before beginning the export process, insert a USB drive into any of the available USB ports located on left side of the instrument.

- To begin the export process to a USB drive, touch the **Export Optical Data** button found on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.

- After touching the **Export Data to USB** button, the system will display a message to the Admin with a warning that the optical data may contain STR profile information and should be exported only if consistent with jurisdictional policy. Touch the **OK** button to initiate optical data export.

NOTICE. If the USB drive has not been properly inserted into the ANDE instruments USB port or if the USB drive has not properly read, a message will inform the Admin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data**

to USB button again.

NOTICE. If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your NetBio representative for assistance.

- As data is being exported, a progress bar will appear to display export progress.

- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

To import optical data directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see "Section 7.3.2 Manage Data on ADMS" for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.3.3.6 ANDE database capacity

The ANDE database can hold up to 1000 runs (5000 samples and associated run data). If the database capacity is reached, the instrument will no longer allow runs to be performed until run data has been deleted from the database in sufficient capacity to allow new run data to be stored. Only a SuperAdmin can delete run data from the database.

NOTICE. If the System Space Warning message appears, immediately inform a SuperAdmin.

- As the ANDE database nears its capacity (i.e., when the database contains 901 runs), a **System Space Warning** message will be displayed immediately after Log In to inform the Users how

many more runs can be performed before the database reaches its capacity and no more runs will be allowed by the ANDE instrument.

- Once the ANDE database reaches it capacity of 1000 run files (5000 samples), the instrument will not allow any more runs to be performed. An Error message will be displayed to inform the User that the database capacity is full, no runs may be performed, and a SuperAdmin should be contacted. Touch **OK** to clear the message.

- In addition to the warning message above, the **Perform Run** button on all Menu screens will be disabled and remain as such until run data has been deleted from the database in sufficient capacity to allow new runs to be stored.

6.3.3.7 Generate run reports

A run report can be generated for every run performed by the ANDE instrument. Run reports are intended for a NetBio representative to review run performance while having no access to the data or donor information. Note that all run reports are encrypted and can only be decrypted by a qualified NetBio representative. Run reports can be generated and exported to a USB drive as a single-step process using the **Generate Run Reports** feature on the Admin Menu screen.

A run report will contain the following information:

1. Lane # for each sample
2. Green/yellow/red (pass/review/fail) run results
3. Date and time of the run
4. Name of the User who performed the run
5. Errors, if any, report during the run
6. Sample ID field for BLANK samples only (samples IDs associated with DNA samples will not be reported).

To generate and export a run report to a USB drive, follow the instructions below:

- Before beginning, insert a USB drive into any of the available USB ports located on left side of the instrument.

- To generate a run report, touch the **Generate Run Report** button from the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus to display the runs for which a run report is desired.

- Select one or more run files for which a run report is desired by touching the box to the left of the file, and then touch the **Generate Run Report** button. Run reports will automatically be generated and exported to the USB. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.

NOTICE. If the USB drive has not been properly inserted into the ANDE USB port or if the USB drive is not being properly read, a message will inform the User to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Generate Run Report** button again.

NOTICE. If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your NetBio representative for assistance.

- As the run reports are being exported, a progress bar will be displayed to display export progress.

- When the run reports have been successfully exported, an export complete message will be displayed. Touch the **OK** button to clear the message.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

To import run reports directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see Section “7.3.2 Manage Data on ADMS” Import Data.

- When finished with data management tasks, the Admin should touch the **Done** button on the **Manage Data Menu** screen to return to the **Admin Menu** screen.

6.3.4 Manage User accounts on the ANDE instrument

The Admin can manage Operator accounts by touching the **Manage User Accounts** button.

The **Manage User Accounts** screen will open and allows the Admin to perform the following tasks:

- Add Operator accounts
- Modify Operator accounts
- Delete Operator accounts
- Close the **Manage User Accounts** screen

Manage User Accounts screen:

6.3.4.1 Add Admin and Operator accounts

The Admin can create Operator accounts (see “Section 6.2 Operator account” for more information on the features and functions of Operator accounts).

- To create a new Operator account, touch the **Add** button at the bottom of the **Manage User Accounts** screen to bring up the **Account Information Input** screen:

The Operator's account information can be entered into the account information fields by touching the white box next to each field and entering the appropriate information using the on-screen keyboard. (To exit this screen and return to the **Manage User Accounts** screen at any time during this process without creating the account, touch the **Cancel** button.)

- The User Name should have 7-14 characters and is case specific.
- The Admin should create a password for the account using the following rules:
    a. 7-14 characters long
    b. contains at least one uppercase letter (A-Z)
    c. contains at least one lowercase letter (a-z)
    d. contains at least one number (0-9)
    e. contains at least 1 symbol (` ! @ # $ % ^ & * ( ) _ + - = { } | [ ] \ : ; ‘ < > ? , . /)
    f. last character must be upper or lower case letter

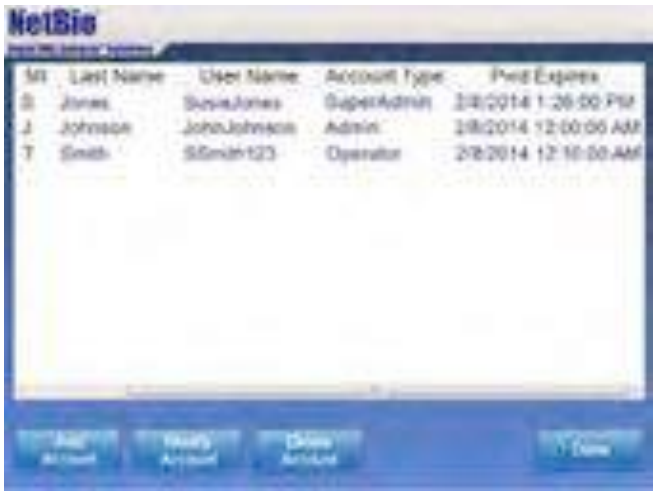
g. cannot reuse your 10 most recent passwords

NOTICE. The password created by the Admin for the Operator accounts is only to establish initial log in credentials and is not permanent. The first time the Operator logs into the system with the Admin designated temporary credentials, he or she will be prompted to create a unique password that will replace the Admin-designated password.

- The Admin should touch **User Password** field and use the on-screen keyboard to enter a password. The Admin should then confirm the password by entering it again in the **Confirm New Password** field.

- Once the User information fields have been completed, touch the **Add** button to create the account and return to the **Manage User Accounts** screen.

- The new account will now be visible on the **Manage User Accounts** screen:



- To return to the **Admin Menu** screen, touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, select the desired User account and touch the appropriate button on the bottom of the screen.

6.3.4.2 Modify accounts

To modify an existing User account, highlight the account to be modified by touching it, and then touch the **Modify** button at the bottom of the screen to open the **Modify Account** window.

The following account information can be modified:

Personal Information: First, Last, and Middle Initial fields can be modified by touching the appropriate field, deleting the current information using the arrow key at the top right of the User Touch Screen, and then entering the new information using the on-screen keyboard.

User Name: The User Name can be modified by touching the **User Name** field, deleting the current information using the arrow key at the top right of the User Touch Screen, and then entering the new User Name using the on-screen keyboard.

Account Type: A User's Access Level cannot be modified. To change a User's account type, delete the account and create a new one with the new account type.

Locked User Account: Operators are allowed three attempts to log into the instrument via the **Log In** screen. If the Operator enters the incorrect password three times, the system will lock the User out.

- If an Operator's account is locked, the **Locked** field will have a check mark in it.
- To unlock the account, touch the check mark and it will disappear.

Change Password: The Admin can change/reset Operator account passwords. There are two primary reasons to change a User password:

1. **Forgotten Password:** If an Operator forgets their password, a new password can be created. If an Admin forgets their password, contact a SuperAdmin for assistance.

2. **Compromised Account:** If for any reason a User believes their password has been compromised, a new password should be created immediately.

- When an Operator needs to change their account password, the Admin must create a new password for the User by touching the **Change Password** button found on the **Modify User** screen. Just as with first-time User account log in, the next time an Operator logs into their account with the Admin-designated password, a prompt will be displayed to create a unique password that will replace the Admin-designated password.

- A screen will be displayed that provides instructions for creating a new password and has fields to input and confirm the new password.

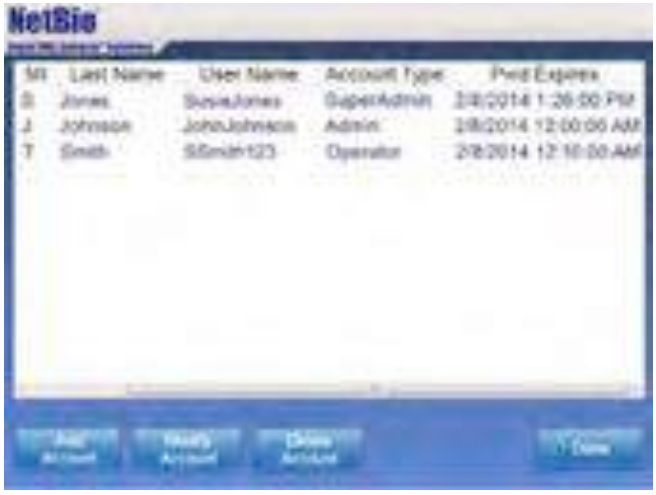
- Enter a new password by touching the **New Password** field and using the on-screen keyboard to enter the new password. Confirm the new password by typing the same password into the **Confirm New Password** field, and then touch the **Change** button to initiate the change.

- A message will be displayed to inform the Admin that the password has been successfully changed. Touch the **OK** button to clear the message.

- The Operator password has now been successfully changed and the Admin will be returned to the **Modify User** screen. The password expiration date will automatically be set from the date of change.

- Touch the **Save** button to save all changes made and to return to the **Manage User Accounts** screen. Touching the **Cancel** button will void all changes and return the User to the **Manage User Accounts** screen.

- After touch the **Save** button, **Manage User** screen will be displayed and the modified information, if appropriate, will be displayed.



To return to the **Admin Menu** screen touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, touch the desired account and then touch the button of the task you would like to perform from the bottom of the screen.

6.4.4.3 Delete Admin or Operator accounts

- To delete an existing Operator account, highlight the account to be deleted by touching it and then touch the **Delete** button at the bottom of the screen:

- The system will prompt the Admin to confirm that the account is to be deleted. Touch **No** to keep the account and return to the **Manage User Accounts** screen; touch **Yes** to delete the account:

- If the **Yes** button is touched, this account will be permanently deleted from the system. If the **No** button is touched, the account will remain active and will not be deleted. The Admin will be returned to the **Manage User Accounts** screen after confirming the account deletion.

- The deleted account will no longer be visible on the list of Users and the deleted User will no longer be able to log in to the instrument, perform runs, or access their account.

To return to the **Admin Menu** screen touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, touch the button of the task you would like to perform from the bottom of the screen.

6.3.4.4 Exit the Manage User Accounts screen

To exit the **Mange User Accounts** screen and return to the **Admin Menu** screen, touch the **Done** button on the bottom right of the screen:

6.3.5 Get Info

The Get Info function allows the Admin to view the version numbers of both the System and the Expert System software programs that are currently installed on the ANDE instrument. Version numbers will automatically update when a new version of System software is installed.

- Touch the **Get Info** button on the **Admin Menu** screen to open the **Get Info** screen:

- Touch the **Software Versions** button to display the software versions currently installed on the instrument.

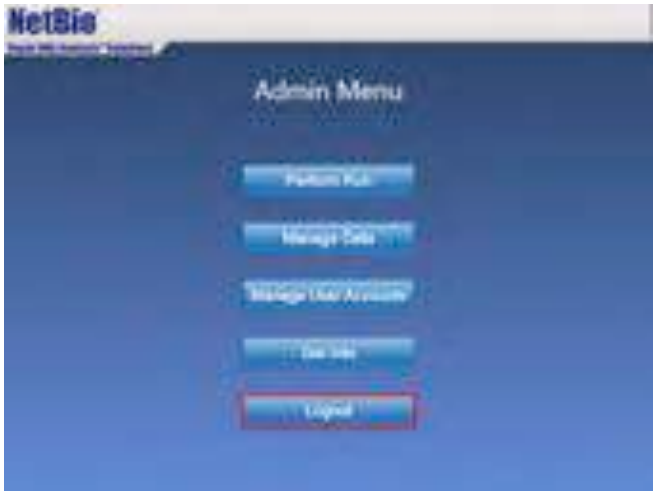
- Touch the **Close** button at the bottom of the screen to return to the **Get Info** screen.

- Touch the **Close** botton at the bottom of the screen to return to the **Admin Menu** screen.

6.3.6 Logout

The Admin should always Logout of the instrument when finished performing tasks. Follow the instructions below to Logout:

- The Admin can Logout by touching the **Logout** button on the **Admin Menu** screen:



- After touching the **Logout** button, the **Log In** screen will be displayed:

- If all work to be performed on the ANDE instrument is complete and the Admin wishes to shutdown the instrument, see “Section 5.3.2 Shut down the instrument” for instructions on how to shutdown the instrument.

6.4 SuperAdmin Account

Each ANDE instrument comes with multiple pre-configured SuperAdmin accounts. Those Uses given SuperAdmin accounts will have the most advanced privileges and access to the features of the instrument. SuperAdmin accounts should be reserved for those Users who require the most advanced access to the ANDE instrument. SuperAdmin is the only User class that is allowed to configure system settings, create and manage data security certificates, create and manage Admin accounts, access usage logs, and delete data.

A NetBio representative will provide the customer with SuperAdmin temporary User Names and Passwords at the time of delivery that will allow a designated SuperAdmin to log in for the first time and then create a unique SuperAdmin account. See "Section 6.4.1 SuperAdmin account access: log in and password management" for instructions on how to log in to the ANDE instrument for the first time.

The following functions can be performed by a SuperAdmin by accessing the **SuperAdmin Menu** screen of the ANDE instrument:

- Perform Run
- Manage Data
- Manage User Accounts
- Calibrate Touch Screen
- Configure System
- Upgrade Software
- Manage Certificates
- Get Info
- Logout

The following table summarizes the SuperAdmin privileges:

ANDE User Account Privilege	SuperAdmin
Perform a Run	X
Manage Data	
• View late success results (green/yellow/red indicators)	X
• View run data	X
• Export encrypted run and telemetry data	X
• Export optical data	X
• Delete run data	X
• Generate run reports	X
• Export data usage	X
• Export System Logs	X
Manage User Accounts	
• Add Admin accounts	X
• Add Operator accounts	X
• Modify Admin accounts	X
• Modify Operator accounts	X
• Manage Admin passwords	X
• Manage Operator passwords	X
• Delete Admin accounts	X
• Delete Operator accounts	X
Get Info	X
Configure System	X
Upgrade Software	X
Manage Certificates	X
Calibrate Touchscreen	X

6.4.1 SuperAdmin account access

6.4.1.1. Log in to the ANDE instrument

6.4.1.1.1. Log in for the first time

The SuperAdmin who performed initial set up of the ANDE instrument should have already logged in for the first time (see “Section 4.5.2. Log in to the instrument for the first time”). To create additional SuperAdmin accounts, contact a NetBio representative to obtain a temporary SuperAdmin name and password and then follow the instructions below.

After powering up the instrument and allowing it complete the 15 minute warm up cycle, the Log In screen will be displayed. Select the User Name field on the User Touch Screen by touching the white box; a cursor will appear. Use the on-screen keyboard to enter the temporary User Name. Then touch the white box next to the Password field. Enter the temporary password, and touch the **Log In** button. In the following example, the designated temporary User Name is “SuperAdmin”.

- If the password is incorrectly entered, a “Login Failed” message will be displayed. Touch the **OK** button to clear the message and try again.

- After successful log in, the User will be prompted to create a new User Name and Password. Enter the required information into the fields provided. The User Name should be 7-14 characters, and the password should adhere to the rules below. After all fields have been completed, touch the **OK** button.

Passwords rules:

a. 7-14 characters long
b. contains at least one uppercase letter (A-Z)
c. contains at least one lowercase letter (a-z)
d. contains at least one number (0-9)
e. contains at least 1 symbol (` ! @ # $ % ^ & * ( ) _ + - = { } | [ ] \ : ; ‘ < > ? , . /)
f. last character must be upper or lower case letter
g. cannot reuse your 10 most recent passwords

CAUTION
Each User should take care to protect his or her password. Do not give out your password to other Users or store it in a common place where it could be compromised.

- A message will be displayed to inform the User that the password has been successfully changed. After this message is displayed, a secure, customer-specific User account has been successfully created. Touch the **OK** button to clear the message and continue.

- The User will be returned to the Log in screen. Enter the newly created User Name and password to Log in.

6.4.1.1.2. Log in after a unique account has been created

If the ANDE instrument is not on, push the power switch on the back of the instrument to the **I (ON)** position. After the 15-minute warm-up cycle is complete, the **Log In** screen will be displayed.

On the **Log In** screen, select the User Name field on the User Touch Screen by touching the white box; a cursor will appear. Use the on-screen keyboard to enter the User Name. Then touch the white box next to the Password field. Enter the temporary password, and touch the **Log In** button.

The **SuperAdmin Menu** screen will be displayed:

6.4.1.2 SuperAdmin password management

6.4.1.2.1. Expired password

The manufacturer default setting for the SuperAdmin password expiration is six months, but the password expiration time can be set at 1-12 months by the SuperAdmin (See section 6.4.6 Configure System).

Follow the instructions below to reset an expired password:

- When a SuperAdmin attempts to logs in after their password has expired, the system will display a message the password has expired. Touch the **OK** button to clear the message and create a new password.

- The **Change Password** screen will be displayed to allow the SuperAdmin to create a new password. The SuperAdmin should enter a new password into the New Password field and then confirm the new password in the field below. Adhere to the password rules displayed on the **Change Password** screen. Select the **Change** button to complete the change password process.

- A message will be displayed to inform the User the password has been successfully changed. The User should touch the **OK** button to clear the message and return to the log in screen. The User can now log in with their User Name and new Password.

6.4.1.2.2. Incorrect login or forgotten password

SuperAdmins are allowed five attempts to log into the instrument via the **Log In** screen. If the SuperAdmin enters their password incorrectly five times, the account will be permanently disabled. The SuperAdmin must contact a NetBio representative for a new temporary SuperAdmin user name and password. Follow instructions in "Section 6.4.1 SuperAdmin account access: log in and password management". All data associated with the locked account will be maintained and will be accessible to the SuperAdmin.

6.4.2 Perform Run

NOTICE
Before selecting **Perform Run**, ensure that all samples have been collected and the BioChipSet Cassette has been unpackaged, positioned on the BioChipSet Cassette Loading Fixture, and is ready to load samples.

The SuperAdmin can perform a run by touching the **Perform Run** button on the SuperAdmin Menu:

This action will bring up the first screen in the sample loading process. “Section 5. Performing a Run” for sample loading and run procedures.

6.4.3 Manage data on the ANDE instrument

The **Manage Data** feature allows the SuperAdmin to access and manage data directly on the ANDE instrument. Data can also be managed using the ANDE Data Management Software by exporting it off the instrument via USB or Ethernet and importing to a computer with the ANDE Data Management Software installed. The data export instructions provided in this section are intended to instruct SuperAdmins on how to export data from the ANDE using a USB drive. See Section 7.0 for instructions on importing and managing ANDE data using the ANDE Data Management Software.

CAUTION
Do not attempt to export data to a USB drive or to import data directly via Ethernet while a run is in progress. Data should be exported to USB or imported via Ethernet only while the instrument is not performing a run.

The SuperAdmin can manage data on the ANDE instrument by touching the **Manage Data** button.

The **Manage Data** screen will open and allow the SuperAdmin to perform the following tasks:

1. View Lane Success Results
2. View Run Data
3. Export Run Data
4. Export Telemetry Data
5. Export Optical Data
6. Delete Run Data

7. Generate Run Reports
8. Export Usage Data
9. Export System Logs
10. Done (Close the **Manage Data Menu** screen to return to the **SuperAdmin Menu** screen)

To perform any of the above tasks, the Super Admin should touch the appropriate button.

6.4.3.1 View Lane Success Results

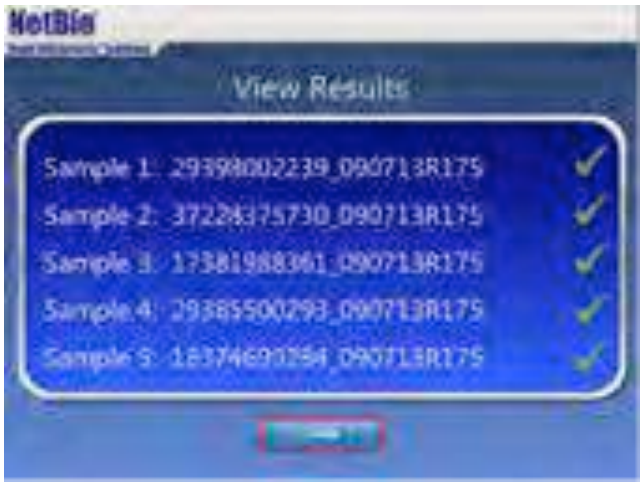
The **View Lane Success Results** feature allows the SuperAdmin to view the success results from a run, in the form of a green check, yellow check, or red X. The success results are displayed to ANDE system operator at the end of every run on the **Process Complete** screen (see "Section 5.2.5 Complete the Run"). The **View Lane Success Results** feature allows the SuperAdmin to view the results at a later time by accessing the **Manage Data Menu** screen and touching the **View Lane Success** button.

- Touch the **View Lane Success Results** button.

- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated. The runs performed within the designated date range will be displayed.

- Select the run to be viewed by touching the circle to the left of the run file, and then touch the **View Results** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

- The **View Results** screen will now be displayed.



- Touch the **Done** button to close the screen and return to the previous **Run Selection** screen.
- To view more run results, select the run of interest and touch the **View Results** button.
- When finished viewing results, touch the **Done** button to return to the **Manage Data Menu** screen.

6.4.3.2 View Run Data

The **View Run Data** feature allows SuperAdmin and Admin Users to view the STR profiles from each of the five samples and the run allele table. Only one run can be viewed at a time. Follow the instructions below to view run data:

- Touch the **View Run Data** button on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated.

- Select run data to be viewed by touching the circle to the left of the run file, and then touch the **View Run Data** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

- The STR profiles from all five samples will now be displayed. Touch the **Lane** tab at the top of the screen to view the each of the five profiles.

Note that STR profiles with ILS displayed can be viewed using the ANDE Data Management Software.

- Touch the **Allele Table** tab to view a table showing all allele calls at each locus for each sample.

- Touch the **Done** button to close the screen and return to the **View Run Data** screen. To view data from a different run, select the run of interest and touch the **View Results** button.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

6.4.3.3 Export run data

For every run performed, the instrument generates and can export a run file containing the following four data files:

- A CODIS compatible .xml file for database searching. This file can be customized to be compatible with other international databases).
- A standard .fsa file containing the raw data that is compatible with other commercially available genotype analysis software programs
- A .png file that displays an image of the electropherograms and all designated alleles.
- An allele table in a .cvs file (Microsoft Excel™ compatible).

All data stored on the ANDE instrument are encrypted with a FIPS-140-2 compliant algorithm. The SuperAdmin is required to either export the encrypted data from the ANDE instrument onto a USB drive

or import it directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software. See Section 7 for instructions on data export and data decryption using the ANDE Data Management Software program.

To export data to a USB drive follow the instructions below:

- Before beginning the export process, insert a USB drive into any of the available USB ports located on the left side of the instrument.

- To begin the export process to a USB drive, touch the **Export Run Data** button found on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.

- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the

Next Page/Previous Page arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed run files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all run files within the selected data range for export.

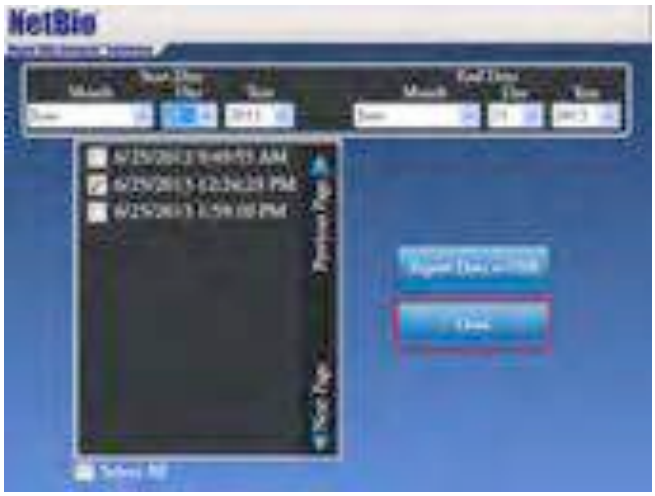
NOTICE. If the USB drive has not been properly inserted into the ANDE instruments USB port or if the USB drive has not properly read, a message will inform the SuperAdmin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

NOTICE. If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your NetBio representative for assistance.

- As data is being exported, a progress bar will be displayed to display export progress.

- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.

- Touch the **Done** button to return to the **Manage Data Menu** screen.



To export run data from the ANDE instrument directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see “Section 7.2.3 Manage data on ADMS” for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.4.3.4 Export Telemetry Data

For every run performed, the instrument records all the telemetry associated with the subsystems within the instrument. The telemetry data contains only subsystem measurement information and does not contain any STR profile or sample identification information. The purpose of the telemetry data is to allow technical issues to be remotely diagnosed and triaged by a qualified NetBio service engineers. If the customer reports a problem, in certain cases the SuperAdmin will be asked to export the telemetry data for this purpose. Note that all telemetry data is encrypted and can only be decrypted by a NetBio service engineer.

To export data to a USB drive follow the instructions below:

- Before beginning the export process, insert a USB drive into the any of the available USB ports located on the left side of the instrument.

- To begin the export process to a USB drive, touch the **Export Telemetry Data** button found on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.

- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed telemetry files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all telemetry files within the selected data range for export.

NOTICE. If the USB drive has not been properly inserted into the ANDE instruments USB port or if the USB drive has not properly read, a message will inform the SuperAdmin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

NOTICE. If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your NetBio representative for assistance.

- As data is being exported, a progress bar will appear to display export progress.

- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

To import telemetry data directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see Section “7.2.3 Mange data on ADMS” for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.4.3.5 Export optical data

The instrument generates raw optical data associated with STR fragment detection for each run performed on the ANDE instrument. A qualified NetBio service engineer may require these data to diagnose and triage certain technical issues associated with the optical subsystem. The optical data does contain information that could be used to recreate an STR profile, and as such these data should be provided to NetBio only with approval from the customer. Note that all optical data is encrypted and can only be decrypted by a qualified NetBio service engineer.

To export data to a USB drive follow the instructions below:

- Before beginning the export process, insert a USB drive into any of the available USB ports located on left side of the instrument.

- To begin the export process to a USB drive, touch the **Export Optical Data** button found on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.

- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.

- After touching the **Export Data to USB** button, the system will display a message to the SuperAdmin with a warning that the optical data may contain STR profile information and should be exported only if consistent with jurisdictional policy. Touch the **OK** button to initiate optical data export.

NOTICE. If the USB drive has not been properly inserted into the ANDE instruments USB port or if the USB drive has not properly read, a message will inform the SuperAdmin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export**

Data to USB button again.

NOTICE. If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your NetBio representative for assistance.

- As data is being exported, a progress bar will appear to display export progress.

- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

To import optical data directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see "Section 7.2.3 Manage data on ADMS" for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.4.3.6 Delete run data

The ANDE database can hold up to 1000 runs (5000 samples and associated run data). If the database capacity is reached, the instrument will no longer allow runs to be performed until run data has been deleted from the database in sufficient capacity to allow new run data to be stored. Therefore, to maintain a continuous workflow, the SuperAdmin should periodically export, decrypt, and archive all ANDE-generated data, and then delete the corresponding data from the ANDE instrument.

When run data are deleted, the STR data output files along with the associated telemetry data, optical data, lane success results, and run reports will all be permanently removed from the instrument's database. Once deleted, all associated files can no longer be retrieved, so take caution when deleting run data. Only a SuperAdmin can delete run data.

NOTICE. The ANDE system records all actions performed by a User in the Usage Data log. Data deleted by a SuperAdmin will be logged, see Section 6.4.3.8 Export usage data.

6.4.3.6.1 Database capacity is full

- As the ANDE database nears its capacity (i.e., when the database contains 901 run or 4505 sample files), a **System Space Warning** message will be displayed immediately after Log In to inform all Users, SuperAdmin, Admin, and Operators, how many more runs can be performed before the database reaches its capacity and no more runs will be allowed by the ANDE instrument.

- Once the ANDE database reaches it capacity of 1000 run files (5000 samples), the instrument will not allow any more runs to be performed. An Error message will be displayed to inform the User that the database capacity is full, no runs may be performed, and a SuperAdmin should be contacted. Touch **OK** to clear the message.

- In addition to the warning message above, the **Perform Run** button on the SuperAdmin, Admin and Operator Menu screens will be disabled and remain as such until run data has been deleted from the database in sufficient capacity to allow new runs to be stored.

NOTICE. The ANDE instrument maintains a log of all deleted files and records the following information for all deleted runs:

1. Sample ID
2. Sampled date and time
3. Name of the Operator, Admin , or SuperAdmin that performed the run
4. Lane success results for the run (presented as green/yellow/red marks)
5. Date and time of deletion
6. Name of the SuperAdmin that performed the deletion

To view information on deleted runs, the SuperAdmin must access the **Export Usage Data** feature from the **Manage Data Menu** screen. For more information, see Section 6.4.3.8 Export usage data.

6.4.3.6.2 Deleting run data from the ANDE instrument database

- To delete run data, touch the **Delete Run Data** button found on the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus to display the desired run data for deletion.

- Select data to be deleted by touching the square to the left of the run file, and then touch the **Delete Run Data** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed run files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all run files within the selected data range for export.

- A Run Data Deletion Warning message will be displayed to inform the SuperAdmin that runs are being deleted and to allow confirmation that the selected files should be deleted. Touch the **Yes** button to delete the selected files and clear the Warning message. Touch the **No** button to abort the deletion process and return to the **Delete Run Data** screen.

NOTICE. Deleted files will be permanently removed from the ANDE database and will no longer be retrievable.

- Once the run files have been deleted, a message will inform the SuperAdmin that the deletion process is complete. Press the **OK** button to clear the message and return to the **Delete Run Data** screen.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

6.4.3.7 Generate run reports

A run report can be generated for every run performed by the ANDE instrument. Run reports are intended for a NetBio representative to review run performance while having no access to the data or donor information. Note that all run reports are encrypted and can only be decrypted by a qualified NetBio representative. Run reports can be generated and exported to a USB drive as a single-step process using the **Generate Run Reports** feature on the SuperAdmin Menu screen.

A run report will contain the following information:

1. Lane # for each sample
2. Green/yellow/red (pass/review/fail) run results
3. Date and time of the run
4. Name of the User who performed the run
5. Errors, if any, report during the run
6. Sample ID field for BLANK samples only (samples IDs associated with DNA samples will not be reported).

To generate and export a run report to a USB drive, follow the instructions below:

- Before beginning, insert a USB drive into any of the available USB ports located on left side of the instrument.

- To generate a run report, touch the **Generate Run Report** button from the **Manage Data Menu** screen.

- Select the date range (month, date, and year) from the dropdown menus to display the runs for which a run report is desired.

- Select one or more run files for which a run report is desired by touching the box to the left of the file, and then touch the **Generate Run Report** button. Run reports will automatically be generated and exported to the USB. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

NOTICE. To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.

NOTICE. If the USB drive has not been properly inserted into the ANDE USB port or if the USB drive is not being properly read, a message will inform the User to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Generate Run Report** button again.

NOTICE. If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your NetBio representative for assistance.

- As the run reports are being exported, a progress bar will be displayed to display export progress.

- When the run reports have been successfully exported, an export complete message will be displayed. Touch the **OK** button to clear the message.

- Touch the **Done** button to return to the **Manage Data Menu** screen.

To import run reports directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see “Section 7.2.3 Manage data on ADMS” for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.4.3.8 Export Usage data

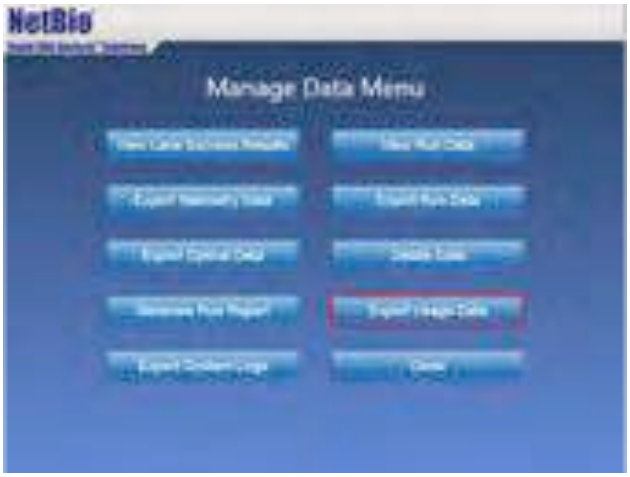
The ANDE system keeps a record of all actions performed on the instrument by SuperAdmin, Admin, and Operators. The **Usage Data** feature allows the SuperAdmin to access and export the log of User actions. The Usage Data report will contain the following information on User actions:

1. User Account type (SuperAdmin, Admin, or Operator)
2. User Login data and time
3. Run date and time
4. Data export date and time
5. Data deletion date and time

To generate and export a Usage Data report to a USB drive, follow the instructions below:

- Before beginning, insert a USB drive into any of the available USB ports located on left side of the instrument.

- To export a Usage Data report, touch the **Export Usage Data** button on the **Manage Data Menu** screen.



- Select from the dropdown menus the date range (month, date, and year) of the Usage data the SuperAdmin would like to export. For example, if the SuperAdmin would like to export the log of the User actions on the date of August 9, 2013, select that date for both the Start and End Dates. Then Touch the **Export Data to USB** button to export a report of all User actions within specified date or date range.

- When the Data Usage report has been successfully exported, an Export Complete message will be displayed. Touch the **OK** button to clear the message.

- If there are no more reports to generate, touch the **Done** button to return to the **Manage Data Menu** screen.

To import Usage Data reports directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software, see “Section 7.2.3 Manage data on ADMS” for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.4.3.9 Export System Logs

The System Logs function allows the SuperAdmin to export the system software logs should a software error occur and troubleshooting or servicing be required. No run data, profiles, telemetry, or optical data are contained within these log files. The purpose of the System Logs function is to allow technical issues to be remotely diagnosed and triaged by a qualified NetBio service engineer. If the customer reports a problem, in certain cases the SuperAdmin would be asked to export the software logs for this purpose. Note that all software logs are encrypted and can only be decrypted by a NetBio service engineer.

- To begin this process, insert a USB drive into any available USB port on the left side of the instrument.

- Touch the **Export System Logs** button on the **Manage Data Menu** screen to open the **System Logs** window.

- Select the date range for the logs you want export to the USB drive by touching the dropdown menus and selecting the Month, Day, and Year.
- Select the USB drive (D:\ < >) by touching the dropdown menu and then touching the D drive.

- Touch the **Save Logs** button at the bottom of the screen to save the logs to the USB drive.

- When the logs have successfully saved, the following message will be displayed:

- Touch the **OK** button on the bottom of the message to clear the message and return to the **System Logs** screen.
- Touch the **X** on the top right corner of the **System Logs** window to close and return to the **Manage Data Menu** screen.

- Remove the USB drive from the ANDE instrument and follow the instructions provided by the NetBio representative to transfer the data for troubleshooting.

6.4.3.10 Done

Once all the desired Data Management functions have been completed, the User can return to the SuperAdmin Main Menu by touching the **Done** button.

- The SuperAdmin should touch the **Done** button on the **Manage Data Menu** screen when finished with data management tasks to return to the **SuperAdmin Menu** screen.

6.4.4 Manage User accounts on the ANDE instrument

The SuperAdmin can manage both Admin and Operator accounts by touching the **Manage User Accounts** button.

The **Manage User Accounts** screen will open and allows the SuperAdmin to perform the following tasks:

- Add Admin and Operator accounts
- Modify Admin and Operator accounts

- Delete Admin and Operator accounts
- Close the **Manage User Accounts** screen

Manage User Accounts screen:

6.4.4.1 Add Admin and Operator accounts

The SuperAdmin can create both Admin and Operator accounts. See Sections 6.2 Operator Accounts and 6.3 Admin accounts for more information on the privileges for these User classes.

- To create a new account, touch the **Add** button at the bottom of the **Manage User Accounts** screen to bring up the **Account Information Input** screen:

The Admin or Operator's account information can be entered into the account information fields by touching the white box next to each field and entering the appropriate information using the on-screen keyboard. (To exit this screen and return to the **Manage User Accounts** screen at any time during this process without creating the account, touch the **Cancel** button.)

- The User Name should have 7-14 characters and is case specific.
- The SuperAdmin should create a password for the account using the following rules:
    a. 7-14 characters long
    b. contains at least one uppercase letter (A-Z)
    c. contains at least one lowercase letter (a-z)
    d. contains at least one number (0-9)
    e. contains at least 1 symbol (` ! @ # $ % ^ & * ( ) _ + - = { } | [ ] \ : ; ' < > ? , . /)
    f. last character must be upper or lower case letter
    g. cannot reuse your 10 most recent passwords

NOTICE. The password created by the SuperAdmin for Admin and Operator accounts is only to establish initial log in credentials and is not permanent. The first time the Admin or Operator logs into the system with the SuperAdmin=designated password, the User will be prompted to create a unique password that will replace the SuperAdmin-designated password.

- The SuperAdmin should touch **User Password** field and use the on-screen keyboard to enter a password. The SuperAdmin should then confirm the password by entering it again in the **Confirm New Password** field.

- The SuperAdmin should designate the appropriate Access Level for the User by touching the dropdown menu for the **Access Level** field. The two User Access Level options available are **Admin** and **Operator**.

- Once the appropriate level of access has been selected, touch the **Add** button to create the account and return to the **Manage User Accounts** screen.

- The new account will now be visible on the **Manage User Accounts** screen:

- To return to the **SuperAdmin Menu** screen, touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, select the desired User account and touch the appropriate button on the bottom of the screen.

6.4.4.2 Modify accounts

To modify an existing User account, highlight the account to be modified by touching it, and then touch the **Modify** button at the bottom of the screen to open the **Modify Account** window.

The following account information can be modified:

Personal Information: First, Last, and Middle Initial fields can be modified by touching the appropriate field, deleting the current information using the arrow key at the top right of the User Touch Screen, and then entering the new information using the on-screen keyboard.

User Name: The User Name can be modified by touching the **User Name** field, deleting the current information using the arrow key at the top right of the User Touch Screen, and then entering the new User Name using the on-screen keyboard (see example below).

- Touch the User Name field and then touch the arrow key to delete current information:

- Enter the new User Name:

Account Type: A User's Access Level cannot be modified. To change a User's account type, delete the account and create a new one with the new account type.

Locked User Account: Admin and Operators are allowed three attempts to log into the instrument via the **Log In** screen. If the Admin or Operator enters the incorrect password three times, the system will lock the User out.

- If an Admin or Operator is locked out of their account, the **Locked** field will have a check mark in it.
- To unlock the account, touch the check mark and it will disappear.

NOTICE.
A SuperAdmin will have five opportunities to log in correctly. After the fifth unsuccessful attempt the account will be locked. If a SuperAdmin is locked out, please contact a NetBio representative.

Change Password: A SuperAdmin can change both Admin and Operator account passwords. There are two primary reasons for a SuperAdmin to change a User password:

1. **Forgotten Password:** If an Admin or Operator forgets their password, a new password can be created by the SuperAdmin. If the SuperAdmin forgets their password, contact a NetBio representative for assistance.

2. **Compromised Account:** If for any reason a User believes their password has been compromised, a new password should be created immediately.

- When a SuperAdmin, Admin, or Operator needs to change their account password, the SuperAdmin must create a new password for the User by touching the **Change Password** button found on the **Modify User** screen. Just as with first-time User account log in, the next time an Admin or Operator logs into their account with the SuperAdmin-designated password, a prompt will be displayed to create a unique password that will replace the SuperAdmin-designated password.

- A screen will be displayed that provides instructions for creating a new password and has fields to input and confirm the new password.

- Enter a new password by touching the **New Password** field and using the on-screen keyboard to enter the new password. Confirm the new password by typing the same password into the **Confirm New Password** field, and then touch the **Change** button to initiate the change.

- A message will be displayed to inform the SuperAdmin that the password has been successfully changed. Touch the **OK** button to clear the message.

- The Admin or Operator password has now been successfully changed and the SuperAdmin will be returned to the **Modify User** screen. The password expiration date will automatically be set from the date of change.

- Touch the **Save** button to save all changes made and to return to the **Manage User Accounts** screen. Touching the **Cancel** button will void all changes and return the User to the **Manage User Accounts** screen.

- After touch the Save button, Manage User screen will be displayed and the modified information, if appropriate, will be displayed (for this example, the User name was changed to JJohnson).

To return to the **SuperAdmin Menu** screen touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, touch the desired account and then touch the button of the task you would like to perform from the bottom of the screen.

6.4.4.3 Delete Admin or Operator accounts

- To delete an existing Admin or Operator account, highlight the account to be deleted by touching it and then touch the **Delete** button at the bottom of the screen:

- The system will prompt the SuperAdmin to confirm that the account is to be deleted. Touch **No** to keep the account and return to the **Manage User Accounts** screen; touch **Yes** to delete the account:

- If the **Yes** button is touched, this account will be permanently deleted from the system. If the **No** button is touched, the account will remain active and will not be deleted. The SuperAdmin will be returned to the **Manage User Accounts** screen after confirming the account deletion. The deleted account will no longer be visible on the list of Users.

- The deleted User will no longer be able to log in to the instrument, perform runs, or access their account.

To return to the **SuperAdmin Menu** screen touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, touch the button of the task you would like to perform from the bottom of the screen.

6.4.4.4 Exit the Manage User Accounts screen

To exit the **Mange User Accounts** screen and return to the **SuperAdmin Menu** screen, touch the **Done** button on the bottom right of the screen:

6.4.5 Calibrate the ANDE touch screen monitor

The User Touch Screen of the ANDE instrument may periodically require recalibration. For example, if a key or button is not responsive and must be touched several times to initiate the action, or if the keys being touched while entering information are inputting the neighboring character instead of the desired one, the monitor should be recalibrated.

- Log in using the SuperAdmin credentials and touch the **Calibrate Touch Screen** button from the **SuperAdmin Menu** screen.

- The **Touch Screen Calibration** screen will be displayed, and after several seconds the calibration process will initiate. To calibrate the User Touch Screen, four points on the screen must go through the calibration process. The User should touch and hold on the red circles, one at a time, as they appear in each of the four corners of the screen, from the lower left, to the lower right, to the upper right, and ending with the upper left.

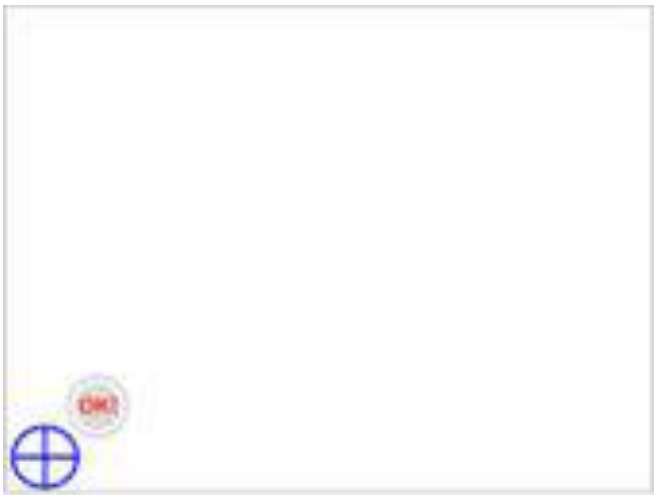
First of four calibration points: lower left-hand corner:

- Touch and hold a finger on the red circle in the lower left corner of the monitor to initiate the first of four point calibrations (the User is given 15 second to initiate this action; a counter will be displayed in a grey circle with the remaining time).

NOTICE.
If at any time during the four-point calibration sequence the red circle is not touched by the time the counter reaches zero, the **Touch Screen Calibration** screen will automatically close and return to the **SuperAdmin Menu** screen, and the calibration will be aborted.

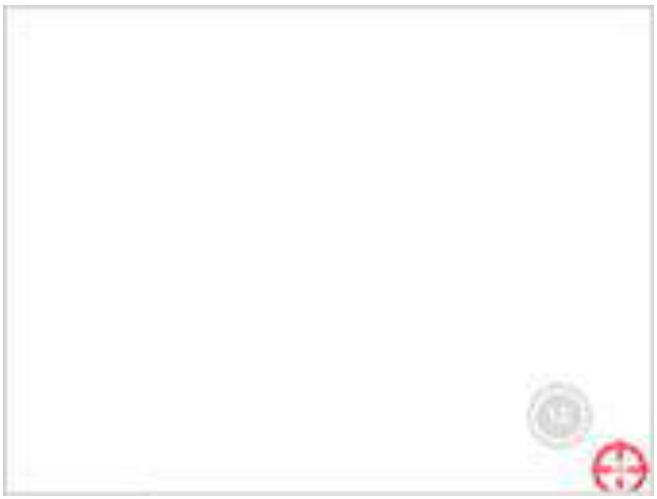
- When the red circle is first touched, its will change color to blue and it will build as the calibration is completing. This will only take a few seconds. Progress will be displayed in the counter as a % complete.

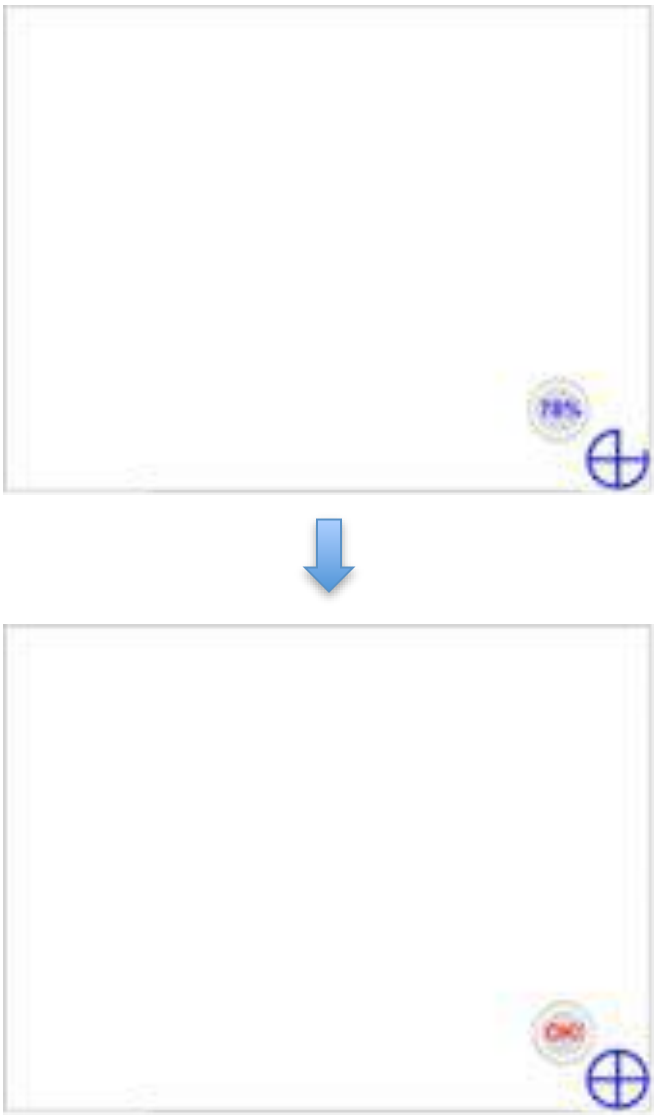
- Once the counter displays **OK!**, the single-point calibration is complete. At this time it is okay for the User to release their finger from the screen.



Second of four calibration points, lower right hand corner:

- The same calibration procedure will occur immediately after releasing the first calibration point, but this time in the lower right hand corner.





Last two calibration points. Upper right hand corner and upper left hand corner:

- Repeat the same calibration procedure in the upper right hand corner, then again in the upper left hand corner.
- After all four point calibrations have completed, the system will go through a reset period and a series of reading and writing progress bars will flash onto the screen. This happens very quickly, within ~3 seconds.

- After the calibration is complete, the **Touch Screen Calibration** screen will say a message that the calibration is complete. The screen will then automatically disappear and return to the **SuperAdmin Menu** screen.

6.4.6 Configure ANDE System features

The **Configure System** feature in the System Software of the ANDE instrument allows a SuperAdmin to turn on or off (or enable or disable) certain instrument features and to configure several of the instrument's settings. The ANDE instrument comes with the manufacturer-configured settings shown below on the **Configure System** screen, but these features should be reviewed and customized by a SuperAdmin according to operational requirements or jurisdictional policy.

Below are the manufacturer default settings:

6.4.6.1 Features that can be configured

The following features of the ANDE instrument can be turned on or off (or enabled or disabled) by a SuperAdmin:

1. **RFID Swab** (Default Setting = ON)**:** The RFID readers used for sample loading and lane placement tracking can be turned on or off. When the **RFID Swab** feature is turned on, the RFID readers (internal and external) will be enabled so that the RFID tags found in the caps of the NetBio BioChipSet Swabs can be scanned and their lane placement within the BioChipSet Cassette tracked. When this feature is turned off, the RFID readers will be disabled and will not be able to read and record the RFID tag in the caps of the Swabs.

NOTICE

The **RFID Swab** feature can be turned off by a SuperAdmin based on operational requirements or jurisdictional policies. If the **RFID Swab** feature has been turned off, the lane position of each of the 5 samples within the BioChipSet Cassette will no longer be tracked by the instrument. To avoid sample mix up when the RFID Swab feature is turned off, it is recommended that the position of each sample in the BioChipSet Cassette be recorded. Lane 1 corresponds to the first Swab Chamber, closest to the far right side of the BioChipSet Cassette (see photo below), Lanes 2–5 follow Lane 1 in order, and Lane 5 corresponds to the Swab Chamber on the far left of the BioChipSet Cassette. With RFID tracking off, the Scan Sample screen will no longer appear as a part of the on-screen sample loading procedures.

2. **RFID BioChipSet** (Default Setting = ON)**:** When this feature is turned on, the instrument's internal RFID reader reads the RFID on-board the BioChipSet Cassettes. When this feature is turned off, the BioChipSet RFID reader will be disabled and the instrument will no longer track the BioChipSet Cassettes that are processed.

3. **GPS** (Default Setting = ON)**:** The instrument comes with a Global Positioning System (GPS) device that, when GPS signal is available, tags all ANDE runs with location and time information. Turning this feature off will disable the GPS and the runs will no longer be tagged with GPS-derived information.

4. **WI-Fi** (Default Setting = OFF) **:** Currently, this capability is not operational.

5. **Ethernet Data Export** (Default Setting = ENABLED)**:** Enabling Ethernet data export will allow encrypted data to be exported via an Ethernet connection from the instrument to a customer's desktop or laptop computer using the ADMS data import capability. Disabling this feature will turn off the system's capability of exporting data via Ethernet connection.

6. **Lane Flag** (Default Setting = ENABLED): When this feature is enabled, the instrument employs a flagging system to inform the User regarding the success of each swab from the run. The flagging system is based on two criteria: 1) the Expert System rules; and 2) the minimum number of CODIS core loci required to pass as preconfigured by the SuperAdmin. There are three flag options:

    - A green checkmark indicates that the sample successfully passed the Expert System rules for all 13 CODIS core loci and also met the success criteria preconfigured (minimum number of CODIS core loci) by the SuperAdmin. An .xml (databasing) file is generated with the allele calls for all loci.
    - A yellow checkmark indicates that the sample has at least one CODIS core locus that did not meet an Expert System Software rule, but the profile did contain passing results for the minimum number of CODIS core loci preconfigured by the SuperAdmin. The purpose of the yellow indicator is to alert the User that a trained DNA analyst may need to examine the profile. An .xml (databasing) file is generated for samples assigned a yellow checkmark, but the file only contains the loci that passed all Expert System rules.
    - A red "X" indicates that the sample did not generate a profile that passed the Expert System rules for the minimum number of required CODIS core loci as preconfigured by the SuperAdmin. An .xml (databasing) file is not generated for samples assigned a red "X".

The following features of the ANDE instrument can be configured by the SuperAdmin:

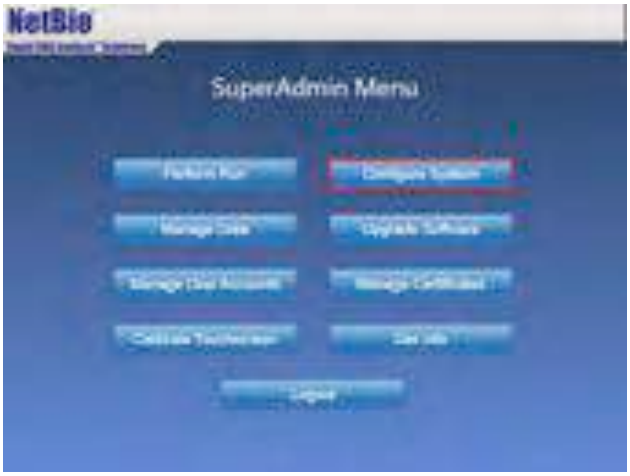
1. **Loci Required to Generate a CMF (database compatible file)** (Default Setting = 10, Range 1-13)**:** The Expert System software assigns each DNA profile a pass or fail designation. The determination of whether a DNA profile passes or fails is configurable by the SuperAdmin based on the number of loci that are assigned allele calls. For example, if the customer requires all 13 CODIS loci to have allele designations in order to qualify for database searching, and thus considers a profile successful only when all 13 CODIS loci have allele designations, then all profiles having 13 CODIS or more loci called would be reported as a "passed" sample, and the Expert System software would generate a .xml (databasing) file for database searching. For those DNA profiles having less than the 13 CODIS loci called, the sample would be reported as

"failed", and no .xml file would be generated for database searching. The **Loci Required to Generate a CMF** setting should be configured according to institutional, national, regional, local, or institutional law and policies that govern database searching.

2. **Password Expiration** (Default Setting = 6 months, Range 1-12 months)**:** The ANDE instrument User account passwords will periodically expire. Time to password expiration can be configured by the SuperAdmin and should be based on the organization's internal policies and procedures. Options for setting the time to password expiration range from 1 to 12 months.
3. **Lane Success Results Screen Timeout** (Default Setting = 120 minutes, Range 1-120 minutes)**:** At the end of a run, a **Processing Complete** screen is displayed on the ANDE touch screen monitor that informs the User of the lane success results for each of the five samples. These results will be determined by the **Loci Required to generate CMF** configuration (see above). Yellow check marks may be displayed if the **Lane Flag** feature is enabled. This screen will remain displayed for the User for a period of time that can be set by the SuperAdmin.

6.4.6.2 Changing the default configuration settings

To set the configurable features, touch the **Configure System** button on the **SuperAdmin Menu** screen.

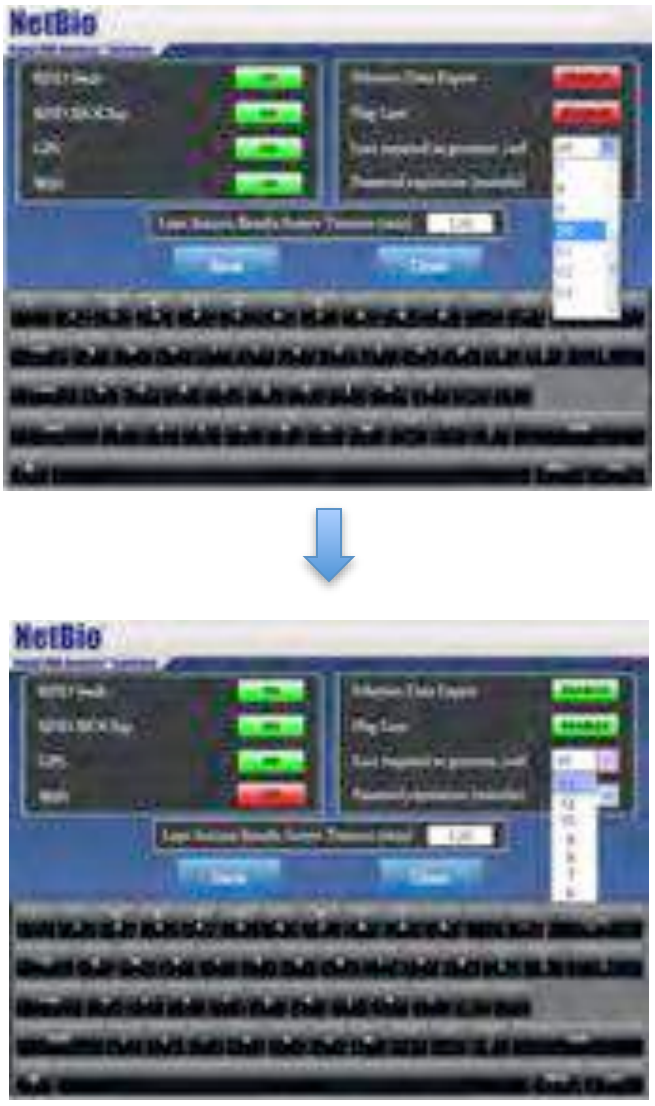


- To modify the settings of the above features, touch the **ON/OFF** or **ENABLE/DISABLE** buttons on the **System Configuration** screen. When a feature is ON or ENABLED, the button will display this setting and the color will be green. When a feature is OFF or DISABLED, the button will display this setting and the color will be red.

Features ON/ENABLED

Features OFF/DISABLED

- To set the number of loci required to generate a CMF, touch the dropdown arrow to display the options and then touch the number from the menu. 1 to 13 Loci can be selected. Use the scroll bar to move up and down through the different options.



- To set the time to password expiration (months), touch the dropdown arrow to display the options and then touch the number from the menu. 1 to 12 months can be selected.

- To set the lane success results screen timeout (min), touch the field to the right, use the left arrow on the on-screen keyboard to delete the current setting, and then enter the preferred time in minutes.

- To save the newly configured settings touch the **Save** button. A message will be displayed asking the SuperAdmin to confirm the changes, touch the **Yes** button to confirm and accept the changes.

Touching the **No** button will return the SuperAdmin to the **System Configuration** screen and changes will not have been saved.

- The system will inform the SuperAdmin that configurations were successfully saved. Touch the **OK** button to return to the **System Configuration** screen.

- To close the **System Configuration** screen and return to the **SuperAdmin Menu** screen, touch the **Close** button.

- If the SuperAdmin touches the **Close** button before saving the changes, a message will be displayed to confirm that the SuperAdmin wants to close the **System Configuration** screen without saving the changes. Touch the **Yes** button to close the **System Configuration** screen without saving the changes to return to the **SuperAdmin Menu** screen. Touch the **No** button to return to the **System Configuration** to further modify the settings. Touch the **Save** button to save all changes as instructed above.

6.4.7 Upgrade ANDE software

Software upgrades for the ANDE System are easily performed using the **Upgrade Software** feature. The SuperAdmin simply inserts a USB drive with the desired software upgrade into the instrument's USB port and then, with the touch of a few buttons, the system's automated **Upgrade Software** feature will install the update.

The ANDE **Upgrade Software** feature enables upgrades of:

1. System Software: Controls the GUI screens with which the User interfaces when operating the system, including the SuperAdmin, Admin, and Operator account functionalities, and all of on-screen sample loading and operating instructions.

2. Expert System Software: Performs data analysis and allele designation to create STR profiles.

3. Data Processing Software: Processes raw signal to generate data in a form capable of analysis by the Expert System software.

4. PCSS: Process Control Subsystem Software is the control system software for the instrument and includes the process control scripts used to control all of the process steps driving the microfluidics during sample processing within the BioChipSet Cassette.

NetBio will notify customers when upgraded software becomes available.

6.4.7.1 System Software upgrade

- Begin a software upgrade by inserting the USB drive containing the updated software into any of the available USB ports located on left side of the instrument.

- Log in using SuperAdmin credentials and touch the **Upgrade Software** button from the **SuperAdmin Menu** screen.

- The **Upgrade Software Menu** screen will open and display the software upgrade options. Touch the **System Software** button to upgrade the System Software.

- The system will display a confirmation message to verify that the SuperAdmin wants to continue with the upgrade. The SuperAdmin should touch the **Yes** button to proceed with the system software upgrade. Touching the **No** button will cancel the upgrade and return the SuperAdmin to the **Upgrade Software Menu** screen.

NOTICE.
If the USB drive with the software upgrade has not been properly inserted into the ANDE USB port or if the software is not on the USB drive, a message will inform the SuperAdmin that no device was found with the software upgrade. Touch the **OK** button to clear the message, then insert the USB drive with the software upgrade and attempt the upgrade again.

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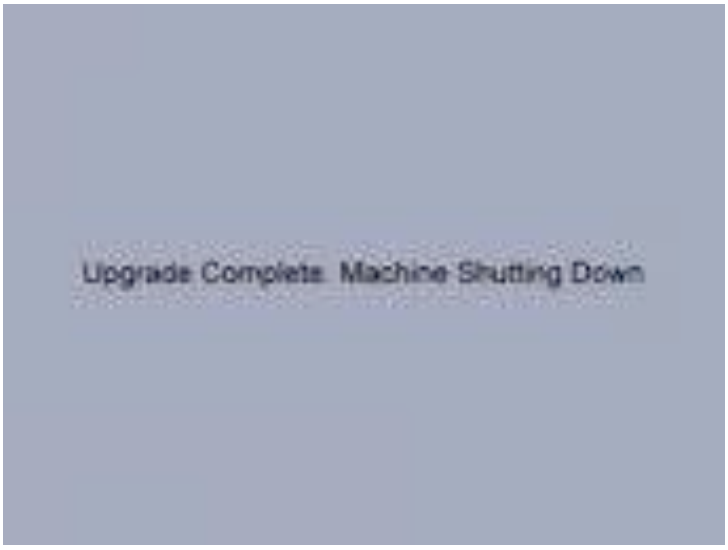
- The following screen will be displayed while the System Software is upgrading:

- When the software upgrade is complete an **Upgrade Complete** screen will be displayed and the ANDE instrument will shut itself down.



- When the instrument completes its shutdown cycle, the power switch on the back of the instrument should be turned off.
- The system can now be powered on and runs can be performed.

6.4.7.2 Expert System Software upgrade

- Begin a software upgrade by inserting the USB drive containing the updated software into any of the available USB ports located on left side of the instrument.

- Log in using SuperAdmin credentials and touch the **Upgrade Software** button from the **SuperAdmin Menu** screen.

- The **Upgrade Software Menu** screen will open and display the software upgrade options. Touch the **Expert System Software** button to upgrade the Expert System Software.

- The system will display a confirmation message to verify that the SuperAdmin wants to continue with the upgrade. The SuperAdmin should touch the **Yes** button to proceed with the Expert System Software upgrade. Touching the **No** button will cancel the upgrade and return the SuperAdmin to the **Software Upgrade Menu** screen.

NOTICE

If the USB drive with the software upgrade has not been properly inserted into the ANDE USB port or if the software is not on the USB drive, a message will inform the SuperAdmin that no device was found with the software upgrade. Touch the **OK** button to clear the message, then insert the USB drive with the software upgrade and attempt the upgrade again.

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- When the SuperAdmin confirms the upgrade by touching the **Yes** button, the software will be automatically upgraded. This process will only take a few seconds.
- A message will inform the SuperAdmin when the software upgrade is complete. Touch the **OK** button to clear the message and return to the **Upgrade Software Menu** screen.

- The Expert System Software has now been upgraded. The instrument does not need to be shut down after this software upgrade. The SuperAdmin can now perform runs with the upgraded software.

6.4.7.3 Data Processing Software upgrade

Select the **Data Processing** button to upgrade the Data Processing Software. Follow the procedures from "Section 6.4.7.2 Expert System software" to upgrade the Data Processing software.

6.4.7.4 PCSS Software upgrade

Select the **PCSS** button to upgrade the PCSS software. Follow the procedures from “Section 6.4.7.2 Expert System” software to upgrade the PCSS software.

6.4.7.5 Closing the Upgrade Software Menu

Touch the **Close** button on the bottom of the screen to close the **Upgrade Software Menu** screen and return to the **SuperAdmin Menu** screen.

6.4.8 Manage ANDE Encryption Certificates

The **Manage Certificates** feature allows the SuperAdmin to install and view the Encryption Certificate required to secure the data on-board the ANDE instrument. Installing the Encryption Certificate is essential for data management and security and should be performed during System installation by a SuperAdmin. For detailed instructions on generating and installing the Encryption Certificate, see “Section 4.5.4.2 Creating Encryption Certificate and Decryption Key” with the ANDE Data Management Software and “Section 4.5.5 Install Encryption Certificate on the ANDE instrument”.

- To verify the encryption certificate installed on the instrument, touch the **Manage Certificate** button from the **SuperAdmin Main Menu** screen.

- The **Manage Certificates** screen will appear but will not display the installed certificates until the **Show Machine Specific Certificates** button in touched. Touch this button to display the installed certificate.

Touch the **Close** button at the bottom of the screen to return to the **SuperAdmin Menu** screen.

NOTICE

Creating and installing a new encryption certificate on the instrument will automatically override the existing certificate. All data on board the ANDE instrument can be exported with the new encryption certificate and decrypted with the corresponding decryption key using the ADMS software.

6.4.9 Get Info: installed software version numbers

The Get Info function allows the SuperAdmin to view the version numbers of both the System and the Expert System software programs that are currently installed on the ANDE instrument. Version numbers will automatically update when a new version of System software is installed.

- Touch the **Get Info** button on the **SuperAdmin Menu** screen to open the **Get Info** screen:

- Touch the **Software Versions** button to display the software versions currently installed on the instrument.

- Touch the **Close** button at the bottom of the screen to return to the **Get Info** screen.

- Touch the **Close** botton at the bottom of the screen to return to the **SuperAdmin Menu** screen.

6.4.10 Logout

The SuperAdmin should always Logout of the instrument when finished with performing tasks. Follow the instructions below to Logout:

- The SuperAdmin can Logout by touching the **Logout** button on the **SuperAdmin Menu** screen:

- After touching the **Logout** button, the **Log In** screen will be displayed:

- If all work to be performed on the ANDE instrument is complete and the SuperAdmin wishes to shutdown the instrument, see “Section 5.3.2 Shut down the instrument” for instructions on how to shutdown the instrument.

8. MAINTENANCE

To ensure optimal performance, the ANDE Rapid DNA Analysis System instrument and accessories should be maintained regularly. This chapter describes the maintenance that should be performed on a regular basis.

WARNING
Internal access to the ANDE instrument should be limited to qualified NetBio personnel only. The ANDE Rapid Analysis System instrument is not User serviceable. Please contact your NetBio representative for additional information.

CAUTION
Before performing any maintenance on the exterior of the ANDE instrument, be sure to turn off the power switch and remove the power plug from the electrical outlet.

CAUTION
Take care when connecting the power cord. Do not tug at the power cord and do not handle the connection plugs with wet hands.

CAUTION
Do not press too hard onto the surface of the touch screen. This may cause the surface to break and lead to injury.

NOTICE
Do not use organic solvents. These may damage the exterior of the instrument.

8.1. Maintenance overview

The ANDE instrument should undergo routine system maintenance every 12 months (annually). Only qualified NetBio personnel should perform routine maintenance. Please contact your NetBio representative to schedule routine system maintenance.

8.2. Regular User inspections

Users should regularly inspect the ANDE instrument to ensure the following:

- The power supply plug is firmly secured in the power outlet.
- The power supply plug and cord do not become overheated.
- The power supply plug and cord are not damaged in any way.
- The ventilation holes in the instrument are not blocked and are free from dust and dirt.
- There is no residue or debris in the BioChipSet Cassette docking area.

8.2.1. User inspection/cleaning/replacement of cooling fan air filter

The cooling fan air filter will be replaced by qualified NetBio personnel during routine maintenance. If the filter should build up with excessive dust and debris between maintenance visits, a new cooling fan air filter can be purchased from NetBio and replaced by the User.

Instructions for replacing the air filter:

- Turn off the instrument's power and remove the power cord from the back of the instrument to allow the filter to be lifted out of its holder.
- Remove the old filter from the rear of the instrument by lifting it up and out of its holder.

- Insert the replacement filter into the filter holder and slide all the way down it down into place. Make sure it fits securely within the filter holder and that has been inserted all the way down.

- Plug the power cord back into the ANDE instrument. The system can now be turned on and runs can be performed.

8.2.2. External surface cleaning

NOTICE
The User Touch Screen is cleaned differently from the rest of the exterior surfaces on the ANDE instrument. Do not use isopropyl alcohol to clean the touch screen.

8.2.2.1 Cleaning the touch screen

Use a clean, soft lint-free cloth to gently wipe the touch screen. The cloth may be slightly dampened with water or may be used dry. Do not use any other chemicals to clean the touch screen.

8.2.2.2 Cleaning the rest of the instrument's exterior

Lightly dampen a clean, dry lint-free cloth with a solution of 50% isopropyl alcohol and 50% water. Lightly scrub the exterior of the instrument until clean. Do not spray cleaning agent directly onto the instrument. Work carefully to avoid getting cleaning agent on the touch screen.

8.3. Routine System maintenance

Routine system maintenance should be carried out every 12 months (annually). Other than inspection and replacement of air filters, only trained NetBio personnel should perform routine maintenance. The maintenance schedule and tasks below assume system use as follows:

- At an operating temperature of 20–30°C (68–86°F).
- All instructions in this User Manual and the Health and Safety Manual are followed correctly.

9. TROUBLESHOOTING

9.1. General

This chapter describes various problems that could occur with the ANDE Rapid DNA Analysis System and the actions the User should take if they occur. For all other errors not described here, the User should contact NetBio before taking any action.

If an error message appears on the User Touch Screen, take note of it. Taking a photo is a good way of capturing the error message.

CAUTION

If power to the instrument is turned off or lost during DNA analysis, run data will be lost. Do not attempt to re-run a cassette if the run is prematurely terminated.

9.2. User operation issues

9.2.1 Swab is loaded into BioChipSet Cassette without scanning the RFID tag

There may be instances when a User loads a swab into the swab chamber of the BioChipSet Cassette without scanning the swab cap with the RFID Reader. Once the swab is loaded into the cassette, it is locked in place and cannot be removed to scan the cap. Do not attempt to scan the swab while it is loaded in the cassette. To alleviate this issue, the User can scan any unused swab as a substitute. This unused swab can be used in a different run.

Guidelines:

- It is not necessary to remove the substitute swab from its packaging.
- Record the sample ID of the sample with the scanning issue and record the lane number it was placed in.

Directions:

- Find an unused NetBio BioChipSet Swab to use as a substitute for the unscanned sample.
- Move the swab cap to the edge of the package so it can be scanned by the instrument's RFID reader.

- Insert the cap of the swab into the RFID Reader on the front of the instrument to input an RFID tag for the unscanned sample.

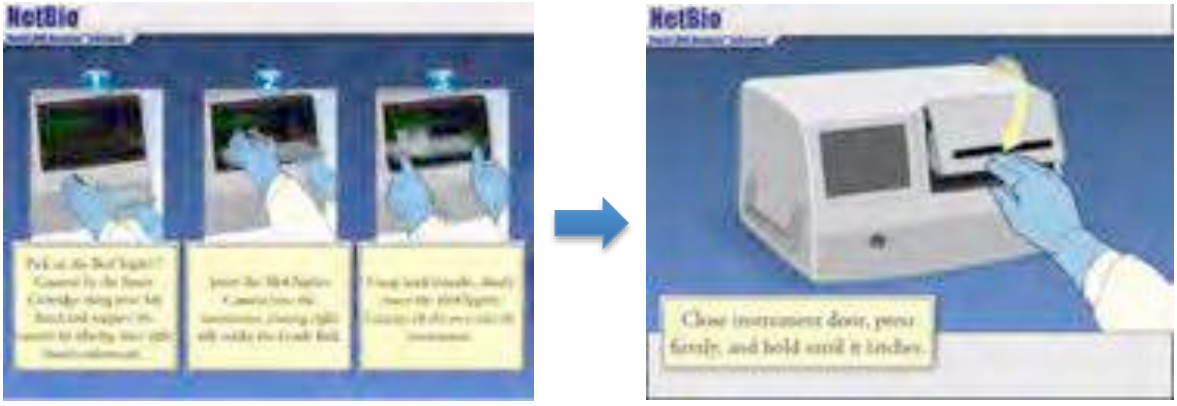
- The system now has an RFID input that will allow the sample loading process to continue. Continue as normal with sample loading.
- When the cassette is loaded into the instrument for sample processing, a 2nd internal RFID reader will automatically read the RFID chips in the 5 sample caps to determine the lane placement of each sample. The instrument will identify that there is a discordant RFID tag and will display an on-screen error message:

- Touch the **Yes** button to continue. Sample loading and the run will progress as normal.

When a single sample is mistakenly not scanned during sample loading and a substitute swab is used, the instrument will still be able to correctly link the sample ID to the lane in which it was placed and to the appropriate DNA profile. If more than one swab was inserted and not scanned, the system can no longer properly track the sample placement within the chip and sample mix up could occur. Sample ID and its placement in the chip (Lane number) should be carefully recorded. Proceed with caution.

9.2.2 Screen does not advance when the BioChipSet Cassette is loaded into the instrument

After loading the BioChipSet Cassette into the instrument, the BioChipSet Loading screen should automatically advance to the Close Instrument Door screen when the BioChipSet is properly loaded:



If the screen does not advance, ensure that the cassette is properly loaded:

- The Smart Cartridge should be on the left side of the BioChipSet Cassette docking station:

- The right side end of the cassette should be UNDER the docking station guide rail:

- The cassette should be pushed all the way into the docking station. Using your thumbs, press firmly on the outside edges of the BioChipSet to push it all the way into the docking station.

- If the BioChipSet Loading screen still does not advance to the Close instrument door screen, remove the BioChipSet Cassette and attempt to re-insert it.
- If the error persists, call NetBio.

9.2.3 The BioChipSet Cassette Access Door does not close

To properly close the BioChipSet Cassette Access Door, the user should hold the Access Door in the closed position by pressing just under the black handle until the instrument locks it. If the door does not lock and opens after it has been closed, the user should:

- Attempt to shut the door again and hold it firmly closed until the instrument has locked it (door should not require holding down for more than 15 seconds).
- If this issue persists, contact NetBio.

9.2.4 The BioChipSet Cassette Access Door was left open after a run

If the User does not close the Access Door after a run has been completed, the instrument will time out and automatically revert to the Log in screen. The User should log in to the instrument by entering their User Name and Password. The instrument will automatically display the Close instrument door screen. The User should then close the door and continue with the user interface actions on the User Touch Screen to complete the run. If a cassette was left in the instrument, remove it before shutting the door. The system can now be shut down and the power switch can be turn off.

9.3 System error messages and User actions

There are two classes of errors that can occur on the ANDE system: User Errors, as discussed above, and System Errors. When a System Error occurs, the ANDE System will display an error message in one of three error categories:

1. Hardware error
2. Safety interlock error
3. Software error

The error message will provide instructions to the User for the next steps. Adhere to the instructions and do not attempt to bypass the error and continue on with a run unless instructed to do so by a NetBio Service Representative. If at any time a User has questions or concerns about taking an action, call NetBio.

9.3.1 Hardware error

A hardware error could occur if one or more of the system's subcomponents did not pass its Pre Operating System Test (POST) tests during the initial warm up cycle or was not performing within specification during a run.

If a Hardware Error occurs, the system will present a Hardware Error message on the Touch Screen monitor:

If an error message is presented, the User should:

- Record the Error Code number displayed on the message
- Record the description of the error displayed on the message
- Follow the instructions displayed on the error message:
  - Turn off the instrument.
  - Contact a NetBio Service Representative and report the error code and description
  - Do not restart the instrument until instructed to do so.
- Once error code and instructions have been recorded, the error message can be cleared by touching the **OK** button.

9.3.2 Safety interlock error

The ANDE System has safety interlocks to ensure that Users are not able to access the internal components of the instrument while it is operational.

If an Interlock Error occurs, the system will present an Interlock Error message on the Touch Screen monitor:

If an error message is presented, the User should:

- Record the Error Code number displayed on the message.
- Record the description of the error displayed on the message.
- Follow the instructions displayed on the error message:

- Turn off the instrument
- Restart the instrument
- If the error persists, contact a NetBio Service Representative to report the error code and description. Do not restart the instrument until instructed to do so.

- Once error code and instructions have been recorded, the error message can be cleared by touching the **OK** button.

9.3.3 Software error

A Software error may occur when starting up or operating the ANDE System. A Software error usually indicates that there was a communications error where communications could not be established or were lost, or a subcomponent was not responding causing some portion of the system's software to stop working.

If a Software Error occurs, the system will present a Software Error message on the Touch Screen monitor:

If an error message is presented, the User should:

- Record the Error Code number displayed on the message.
- Record the description of the error displayed on the message.
- Follow the instructions displayed on the error message:
  - Turn off the instrument.
  - Restart the instrument (in most cases this should resolve the issue).
  - If the error persists, contact a NetBio Service Representative to report the error code and description. Do not restart the instrument until instructed to do so.
- Once error code and instructions have been recorded, the error message can be cleared by touching the **OK** button.

9.4. Environmental events

In case of fire, earthquake, flood, or any other environmental disaster

- Follow established site-specific emergency procedures
- If appropriate, safely remove power to the system

 **WARNING**
Use of damaged equipment may result in personal injury or death.

 **WARNING**
Damage caused by fire, earthquake or flooding may create electrical hazards that could result in personal injury or death.

 **CAUTION**
If power to the instrument is turned off or lost during DNA analysis, run data will be lost. Do not attempt to re-run a cassette if the run is prematurely terminated.

 **CAUTION**
Do not activate a damaged ANDE instrument until it has been cleared for operation by a NetBio representative.

10. APPENDIX: STR Loci Assayed In The BioChipSet Cassette

The text in this section has been adapted from the Technical Manual of the PowerPlex™ 16 HS System (Instructions for use of products DC2100 and DC2101, June, 2012 version) developed by Promega Corp. The lyophilized PCR reaction within the BioChipSet Cassette uses an optimized version of the PowerPlex 16 HS System to achieve rapid PCR (< 20 min). Just as in conventional PCR, all 16 loci are amplified simultaneously in a multiplexed reaction, and the primer sequences and dyes have not been modified from those of the original PowerPlex kit. Each sample is processed independently within the BioChipSet Cassette via its own lane with its own lyophilized PCR cake.

The loci targeted by the PowerPlex 16 HS System have been selected because they satisfy the needs of several major standardization bodies throughout the world. The United States Federal Bureau of Investigation (FBI) has selected 13 STR core loci to be typed prior to searching or including (submitting) samples in CODIS (Combined DNA Index System). INTERPOL, the European police network, has established a set of seven STR loci (FGA, TH01, vWA, D3S1358, D8S1179, D18S51, D21S11; optional: Amelogenin) as a pan-European standard. The European Network of Forensic Science Institutes (ENFSI) has recommended seven STR loci (FGA, D21S11, TH01, vWA, D8S1179, D18S51 and D3S1358), and GITAD (Grupo Iberoamericano de Trabajo en Análisis de DNA) has recommended six loci (CSF1PO, TH01, TPOX, D16S539, D7S820 and D13S317). The loci amplified in the BioChipSet Cassette include all of these standard loci.

The PowerPlex 16 HS System also contains two low-stutter, highly polymorphic pentanucleotide repeat loci, Penta E and Penta D. These additional loci add to the discrimination power of the system.

The Amelogenin locus is also included to allow gender determination for each sample.

Details of the 16 loci utilized within the BioChipSet Cassette

STR locus	Label	Chromosomal location	GenBank™ locus and locus definition	Repeat sequence* 5' to 3'
Penta E	FL	15q	N/A	AAAGA
D18S51	FL	18q21.3	HUMUT574	AGAA (1)
D21S11	FL	21q11–21q21	HUMD21LOC	TCTA Complex (1)
TH01	FL	11p15.5	HUMTH01, Human tyrosine hydroxylase gene	AATG (1)
D3S1358	FL	3p	N/A	TCTA Complex
FGA	TMR	4q28	HUMFIBRA, Human fibrinogen alpha chain gene	TTTC Complex (1)
TPOX	TMR	2p24–2pter	HUMTPOX, Human thyroid peroxidase gene	AATG
D8S1179	TMR	8q24.13	N/A	TCTA Complex (1)
vWA	TMR	12p13.31	HUMVWFA31, Human von Willebrand factor gene	TCTA Complex (1)
Amelogenin†	TMR	Xp22.1–22.3 and Y	HUMAMEL, Human Y chromosomal gene for Amelogenin-like protein	N/A
Penta D	JOE	21q	N/A	AAAGA
CSF1PO	JOE	5q33.3-34	HUMCSF1PO, Human c-fms proto-oncogene for CSF-1 receptor gene	AGAT
D16S539	JOE	16q24.1	N/A	GATA
D7S820	JOE	7q11.21–22	N/A	GATA
D13S317	JOE	13q22–q31	N/A	TATC
D5S818	JOE	5q23.3–32	N/A	AGAT

*The August 1997 report (2,3) of the DNA Commission of the International Society for Forensic Haemogenetics (ISFH) states, "1) for STR loci within coding genes, the coding strand shall be used and the repeat sequence motif defined using the first possible 5′ nucleotide of a repeat motif; and 2) for STR loci not associated with a coding gene, the first database entry or original literature description shall be used".

†Amelogenin is not an STR but displays a 106-base, X-specific band and a 112- base, Y-specific band.

TMR = carboxy-tetramethylrhodamine FL = fluorescein

JOE = 6-carboxy-4′,5′-dichloro-2′,7′-dimethoxyfluorescein N/A = not applicable

Details of the Allelic Ladder on the BioChipSet Cassette

STR locus	Label	Size range of allelic ladder components (bases)*†	Repeat numbers of allelic ladder components‡
Penta E	FL	379–474	5–24
D18S51	FL	290–366	8–10, 10.2, 11–13, 13.2, 14–27
D21S11	FL	203–259	24, 24.2, 25, 25.2, 26–28, 28.2, 29, 29.2, 30, 30.2, 31, 31.2, 32, 32.2, 33, 33.2, 34, 34.2, 35, 35.2, 36-38
TH01	FL	156–195	4–9, 9.3, 10–11, 13.3
D3S1358	FL	115–147	12–20
FGA	TMR	322–444	16–18, 18.2, 19, 19.2, 20, 20.2, 21, 21.2, 22, 22.2, 23, 23.2, 24, 24.2, 25, 25.2, 26–30, 31.2, 43.2, 44.2, 45.2, 46.2
TPOX	TMR	262–290	6–13
D8S1179	TMR	203–247	7–18
vWA	TMR	123–171	10–22
Amelogenin§	TMR	106, 112	X, Y
Penta D	JOE	376–449	2.2, 3.2, 5, 7–17
CSF1PO	JOE	321–357	6–15
D16S539	JOE	264–304	5, 8–15
D7S820	JOE	215–247	6–14
D13S317	JOE	176– 208	7–15
D5S818	JOE	119–155	7–16

*The length of each allele in the allelic ladder has been confirmed by sequence analyses

†When using an internal lane standard, such as the Internal Lane Standard 600, the calculated sizes of allelic ladder components may differ from those listed. This occurs because different sequences in allelic ladder and ILS components may cause differences in migration. The dye label also affects migration of alleles

‡For a current list of microvariants, see the Variant Allele Report published at the U.S. National Institute of Standards and Technology (NIST) web site at: www.cstl.nist .gov/div831/strbase/

§Amelogenin is not an STR but displays a 106-base, X-specific band and a 112- base, Y-specific band

Internal Lane Standard

The Internal Lane Standard (ILS) run with each sample contains 22 synthetic DNA fragments of 60, 80, 100, 120, 140, 160, 180, 200, 225, 250, 275, 300, 325, 350, 375, 400, 425, 450, 475, 500, 550 and 600 bases in length.

Each fragment is labeled with carboxy-X-rhodamine (CXR) and is detected separately (as a fourth color) in the presence of BioChipSet Cassette amplified material using the DNAscan Rapid DNA Analysis System. The ILS 600 is designed for use in each capillary electrophoresis (CE) injection to increase precision in analyses when using the BioChipSet Cassette.

References

1. Griffiths R. *et al*. New reference allelic ladders to improve allelic designation in a multiplex STR system. *Int. J. Legal Med*. **111**, 267–272 (1998).
2. Bär W. *et al*. DNA recommendations: Further report of the DNA Commission of the ISFH regarding the use of short tandem repeat systems. *Int. J. Legal Med*. **110,** 175–176 (1997).
3. Gill P. *et al.* Considerations from the European DNA Profiling Group (EDNAP) concerning STR nomenclature. *Forensic Sci. Int*. **87**, 185–192 (1997).
4. Details of the allelic ladder incorporated into the BioChipSet Cassette

11. LEGAL

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User Manuals for Use with the ANDE 4C System

ANDE 4C System User Manual Part Number NB-INST-0005-501 Rev B 10/2015 (this manual).

ANDE 4C Health and Safety Manual Part Number NB-INST-0005-502 Rev B 10/2015.

For the most updated version of this manual see
http://www.netbio.com/solutions/biochipset/usermanual.

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Patents: U.S. Patents 8,858,770; 8,720,036; 8,425,861; 8,206,974; 8,173,417; 8,018,593, and other patents pending. For a listing, please see http://netbio.com/science-and-technology/patents-and-trademarks

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