NetBio®

Rapid DNA Analysis™ Solutions

ANDE™ Rapid DNA Analysis™ System

Product User Manual

Product Number: NB-INST-0005

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1. INTRODUCTION

This User Manual provides the instructions required to operate the ANDE Rapid DNA Analysis System instrument safely.

Prerequisites

In order to operate the ANDE Rapid DNA Analysis System instrument in the intended manner, the following prerequisites must be fulfilled:

- User has read and understood the safety instructions outlined in this User Manual and associated Health and Safety Manual (NB-INST-0005-502-check online at www.netbio.com for most updated versions of manuals).
- ANDE instrument has been installed according to the instructions in this User Manual.

About this chapter

This chapter contains important User information, description of safety notices, regulatory information, and a general description of the intended use of the ANDE Rapid DNA Analysis System instrument.

1.1. Overview of the ANDE System

NetBio has developed a platform system for fully automated and rapid human identification that integrates and automates all of the traditional DNA forensic laboratory process steps to create an easy to use, field-forward DNA analysis capability for operation by non-technical personnel outside a formal laboratory environment. The ANDE System is operated by inserting 5 buccal swab samples into a BioChipSet Cassette, placing the BioChipSet Cassette into the ANDE instrument, and then closing the BioChipSet access door to initiate a run. The ANDE instrument contains all the subsystems required to perform STR analysis. The BioChipSet Cassette is a fully integrated lab-on-a-chip that uses microfluidic technology to integrate all of the process steps required to generate STR profiles. The major attributes of the ANDE System are:

- The ANDE System produces STR profiles in 84 minutes and can be operated by a non-technical user with minimal training.
- The System generates full profiles using 16 STR loci (including 13 CODIS loci) and is designed to securely transfer data to a user workstation for DNA profile searches and matching.
- The BioChipSet Cassette contains all reagents on-board. The user neither loads the instrument nor the BioChipSet Cassette with reagents. Several reagents are lyophilized (e.g. amplification reaction mix) and others are in liquid form (e.g. purification reagents). The BioChipSet Cassette is stable for 6 months at room temperature.
- The BioChipSet Cassette is closed: Each buccal sample is processed through its own sealed processing path, and samples and reagents do not come in contact with the instrument itself.

- The BioChipSet Cassette is a single part; the operator has nothing to connect. It is a single-use plastic disposable—no washing or opening of the disposable is required, minimizing the possibility of run-to-run contamination.
- The ANDE instrument is ruggedized for transport and shock and has been tested in accordance with Military Standard 810F. No routine alignment or manual recalibration is required following transport or after installation.
- The instrument contains an on-board computer and touchscreen monitor. It includes a sample tracking system, internal database to store STR profiles, and GPS-derived tagging of data products with location and time data. The instrument's connectivity and tagging can be configured based on user requirements.
- The instrument has on-board software for automated signal processing and an on-board Expert System for data analysis and conversion of electrophoretic traces to CODIS/NDIS compatible STR profiles.
- The instrument provides data security and privacy protection by employing database encryption for the on-board database, data export encryption, tiered User classes for controlled access to STR profile data, partitioned manufacturer/customer system access to protect customer data, and an ANDE Data Management software for controlled data decryption and management.

ANDE System specifications:

- Sample Types: Fresh and dried buccal swabs and purified DNA
- Processing Capacity: 5 samples per BioChipSet Cassette
- Set-up Time: 15 minutes from uncrating to operation*
- Dimensions: ≤6 cubic feet; 26.6" x 16.5" x 23.1"
- Weight: 51.3 kg (113 lb)

* *Set-up time does not include time to install the ANDE Data Management Software (ADMS) and encryption/decryption certificates.*

1.2. Important User information


Read this section before using the ANDE Rapid DNA Analysis System instrument.

All Users must read the safety instructions in the ANDE Rapid DNA Analysis System instrument User Manual and accompanying Health and Safety Manual (NB-INST-0005-502) before installing, using, or maintaining the ANDE instrument.

NOTE: Users should operate the ANDE Rapid DNA Analysis System instrument only as described in this User Manual. Failure to operate the ANDE instrument in the approved manner may expose the User to hazards that can lead to personal injury and may cause damage to the ANDE instrument.

1.2.1. Intended use

This manual is written for people who will process human buccal or blood samples collected on NetBio BioChipSet™ Swabs using the ANDE instrument to generate DNA profiles for human identification (HID). It provides step-by-step instructions on how to operate the ANDE instrument in conjunction with its associated consumables (BioChipSet Cassettes and ANDE Collection Kits).

This instrument is not to be used in clinical procedures or for diagnostic purposes.

1.2.2. Safety notices

This User documentation contains WARNINGS, CAUTIONS and NOTICES concerning the safe use of the product. See definitions.

Warnings

WARNING

Indicates a hazardous situation that, if not avoided, could result in death or serious injury.

It is important not to proceed until all stated conditions are met and clearly understood.

Cautions

CAUTION

Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

It is important not to proceed until all stated conditions are met and clearly understood.

Notices

NOTICE

Indicates information that is important for the use of the product.

A notice indicates instructions that must be followed to avoid damage to the product or other equipment.

1.2.3. Acronyms, abbreviations, and terms

Acronyms, abbreviations, and product- or technology-related terms are spelled out and explained at first occurrence in this manual. The following table is a list of acronyms, abbreviations, and terms related to ANDE Rapid DNA Analysis System instrument design and operation.

Acronym	Term	Description
ADMS	ANDE Data Management Software	Software for the management of ANDE data on a standalone computer
	Buccal	From inside of cheek
CFR	Code of Federal Regulations	The codification of the general and permanent rules published in the Federal Register by the departments and agencies of the United States government
CMF	Common Message Format	A file formatting standard for packaging of information for import into CODIS based on Extensible Markup Language (XML)
CODIS	Combined DNA Index System	The FBI's program of support for criminal justice DNA databases as well as the software used to run these databases
DNA	Deoxyribonucleic acid	Inherited (genetic) information in humans and most other organisms
DVI	Digital Visual Interface	Digital video connection to high-quality display devices
ES	Expert System	Automated software used in the ANDE Rapid DNA Analysis System instrument that interprets electropherograms and generates called STR profiles
ESD	Electro-Static Discharge	Sudden flow of electricity between two objects with different electrical potentials
EMC	Electro-Magnetic Compatibility	Means that an instrument does not emit electromagnetic energy that interferes with other instruments
FBI	Federal Bureau of Investigation	United States governmental agency concerned with national security and law enforcement
GPS	Global Positioning System	Satellite navigation system to provide location information
GUI	Graphical User Interface	The touchscreen computer and software that allows the User to interact with the ANDE instrument
HID	Human Identification	Use of DNA analysis results, conventional fingerprints, or other modalities to identify individuals
NDIS	National DNA Index System	A United States FBI DNA database that facilitates the electronic comparison and exchange of DNA profiles between participating local, county, state, and federal law enforcement agencies and forensic laboratories
NRTL	Nationally Recognized Testing Laboratory	Laboratory recognized by OSHA as meeting specific legal requirements
OSHA	Occupational Safety and Health Administration	A part of the United States Department of Labor that establishes, issues, and enforces national workplace safety regulations
PCR	Polymerase Chain Reaction	A process in which small stretches of DNA are copied

		(amplified)
POST	Power On Self Test	Instrument self-diagnostic test performed upon power up of the ANDE instrument
RFID	Radio Frequency Identification	Technology that uses electronic tags to collect and store data
RH	Relative Humidity	The amount of water vapor present in the air divided by the amount the air can hold; expressed as a %
STR	Short Tandem Repeat	Short DNA sequences that are repeated multiple times and are widely found throughout the human genome. The lengths of STRs can vary and are passed from parent to child
STR profile	Short Tandem Repeat profile	An STR profile is defined as the result of the analysis of a standardized set of STR loci. An STR profile of an individual is unique (except for cases of identical twins). An STR profile can also be called a "DNA profile" or a "DNA fingerprint"
SWGDAM	Scientific Working Group on DNA Analysis Methods	A group of forensic scientists that evaluates forensic biology methods, protocols, training, and research to enhance forensic biology services and provides recommendations to the FBI Director on quality assurance standards for forensic DNA analysis
USB Drive	Universal Serial Bus drive	A data storage device that includes flash memory with an integrated USB interface. Also known as a flash or thumb drive
UPS	Uninterruptible Power Supply	System to prevent loss of power to instrument during a run (not provided with instrument)
WEEE	Waste Electrical and Electronic Equipment	A European Commission directive for handling electronic waste

1.2.4. User Manual format

Throughout this manual, certain text formatting indicates commands and highlights various graphic user interface (GUI) elements:

- Menu options, window/dialog box titles, and graphical button names appear in bold face. For example, **System, Log in** dialog, **Start** button.
- The text of onscreen prompts and messages will be italicized and in quotes. For example, *"It is now OK to turn off power."*
- Text referring to keyboard keys appears in bold face and will be italicized. For example, Press ***Enter*** to continue.
- Whenever this manual directs the User to "Press" or "Touch" Buttons, Menu Options, or List Items, it is referring to the User lightly touching the screen to activate on-screen items.

1.3. Regulatory information

This section describes the directives and standards that are fulfilled by the ANDE Rapid DNA Analysis System instrument.

1.3.1. Manufacturing information

The table below summarizes the required manufacturing information:

Name and address of Manufacturer	
NetBio	NetBio 266 Second Ave Waltham MA 02451 USA

1.3.2. International safety standards

This product fulfills the requirements of the following standards:

Standard	Description	Notes
IEC 61010-1, EN 61010-1, IEC 61010-2-081, IEC 61010-2-010, UL 61010-1, CAN/CSA-C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use	EN 61010-1 harmonized with 2006/95/EC
EN 61326-1, IEC 61326-1, FCC Part 15 B	Electrical equipment for measurement, control and laboratory use Electromagnetic Compatibility (EMC) requirements	EN 61326-1 harmonized with 2004/108/EC
IEC 60825-1	Laser safety	
FCC 47CFR 15C, RSS 210, ETSI EN 300-440, ETSI EN 300-330	Radio frequency testing	

1.3.3. Environmental conformity

This product complies with the European directives listed in the table, by fulfilling the corresponding harmonized standards:

Directive	**Title**
2002/96/EC	Waste Electrical and Electronic Equipment (WEEE) Directive (category 9)

1.3.4. Regulatory compliance of connected equipment

Any equipment connected to the ANDE instrument should meet the safety requirements of EN 61010-1/IEC 61010-1, or relevant harmonized standards. Within EU, connected equipment must be CE marked.

2. SAFETY INSTRUCTIONS

The Health and Safety Manual for this product describes safety precautions, safety labels, and emergency procedures for the ANDE Rapid DNA Analysis System instrument, in addition to providing information on the safe disposal of the ANDE instrument.

See Health and Safety Manual (NB-INST-0005-502).

Operator/Maintainer responsibility

This instrument design provides numerous safety features that protect operating personnel and protect the system from damage, including interlocks on covers and doors. It is impossible, however, to provide complete protection for every situation. Review this chapter to familiarize yourself with all the safety and operation requirements.

Introduction

During regular operation, the ANDE Rapid DNA Analysis System instrument uses high voltage and a high-power laser. It is used to generate STR profiles using disposable items (consumables) that may be hazardous. Before installing or operating the ANDE instrument, the User must be aware of the hazards described in the User Manual and Health and Safety Manual for ANDE Rapid DNA Analysis System instrument. Follow the instructions provided to avoid personal injury or damage to the instrument.

2.1. Safety precautions

2.1.1. General precautions

WARNING

Do not use the ANDE instrument if smoke, strange noises, or strange odors are observed or if the instrument becomes unusually hot. Use under these circumstances may result in fire or electric shock.

Stop using the instrument immediately, turn off the power switch, and unplug the instrument from the power outlet. Contact your NetBio representative to request repair.

WARNING

Do not damage the power supply cord by bending, twisting, heating or allowing it to become pinned under the instrument. Using damaged power cords could result in fire or electric shock.
If the power supply cord is damaged, contact your NetBio representative for a replacement.

WARNING

Access to power switch and power cord with plug.
Do not block access to the power switch and power cord. The power switch must always be easy to access. The power cord with plug must always be easy to disconnect.

CAUTION
Do not defeat interlocks or other built-in equipment safety features.

CAUTION
Use of this ANDE instrument in ways other than those specified in the user documentation may result in hazardous laser radiation exposure.

CAUTION
Do not block the vents, and ensure that the vents are kept free of dust and dirt. Blockage of the vents can result in overheating of the instrument and malfunction. Place the instrument so that there is at least 20 cm in front of the machine to the walls or other instrument, and 10 cm on all other sides to ensure adequate cooling.

NOTICE
This instrument is generally intended for indoor use.

2.1.2. Personal protection

CAUTION
If the door is opened and the interlock has been tampered with, laser light may be emitted. Never look into the laser light source or at scattered laser light from any reflective surface.

CAUTION
Always wear gloves when handling BioChipSet Cassettes and NetBio BioChipSet Swabs.

2.1.3. Installing and moving the ANDE instrument

WARNING
Use a proper power cord that complies with the local laws and regulations and is delivered by NetBio. Do not use any other power cord.

WARNING
Connect the power supply directly to a grounded wall power outlet. The use of extension cords or multiple loads on one electrical outlet could result in fire and electric shock. Optionally, the User may employ a suitable Uninterruptible Power Supply (UPS) system (not provided with the instrument).

CAUTION
Do not place the instrument on unstable tables or on inclined surfaces as the instrument could be tipped over or fall, resulting in instrument damage or injury.

CAUTION
Turn off the power switch, remove the power cord, and disconnect computer connections before moving the instrument.

2.1.4. Operation

WARNING
Do not use the instrument near a sink or in areas potentially containing explosive gases because fire and electric shock could result.

WARNING
Do not eat or drink around the instrument. Do not set liquids on the instrument. Spilling of liquids on or around the instrument could cause damage and electrical hazards.

WARNING
Do not place liquids on or around the instrument. These may spill and cause electric shock.

WARNING
Do not place instrument on a wet surface. This may cause electric shock.

CAUTION
BioChipSet Cassettes and BioChipSet Swabs should be used in accordance with the relevant Instructions for Use (IFU).

CAUTION
Do not lean on the ANDE instrument or its BioChipSet Cassette Access Door because this may cause damage to the instrument or may cause the instrument to fall off its surface and injure the User.

CAUTION
Use the handle when opening or closing the BioChipSet Cassette Access Door. Take care not to catch objects or fingers in the door when closing.

CAUTION
Immediately remove the BioChipSet Cassette from the instrument after completion of the run. If a used cassette is left in the instrument it may degrade and damage the instrument.

CAUTION
Do not place heavy objects on the instrument. These may fall and cause injury.

2.1.5. Maintenance

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

WARNING
Do not open the ANDE instrument or attempt to modify the ANDE instrument. Doing so will void the warranty and may result in fire and electric shock.

WARNING
The user should not attempt to clean inside of the ANDE instrument. If required, cleaning the internal

components of the instrument should be carried out by qualified NetBio personnel only.

WARNING
Do not use excessive amounts of liquids for external cleaning of the ANDE instrument. This may result in product malfunction or electric shock.

CAUTION
Wear gloves while cleaning the exterior of the ANDE instrument.

CAUTION
Wear gloves when handling used BioChipSet Cassettes to prevent direct contact with chemical substances.

CAUTION
Turn the power switch off before cleaning the exterior of the ANDE instrument.

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 touchscreen monitor. This may cause the surface to break and lead to injury.

NOTICE
Do not use abrasive cleaning materials, such as a scouring pad, for external cleaning. This may scratch the surface.

2.2. Labels

The ANDE Rapid DNA Analysis System's serial label is located on the back of the instrument and describes certain electrical specifications. Inside the instrument's BioChipSet Cassette Access Door and within the internal components are a series of warning and hazard symbols. This section lists the symbols used outside of and inside the ANDE instrument. The User should review this section carefully to be fully informed of all warning and hazards associated with operating the instrument.

ANDE Rapid DNA Analysis System instrument serial number

The ANDE Rapid DNA Analysis System instrument serial number is located on the serial label that is on the back of the instrument.

ANDE Serial Label

2.2.1. Symbols used on the ANDE instrument

The following symbols are used:

	**WARNING!** Read the User Manual and accompanying Health and Safety Manual before using the ANDE instrument. Do not open any covers or replace parts other than the air filter.
	This symbol marks the date of manufacture.
	Consult instructions before use.
	Indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized NetBio representative for information concerning the decommissioning of the ANDE instrument
	Indicates that the ANDE instrument has been certified by a Nationally Recognized Testing Laboratory (NTRL). An NRTL is an organization that

	the Occupational Safety and Health Administration (OSHA) has recognized as meeting the legal requirements in USA title 29 of the Code of Federal Regulations (29 CFR) Part 1910.7.
	Provides warning against actions or situations that could result in contact with electrical circuits, causing personal injury or death.
	Provides warning against actions or situations that could result in direct eye exposure to a laser beam, causing eye injury or blindness. Diffused reflections from mirrors or lenses may also be harmful.
	Provides warning of potential mechanical impact, crush hazard, or potential pinching injury.
	Provides warning against contact with potentially hot surfaces or other burn hazards.
	Alerts the User to the danger of Electro-Static Discharge (ESD) susceptibility.
	Provides Class 1 laser product information. See Health and Safety Manual for additional information.
 	Provides Class 3B laser caution in both French and English to comply with international standards. See Health and Safety Manual for additional information.
I O	Informs the User whether the power switch is ON (I) or OFF (O).

	Informs the User that a two-person lift is required.
	Provides manufacturer information, including serial number and date of manufacture.
CE	The CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC directives.
	The Regulator Compliance Mark (RCM) is a visible assertion that the equipment complies with the requirements imposed by regulations in Australia and New Zealand
FC	The Federal Communications Commission marking is a certification mark that certifies that the electromagnetic interference from the device is under the limits approved by the United States FCC.
	Informs the User of required transportation and storage conditions

The U.S. Federal Communications Commission and Industry Canada Certification for Radio and Broadcasting Equipment require the following warning to be declared, please read carefully:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

French Translation:
Cet équipement a été testé et s'est avéré conforme aux limites pour un appareil numérique de classe B, conformément à la section 15 des règles de la FCC. Ces limites sont conçues pour fournir une protection raisonnable contre les interférences nuisibles dans le contexte d'une installation résidentielle . Cet équipement génère, utilise et peut émettre une énergie de radiofréquence et, s'il n'est pas installé et utilisé conformément aux instructions, il peut causer des interférences nuisibles aux communications radio. Cependant, il n'existe aucune garantie que des interférences ne se produiront pas dans une installation particulière. Si cet équipement provoque des interférences nuisibles à la réception radio ou télévision, ce qui peut être déterminé en éteignant et en allumant l'équipement, l'utilisateur est encouragé à essayer de corriger l'interférence par une ou plusieurs des mesures suivantes:

- *Réorienter ou repositionner l' antenne de réception.*
- *Augmenter la distance entre l'équipement et le récepteur.*
- *Brancher l'équipement dans une prise sur un circuit différent de celui sur lequel le récepteur est branché.*
- *Consulter le revendeur ou un technicien radio / Télévision expérimenté.*

Changes or modifications made to this equipment not expressly approved by NetBio Inc. could void the user's authority to operate the equipment.

2.2.2. Position of Safety labels and additional symbols

Safety warning symbols visible with front access door open:

1.		Electrical Hazard
2.		Laser Caution
3.		Anti-Static
4.		Impact/Crush/Pinch Point Hazard
5.		Thermal Hazard

Safety warning symbols and labels visible on back panel:

1.		Class 3B laser.
2.		Class 1 laser.
3.	**I** **O**	Power ON/OFF
4.		Two-Person Lift
5.		Manufacturer Information
6.		Refer to User Manual
7.		ETL Safety Compliance

Safety labels for the laser system include DANGER text and Laser Warning symbol on the body of the laser system case (Internal system—will not be visible to Users).

ANDE instrument transportation case symbols:

	**Keep away from sunlight**
	**Fragile contents**
	**This way up indicator**
	**Keep package dry**
	**Do not stack**
	**Temperature storage range**
	**Humidity storage range**
	**Multi-person lift**

2.3. Emergency procedures

In case of emergency turn off the ANDE Rapid DNA Analysis System instrument power switch and disconnect the power cord from the wall socket.

2.4. Recycling information

This section contains information about the decommissioning of the ANDE instrument.

2.4.1. Decontamination

The ANDE instrument exterior and accessories must be clean from contaminants before decommissioning, and all local regulations must be observed with regard to waste disposal.

The used BioChipSet Cassettes should be handled and disposed of according to state, regional or local regulations. See relevant BioChipSet Cassette documentation.

2.4.2. Disposal, general instructions

When taking the ANDE Rapid DNA Analysis System instrument out of service, the different materials must be separated and recycled according to U.S. Federal, State, and local environmental regulations. For outside the U.S., National and local environmental regulations should be observed.

2.4.3. Disposal of electrical components

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of the ANDE instrument.

3. SYSTEM DESCRIPTION

NOTICE
All images contained in this manual, including photographs, diagrams, and ANDE instrument screen shots, are for reference only. Refer to NetBio's web site for the most current version of this User Manual.

About this chapter

This chapter contains information on the ANDE Rapid DNA Analysis System hardware components, software, and consumables.

DNA profiling overview

Most human DNA is identical from person to person. However, certain regions of the human genome do vary, and the small differences in these regions can be used to identify an individual. For more than two decades, DNA profiling, the identification of an individual based on an analysis of his or her DNA, has become the evidentiary gold standard throughout the world.

The most commonly used method to generate a DNA profile is based on one type of variable region termed the Short Tandem Repeat (STR). The human genome contains hundreds of thousands of STRs, and a given STR may vary in size from person to person. Each person has a unique set of STRs, just as each person has a unique fingerprint. In fact, STR profiles are sometimes referred to as "DNA fingerprints" for this reason. Only identical twins share identical STR profiles. An excellent summary of the molecular biology of STRs can be found on a website created by the National Institute for Standards and Technology (http://www.cstl.nist.gov/strbase/).

Several countries have selected sets of specific STRs to be used in identification for law enforcement and other applications. Country- or agency-specific loci for use in the ANDE Rapid DNA Analysis System have been selected because they satisfy the needs of several major law enforcement agencies throughout the world. Each STR selected has a defined position on a human chromosome, and the position is referred to as an STR "locus." For example, in 1997, the FBI defined a set of 13 STR loci, often referred to as the "CODIS loci". See "Chapter 10. STR Loci Assayed in the BioChipSet Cassette" for additional information.

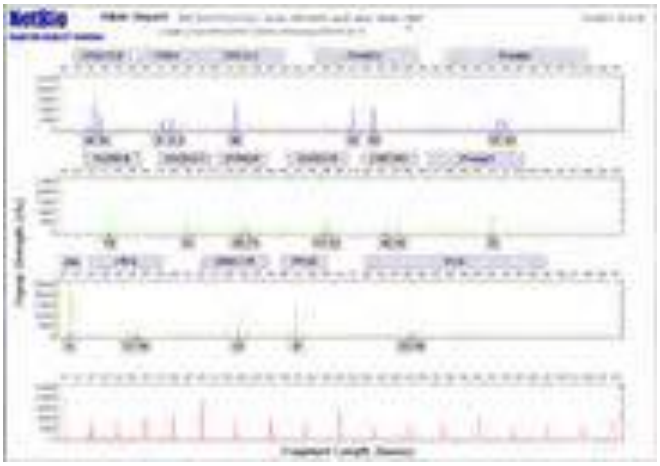
STR profiles are generated by a series of three basic processes. First, DNA is purified from the cells on a sample swab. This involves breaking open the cells and removing proteins and other cellular materials. Second, the set of STR loci are copied (amplified) using a process known as Polymerase Chain Reaction (PCR). During PCR the amplified STR regions are modified by the addition of a fluorescent dye. Depending on the STR locus, one of three dyes is added. The use of these three dyes (plus a fourth to help calculate the size of the STR fragments) allows laser-based detection.

The size of the copied STR fragments is determined by electrophoresis. The STR fragments are pulled by an electric current through a gel-like substance, and the smaller fragments travel more quickly through the gel than the larger fragments. At a detection window, a laser is used to excite the four fluorescent dyes. The dyes give off light, which is then detected and used to determine the size of each STR fragment. An Expert System analyses the size pattern and generates the final STR profile--the individual's DNA fingerprint.

After STR profiles are generated using the ANDE Rapid DNA Analysis System the results can be collected and compared in local, state, national, or international DNA databases. Profiles recovered from forensic evidence collected at crime scenes can also be uploaded, and comparisons can be made to link suspects to one or a series of crime scenes.

The sensitivity, specificity, and reliability of STR technology has led to the widespread use of DNA profiles to match criminal suspects with evidence samples in criminal investigation, exonerate the innocent, determine paternity, and reunite families.

Note: For purposes of human identification, the terms DNA analysis, DNA or STR typing, DNA fingerprint, and DNA or STR profile are often used interchangeably.



Electropherogram of an STR profile generated using the ANDE Rapid DNA Analysis System.

3.1. DNA analysis using the ANDE Rapid DNA Analysis System - overview

The system consists of three components:

1. An ANDE instrument that tracks samples, interfaces with the BioChipSet Cassette, controls all process steps within the BioChipSet Cassette used to perform STR profiling, processes data and analyzes the results using automated on-board Expert System software, and stores and transmits data from STR profiles.

2. A disposable BioChipSet Cassette that contains all required reagents for STR profiling and accepts five sample swabs. Each BioChipSet Cassette also contains a pre-loaded allelic ladder sample.

3. BioChipSet Swab for sample collection. The swab is specifically designed for use with the BioChipSet Cassette.

Via the User Touch Screen, the User interface software provides step-by-step graphical depictions and instructions to the User for each step required to load the samples and perform a run. There are no manual manipulations after the User inserts the BioChipSet Cassette into the ANDE instrument. The

ANDE instrument has an RFID system to track the placement of each sample to ensure there is no sample mix up during the loading procedure.

Each BioChipSet Cassette will process up to five (5) samples. If fewer than five samples are available for a run, blank swabs (unused) should be loaded into the Swab Chambers. The ANDE instrument is configured for data export by a USB drive or via a direct Ethernet connection to a laptop or desktop computer.

3.2. ANDE System overview

3.2.1 ANDE Instrument

The ANDE instrument integrates all the subsystems required for the completion of STR analyses. These integrated components include high and low voltage power, thermal cycling, pneumatic, optical, ruggedization, process control, and computer subsystems. The instrument interfaces with the BioChipSet Cassette using a number of features, including a pneumatic manifold (to allow fluids to be driven), a thermal plate (to maintain an appropriate temperature during electrophoresis), a PCR chamber (to allow for efficient heat transfer for rapid STR amplification), an optical excitation and detection window (to allow laser-induced detection of separated STR fragments), and electrical connections (to allow electrophoresis). The instrument has on-board software for automated signal processing and an on-board Expert System for data analysis and conversion of electrophoretic traces to CODIS/NDIS compatible STR profiles. Upon completion of sample processing, the data will be automatically processed and the Expert System will designate alleles, generate the STR profiles, and produce files for database searching.

The ANDE instrument has been ruggedized according to U.S. Military Standard 810F for transportation vibration and shock, and as such requires no routine alignment or manual recalibration is required following transport or after installation. It can be carried via a two-person lift using the two carrying handles located on the sides of the instrument. The instrument is easy to install: the user simply removes it from is transport case, plugs it in, and turns on the power switch. The system will perform an initial 15 minute warm-up cycle to assess the various subsystems. After completion of the warm up, the system is ready to begin processing samples.

The modular nature of the ANDE Rapid DNA Analysis System provides a customizable foundation for STR profiling that supports future expanded forensic sample analysis capabilities.

3.2.1.1. ANDE instrument external features

External features of the ANDE instrument include:

1. User Touch Screen.
2. RFID Reader.
3. BioChipSet Cassette Access Door.
4. Carrying Handles (also on opposite side).
5. GPS Window.
6. Key Lock.
7. Cooling vents.
8. On/Off Switch and Power Connector
9. Cooling Fan
10. Computer Connections

Features on the Front of ANDE Instrument

Features on the Back of ANDE Instrument

The information below describes in detail the ANDE instrument external features:

1. **User Touch Screen:** When the ANDE instrument is powered on, this screen provides the User with graphical depictions and instructions for logging in, sample loading, placing the BioChipSet Cassette into the ANDE instrument, and, following process completion, removing the BioChipSet Cassette from the ANDE instrument.

    - The ANDE instrument utilizes a touch screen monitor for information display and ANDE instrument control. The User firmly touches the screen to activate on-screen control buttons.

    - For data entry, such as log in name and password or entering sample ID information, a virtual keyboard appears on-screen.

2. **RFID Reader:** As a part of the sample loading process, each swab is scanned by the RFID reader to electronically identify individual swabs. When instructed by the on-screen GUI, the blue plastic cap of each NetBio BioChipSet Swab should be placed in front of the RFID reader located just below the touch screen.

The blue cap of each Swab contains an RFID chip that, once scanned, will track the placement of the swab within the BioChipSet Cassette so that the User does not have to keep track of the swab chamber into which each sample is placed. This tracking system minimizes the possibility of sample mix up.

The default system setting for this feature is RFID on. RFID tracking can be turned off by a SuperAdmin via the Configure System function on the SuperAdmin Menu screen. See "Chapter 6.x" for more information.

3. **BioChipSet Cassette Access Door:** After loading the 5th sample into the BioChipSet Cassette, the access door opens automatically to allow the BioChipSet Cassette to be placed inside the ANDE instrument. The door is closed manually by the User and is locked automatically by the System Software. The run is then initiated automatically. When a run is complete, the access door opens automatically to allow removal of the BioChipSet Cassette. After the BioChipSet Cassette is removed, the User should close the door. The User Access Door is hinged and swings up to open and down to shut. The door is equipped with an interlock mechanism that is automatically engaged once a BioChipSet Cassette is loaded and the door is shut to ensure the door remains locked during testing to ensure User safety and ANDE instrument integrity.

   The Access Door is hinged and swings up to open and down to shut. The door is equipped with an interlock mechanism that is automatically engaged once a BioChipSet Cassette is loaded and the door is shut. This process keeps the door locked during operation to ensure User safety and ANDE instrument integrity.

NOTICE
The BioChipSet Cassette Access Door cannot be opened during instrument runs.

CAUTION
The BioChipSet Cassette Access Door will open automatically at completion of DNA processing. Do not block the door. Do not force the door.

4. **Carrying Handles:** The ANDE instrument can be moved using these handles. Two people are required to lift the instrument, one person holding each handle. The stand-alone ANDE Rapid DNA Analysis System instrument weighs 51.3 kg/113 lb.

5. **GPS Window:** The default system setting for this feature is GPS on. GPS can be turned off by a SuperAdmin via the Configure System option on the SuperAdmin Menu screen. See "Chapter 6.x." for more information.

NOTICE
In general, GPS systems do not perform well in indoor locations. High power radio, TV, and radar signals and other strong electrical or magnetic fields, tall trees, and buildings may also interfere with GPS reception.

6. **Key Lock:**

The Key Lock for use by qualified NetBio Service Personnel only.

NOTICE

Users should not attempt to open the ANDE instrument via the key lock. Doing so will void the warranty. Tampering with internal components of the instrument may result in fire and/or electric shock. Only qualified NetBio personnel should open the ANDE instrument.

7. **Cooling Vents:**

Cooling vents allow appropriate air circulation while the instrument is operational.

NOTICE

Keep cooling vents clear from obstruction and debris to maintain optimal instrument performance.

8. **On/Off Switch and Power Connector:**

Power Switch: On/Off rocker switch; C20 male power cable inlet for IEC-C19 cable.

9. **Cooling Fan:**

An air filter covers the cooling fan externally.

10. Computer Connections:

	Connector Connections* / Description
A	Standard PS/2 DIN connectors
B	COM1 (Top) - Serial port connector x 1 D-sub 9-pin, male
C	COM2 (Bottom) - Serial port connector x 1 D-sub 9-pin, male
D	DVI-D port - Digital graphical output
E	VGA port - Analog graphical output
F	Ethernet ports: LAN1 LAN2 - Gigabit connection to a Local Area Network (LAN)
G	USB Ports 1, 2, 3, 4 (USB 2.0 Compliant)
H	Line In
I	Speakers
J	Microphone

* With the exception of the USB, PS/2 and LAN ports, external connections are only for use qualified NetBio personnel.

3.2.1.2. ANDE instrument subsystems

Subsystems of the ANDE instrument include:

1. **Computer:** Manages the graphical User interface, STR profiling, database management, reporting systems, external communications, secure log in, safety and interlocks, and other ANDE instrument operations.
2. **Process Control:** Manages process sequencing, subsystem coordination, and device interfaces.
3. **Pneumatic:** Drives fluids through the BioChipSet Cassette by applying air pressure.
4. **Thermoelectric Cooler:** Performs rapid temperature cycling for the amplification of STR fragments.

5. **Optical:** Consists of a 200 mW, 488 nm laser, detectors, and optical train. It provides laser excitation and fluorescent detection of dye-labeled DNA molecules that travel electrophoretically along the separation channels to the excitation and detection window of the BioChipSet Cassette.

6. **High and Low Voltage Power Supply:** Provides power to the various subsystems.

7. **Ruggedization:** The ANDE instrument has been ruggedized according to U.S. Military Standard 810F for transportation vibration and shock, and as such requires no routine alignment or manual recalibration is required following transport or after installation.

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

3.2.1.3. ANDE instrument specifications

The ANDE instrument is a standalone, computer-controlled, electromechanical instrument.

Internal Memory	Capable of storing results from 1000 runs (5000 samples and associated run data)
External Connections	USB 2.0 GPS (USB 2.0, L1 frequency reception; sensitivity > -150 dBm) Wi-Fi 802.11; Ethernet (RJ45 10/100/1000 megabit data rates); SVGA, DVI
Security	Multiple Encryption systems for stored data; WPA2 encryption Strong passwords; Secure logging of all accesses to local database
Weight/Dimensions (without shipping container)	51.3 kg (113 lb) with dimensions 67.6 (W) × 41.9 (H) × 57.4 (D) cm (26.6” (W) × 16.5” (H) × 22.6” (D))
Weight/Dimensions (in hard transport)	80 kg (177 lb) with dimensions 101.6 (L) x 91.4 (W) x 96.5 (H) cm (40” (L) x 36” (W) x 38” (H))
Power	100 to 240 V +/-10%, (50 or 60 Hz) line power; < 5 A peak load at 120 V (60Hz) line power, < 3 A peak load at 230 V (50 Hz) line power Power cables with plugs fitted for the United States, EU, and United Kingdom are supplied with the ANDE instrument: IEC-320-C19 / NEMA 5-15 plug / 3×14 AWG SJTW cable for 125 V, 15 A (U.S.) or equivalent IEC-320-C19 / CEE 7 plug / H05VV-F cable for 230 V, 16 A (EU) or equivalent IEC-320 EN 60320 C19 to UK plug / BS1363A cable for 200-240 V, 16 A (UK) or equivalent Generator: Sine wave AC power ONLY, as rated above. Uninterruptable Power Supply (UPS): double conversion

	recommended (not supplied with the ANDE instrument)
Altitude	Operating range is 1000 ft below sea level to ~10000 ft (1060 mbar to 700 mbar)
Operating Temperature	Climate controlled environment at 20–30°C (68–86°F)
Humidity	Operating range is 20–80% relative humidity (RH), non-condensing
Ruggedization	No recalibration or optical realignment is required following transport and hand carry. The ANDE Rapid DNA Analysis System instrument will run a self-test upon power up. The ANDE instrument conforms to the following conditions under U.S. Military Standard 810 F: (1) Transportation Vibration: Method 514.5, Category 4 in the U.S. highway truck vibration exposures. Table 514.C-VII, Figure 514.5C-1, (2) Shock: Method 516.5, Procedure II, (3) Bench Handling Test: Method 516.5, Procedure VI, (4) Fragility: Method 516.5, Procedure III, paragraph 4.5.4.b
Inputs	Up to five (5) buccal samples on NetBio BioChipSet Swabs, plus one pre-loaded allelic ladder
Output Format	STR profiles with 16 loci, including 13 core CODIS/NDIS loci. Four files are created for each sample - .xml (in common message format for CODIS compatibility), fsa, .png, and .csv. (Customizable data formats available upon request.)

NOTICE

IMPORTANT: Maximum storage temperature is 50°C (122°F) for the ANDE instrument.

3.2.2. ANDE Expert System Software

The Expert System (ES) software makes all allele assignments without assistance or interpretation from a forensic analyst. It comes installed on the ANDE instrument and is fully integrated into the sample-in to results-out process flow of the ANDE Rapid DNA Analysis System. An important characteristic of this software that distinguishes it from conventional ES packages is that it does not require any User interactions to generate STR profiles.

The ES software automatically delivers the results in four files formats to simplify data export and handling:

- 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 .csv file (Microsoft Excel™ compatible).

3.2.3. ANDE System Software

The ANDE System comes with an on-board User account management system that supports three types of Users:

- **Operator** accounts allow the User to perform runs and export encrypted data files. Operators do not have access to STR profiles generated by the system.
- **Admin** accounts allow the User to perform runs, create and manage Operator accounts, export encrypted data files, and view STR profiles generated by the system.
- **SuperAdmin** accounts provide access to all User functions and allow the User to perform runs, create and manage Operator and Admin accounts, export encrypted data files, view STR profiles generated by the system, set the system's configurable features, and create and modify the system's data encryption/decryption certificates.

Below is a complete table of the ANDE system software features and associated User privileges:

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

See "Chapter 6. ANDE User Account Management: Features and Functionality" for more information about specific features and for instructions on software use.

3.2.4. ANDE Data Management Software

The ANDE Rapid DNA Analysis System includes the ANDE Data Management Software (ADMS), which can be installed on multiple computers by a SuperAdmin to allow management of ANDE data at a wide range of locations based on operational requirements. The ADMS allows Users to:

- Import, decrypt, and manage data directly from a laptop or desktop computer that is connected to the ANDE instrument via an Ethernet connection
- Import, decrypt, and manage data from a USB drive used to export data from the instrument
- Create, export, and manage encryption/decryption certificates

Below is a complete table of ADMS features and associated User privileges:

User account privilege		Operator	Admin	SuperAdmin
MANAGE DATA				
View data	View lane success results	•	•	•
	View run data		•	•
Encrypted data: import to DDMS Data Repository or move (export) to computer's desktop	Encrypted run data	•	•	•
	Encrypted run reports	•	•	•
	Encrypted telemetry data	•	•	•
	Encrypted optical data		•	•
	Encrypted usage data			•
Encrypted data: Decrypt and move (export) to computer's desktop	Decrypt and move run data		•	•
	Decrypt and move usage data			•
DELETE DATA				•
MANAGE USER ACCOUNTS				
Add User accounts	Add Operator accounts		•	•
	Add Admin accounts			•
	Add SuperAdmin accounts			•
Modify User accounts	Modify Operator accounts		•	•
	Modify Admin accounts			•
	Modify SuperAdmin accounts			•

User account privilege		Operator	Admin	SuperAdmin
MANAGE USER ACCOUNTS				
Manage User accounts	Manage Operator passwords		•	•
	Manage Admin passwords			•
	Manage SuperAdmin passwords			•
Delete User accounts	Delete Operator accounts		•	•
	Delete Admin accounts			•
	Delete SuperAdmin accounts			•
CREATE AND MANAGE CERTIFICATES				•

See “Chapter 7. ANDE Data Management Software” for more information about specific features.

The ADMS must be installed on a desktop or laptop computer with a Windows™ 7 operating system. The ADMS allows a standalone computer to communicate with the ANDE instrument via an Ethernet connection and allows ANDE data to be imported into the computer. Alternatively, encrypted data can be exported onto a USB drive using the Data Export features on-board the ANDE instrument, and then the ADMS will import the data from the USB drive.

To ensure an uninterrupted workflow, we recommend that the SuperAdmin install the ADMS onto a standalone computer designated for use with the ANDE instrument and create and install the appropriate encryption/decryption files immediately after the ANDE System is installed (see “Chapter 4.5.3. Install the ADMS on the first standalone computer designated for ANDE data management”).

3.2.5. NetBio BioChipSet Swab

The ANDE Rapid DNA Analysis System uses buccal or purified DNA samples as the DNA source for STR profiling. Samples are collected on specially designed swabs. The ANDE Rapid DNA Analysis System requires the use of NetBio BioChipSet Swabs, which are included with the BioChipSet Cassettes. For buccal sample collection instructions, see the BioChipSet Cassette User Manual (NB-BCS-0005-501). *Contact a NetBio representative for protocols for processing blood or purified DNA samples.

BioChipSet Swab

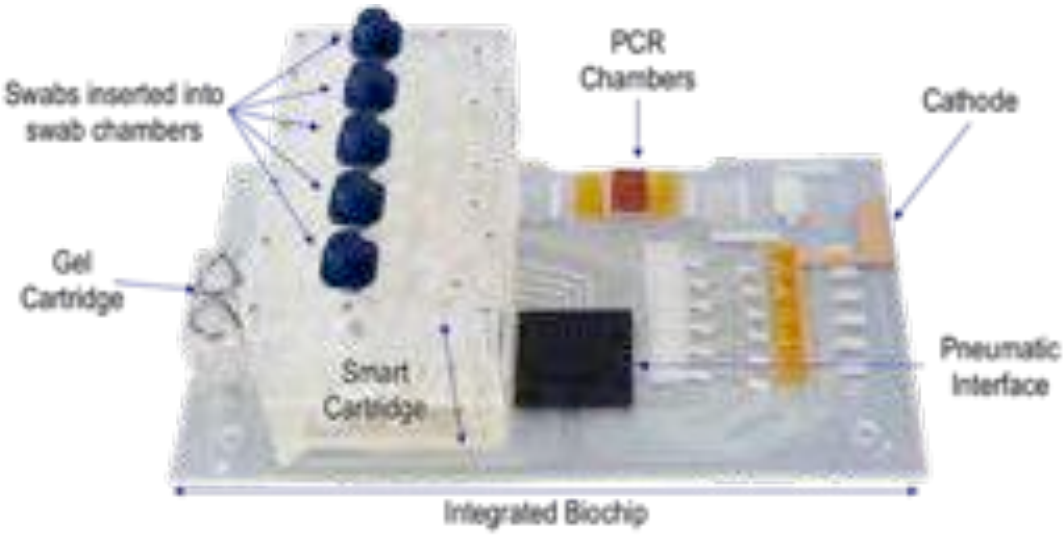
3.2.6. NetBio BioChipSet Cassette

BioChipSet Cassettes have a separate User Manual (NB-BCS-0002-501). The BioChipSet Cassette User Manual must be read before operating the ANDE System. Refer to http://www.netbio.com/solutions/biochipset/usermanual for the most current version of BioChipSet Cassette User Manual.

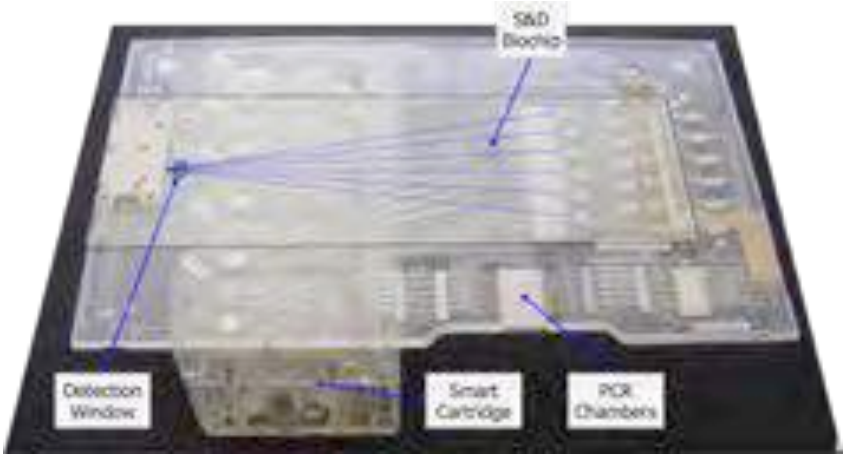
The BioChipSet Cassette contains all reagents on-board required to perform STR analysis. Several reagents are lyophilized (including the amplification reaction mix, allelic ladder, and internal lane standard), and others are in liquid form (including purification and separation reagents). The BioChipSet Cassette is closed, meaning that each sample is processed through its own sealed processing path to prevent cross contamination and to ensure that samples and reagents do not come in contact with the instrument itself. The BioChipSet Cassette integrates all DNA process steps based on microfluidic technology and is made of injection-molded plastic parts. The single integrated unit is comprised of four major components:

- The Smart Cartridge (SC) accepts the swab, contains all liquid purification reagents, and performs cell lysis and DNA purification.
- The Gel Cartridge (GC) contains the sieving matrix used for electrophoretic separation.
- The Integrated Biochip (IB) interfaces with the SC and Gel SC, contains all lyophilized reagents, and integrates all microfluidic processes including purification, STR amplification, and preparation of sample for separation.
- The Separation and Detection (S&D) Biochip, which is on the underside of the IB, performs size separation of STR fragments by electrophoresis and laser-induced fluorescence detection.

BioChipSet Cassette: Top View



BioChipSet Cassette: Bottom View



The User loads a sample swab into each of the five Sample Chambers of the BioChipSet Cassette. If the User wants to perform a run with less than five samples, a blank swab should be placed into each empty Sample Chamber. For detailed instructions on how to load a sample swab see "Section 5. Performing a run". After all five Sample Chambers are loaded, the User inserts the BioChipSet Cassette into the ANDE instrument and closes the BioChipSet Cassette Access Door. The run starts automatically.

The System software coordinates the required sequence of events within the instrument and the BioChipSet Cassette to perform the following functions:

1. Locking of the access door to prevent accidental interruption of the sequential processes.
2. Sample processing:
   - DNA purification.

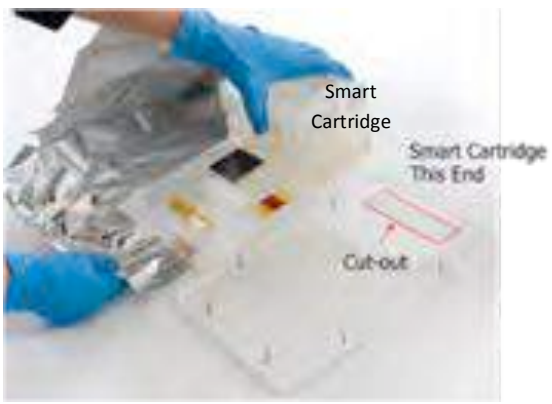
- STR amplification.
- Separation and detection of STR fragments.

3. Initiation of the on-board Expert System to perform signal processing, data analysis, and conversion of electrophoretic traces to CODIS/NDIS compatible STR profiles.
4. Unlocking and opening of the access door to permit removal of the BioChipSet Cassette.
5. Secure export of encrypted run, telemetry, and optical data to a USB drive or directly to a laptop or desktop computer via an Ethernet connection.
6. Secure storage of data from STR profiling results in a local encrypted database on the instrument until the data are deleted.

3.2.7. BioChipSet Cassette Loading Fixture

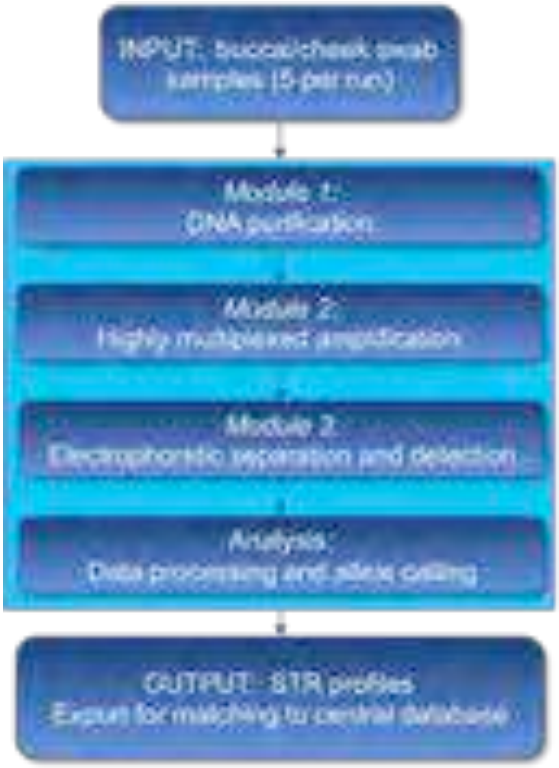
The BioChipSet Cassette Loading Fixture is supplied with the ANDE instrument.

The BioChipSet Cassette must be placed on the Sample Loading Fixture prior to loading samples by positioning the Smart Cartridge towards the cut-out in the Loading Fixture (see image for orientation). The Loading Fixture helps to protect the Detection Window from dirt and debris on work surfaces.



3.3. ANDE System Process flow

The process flow for generating DNA profiles using the ANDE Rapid DNA Analysis System is outlined in the image below. All processing steps performed automatically by the ANDE instrument are highlighted in the light blue box. Processing steps noted in Modules 1, 2, and 3 are performed inside the BioChipSet Cassette in concert with ANDE instrument subsystems.



Following initiation of the run, a series of automated steps occurs to achieve the process flow shown above. Samples undergo multiple processing steps within the BioChipSet Cassette that can be grouped into three major modules:

Module 1: DNA Purification. Cells on the swab are lysed, and DNA is purified using a guanidinium- and silica binding-based approach. The BioChipSet Cassette is designed to generate STR profiles from any reference sample swab without the need for DNA quantitation, provided that the sample collection instructions are followed.

Module 2: DNA Amplification. Purified DNA is subjected to multiplexed Polymerase Chain Reaction (PCR) to amplify and fluorescently label the targeted loci. See “Chapter 10. STR loci assayed in the BioChipSet Cassette” for specific information about the loci used.

Module 3: Electrophoretic Separation and Detection. DNA fragments from the multiplexed amplification reaction are separated based on their size and detected based on laser-induced fluorescence of their

attached label. Following detection and signal processing, the Expert System Software performs data analysis and converts the electrophoretic traces to CODIS/NDIS compatible STR profiles.

The modular nature of the ANDE Rapid DNA Analysis System provides a customizable foundation for DNA analysis that supports future expanded STR assay and sample capabilities.

4. INSTALLATION

This chapter contains information on how to transport, store, unpack, install, and move the ANDE instrument.

4.1. Transport

The ANDE instrument conforms to U.S. Military Standard 810F to withstand truck vibration exposure for restrained cargo and shock when contained in a NetBio-approved Transport Container.

4.2. Shipping and storage specifications

Store in a climate-controlled, secure facility within limits as follows:

Parameter	**Requirement**
Temperature	-20°C to +50°C (-4°F to 122°F)
Humidity	10 to 90% condensation possible
Altitude	1000 ft below sea level to ~10 000 ft (1060 mbar to 700 mbar)

4.3. Site requirements/environmental conditions

Parameter	**Requirement or condition**
Supply Voltage	100–240 V +/- 10%
Phases	Sine wave AC power ONLY
Frequency	50 or 60 Hz
Maximum Power	600 W
Grounding	System should be earthed
Overvoltage category	Cat II
Operating temperature/humidity conditions	20–30°C (68–86°F). Humidity 20–80% non-condensing
Placement	Stable flat work surface (minimum 1.2 x 0.9 m or 4 ft x 3 ft) able to support weight of system and accessories
Space and tools for uncrating	Floor space: 2.4 x 1.2 m (8 x 4 ft); tools: none
Free space required around instrument	Front 20 cm (7.9 in); Right 10 cm (3.9 in); Left 10 cm (3.9 in); Rear 10 cm (3.9 in)

Other conditions	Do not site next to a sink or in direct sunlight
Floor vibration conditions	Stable flooring desirable
Installation location conditions	Low dust environment preferable
Operation site	High power radio or radar signals may interfere with optional GPS reception. For ideal reception, avoid use near radar, TV or other transmitters, other strong electrical or magnetic fields or tall trees and buildings
Maximum operating altitude	10 000 ft
Rated Pollution applied	Pollution degree 2
Noise	70 dB(A) or lower. Fast Lmax ≤60 dB(A), and average Leq ≤ 54 dB(A).
Degrees of protection provided by enclosure	IP21
Requirements for standalone computers designated for ANDE data management	Windows 7 operating system

4.4. Unpacking

4.4.1. Unpacking instruction

Check the package for any apparent damage. If damage is found, document it and contact your NetBio representative immediately. Follow the instructions below to uncrate the ANDE instrument from the hard transport case. The ANDE hard transport case should be stored in the closed position in a dry, moisture free, and clean environment for future instances where the ANDE system will require transport. The hard transport case is not waste and should not be discarded.

The transport case with the instrument inside can be moved using a pallet jack or forklift, or can be manually carried using the four carrying handles on each side. The transport case with the ANDE instrument inside weights 80 kg (177 lbs) and should be carried by four people.

Hard transport case containing the ANDE instrument

Proceed as follows to unpack the ANDE instrument from the hard transport case:

Step 1: Open the 14 Exterior Latches found on all four sides of the hard transport case by:

- Pulling up on the butterfly handle of the bottom clasp

- Twist the clasp handle to your left (counterclockwise) to loosen the clasp

- Push up slightly on the clasp to release it and then pull the clasp down away from the case

- Repeat this process until all 14 latches have been opened

Step 2: Using the carrying handles on each side of the top cover of the transport case and at least two people standing on opposite sides, lift the top cover straight up so that has completely separated from the instrument inside, then set it off to the side. Make sure the top cover is place out of the immediate area to avoid a tripping hazard.

Step 3: Using two people standing on opposite sides, grasp the ANDE carrying handles located on left and right sides of the instrument and lift it upwards from the protective foam (pink) to remove it from the bottom piece of the transport case. The instrument can be hand carried to its workbench, or placed on a stable cart and rolled to its workbench. Avoid tipping or banging the instrument.

4.4.2. Visual inspection

Perform the following checks before starting installation:

- Check the instrument for any apparent damage and document carefully if found.
- Check to determine whether all parts are present:
    1. BioChipSet Cassette Loading Fixture
    2. Three power cables with plugs (US, UK, EU)
    3. CD containing product literature
    4. CD containing ANDE Data Management Software. Refer to the User Manual on the enclosed CD for additional information.

- If any equipment appears missing or damage, take note and immediately contact your NetBio representative.

4.5. ANDE instrument set up

Follow the instructions in this manual to set up the ANDE instrument for the first time.

NOTICE
The steps in sections 4.5.2. to 4.5.8. must be performed by a SuperAdmin, a customer-authorized individual who has the rights to view all system-generated DNA data, to control User access to the instrument, and to set the system's configurable features. The SuperAdmin will receive an initial User Name and Password from a NetBio representative.

ANDE Instrument Set Up Requirements

ANDE instrument set up requires the following tasks, which have been divided into subsections. The steps in section 4.5.1 do not have to be performed by a SuperAdmin.

4.5.1. Set up the ANDE instrument

4.5.2. Log in to the instrument for the first time

4.5.3. Install the ADMS for ANDE data management

4.5.4. First time set up of the ADMS

4.5.5. Install the Encryption Certificate on the ANDE instrument

4.5.6. Configure the ANDE instrument

4.5.7. Add User accounts

NOTICE. The computer with the ADMS can be connected directly to the ANDE instrument via an Ethernet cable for data import. Alternatively, a USB drive can be used to export data from the ANDE instrument for import to the ADMS.

NOTICE

Retain the hard transport case and all incorporated protective foam for future transport of the instrument outside your facility. This case will protect the instrument from transportation vibrations and shock.

CAUTION

Do not drop the ANDE instrument. Handle with care. Two-Person Lift

The standalone ANDE Rapid DNA Analysis instrument weighs 51.3 kg (113 lbs). Use a two-person lift to hand-carry the instrument. Alternatively, the instrument may be moved inside your facility by placing it on a rolling cart.

CAUTION

Do not place the instrument on unstable tables or on inclined surfaces, as the instrument could tip over or fall, resulting in injury.

CAUTION

Do not place the instrument or parts in direct sunlight. This may degrade performance.

CAUTION

Do not block the vents, and ensure that the vents are kept free of dust and dirt. Blockage of the vents can result in overheating of the instrument and malfunction. Place the instrument so that there is at least 20 cm (7.9 inches) in front of the instrument to the walls or other instrument, and 10 cm (3.9 inches) on all other sides to ensure adequate cooling.

4.5.1. Set up the ANDE instrument

Step 1: Transport the ANDE instrument to an appropriate workstation and observe the following requirements

- Place the ANDE instrument in a climate-controlled area on a level surface. Avoid placing near strong electrical or magnetic fields that could interfere with GPS or other on board operations. The instrument has been tested for functionality at a temperature range of 20–30°C and at 20–80% relative humidity (non-condensing).
- The ANDE workstation should be clean and clear from debris. Do not place it where objects could easily fall onto the instrument.
- Avoid placing the ANDE instrument near flowing water (sinks) water or in areas of excessive moisture.
- Instrument must remain stationary during use.

Step 2. Connect the AC power cord to the ANDE instrument. The power inlet connector is situated at the rear of the instrument above the filter unit.

WARNING

Use a proper power cord that complies with the local laws and regulations and is delivered by NetBio. Do not use any other power cord.

WARNING

Connect the power supply directly to a grounded wall power outlet. The use of extension cords or multiple loads on one electrical outlet could result in fire and electric shock. The User may employ a suitable UPS system (not supplied with the ANDE instrument).

- Plug in the appropriate NetBio-supplied power cable based on your location. The instrument is supplied with the following power cables and plugs:

    1. United States: IEC-320-C19 / NEMA 5-15 plug / 3×14 AWG SJTW cable for 125 V, 15 A (U.S.) or equivalent
    2. Europe: IEC-320-C19 / CEE 7 plug / H05VV-F cable for 230 V, 16 A (EU) or equivalent
    3. United Kingdom: IEC-320 EN 60320 C19 to UK plug / BS1363A cable for 200-240V, 16 A (UK) or equivalent

Step 3. Turn on the power to the ANDE instrument by pushing the power switch to the **I (ON)** position.

The ANDE instrument will power up and proceed through a 15-minute warm up cycle that includes a Power On Self Tests (POST) and calibrations to check the functionality of the critical modules of each subsystem. The User Touch Screen will display a **Warm Up** screen that shows the time remaining.

During warm up, if there is no GPS signal available, a notification message will appear on-screen. The message says GPS error: no GPS signal. Press ***OK*** to close the message. Warm up will continue even with the GPS message present.

NOTICE
The SuperAdmin can disable the GPS using the Configure System option to stop this message from popping up every time. See "Section 6. ANDE User Account Management: Features and Functionality" for additional information.

- Once the warm up process is complete, the **Log In** screen will be displayed.

- The instrument is now ready for operation.
- User accounts must be created before the runs can be made. The person granted the SuperAdmin privilege should follow the instructions in “Section 4.5.2. Log in to the instrument for the first time”.

4.5.2. First time Log In on ANDE

A secure, customer-specific, SuperAdmin account must be created before runs can be performed on the ANDE System. NetBio provides a temporary User Name and Password for first-time log in of each SuperAdmin.

- The person granted the SuperAdmin privileges should log into the ANDE instrument using the temporary User Name and Password provided by the NetBio representative. On the **Log in**

screen, touch the white box next to the User Name field. Use the on-screen keyboard to enter the temporary User Name. Then touch the white box next to the Password field, and enter the temporary Password. Touch the **Log In** button.

- If the User Name or Password is incorrectly entered, a *"Login failed"* message will be displayed. Touch the **OK** button to clear the message and try again.

NOTICE

The SuperAdmin can attempt to log in up to five times before the system deletes the account. If

the provided login information is not allowing login after three attempts, contact your NetBio representative before continuing, to verify that the provided login information is correct and to receive assistance with the remaining login attempts.

- Once a SuperAdmin has successfully logged in using the temporary User Name and Password, the system will display a message indicating that a SuperAdmin account must be created upon first login. Touch the **OK** button to create a new secure and customer-specific SuperAdmin account. The User Name and Password provided by NetBio will be overridden, which will prevent unauthorized access of the system.

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

Password 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

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

- The **SuperAdmin Menu** screen will now be displayed.

To ensure an uninterrupted workflow, the SuperAdmin should follow the instructions in "Section 4.5.3 Install the ADMS on the first standalone computer designated for ANDE data management" to set up the ANDE Data Management Software (ADMS) on a standalone laptop or desktop computer that is designated for ANDE data management. The ADMS creates the Encryption Certificate that enables encryption of the ANDE data when it is exported from the instrument. It also creates the Decryption Key, which is used to decrypt the exported data that is imported into a standalone computer on which the ADMS is installed. The data security features employed by the ANDE System are intended to protect the data both on and off the instrument from misuse, malfeasance, and/or inadvertent disclosure.

NOTICE

There can be more than one SuperAdmin account on each instrument. To create additional SuperAdmin accounts, contact your NetBio representative for additional temporary SuperAdmin User Names and Passwords. As described previously, the SuperAdmin should enter the temporary SuperAdmin User Name and Password. After the **Log In** button is touched, the system will prompt the SuperAdmin to create a new SuperAdmin account.

4.5.3. Install the ANDE Data Management Software

The ANDE Data Management System (ADMS) must be installed on customer computer (laptop or desktop) with a Windows 7 operating system. A Windows Administrator must install the ADMS. A standard Windows account is required for all ADMS Users. It is recommended that a single computer be designated to manage the ANDE data and that a single Windows ADMS User account be created for all ADMS Users. Note that the ADMS software itself allows for the creation of individual User accounts with appropriate User account designations (SuperAdmin, Admin, or Operator) to allow a SuperAdmin to assign Users and designate their access to the ADMS and thus ANDE data. Should multiple installations of the ADMS be required, an ANDE SuperAdmin should control and document all installations and Users. For more detailed information on the ADMS see Section 7. ANDE Data Management Software.

Follow the instructions below to install the ADMS onto a designated laptop or desktop computer, create a first time SuperAdmin account, and generate and install an Encryption Certificate and Decryption Key for each ANDE instrument.

NOTICE

Only a SuperAdmin should install and set up the ADMS.

NOTICE

ADMS must be installed with a Windows Administrator Account

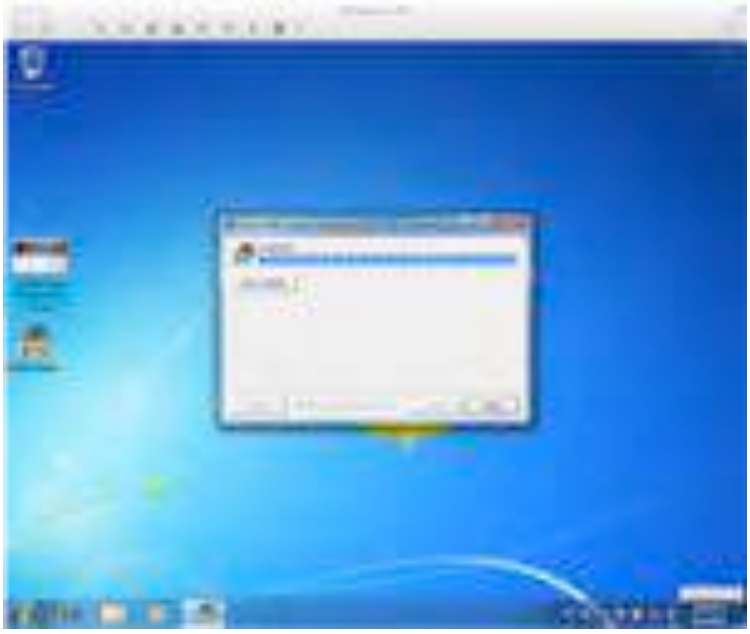
Step 1: Log into the computer with a Windows Administrator User Name and Password.

Step 2: Insert the CD containing the ADMS (included with the ANDE instrument) into the CD drive on the laptop or desktop computer designated to manage the ANDE data.

Step 3: Double-click on the CD drive to access the content on the ADMS CD.

Step 4: Drag and drop the ADMS Setup Application from the CD onto the computer desktop.

Step 5: Double-click on the **ADMS Setup Application** icon on the desktop to install the program. An installation progress window will be displayed. When installation is complete, the ADMS icon will appear on the desktop. Click **Close** on the progress window. The ADMS has not been successfully installed.



Step 6: The Windows Administrator should now make standard Windows User accounts for ADMS users.

Step 7: The Windows Administrator should log off.

4.5.4. First-time set up of the ADMS

4.5.4.1. Create an initial SuperAdmin account

The designated SuperAdmin responsible for overall management of the ADMS must create a unique SuperAdmin account on the AMDS. SuperAdmin accounts have the most advanced User privileges and should be reserved for those individuals who require advanced access and will provide oversight and management of the ANDE System, ANDE and ADMS User accounts and privileges, and ANDE data security and privacy. Follow the instructions below to create an initial SuperAdmin account.

Step 1: The designated SuperAdmin should log in to the computer using their Windows account

Step 2: Double click on the ADMS icon on the desktop to open the ADMS. The ADMS log in screen will be displayed.

NOTICE

If security messages appear during the installation or operation of the software, the SuperAdmin should consult their IT support. If additional support is needed, contact the NetBio representative.

Step 3: For first-time use only, the SuperAdmin should log in to the ADMS by typing "SuperAdmin" in the User Name field. No password is required; leave this field blank. Click on the **Log in** button.

Step 4: The SuperAdmin will be immediately prompted to set up a customer-specific SuperAdmin account on the **Setup SuperAdmin Account** screen. This process will only occur when the ADMS is opened for the first time after installation.

Step 5: The SuperAdmin should complete each field and designate a User Name and unique Password for their account. The User Name is required to have 7-14 characters and is case-specific. The Password is required to comply with 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 last password

Step 6: Click on the **OK** button on the completed **Setup SuperAdmin Account** screen to set up the SuperAdmin account.

Step 7: SuperAdmin account generation is now complete. The **SuperAdmin Menu** screen will be displayed.

Before taking further actions on the ADMS, the SuperAdmin must generate an Encryption Certificate and Decryption Key (for decryption) for each ANDE instrument. The creation and installation of these files are required to implement the ANDE data security and privacy features and can only be performed by a SuperAdmin. The generated Encryption/Decryption files will enable encryption of data being export from the ANDE instrument and decryption of data via the ADMS. Proceed to Section 4.5.4.2. to complete this process.

4.5.4.2. Create the Encryption Certificate and Decryption Key

Data exported from the ANDE instrument are automatically encrypted for protection. Data encryption features have been incorporated to protect ANDE data from being tampered with, exploited, or viewed by unauthorized individuals once it has been exported from the ANDE instrument to ensure both data security for the customer and privacy for the DNA donor.

To ensure an uninterrupted workflow, the SuperAdmin should generate via the ADMS the Encryption/Decryption files and install the encryption certificate on the ANDE instrument before the first ANDE run is performed. The ADMS certificate creation process will generate the following Encryption/Decryption files:

1. **Encryption Certificate:** The Encryption Certificate (.cer file) can only be generated via the ADMS and installed onto the ANDE instrument by a SuperAdmin. Data stored within the ANDE instrument resides in an encrypted database; the Encryption Certificate further protects the data by adding a layer of encryption as data are exported off the instrument. The Encryption Certificate will be saved onto a USB drive during the ADMS's certificate creation process and must then be transferred to and installed by a SuperAdmin on the ANDE instrument for which it was created (see "Section 4.5.5. Create the Encryption Certificate and Decryption files").
2. **Decryption Key:** The Decryption Key (.pfx file) will be used by the ADMS to decrypt ANDE data that has been transferred from the ANDE instrument to a laptop or desktop computer that has the ADMS installed. This key can only decrypt data that was encrypted by the corresponding Encryption Certificate. The Decryption Key will be automatically installed on the computer when it is created during the ADMS's certificate creation process. It will also be saved onto a USB drive for two purposes: (1) to create a backup of the Decryption Key in case the existing key should be mistakenly deleted or corrupted; and (2) to allow a SuperAdmin to import the Decryption Key to additional ADMS installations on other computers. Importing the key to additional ADMS installations is essential to allow those computers to decrypt the ANDE data from the corresponding ANDE instrument. The USB drive with the Decryption Key should be labeled and stored securely at all times according to organizational requirements.
3. **Decryption Key Password:** To protect the Decryption Key against unauthorized use, the ADMS certificate creation process creates a unique Decryption Key Password when each Decryption Key is created. The corresponding password will be required to import a Decryption Key to additional ADMS installations. Without this password, the Decryption Key will not be active, and that particular installation of the ADMS will not be able to decrypt the corresponding encrypted ANDE data. This password should be stored securely in a separate location from the USB drive containing the Encryption Certificate and Decryption Key, according to organizational requirements.

Follow the instructions below to create the Encryption Certificate, Decryption Key, and Decryption Key Password using the ADMS.

Step 1: The SuperAdmin should log in to the ADMS to display the **SuperAdmin Menu** screen and then click on the **Manage Certificates** button.

Step 2: The **Manage Certificates** screen will be displayed. To create the Encryption/Decryption files for the first time, click on the **Create Certificate** button on the bottom of the screen.

Step 3: Enter the last four digits of the ANDE instrument serial number into the input field on the **Create Certificate** screen and then click on the **Continue** button to create certificates and advance the screens. Clicking on the **Back** button will return the User to the **Manage Certificates** screen.

*Note: The serial number can be found on the serial label on the back of the instrument.

Once the **Continue** button is clicked on the above **Create Certificate** screen, three files will be created and will require safe storage:

1. Encryption Certificate (example: i0215_082514_130206.cer)
2. Decryption Key (example: i0215_082514_130206.pfx)
3. Decryption Key Password: (example: C718A6F4A405)

CAUTION

The Decryption Key Password will NOT be saved by the ADMS or onto a USB drive as part of the certificate creation process. The SuperAdmin must follow organizational requirements to record this password and store it securely in a location separate from the USB drive with the Encryption Certificate and Decryption Key. Storing the Decryption Key and password together could compromise data security should unauthorized personnel find these two items and try to gain access to the ANDE data.

Step 4: The SuperAdmin should follow the instructions displayed on **Create Certificate** screen.

- Write down the Encryption Certificate name and the associated Decryption Key Password displayed in the Step 2 window. Store this documented information in a secure location, separate from the USB drive containing the certificates.

- As instructed by the Step 3 window of the **Create Certificate** screen, insert a USB drive into the USB port on the computer and click on the **Save** button on the bottom right of the screen to export the Encryption Certificate and Decryption Key to the USB drive. Click on the **Back** button to return to the previous screen to view the Encryption Certificate name and Decryption key password.

This USB drive now contains the Encryption Certificate (.cer file) and the Decryption Key (.pfx file). This USB drive is required to: 1) import the Encryption Certificate to the corresponding ANDE instrument, 2) store the certificate and Decryption key as back up if needed; and 3) import the Decryption key to other installations of the ADMS to allow data decryption.

CAUTION
Label and store this USB drive in a secure location according to organizational requirements.
Store recorded Decryption key password separate from the USB drive in a secure location.

Step 5: A message will appear to inform the SuperAdmin of the next steps to continue with the certificate installation process.

1) Remove the USB stick from this computer and transfer to the ANDE instrument.
2) SuperAdmin should Log in to ANDE #0233
3) On the SuperAdmin Menu screen, select the Manage Certificates button
4) Follow the on screen instructions on the ANDE instrument #0233

Click on the **OK** button to clear the message and return to the **SuperAdmin Menu** screen.

NOTICE

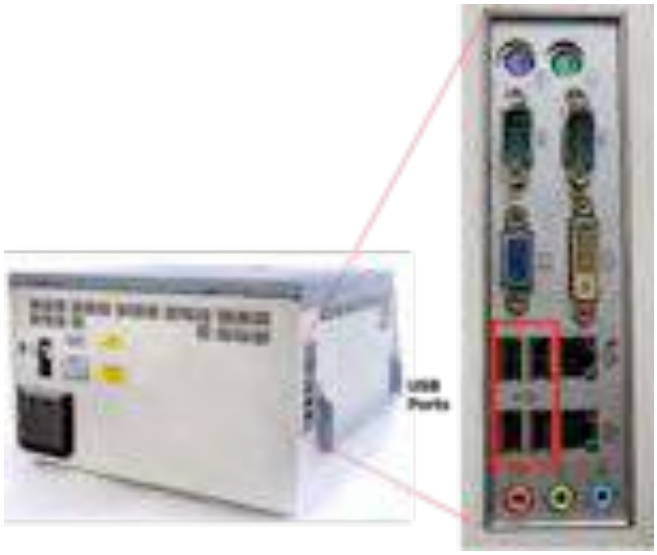
Each Encryption Certificate/Decryption Key combination is specific to the ANDE instrument-per the serial number that was entered at the beginning of the certificate generation process. The Decryption key can only decrypt data from the designated instrument with the corresponding Encryption certificate installed. Certificates cannot be shared among ANDE instruments. Each ANDE instrument has only one Certificate.

Eject the USB drive with the saved Encryption Certificate and Decryption Key from the computer and transport it to the appropriate ANDE instrument. Proceed to Section 4.5.6. to install the Encryption Certificate onto the ANDE Instrument.

4.5.5. Install the Encryption Certificate on the ANDE instrument

The following steps should be performed on the ANDE instrument by a SuperAdmin:

Step 1: Insert the USB drive containing the Encryption Certificate into any available USB port on the appropriate ANDE instrument.

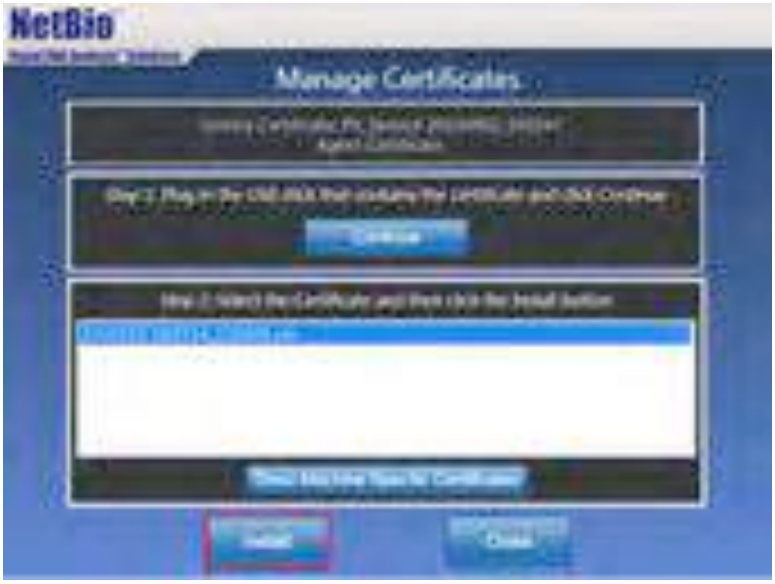


Step 2: Log into the ANDE instrument to display the **SuperAdmin Menu** screen and then touch the **Manage Certificates** button.

Step 3: Within the **Manage Certificates** screen, touch the **Continue** button to import the Encryption Certificate. The certificate file will be displayed in the white box in Step 2.

Step 4: If multiple Encryption Certificates (corresponding to multiple ANDE Systems) are on the USB drive, they will all be displayed in the **Select the Certificate** window. To display the Encryption Certificate for the current instrument undergoing certificate installation, touch the **Show Machine Specific Certificates** button on the bottom of the screen. The displayed incompatible certificates will disappear to allow unambiguous installation of the correct certificate.

Step 5: Select the instrument-specific Encryption Certificate to be installed by touching the file in the window, and then touch the **Install** button on the bottom of the screen.



Step 6: The SuperAdmin will be asked to confirm that the selected certificate should be installed. Touch the **Yes** button at the bottom of the message to proceed with certificate installation. Alternatively, touch the **No** button at the bottom of the message to cancel certificate installation and return to the **Manage Certificates** screen.

Step 7: A message box will inform the SuperAdmin that the Encryption Certificate installation has been successfully completed. Touch the **OK** button to clear the message and return to the **Manage Certificates** screen.

Step 8: Touch the **Close** button to return to the **SuperAdmin Menu** screen.

4.5.6. Configure the ANDE instrument

Before performing a run, the configurable features of the ANDE instrument should be set by a SuperAdmin. The default settings are shown here:

See “Section 6.4.7. Configure System” for more information.

4.5.7. Add User accounts

The SuperAdmin can create and manage Users accounts on the ANDE instrument and the ADMS as required. See Section 6.4.4 Manage User Accounts on the ANDE Instrument for SuperAdmin ANDE account management and Section 7.2.2 Manage ADMS User Accounts for ADMS account management.

Installation is now complete.

4.6. Moving the ANDE instrument

CAUTION

Do not drop the ANDE instrument. Handle with care. Two-Person lift. The standalone ANDE instrument weighs 51.3 kg (113 lb). Use a two-person lift to hand-carry the instrument. Alternatively, the instrument may be moved inside your facility by placing it on a rolling cart.

Before moving the instrument:

1. Confirm that there is no BioChipSet Cassette in the instrument and that the access door is closed.
2. Turn off the instrument.
3. Disconnect the power cord from both the instrument and power outlet, and disconnect any computer connections.
4. Remove any loose item from around the instrument.

Moving the instrument:

Using two people, lift the instrument by its carrying handles and carry or roll on a cart to its next destination. If the system is to be transported in a vehicle, it should be placed back into the hard transport case it was delivered in with all corresponding foam packaging materials. The hard transport case can be set on a pallet for transport by a pallet jack or fork lift, but it should be securely strapped onto the pallet before moving.

NOTE: If the instrument is being returned for servicing, contact your NetBio representative for

any additional packaging and shipping instructions.

5. PERFORMING A RUN

This chapter describes how to operate the ANDE instrument for sample analysis.

NOTICE

The ANDE system comes with an on-board User account management system that supports three User classes:

- Operator accounts allow the User to perform runs and export encrypted data files. Operators do not have access to STR profiles generated by the system.
- Admin accounts allow the User to perform runs, create and manage Operator accounts, export encrypted data files, and view STR profiles generated by the system.
- SuperAdmin accounts provide access to all User functions. In addition to performing runs, SuperAdmins can manage Operator and Admin accounts, all data types, and encryption/decryption files.

A complete listing of the ANDE System Software features and associated User privileges is found in "Section 3.2.3. ANDE System Software". For detailed overview of the each of the User class capabilities see "Section 6.0 ANDE User Accounts: Features and Functionality"

5.1. Preparation

5.1.1. Prepare before opening the BioChipSet Cassette package

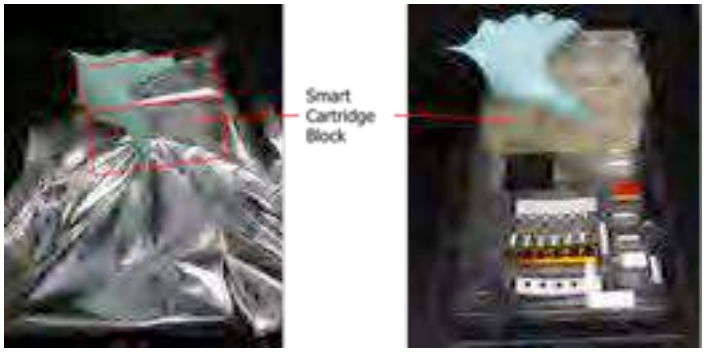
NOTICE. Before selecting ***Perform Run***, ensure that all samples have been collected and the BioChipSet Cassette has been unpackaged, positioned on the BioChipSet Cassette Loading Fixture, and is ready to load samples.

NOTICE

Always wear gloves when handling BioChipSet Cassettes and NetBio BioChipSet Swabs.

NOTICE

Handle the BioChipSet Cassette Package by firmly grasping the Smart Cartridge with one hand and placing your other hand underneath the Integrated Biochip.



To ensure optimal performance, it is recommended that the cassette be used within 15–30 minutes of the packaging being opened. The cassette must be inserted into the ANDE instrument immediately after loading the 5 swabs. **Do not open the package until you:**

- Confirm that the BioChipSet Cassette is not expired (by checking the expiration date on the package) and is equilibrated to room temperature.
- Have 5 swabs ready (test samples and/or “blanks”).
- Warm up the instrument if needed (see “Section 5.1.2. Ready the ANDE instrument”).
- Have the Loading Fixture ready.
- Have your unique User Name and Password readily available. If you have not yet created a unique account, see “Section 6.x.”

5.1.2. Ready the ANDE instrument

If the power to the ANDE instrument is already on (power switch in the **I (ON)** position), proceed directly to “Section 5.1.3. Open the BioChipSet Cassette package”.

- If the power to the instrument is not already on, turn it on by pushing the power switch to the **I (ON)** position.
- The instrument will power up and proceed through a warm up process. The ANDE instrument warm up cycle includes a series of Power On Self Tests (POST) and calibrations to check the functionality of the critical modules of each subsystem. The ANDE instrument warm up will take 15 minutes; the User Touch Screen will display a **Warm Up** screen that shows the time remaining:

- Once the warm up process is complete, the **Log In** screen will be displayed. There is no need for the User to log in until the BioChipSet Cassette has been opened and all samples are ready for processing.

5.1.3. Open the BioChipSet Cassette package

Before opening and handling the BioChipSet Cassette for the first time, the BioChipSet Cassette User Manual (NB-BCS-0002-501) must be read. The BioChipSet Cassette User Manual is included on the product literature CD that accompanies the ANDE instrument. The most updated version of BioChipSet Cassette User Manual can be found on NetBio's web site at www.netbio.com.

Each BioChipSet Cassette comes packaged in two layers of foil pouches to protect the dried reagents from ambient humidity. Both foil layers will need to be opened in order to use the BioChipSet Cassette. The Cassette should be used within 15–30 minutes of the packaging being opened. The Cassette should be inserted into the ANDE instrument immediately after loading the 5 swabs.

NOTICE

Do not open the BioChipSet Cassette package until all 5 NetBio BioChipSet Swabs (test samples or "blanks") are ready to be placed inside the BioChipSet Cassette.

NOTICE

Before opening the BioChipSet Cassette package, confirm that the User Name and unique Password are readily available.

Step 1. Place the box containing the BioChipSet Cassette on a clean, flat surface. Be sure that it is in the upright position. Using scissors or box cutter, cut through the packaging tape and open the top of the box.

Step 2. Pull up on the tape on the top of the white styrofoam packaging material and use it as a handle to lift the styrofoam package from the box.

Step 3. Set the styrofoam package onto a flat surface. Remove the tape holding the top and bottom of the styrofoam package together, and then remove the top piece of styrofoam packaging to expose the BioChipSet Cassette in its foil packaging.

Step 4. Using gloved hands, grasp the BioChipSet-foil package by the Smart Cartridge and gently remove it from the bottom of the styrofoam packaging material. Keep the BioChipSet Cassette level.

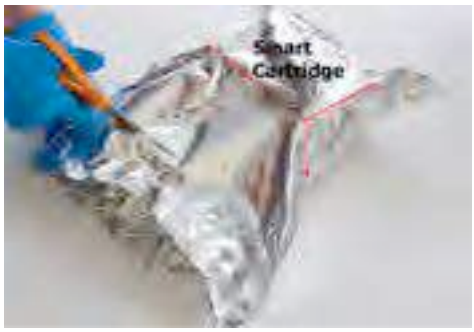
- **Step 5.** Place the package on a clean, flat surface and spread open the foil packaging from around the BioChipSet Cassette. While wearing gloves, carefully cut the outer foil layer along the short edge opposite the Smart Cartridge, then cut along one long edge.

- **Step 6.** Firmly grasp the Smart Cartridge within package and remove the outer foil layer. Discard the outer foil.

NOTICE

Do not grasp or carry the BioChipSet Cassette in its packaging by the thin part (Integrated Biochip), because this may cause damage to the cassette and/or cause the package to be dropped because the weight is unevenly distributed.

- **Step 7.** Cut the inner foil layer using the same process as described above for the cutting the outer foil.



- **Step 8.** Open the inner foil layer. Do not remove the BioChipSet Cassette from the foil until the BioChipSet Cassette Loading Fixture is available (see next bullet).

- **Step 9.** Ready the BioChipSet Cassette Loading Fixture supplied with the system.

- **Step 10.** Place the BioChipSet Cassette on the Loading Fixture (supplied with the ANDE instrument) by positioning the Smart Cartridge towards the cut-out in the Loading Fixture (see image for orientation). The Loading Fixture provides protection for the Detection Window (on the bottom of the BioChipSet Cassette) and keeps it from being exposed to dirt and debris on work surfaces.

5.1.4. Log In to the ANDE instrument

Once the BioChipSet Cassette has been opened and samples are ready for processing, the User should enter his or her unique User Name and Password. If this is the first time you are logging into the instrument, you should log in with your assigned User Name and temporary Password. SuperAdmin and Admin Users can create new accounts and will assign the User Name and Password. SuperAdmin Users should see "Section 6.4.4. Manage User Accounts on the ANDE System" for more information. Admin Users should see "Section 6.3.4. Manage User Accounts on the ANDE System" for more information

- On the **Log in** screen, select the **User Name** field on the touch screen by touching the white box, a cursor will appear. Using the on-screen keyboard enter the User Name. Next, select the **Password** field and enter the password.

A User Menu will be displayed after log in is complete. The ANDE System has three User classes, SuperAdmin, Admin, and Operator. See "Section 3.2.3. ANDE System Software" for an overview of privileges granted to each User class. Depending on the system privileges that the User had been granted, one of the following menus will be displayed.

- **SuperAdmin Menu**

- **Admin Menu**

- **Operator Menu**

In all cases, the User should touch the **Perform Run** button to perform a run.

NOTICE

Operators and Admins are allowed three attempts to log in before the system locks their account. A SuperAdmin can unlock Operator and Admin accounts according to the instructions in "Section 6.x." A SuperAdmin is allowed five attempts to log in. If a SuperAdmin attempts to log in more than five times unsuccessfully, the SuperAdmin account will be permanently deleted. In this case, the SuperAdmin should then contact the NetBio representative to obtain new SuperAdmin log in credentials.

5.2. Perform Run

Before you start:

Read the BioChipSet Cassette User Manual (NB-BCS-0002-501) for important information on how to properly handle and use the BioChipSet Cassette.

Follow the guidelines below when preparing to process samples:

- Always wear gloves when handling BioChipSet Cassettes and BioChipSet Swabs.
- Handle the Cassette by firmly grasping the Smart Cartridge with one hand and supporting the Cassette by placing the other hand underneath.
- Use only BioChipSet Swabs in the Cassette.

- Confirm that the Cassette is not expired and is equilibrated to room temperature (expiration date is located on the BioChipSet Cassette box).
- Run the Cassette within 15–30 minutes after opening. The Cassette must be inserted into the instrument immediately after loading the 5 swabs. Make sure the following steps have been completed prior to opening:
    - All 5 samples have been collected and are ready to load. Have "blanks" ready if running less than 5 samples. ("Blanks" are swabs that do not contain any sample).
    - The instrument has been uncrated, turned on, and has completed its 15-minute warm up cycle.
    - The User is ready to load samples and perform a run.
- Place the Cassette on the Loading Fixture (supplied with the ANDE instrument) immediately after the Cassette package has been opened.

5.2.1. Load samples into the BioChipSet Cassette

The User Touch Screen on the ANDE instrument provides the User with step-by-step instructions in the form of written and graphical depictions on how to load samples and perform a run. It is important for the User to follow these instructions to ensure successful sample processing.

NOTICE
Always wear gloves when handling NetBio BioChipSet Swabs and BioChipSet Cassettes.

NOTICE
Take care not to contaminate the samples. Do not cough or sneeze on the NetBio BioChipSet Swabs or the BioChipSet Cassette. Hold the BioChipSet Swabs by the blue plastic cap only – do not touch the cotton material at the end of the swab.

NOTICE
The Swab RFID feature can be turned OFF by a SuperAdmin based on operational requirements

or jurisdictional policies. See “Section 6.x. Configure the system” for more information.

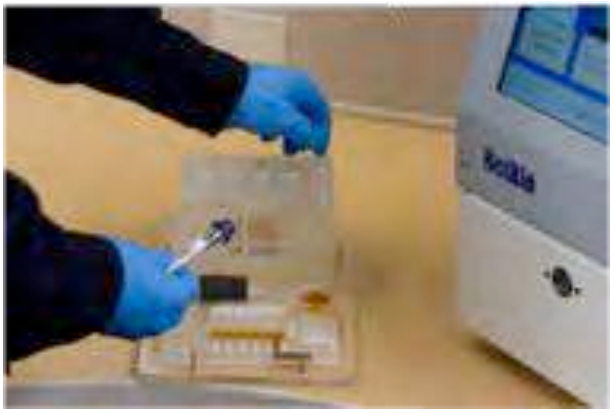
- Select the first NetBio BioChipSet Swab that contains a sample.
- Touch the **Sample #1 ID** field on the User Touch Screen. Use the on-screen keyboard to enter the sample ID. Touch the **Done** button to advance the screen.

NOTE: The sample ID input by the User on this screen will be notated at the bottom of the remaining Sample #1 loading screens to allow the Users to verify/track the sample that is currently being loaded. As an example, if the Sample ID for Sample #1 was input as “A1”, then “A1” will appear at the bottom of the remaining Sample #1 loading screens.

- Scan the blue plastic cap of the swab using the system’s RFID Reader by placing the swab cap into the reader on the front of the instrument. The system will emit a brief beep and the screen will advance automatically after the RFID tag has been read. Repeat this step if the screen does not advance.

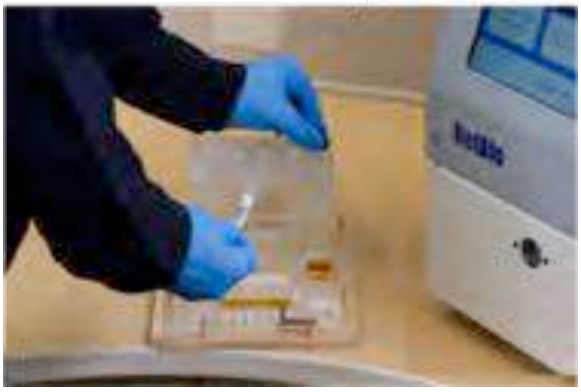
- Load the sample into the BioChipSet Cassette as indicated on the User Touch Screen:

Step 1. Remove the protective plastic seal from the first Swab Chamber of the BioChipSet Cassette. Grasp the pull-tab and lift the seal from the chamber. Discard the seal.



Step 2. Remove the swab from the tube: With one hand grip the blue plastic cap of the NetBio BioChipSet Swab that was just scanned and with the other grip the clear plastic tube. With gentle force, pull the tube away from the NetBio BioChipSet Swab. Do not touch the cotton material on the end of the NetBio BioChipSet Swab.

Step 3. Place the swab into a Swab Chamber and push down on the cap until it clicks. Only gentle force is required.



Step 4. Touch the **Done** button on the User Touch Screen when finished.

- The instructions on the User Touch Screen will prompt the User to load samples 2–5 in the same manner.

NOTICE

If processing fewer than 5 test samples, blank swabs must be used to fill all empty chambers. For blanks enter “Blank” in the Sample ID field. The screen will not advance if this field is not filled in.

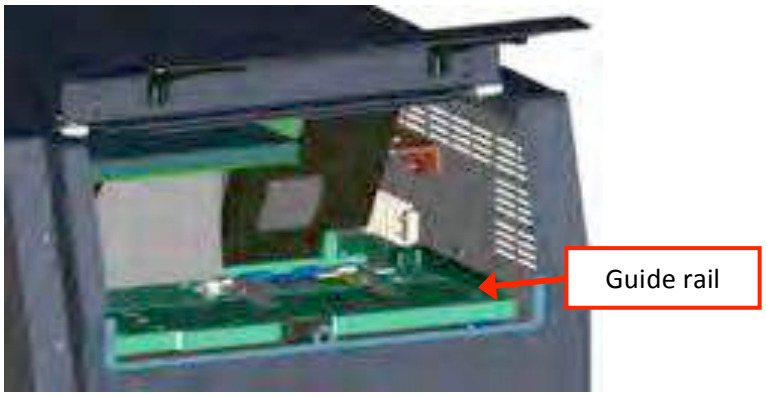
5.2.2. Insert the BioChipSet Cassette into the ANDE instrument

After the fifth sample has been loaded and ***Done*** selected, the BioChipSet Cassette Access Door will open automatically. The User should open the door wider to allow access to the BioChipSet Cassette docking platform.

- There is only one correct orientation for the BioChipSet Cassette. The User should follow the instructions displayed on the User Touch Screen. Graphical depictions demonstrate the proper orientation and loading of the BioChipSet Cassette:

Step 1. Pick up the BioChipSet Cassette by the Smart Cartridge using your left hand and support the cassette by placing your right hand underneath.

Step 2. Insert the BioChipSet Cassette into the instrument, placing the right side under the Guide Rail on the right side of the BioChipSet docking platform.



The BioChipSet should initially be inserted approximately **three-quarters** of the way into the instrument docking platform.

Step 3. Using both thumbs, slowly insert the BioChipSet Cassette all the way into the instrument: Place thumbs on the outer edges of the BioChipSet and press gently to insert it completely into the instrument.

- Once the instrument senses that the BioChipSet Cassette has been properly inserted, the **Insert BioChipSet Cassette** screen will automatically advance to the **Close Instrument Door** screen. If the screen does not advance, use both thumbs to gently press the outside edges of the cassette into the instrument's docking station until the screen advances.

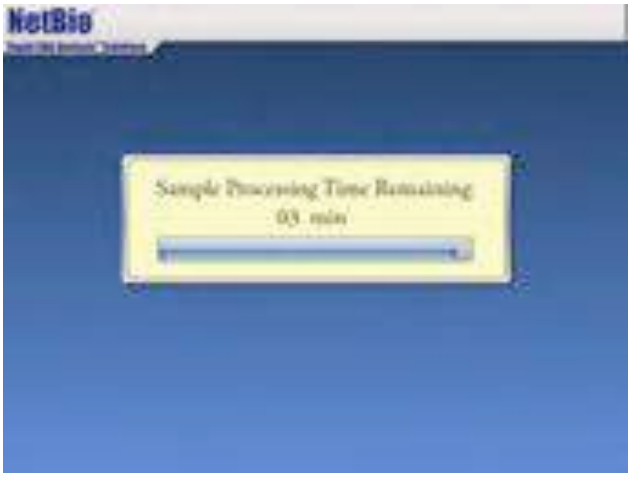
CAUTION
Do not touch internal docking station components. Protect against contamination from environmental or human contact.

5.2.3. Close the access door to initiate the run

Manually close the instrument's access door by pushing down on it just below the black handle. Press the door firmly against the instrument and hold it closed and until the door latches.

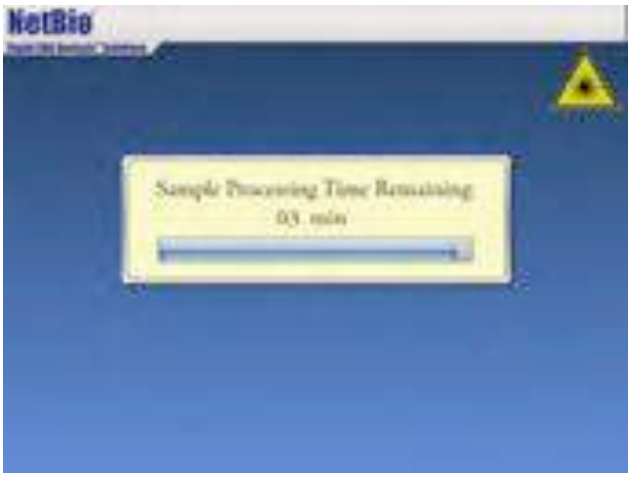
5.2.4. Run the ANDE instrument

Once the BioChipSet Cassette Access Door is closed, the instrument will automatically begin sample processing. There is no “start” button or any further action that the User must take to start the processing. The User Touch Screen will show a progress screen that displays the time remaining.



NOTICE

When the laser is operational, a laser hazard symbol is visible on the touch screen as demonstrated below.



NOTICE

It is not possible to transfer run data from the instrument to a USB stick during a run. Do not insert a USB stick into the instrument via the USB port while the instrument is processing samples. Accessing and downloading run data can only occur when the instrument is not processing samples.

5.2.5 Complete the run

After the sample processing is complete, the instrument door will pop open and a beep will occur every 30 seconds until the BioChipSet Cassette is removed.

- While wearing gloves, remove the BioChipSet Cassette immediately. Use two hands to carefully remove the cassette from the instrument:

- Close the instrument door, press firmly, and hold until it latches.

CAUTION

Immediately remove the BioChipSet Cassette from the instrument after completion of the run. If a used cassette is left in the instrument it may degrade and damage the instrument.

The User Touch Screen will show a **Process Complete** screen that displays the run result status for each of the 5 samples. For each sample, the **Process Complete** screen will display the Sample ID that was designated during the sample loading process. When the Lane Flag 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. See "Section 6.4.6. Configure ANDE system features" to change that setting. There are three flag options:

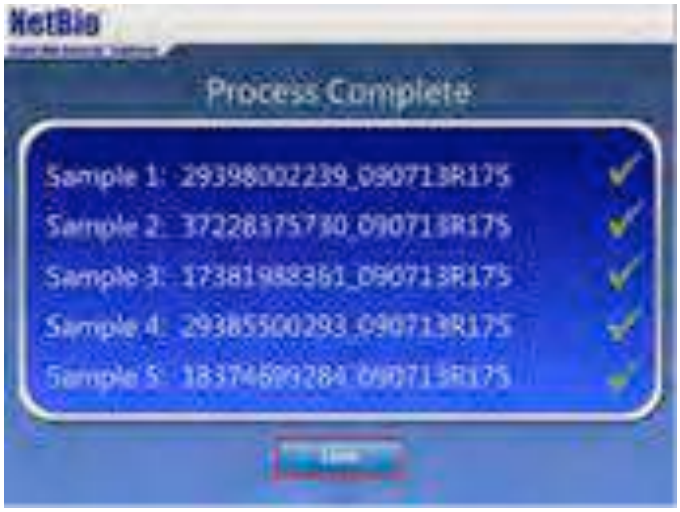
- A green checkmark indicates that the sample successfully passed the Expert System rules for all 13 CODIS core loci and also met the success criteria preconfigured (minimum number of CODIS core loci) by the SuperAdmin. An .xml (databasing) file is generated with the allele calls for all loci.

- 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".

NOTICE

The option for displaying a yellow check mark is a feature that can be enabled or disabled by a SuperAdmin. The default system setting is "enabled". A SuperAdmin should see "Section 6.4.6. Configure the system" to disable the lane flagging. When the yellow check mark option is disabled, the system will only display a green check mark or a red X as indicators of sample success.



- Touch the **Done** button to close the **Process Complete** screen.
- The run is now complete. The **Log In** screen will be displayed.
- The used BioChipSet Cassettes should be handled and disposed of according to state, regional, or local regulations. See the relevant BioChipSet Cassette documentation.

NOTICE

While wearing gloves, the User should place packaging tape over the cassette's pneumatic manifold. The tape should be wide enough to cover the pneumatic manifold with one piece. Do not use regular office tape.

5.3. Routine automated self-testing and instrument shut down

5.3.1. Routine automated self-testing

The instrument does not need to be shut down if used frequently. If the instrument is left on, a weekly Power On Self Test (POST) will take place automatically to verify the operational state of all subsystems. This testing requires 15 minutes.

- The User will receive a message 30 minutes prior to the initiation of POST.

- If the User takes no action, the POST will be initiated automatically in 30 minutes.

The User is given the option to postpone the POST if the timing is not convenient. To postpone the POST, touch the **Postpone** button on the **Weekly Self Test** message screen.

- If the POST is postponed by the User, the system will attempt another POST every 12 hours until it has been completed. It is recommended that the system undergo POST every 7 days and that the User not continually postpone the POST. If the timing of the routine POST is not convenient, at your earliest opportunity, shut down the system and restart it to manually initiate the POST (Warm Up) cycle.

5.3.2. Shut down the instrument

The instrument can be shut down if it is not going to be used for an extended period of time, or if the User would like to initiate a POST to assess the performance of the instrument's subsystems.

- The instrument can be shut down from the **Log In** screen by touching the **Shutdown** button.

- After touching the **Shutdown** button, the instrument will confirm that the User wishes to shut down the instrument. To shutdown touch the **Yes/Shut Down** button. To abort the shutdown and return to the **Log In** screen, touch the **No** button:

- If the **Yes/Shut Down** button is selected, the system software will power itself down. The User Touch Screen will become blank when the system shutdown has been completed. The User should turn the instrument off by pushing the power switch on the back of the instrument into the OFF position. The instrument has now been fully powered down.

6. ANDE USER ACCOUNT MANAGEMENT: FEATURES AND FUCTIONALITY

6.1 Overview of ANDE User accounts and privileges.

Access to ANDE instrument features, functionality, and account management varies by User class. The table below summarizes the privileges granted to the three ANDE User classes; Operator, Admin and SuperAdmin.

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

This chapter provides instructions for and is organized by User class—Users holding Operator accounts see Section 6.2; Admin see Section 6.3; and SuperAdmin see Section 6.4.

6.2 Operator Account

A SuperAdmin or Admin can create Operator account. Operators can perform the following tasks:

- Perform Run
- Manage Data
- Logout

The following table summarizes the Operator privileges:

Account Privileges	Operator
Perform a Run	X
Manage Data	X
• View lane success results (green/yellow/red indicators)	X
• Export encrypted run and telemetry data	X
• Generate run reports	X

6.2.1 Operator account access: log in and password management

SuperAdmin and Admin can create Operator accounts. The first time an Operator account is created, a SuperAdmin or Admin will create a temporary account. When the Operator logs in for the first time with the SuperAdmin or Admin designated User Name and Password, he or she will be immediately prompted by the system to create a new password.

6.2.1.1. Log in to the ANDE instrument

6.2.1.1.1. Log in for the first time

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 provided by the SuperAdmin or Admin. Then touch the white box next to the Password field. Enter the temporary password provided by the SuperAdmin or Admin, and touch the **Log In** button. In the following example, the designated temporary User Name is “Operator”.

- 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 Password. Enter the required information into the fields provided. The password should adhere to the rules below. After all fields have been completed, touch the **Change** 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 designated User Name and new password to Log in.

6.2.1.1.2. Log in after a unique Operator 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 unique User password, and touch the **Log In** button.

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

6.2.1.2 Operator password management

6.2.1.2.1. Expired password

The manufacturer default for passwords expiration is six months, but the password expiration time can be set to 1-12 months by the SuperAdmin. When a User attempts to log in with an expired password, the system displays a message informing the User their password has expired and will prompt him or her to create a new password. Press the **OK** button to create a new password.

- The **Change Password** screen will be displayed to allow the User to create a new password. The User 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.

6.3.1.2.2. Incorrect login or forgotten password

Operators are allowed three attempts to log into the instrument via the **Log In** screen. If the user name or password is incorrectly entered three times, the account will be locked. Contact a SuperAdmin or Admin to unlock the account.

6.2.2 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 Operator can perform a run by touching the **Perform Run** button on the Operator Menu:

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

6.2.3 Manage data on the ANDE instrument

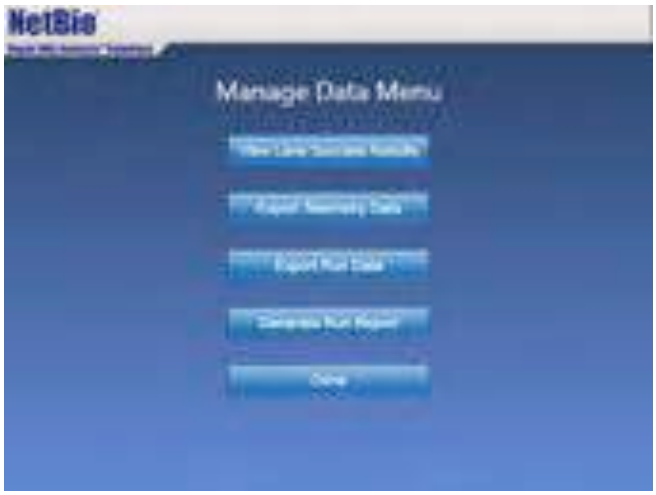
The **Manage Data** feature allows the Operator to access and manage data directly on the ANDE instrument. Data can also be managed using the ANDE Data Management Software by exporting it off the instrument via USB or Ethernet and importing to a computer with the ANDE Data Management Software installed. The data export instructions provided in this section are intended to instruct Operators 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 Operator can manage data on the ANDE instrument by touching the **Manage Data** button.

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

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

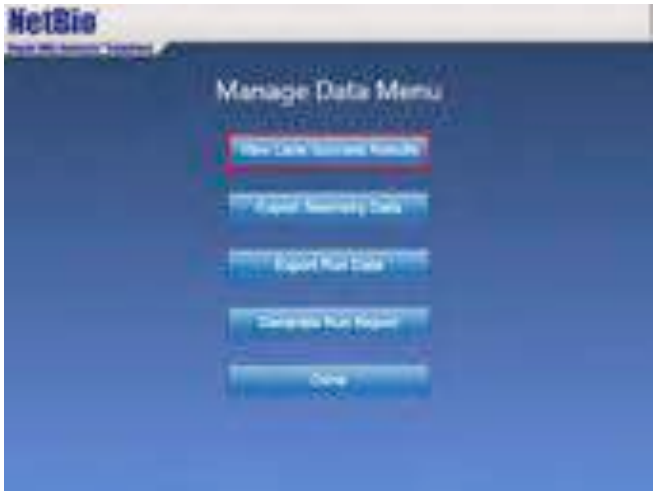


To perform any of the above tasks, the Operator should touch the appropriate button.

6.2.3.1 View Lane Success Results

The **View Lane Success Results** feature allows the Operator 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 Operator to view the results at a later time by accessing the **Manage Data Menu** screen and touching the **View Lane Success** button.

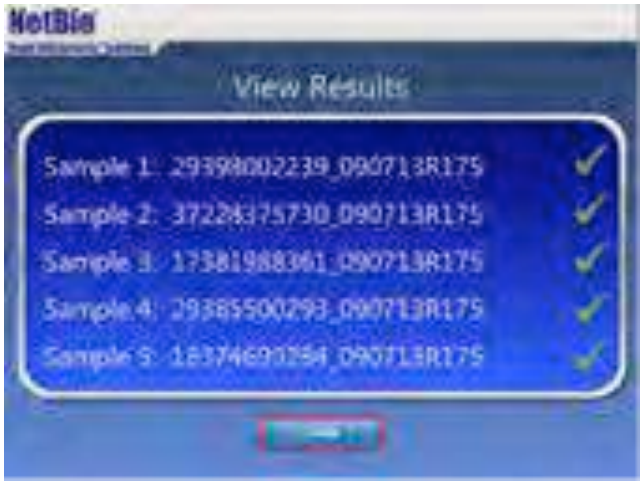
- Touch the **View Lane Success Results** button.



- 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.

6.2.3.2 Export run data

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

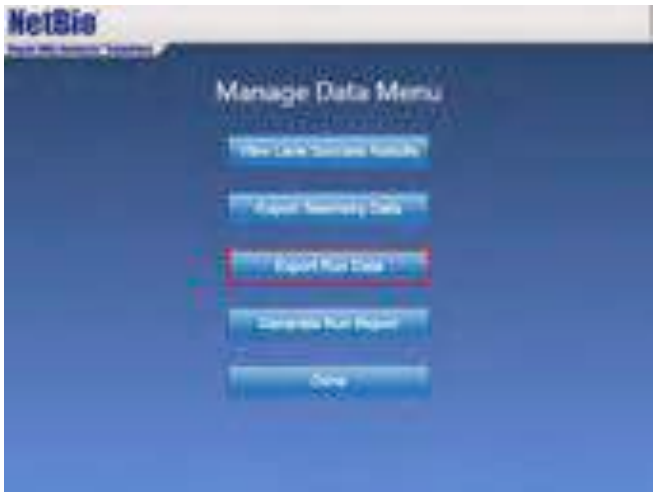
- A CODIS compatible .xml file for database searching. This file can be customized to be compatible with other international databases).
- A standard .fsa file containing the raw data that is compatible with other commercially available genotype analysis software programs
- A .png file that displays 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 Operator 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 7.4.2 Manage Data on ADMS” for instructions on data export using ADMS.

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.

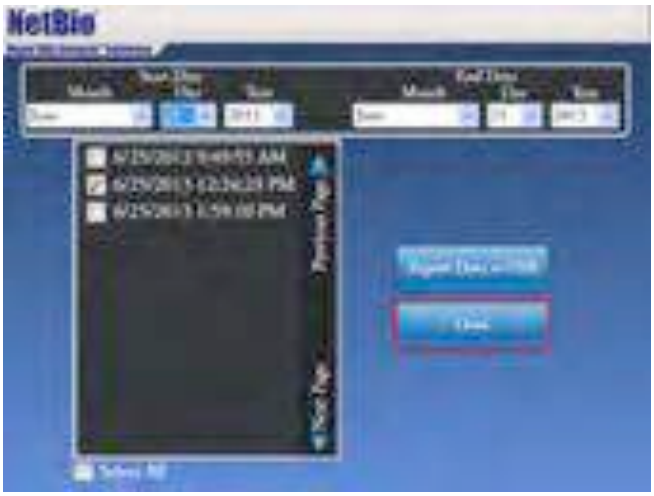
NOTICE. If the USB drive has not been properly inserted into the ANDE instruments USB port or if the USB drive has not properly read, a message will inform the Operator to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export 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 7.4.2 Manage Data on ADMS” for instructions on importing and managing ANDE data using the ANDE Data Management Software.

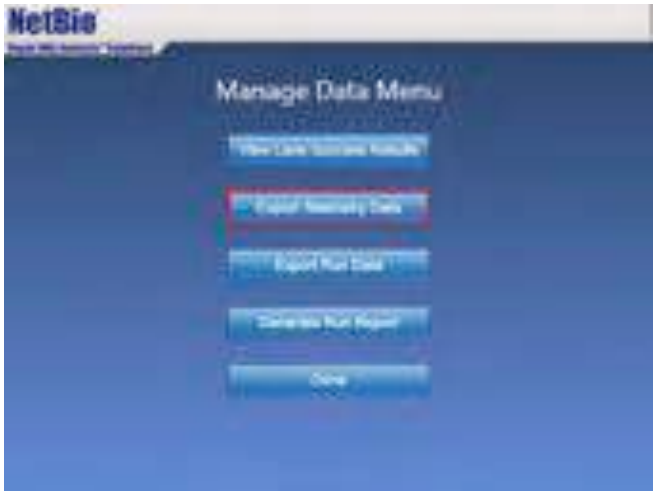
6.2.3.3 Export telemetry data

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 Operator 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 7.4 ADMS Operator account" for instructions on importing and managing ANDE data using the ANDE Data Management Software.

6.2.3.4 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.

6.2.3.5 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 **Manage Data Menu** screen.

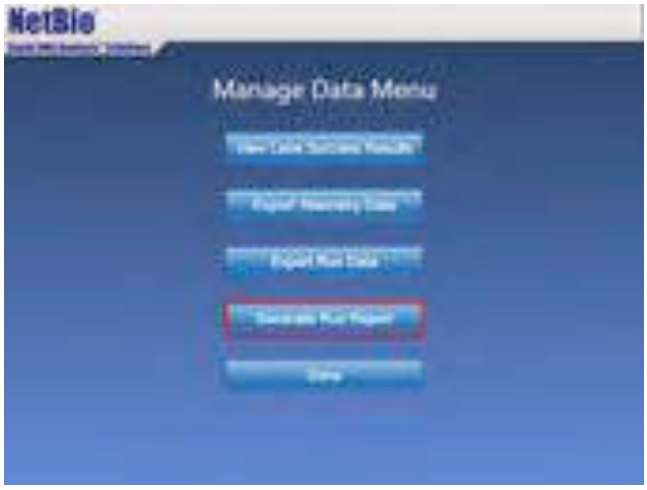
A run report will contain the following information:

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.

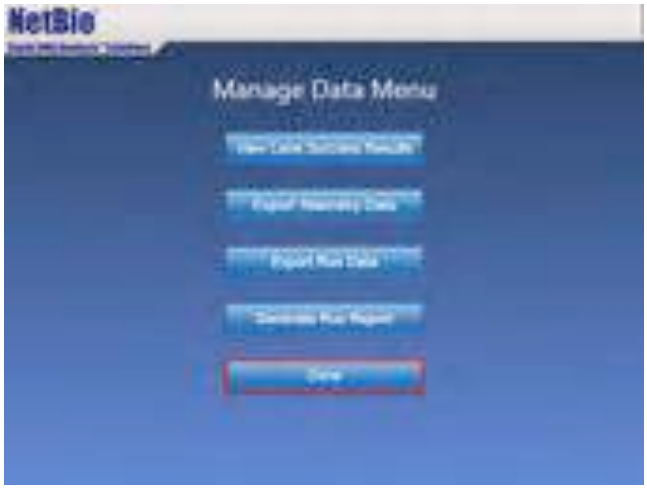
- As the run reports are being exported, a progress bar will be displayed to display export progress.

- 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 7.4 ADMS Operator account" for instructions on importing and managing ANDE data using the ANDE Data Management Software.

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



6.2.4 Logout

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

- The Operator can Logout by touching the **Logout** button on the **Operator 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 Operator wishes to shutdown the instrument, see “Section 5.3.2 Shut down the instrument” for instructions on how to shutdown the instrument.

6.3 Admin Account

Only a SuperAdmin can create Admin account. Admins have more advanced privileges and access to the features of the instrument than Operators, but less privileges and access than SuperAdmins. Admin accounts should be reserved for those Users who will be managing Operator accounts and viewing and managing ANDE data.

The Admin can perform the following tasks:

- Perform Run
- Manage Data
- Manage User Accounts
- Get Info
- Logout

The following table summarizes the Admin privileges:

Account Privileges	Admin
Perform a Run	X
Manage Data	X
- View last run's results (green/yellow/red indicator)	X
- View run data	X
- Export encrypted run and telemetry data	X
- Export optical data	X
- Generate run reports	X
Manage User Accounts	X
- Add Operator accounts	X
- Modify Operator accounts	X
- Manage Operator passwords	X
- Delete Operator accounts	X
Get Info	X

6.3.1 Admin account access: log in and password management

A SuperAdmin can create Admin accounts. The SuperAdmin will create a temporary account for an Admin, and when the Admin logs in for the first time with the SuperAdmin designated User Name and Password, he or she will be immediately prompted by the system to create a new password.

6.3.1.1. Log in to the ANDE instrument

6.3.1.1.1. Log in for the first time

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 provided by the SuperAdmin. Then touch the white box next to the Password field. Enter the temporary password provided by the SuperAdmin, and touch the **Log In** button. In the following example, the designated temporary User Name is “Admin”.

- 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 Password. Enter the required information into the fields provided. The password should adhere to the rules below. After all fields have been completed, touch the **Change** 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 designated User Name and new password to Log in.

6.3.1.1.2. Log in after a unique Admin 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 unique User password, and touch the **Log In** button.

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

6.3.1.2 Admin password management

6.3.1.2.1. Expired password

The manufacturer default for passwords expiration is six months, but the password expiration time can be set to 1-12 months by the SuperAdmin. When a User attempts to logs in with an expired password, the system display a message informing the User their password has expired and will prompt him or her to create a new password. Press the **OK** button to create a new password.

- The **Change Password** screen will be displayed to allow the User to create a new password. The User 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.

6.3.1.2.2. Incorrect login or forgotten password

Admins are allowed three attempts to log into the instrument via the **Log In** screen. If the user name or password is incorrectly entered three times, the account will be locked. Contact a SuperAdmin to unlock the account.

6.3.2 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 Admin can perform a run by touching the **Perform Run** button on the Admin Menu: