

NetBio®

Rapid DNA Analysis™ Solutions

ANDE™ 6C Rapid DNA Analysis™ System

Product User Manual



Product Number: NB-INST-0006

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1. INTRODUCTION

This User Manual provides the instructions required to operate the ANDE 6C Rapid DNA Analysis System safely. In order to operate the ANDE 6C Rapid DNA Analysis System in the intended manner, the following prerequisites must be fulfilled:

- User has read and understood the safety instructions and material outlined in this User Manual.
- User had read understood the safety instructions and material outlined the associated ANDE Health and Safety Manuals (NB-INST-0006-502).
- ANDE 6C instrument has been installed according to the instructions in this User Manual.

This chapter contains important User information, description of safety notices, regulatory information, and a general description of the intended use of the ANDE 6C Rapid DNA Analysis System.



NOTICE

All images contained in this manual, including photographs, diagrams, and ANDE instrument screen shots, are for reference only.

1.1. 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/>).

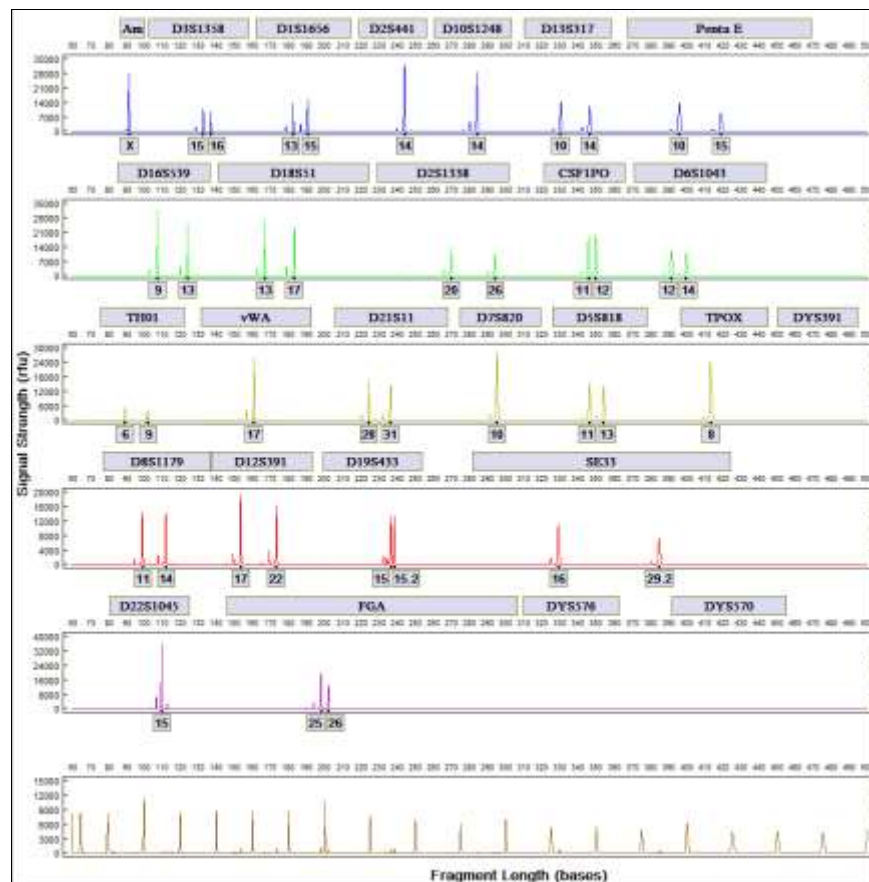
Several countries have selected sets of specific STRs to be used in identification for law enforcement and other applications. Country- or agency-specific loci for use in the ANDE 6C Rapid DNA Analysis System have been selected because they satisfy the needs of several major law enforcement agencies 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 section 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. A concentration step is included for low DNA content samples. 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 several dyes is added. The use of these dyes (one of which is employed to help calculate the size of the STR fragments) allows laser-based detection.

Electrophoresis is used to determine the size of the copied STR fragments. During this process, an electric current is applied that exerts a force on the STR fragments causing them to migrate through a porous gel-like substance. The smaller fragments, being less impeded, travel more quickly through the gel than the larger fragments, thus separating them by size. As the various sized fragments pass through the optical detection zone, a laser excites the fluorescent dyes causing it to emitted light that is then detected and used to determine the size of each STR fragment. An Expert System analyzes the size pattern and generates the final STR profile--the individual’s DNA fingerprint.

FlexPlex 27 DNA Fingerprint Generated by the ANDE 6C Rapid DNA Analysis System

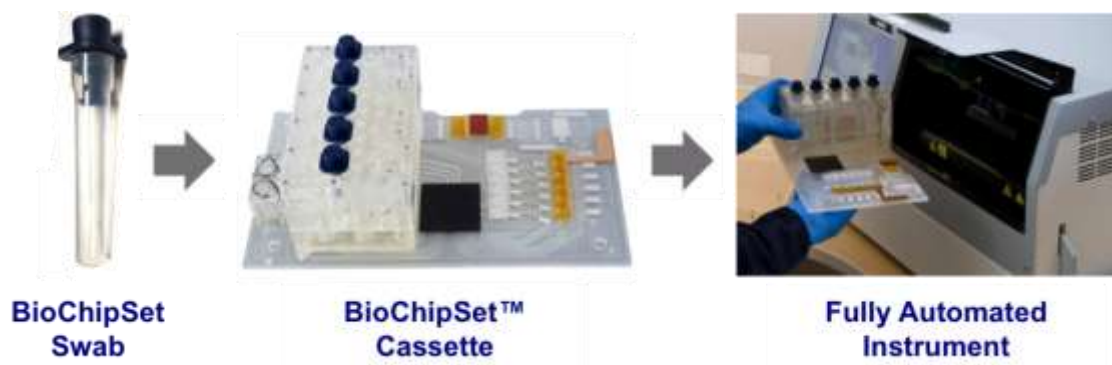


After STR profiles are generated using the ANDE 6C Rapid DNA Analysis System the results can be collected and compared in local, state, national, or international DNA databases. .

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.

1.2. Overview of the ANDE 6C Rapid DNA Analysis System

The ANDE 6C Rapid DNA Analysis System is 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 6C System consists of the BioChipSet Swab, the NetBio BioChipSet™ Cassette, and the ANDE 6C Rapid DNA Analysis instrument.



The ANDE System is operated by inserting up to five swab samples into a BioChipSet Cassette, placing the Cassette into the ANDE instrument, and then closing the instrument's door to initiate a run. The ANDE instrument contains all of the subsystems required to perform STR analysis. The 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.

Major attributes of the ANDE 6C System:

- Produces STR profiles in 85 to 100 minutes (depending on chip type and assay type being used) and can be operated by a non-technical user with minimal training.
- Offers two different chip types, Low and High DNA Content BioChipSet Cassettes, and two different STR assay types, PowerPlex®16 (PP16) and FlexPlex™27 (FP27), providing the broadest possible capabilities for analysis of DNA samples.
- All reagents are contained on-board the BioChipSet Cassettes. The user neither loads the instrument nor the 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 Cassette is closed: Each sample is processed through its own sealed processing path, and samples and reagents do not come in contact with the instrument itself.

- Each 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 instrument is ruggedized for transport and shock and has been tested in accordance with Military Standard 810G. 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 an integrated sample tracking system (using RFID and Barcoding), 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 data analysis for automated 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 utilizes two separate BioChipSet Cassettes, one for high and the other for low DNA content samples, to provide the largest possible range of sample processing. The High DNA Content (HDC) BioChipSet Cassette was designed for the purification and analysis of samples containing a high quantity DNA, e.g. buccal swabs. A typical buccal swab contains in excess of 1 μ g of genomic DNA, but only one-thousandth of this amount is required to generate an STR profile. Accordingly, the HDC BioChipSet purification module was designed to discard ~99.9% of the total sample DNA prior to amplification. To enable processing of samples with a low DNA content, the HDC BioChipSet Cassette purification module was modified for high efficiency DNA purification. This was accomplished by (1) maximizing the volume of cell lysate subjected to DNA purification; (2) increasing the efficiency of the DNA binding protocol; and (3) incorporating a post-purification DNA concentration step. It utilizes the same reagents, form factor, ANDE instrument, and BioChipSet swabs.

Multiplexed STR amplification is performed within the BioChipSet Cassettes with PowerPlex 16 STR chemistry and NetBio's Flexplex 27 STR chemistry, an expanded 27-locus STR assay that incorporates both international, CODIS 13, and CODIS 20 loci.

To perform a run on the ANDE 6C System, the User follows the on-screen GUI instruction to load a sample swabs into each of the Sample Chambers of the Cassette. After all Sample Chambers are loaded, the User inserts the Cassette into the ANDE instrument and closes the Access Door to initiate the run. The System software coordinates the required sequence of steps within the instrument and the Cassette to analyze the samples and generate STR profiles. For a more detailed description of the ANDE 6C Rapid DNA Analysis System and its components, see section 3. *System Description*.

1.3. Important User information



Read this section before using the ANDE 6C Rapid DNA Analysis System instrument.

All Users must read the safety instructions in the ANDE 6C Rapid DNA Analysis System User Manual and accompanying Health and Safety Manual (NB-INST-0006-502) before installing or operating the ANDE 6C System.

Users should operate the ANDE 6C Rapid DNA Analysis System instrument only as described in this User Manual. Failure to operate the ANDE 6C instrument in the approved manner may expose the User to hazards that can lead to personal injury and may cause damage to the ANDE 6C instrument.

1.3.1. Intended use

This manual is written for people who will process human buccal or blood samples collected on NetBio BioChipSet™ Swabs using the ANDE 6C instrument to generate DNA profiles for human identification (HID). It provides step-by-step instructions on how to operate the ANDE 6C instrument in conjunction with its associated consumables (BioChipSet Cassettes and NetBio BioChipSet Swabs).

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

1.3.2. 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.

1.3.3. 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 6C 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
BCS	BioChipSet	ANDE consumable
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 ANDEANDE 6C 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
FP27	FlexPlex 27	NetBio's 27-locus STR chemistry used on board the BioChipSet Cassette for multiplexed STR amplification.
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 ANDEANDE 6C instrument
HID	Human Identification	Use of DNA analysis results, conventional fingerprints, or other modalities to identify individuals
LED	Light-Emitting Diode	Semiconductor that converts electricity to light
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 ANDEANDE 6C instrument
PP16	PowerPlex 16	Promega's PowerPlex 16 STR chemistry used on board the BioChipSet Cassette for multiplexed STR amplification
PPE	Personal protective equipment	Equipment worn to minimize exposure to serious workplace injuries and illnesses
RAPID DNA		The FBI's definition: Rapid DNA, or Rapid DNA Analysis, describes the fully automated (hands free) process of developing a CODIS Core STR profile from a reference sample buccal swab. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention
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"
SWGDM	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
Touch Samples		items containing epithelial cells left by the individual after coming into contact with a surface such as a drinking glass, articles of clothing, or handled objects
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

1.3.4. 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.

1.4. Regulatory Information

This section describes the directives and standards that are fulfilled by the ANDE 6C Rapid DNA Analysis System instrument.

1.4.1. Manufacturing information

The table below summarizes the required manufacturing information:

Name and address of Manufacturer	
NetBio	266 2 nd Avenue Waltham, MA 02451 USA

1.4.2. International safety standards

This product complies with in accordance with EC Directive 2004/108/EC (EMC Directive) and EC Directive 2006/95/EC (Low Voltage Directive) and the standards list below:

EMC	CFR47 FCC Part 15 Subpart C:2015 15.225
	CFR47 FCC Part 15 Subpart B:2015
	IC RSS-210 Issue 8 December 2010 Annex 2.6
	IC RSS-Gen Issue 4 November 2014
	ICES-003 Issue 5 August 2012
	EN 61326-1:2013
	IEC 61326-1:2012
	ETSI EN 300 330-1 V1.7.1 (2010)

	ETSI EN 300 330-1 V1.5.1 (2010)
	ETSI EN 301 489-1:2011
	ETSI EN 301 489-3:2013
Product Safety	UL 61010-1:2012
	CSA C22.2 #61010-1:2012
	EN/IEC 61010-1:2010
	EN/IEC 61010-2-010:2014
	EN/IEC 61010-2-081:2015
	EN/IEC 60825-1:2014

Testing performed by:

Intertek Testing Services NA, Inc. 70 Codman Hill Road Boxborough, MA 01719 USA www.intertek.com

1.4.3. Environmental conformity

The ANDE 6C Rapid DNA Analysis System is covered by the Waste Electric and Electronic Equipment Directive and is designated as category 9 for collection and recycling.

Directive	Title
2012/96/EU	Waste Electrical and Electronic Equipment (WEEE) Directive (category 9)

1.4.4. Regulatory compliance of connected equipment

Any equipment connected to the ANDE 6C System 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

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.

During regular operation, the ANDE 6C 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 6C instrument, the User must be aware of the hazards described in the User Manual and Health and Safety Manual for ANDE 6C Rapid DNA Analysis System instrument. Follow the instructions provided to avoid personal injury or damage to the instrument.

The Health and Safety Manual for this product describes safety precautions, safety labels, and emergency procedures for the ANDE 6C Rapid DNA Analysis System instrument, in addition to providing information on the safe disposal of the ANDE 6C instrument. See Health and Safety Manual (NB-INST-0006-502).

2.1. Safety precautions

2.1.1. General precautions



Do not use the ANDE 6C 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.



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.



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.

**WARNING**

The Integrated RFID/Barcode Reader (LED output) found on the front of the ANDE 6C instrument could cause serious eye injury. Do not view the LED output with optical instruments such as magnifiers, eye loupes or microscopes within a distance of 100 mm. Max LED output: 141.2 μ W.

**CAUTION**

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

**CAUTION**

Use of this ANDE 6C 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.

**WARNING**

Users must reference the Safety data sheets (MSDS or SDS) for the BioChipSet Cassette prior to operating the instrument.

**CAUTION**

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

**CAUTION**

When handling biological samples Users must ensure that they use the appropriate personal protective equipment

2.1.3. Installing and moving the ANDE 6C 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 6C 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 6C Rapid DNA Analysis System instrument should be limited to qualified NetBio personnel only. ANDE 6C Rapid DNA Analysis System instrument is not User serviceable. Please contact NetBio for additional information.



WARNING

Do not open the ANDE 6C instrument or attempt to modify the ANDE 6C 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 6C 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 6C instrument. This may result in product malfunction or electric shock.

**CAUTION**

Wear gloves while cleaning the exterior of the ANDE 6C 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 6C 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.

2.1.6. FCC and IC Caution Statements

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

**CAUTION**

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**CAUTION**

English Translation: 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.



CAUTION

English Translation: This device complies with Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions:

- This device may not cause interference; and
- This device must accept any interference, including interference that may cause undesired operation of the device.

French Translation: Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- l'appareil ne doit pas produire de brouillage;
- l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.



NOTICE

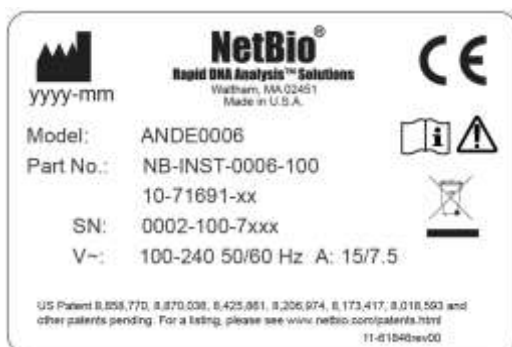
The ANDE system comes with a WiFi USB dongle that is certified under the FCC ID: S9ZTEW664UB. Note that the WiFi capability on board the system is not enabled and is reserved for future use. Contact your NetBio representative for additional information on the ANDE System's WiFi capability.

2.2. Labels







The ANDE 6C 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 6C instrument. The User should review this section carefully to be fully informed of all warning and hazards associated with operating the instrument.





2.2.1. Symbols and labels used on the ANDE 6C instrument



The ANDE 6C serial label is located on the back of the ANDE 6C instrument and provides manufacturer information, including serial number and date of manufacturing:



In addition, the following symbols and labels are used on the ANDE 6C System:

	<p>WARNING! Read the User Manual and accompanying Health and Safety Manual before using the ANDE 6C instrument. Do not open any covers or replace parts other than the air filter.</p>
	<p>This symbol marks the date of manufacture.</p>
	<p>Consult instructions before use.</p>
	<p>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 6C instrument.</p>
	<p>Indicates that the ANDE 6C instrument has been certified by a Nationally Recognized Testing Laboratory (NRTL). 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.</p>
	<p>Provides warning against actions or situations that could result in contact with electrical circuits, causing personal injury or death.</p>

	<p>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.</p>
	<p>Provides warning of potential mechanical impact, crush hazard, or potential pinching injury.</p>
	<p>Provides warning against contact with potentially hot surfaces or other burn hazards.</p>
	<p>Alerts the User to the danger of Electro-Static Discharge (ESD) susceptibility.</p>
<div data-bbox="250 788 599 1046"> <p>CLASS 1 LASER PRODUCT Complies with FDA performance standards for laser product except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007</p> <hr/> <p>Complies with IEC 60825-1 :2007 Wavelength: 488nm Visible Laser Radiation < 1mW</p> <p>11-61516 REV 03</p> </div> <div data-bbox="250 1078 599 1336"> <p>KLASS 1 LASER product uppfyller FDAs krav för laserprodukter Med unantag för Laser Notice No. 50, daterad den June 24, 2007</p> <hr/> <p>uppfyller FDAs krav enligt IEC 60825-1 :2007 Våglängd: 488 nm synlig Laserstrålning < 1 mW</p> <p>11-61544 REV 01</p> </div>	<p>Provides Class 1 laser product information in English and Swedish. See Health and Safety Manual for additional information.</p>
<div data-bbox="250 1384 599 1727"> <p>CAUTION AVOID EXPOSURE TO BEAM CLASS 3B LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED</p> <p>ATTENTION EVITER TOUTE EXPOSITION LASER CLASSE 3B RAYONNEMENT QUAND LE SYSTEME EST OUVERT ET LE VERROUILLAGE EST DESARMÉ</p> <p>11-60271 REV 02</p> </div> <div data-bbox="250 1745 599 1913"> <p>VARNING UNDVIK EXPONERING FÖR LASER STRÅLNING KLASS 3B VID BRUTEN FÖRREGLING</p> <p>11-60271 REV 02</p> </div>	<p>Provides Class 3B laser caution in English, French, and Swedish to comply with international standards. See Health and Safety Manual for additional information.</p>


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.
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
FCC	The Federal Communications Commission (FCC) marking certifies that the electromagnetic interference from the device is under the limits approved by the United States FCC.
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation	The FCC compliance label accompanies the FCC marking.

2.2.2. Position of symbols and labels on the ANDE 6C instrument

Safety warning symbols visible on front of instrument:

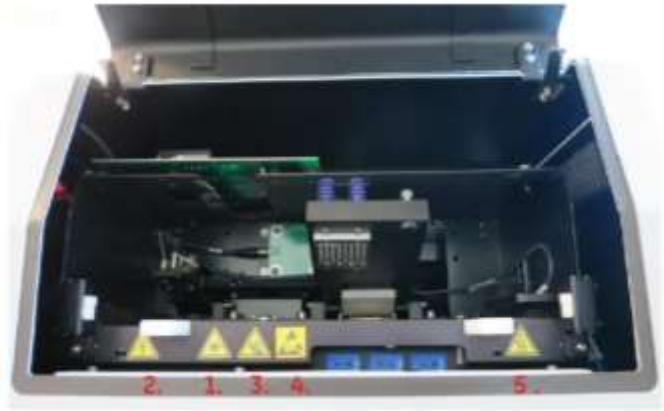
1.		Laser Caution
----	---	---------------



 **WARNING**
 The Integrated RFID/Barcode Reader (LED output) found on the front of the ANDE 6C instrument could cause serious eye injury. Do not view the LED output with optical instruments such as magnifiers, eye loupes or microscopes within a distance of 100 mm. Max LED output: 141.2 μW.

Safety warning symbols visible with front access door open:





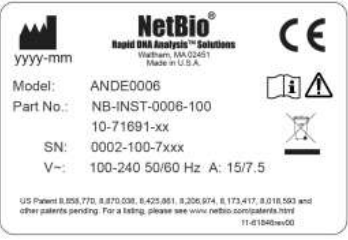


1.		Laser Caution
2.		Electrical Hazard
3.		Impact/Crush/Pinch Point Hazard
4.		Anti-Static
5.		Thermal Hazard





Safety warning symbols and labels visible on back panel:









1.		Two-Person Lift
2.	I O	Power ON/OFF


3.	 <p>CONFORMS TO ANSI/UL Std. E1010-1 & IEC Std. E1010-2-0&1 CERTIFIED TO CAN/CSA Std. C22.2 No. E1010-1 1541715 rev00</p>	ETL Safety Compliance
4.	 <p>CLASS 1 LASER PRODUCT Complies with FDA performance standards for laser product except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007 Complies with IEC 60825-1 :2007 Wavelength: 488nm Visible Laser Radiation < 1mW 11-41518 REV 03</p>	Class I laser – English
5.	 <p>KLASS 1 LASER product uppfyller FDA:s krav för laserprodukter med undantag för Laser Notice No. 50, daterad den 24 juni 2007 uppfyller krav enligt IEC 60825-1 :2007 Våglängd: 488 nm synlig Laserstrålning < 1 mW 11-41518 REV 03</p>	Class 3B laser –Swedish Class 1 laser –Swedish
6.		Refer to User Manual
7.	 <p>yyyy-mm Model: ANDE0006 Part No.: NB-INST-0006-100 10-71691-xx SN: 0002-100-7xxx V-: 100-240 50/60 Hz A: 15/7.5 CE i A US Patent 8,058,770, 8,870,038, 8,425,861, 8,206,974, 8,173,417, 8,018,593 and other patents pending. For a listing, please see www.netbio.com/patents.html 11-41518rev00</p>	Manufacturer Information
8.	 <p>CAUTION AVOID EXPOSURE TO BEAM CLASS 3B LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED ATTENTION EVITER TOUTE EXPOSITION LASER CLASSE 3B RAYONNEMENT QUAND LE SYSTEME EST OUVERT ET LE VERROUILLAGE EST DESARME 11-41518 REV 03</p>	Class 3B laser – English and French
9.	 <p>VARNING UNDVIK EXPONERING FÖR LASER STRÅLNING KLASS 3B VID BRUTEN FÖRREGLING 11-41518 REV 03</p>	Class 3B laser –Swedish

10.		Regulatory Compliance Mark (RCM)
11.		Federal Communications Commission Marking
12.	This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.	FCC Compliance Label

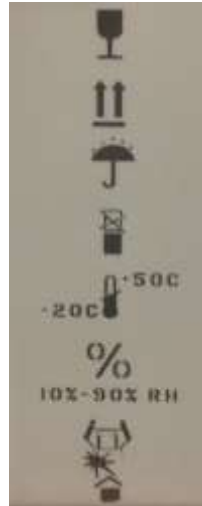
2.2.3. Symbols on transport case

The ANDE 6C instrument transport case has the following symbols:

	Keep away from sunlight
	Fragile contents
	This way up indicator
	Keep package dry
	Do not stack
	Temperature storage range
<p style="text-align: center;">%</p> <p>10% - 90 % RH</p>	Humidity storage range

	Multi-person lift
---	-------------------

2.2.4. Position of labels on transport case



2.3. Emergency procedures

In case of emergency:

- Turn off the ANDE 6C Rapid DNA Analysis System instrument power switch.
- Disconnect the power cord from the wall socket.

2.4. Recycling information

This section contains information about the decommissioning of the ANDE 6C instrument.

2.4.1. Decontamination

The ANDE 6C 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 6C 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 6C instrument.



3. SYSTEM DESCRIPTION



NOTICE

All images contained in this manual, including photographs, diagrams, and ANDE 6C 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 6C Rapid DNA Analysis System hardware components, software, and consumables.

3.1. ANDE 6C Instrument

The ANDE 6C 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 6C instrument has been ruggedized according to U.S. Military Standard 810G 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 its transport case, plugs it in, and turns on the power switch. The system will perform an initial warm-up cycle (approximately 15 minutes) 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 6C Rapid DNA Analysis System provides a customizable foundation for STR profiling that supports future expanded forensic sample analysis capabilities.

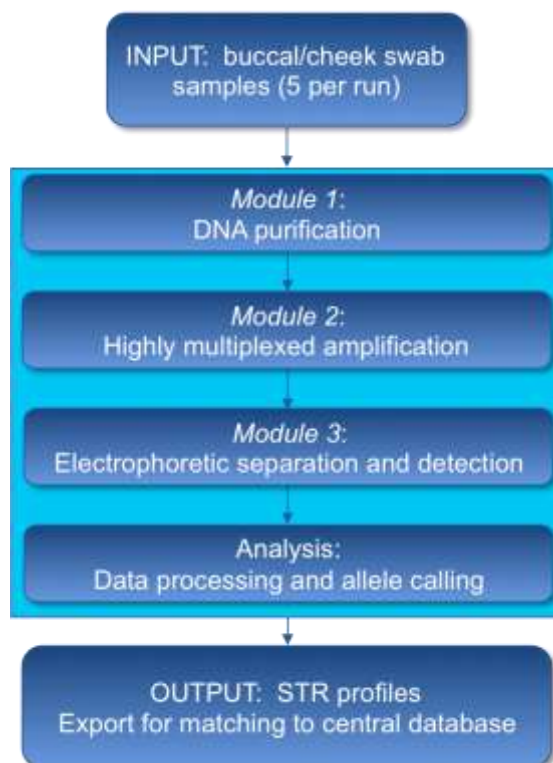
Major attributes of the ANDE 6C System:

- Produces STR profiles in 85-100 minutes (depending on chip type and assay type being used) and can be operated by a non-technical user with minimal training.

- Offers two different chip types, Low and High DNA Content BioChipSet Cassettes, and two different STR assay types, PowerPlex® 16 (PP16) and FlexPlex™ 27 (FP27), providing the broadest possible capabilities for analysis of DNA samples.
- All reagents are contained on-board the BioChipSet Cassette. The user neither loads the instrument nor the 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 Cassette is closed: Each sample is processed through its own sealed processing path, and samples and reagents do not come in contact with the instrument itself.
- Each 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 6C instrument is ruggedized for transport and shock and has been tested in accordance with Military Standard 810G. 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 an integrated sample tracking system (using RFID and Barcoding), 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 data analysis for automated 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.

To perform a run on the ANDE System, the User follows the on-screen GUI instruction to load a sample swabs into each of the Sample Chambers of the Cassette. If the User wants to perform a run with less than the maximum number of samples, a blank swab should be placed into each empty Sample Chamber. After all Sample Chambers are loaded, the User inserts the Cassette into the ANDE instrument and closes the Access Door to initiate the run.

The process flow for generating DNA profiles using the ANDE 6C Rapid DNA Analysis System is outlined in the image below. All processing steps performed automatically by the ANDE 6C 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 6C instrument subsystems. For more details on the BioChipSet Cassette processing steps, see section 3.2.1 *Sample processing steps*.



Once the ANDE system has completed its analysis, the Access Door automatically opens. To complete the run the User simply removes the BioChipSet from the instrument and shuts the door. The STR profile data can be easily exported from the instrument and the results can be collected and compared in local, state, national, or international DNA databases.

3.1.1. Specifications

The ANDE 6C instrument is a standalone, computer-controlled, electromechanical instrument.

Analysis time	85-100 minutes, depending on chip and assay type
STR Analysis	<ol style="list-style-type: none"> 1. Promega’s PowerPlex 16 (PP16): amplifies 16 loci, including CODIS 13 2. NetBio’s FlexPlex 27 (FP27): amplifies 27 loci, including all international, CODIS 13, and CODIS 20 loci
Available BioChipSet Types	<ol style="list-style-type: none"> 1. High DNA Content BioChipSet Cassette (HDC BCS) 2. Low DNA Content BioChipSet Cassette (LDC BCS) 3. Demo BioChipSet Cassette
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	54 kg (117 lbs) with dimensions 75 (W) × 45 (H) × 60 (D) cm (29.5 (W) × 17.6 (H) × 23.6 (D) inches)
Weight/Dimensions (in hard transport case)	99.5 kg (219.4 lb) with dimensions 94.3 (W) × 98.6 (H) × 104.4 (D) cm (37.1 (W) × 38.8 (H) × 41.1 (D) inches)
Power	<p>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</p> <p>Power cables with plugs fitted for the United States, EU, and United Kingdom are supplied with the ANDE 6C instrument:</p> <p>IEC-320-C19 / NEMA 5-15 plug / 3×14 AWG SJTW cable for 125 V, 15 A (U.S.) or equivalent</p> <p>IEC-320-C19 / CEE 7 plug / H05VV-F cable for 230 V, 16 A (EU) or equivalent</p> <p>IEC-320 EN 60320 C19 to UK plug / BS1363A cable for 200-240 V, 16 A (UK) or equivalent</p> <p>Generator: Sine wave AC power ONLY, as rated above.</p> <p>Uninterruptable Power Supply (UPS): double conversion recommended (not supplied with the ANDE 6C instrument)</p>
Altitude	The ANDE 6C System Software includes a range of instrument start-up times in order to accommodate operation at different altitudes and air densities.
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 6C Rapid DNA Analysis System instrument will run a self-test upon power up. The ANDE 6C instrument conforms to the following conditions under U.S. Military Standard 810G: (1) Vibration exposure for secured cargo, Method 514.6, Category 4 --Common carrier (U.S. Highway Truck Vibration Exposures) Table 514.6C-II, Figure 514.6C-1; (2) Drop exposure, Method 516.6, Procedure IV; (3) Shock limit, Method 516.6, Procedure III; (4) Bench handling, Method 516.6, Procedure IV.
Data Output Files	<ol style="list-style-type: none"> *A CODIS compatible .xml file for database searching. This file type is only generated for samples that pass the Expert System rules. 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). *Customizable data formats available upon request
--	---



NOTICE

Maximum storage temperature is 50°C (122°F) for the ANDE 6C instrument.

3.1.2. External features

External features of the ANDE 6C instrument include:

1. User Touch Screen
2. Integrated RFID/Barcode Reader (LED output)
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 6C Instrument



Features on the Back of ANDE 6C Instrument

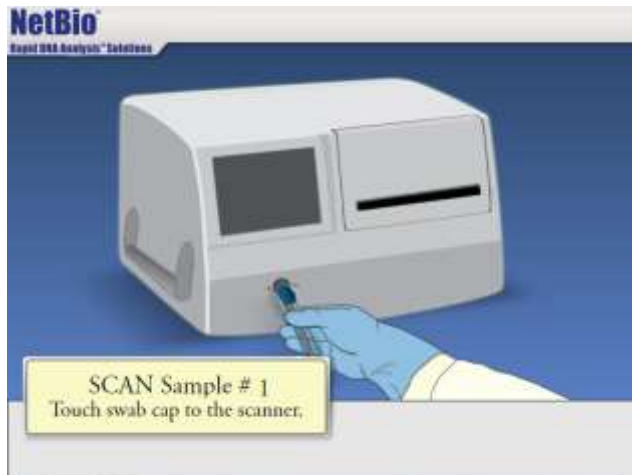


The information below describes in detail the ANDE 6C instrument external features:

- 1. User Touch Screen:** When the ANDE 6C 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 6C instrument, and, following process completion, removing the BioChipSet Cassette from the ANDE 6C instrument.
 - The ANDE 6C instrument utilizes a touch screen monitor for information display and ANDE 6C instrument control. The User firmly touches the screen to activate on-screen control buttons.
 - For manual data entry, such as log in name and password or entering sample ID information (should the customer select to disable the barcode reading functionality), a virtual keyboard appears on-screen.



- 2. Integrated RFID/Barcode Reader (LED output):** As a part of the sample loading process, each swab cap is read by the integrated Barcode/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 – Integrated RFID/Barcode Reader (LED output) 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. In addition, the swab cap is labeled with a 2D barcode that enables the ANDE 6C system to automatically input the corresponding 1D barcode as the sample ID for that sample. Simply place the swab cap up to the Integrated RFID/Barcode Reader (LED output) to automatically read the barcode and RFID chip at the same time.

The default system settings are “On” for the RFID and Barcode readers. RFID tracking and automated barcode reading can each be turned off separately by a SuperAdmin via the Configure System function on the SuperAdmin Menu screen. See section 6.4.6. *ANDE 6C configurable features* for more information.

- 3. BioChipSet Cassette Access Door:** After loading the last sample into the Cassette, the access door opens automatically to allow the Cassette to be placed inside the ANDE 6C 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 Cassette. After the 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 6C 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 6C 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 6C instrument can be moved using these handles. Two people are required to lift the instrument, one person holding each handle. The stand-alone ANDE 6C Rapid DNA Analysis System instrument weighs 54 kg/117 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 section 6.4.6. *ANDE 6C System configurable features* 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 6C 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 6C 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	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.

3.1.3. Subsystems

Subsystems of the ANDE 6C 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 6C 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 6C instrument has been ruggedized according to U.S. Military Standard 810G 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 6C instrument should be limited to qualified NetBio personnel only. The ANDE 6C instrument is not User serviceable. Please contact your NetBio representative for additional information.

3.1.4. 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 6C instrument and is fully integrated into the sample-in to results-out process flow of the ANDE 6C 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).

3.1.5. System Software

The ANDE 6C 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 6C system software features and associated User privileges:

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

SuperAdmins should see section 6.4.4 *Manage User accounts on the ANDE 6C instrument*, and Admins should see section 6.3.4 *Manage User accounts on the ANDE 6C instrument* for more information about specific features and for instructions on software use.

3.1.6. ANDE Data Management Software

The ANDE 6C 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 6C 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	SuperAdmin	Admin	Operator
Manage Data			
• View lane success results (green/yellow/red indicators)	X	X	X
• View run data	X	X	
• Import encrypted run data, telemetry data, run report	X	X	X
• Import encrypted optical data	X	X	
• Import encrypted usage data	X		
• Export to desktop encrypted run, telemetry, run report	X	X	X
• Export to desktop encrypted optical data	X	X	
• Export to desktop encrypted usage data	X		
• Export to desktop decrypted run data	X	X	
• Export to desktop decrypted usage data	X		
• Delete data	X		
Manage User Accounts			
• Add SuperAdmin and Admin accounts	X		
• Add Operator accounts	X	X	
• Modify SuperAdmin and Admin accounts	X		
• Modify Operator accounts	X	X	
• Manage SuperAdmin and Admin passwords	X		
• Manage Operator passwords	X	X	
• Delete SuperAdmin and Admin accounts	X		
• Delete Operator accounts	X	X	
Create and Manage Certificates	X		

See section 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 6C 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 6C 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 6C instrument and create and install the

appropriate encryption/decryption files immediately after the ANDE 6C System is installed. See section 4.2.4.3. *Set up the ANDE Data Management Software (ADMS).*

3.2. BioChipSet Cassettes

The BioChipSet Cassette is a fully integrated lab-on-a-chip that performs all sample processing steps required for STR analysis. It contains all reagents on-board; 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.

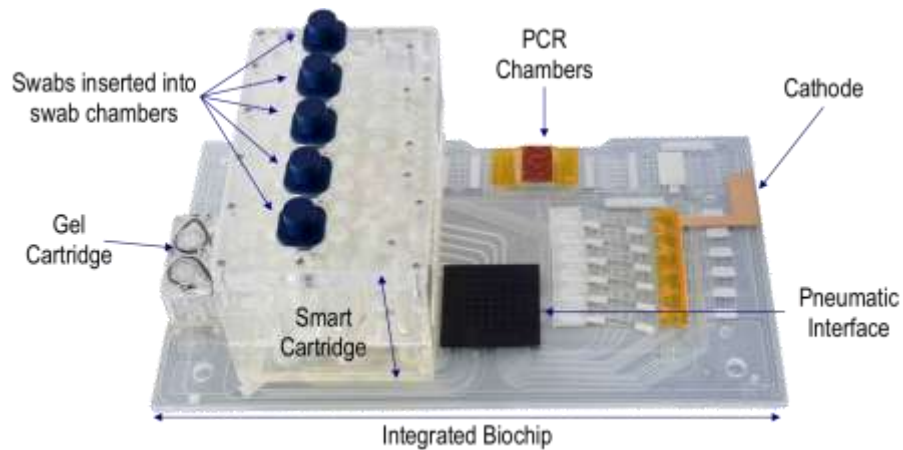
Additional features include:

- Sample Chambers: 5 sample chambers for the HDC BioChipSet Cassette and 4 sample chambers for the LDC Cassettes that accept the sample swabs and lock them into the Smart Cartridge portion of the Cassette.
- PCR Chamber: Microfluidic chambers where multiplexed STR amplification occurs.
- Pneumatic Interface: Interfaces with the ANDE instrument's pneumatic manifold arm once a run has been initiated. This interface is where air pressure is applied from the instrument's pneumatic system to the Cassette to drive all sample processing steps within the Cassette.
- Cathode: Interfaces with the instrument's power supply to deliver the electric current required to drive the electrophoretic separation.
- The Detection Window: The point where laser induced fluorescent detection occurs.

ANDE System utilizes two types of BioChipSet Cassettes, one for high and the other for low DNA content samples, to provide the largest possible range of sample processing. HDC BioChipSet Cassettes are designed for use with buccal swabs and other samples that contain relatively large quantities of DNA, generally more than several hundred nanograms. HDC Cassettes process up to 5 sample swabs simultaneously. The HDC and LDC Cassettes are available with two STR assay options: Promega's PowerPlex® 16 (PP16) or NetBio's Flexplex™ 27 (FP27), an expanded 27-locus STR assay that

incorporates both international, CODIS 13, and CODIS 20 loci. Sample types that can be processed on the HDC Cassette include fresh and dried buccal swabs, purified DNA, tissue, and blood.

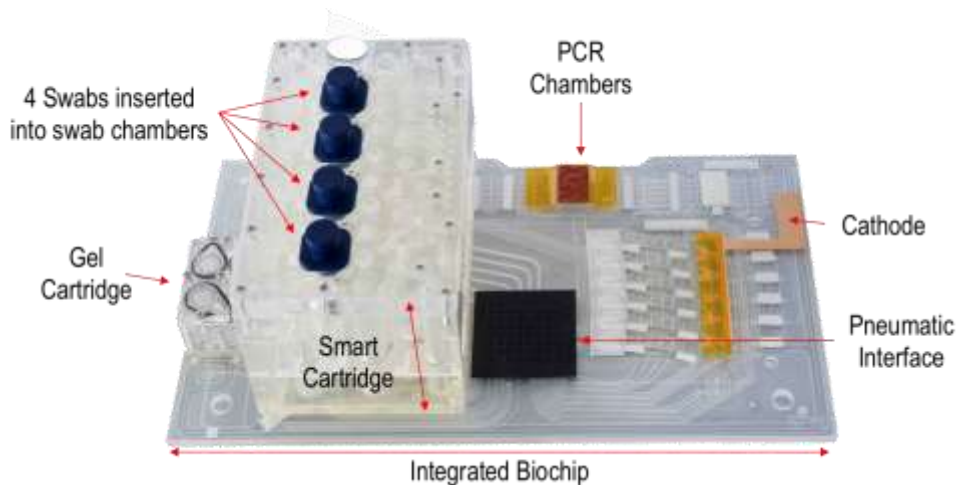
High DNA Content BioChipSet Cassette:



LDC BioChipSet Cassettes are designed for use with samples containing relatively low quantities of DNA. To enable processing of samples with a low DNA content, the HDC BioChipSet Cassette purification module was modified for high efficiency DNA purification. Post-purification, the LDC and HDC processing steps are identical. Both the LDC and HDC Cassettes utilize the same reagents, form factor, ANDE 6C instrument, and BioChipSet swabs.

LDC Cassettes process up to 4 sample swabs (a fifth chamber is not functional and contains a white cap that should not be removed). Sample types that can be processed on the LDC Cassette include oral epithelial samples (e.g. drinking glasses, chewing gum, cigarette butts), touch samples (e.g. fingerprints, caps, and clothing), blood, tissue, purified DNA, FTA™ paper, and untreated DNA storage paper.

Low DNA Content BioChipSet Cassette:



Many other sample types can be processed. Contact NetBio Technical Support for more information.



NOTICE

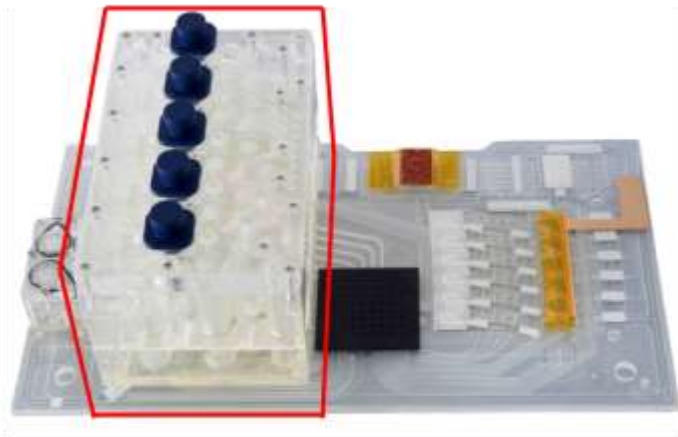
Sample collection and processing protocols for the various sample types must be adhered to. Please contact NetBio Technical Supports for appropriate protocols and procedures.

3.2.1. Sample processing steps

To perform a run on the ANDE 6C system, the User loads a sample swab into each of the Sample Chambers (five for High DNA Content BioChipSets; four for Low DNA Content BioChipSets) of the BioChipSet Cassette. If the User wants to perform a run with fewer 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 Sample Chambers are loaded, the User inserts the BioChipSet Cassette into the ANDE 6C instrument and closes the BioChipSet Cassette Access Door. The run starts automatically. Once a run is initiated, samples undergo multiple processing steps within the Cassette that can be grouped into three modules:

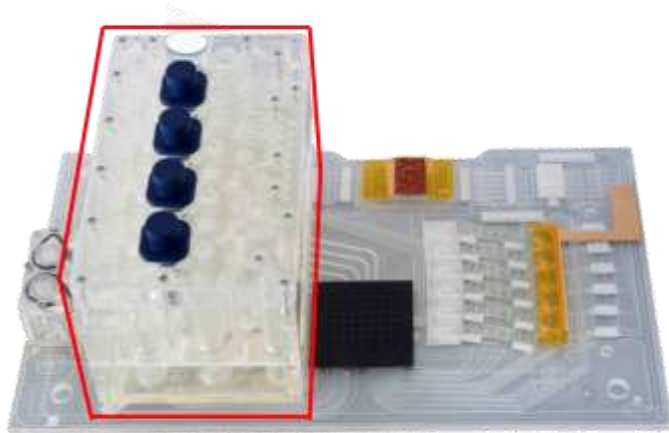
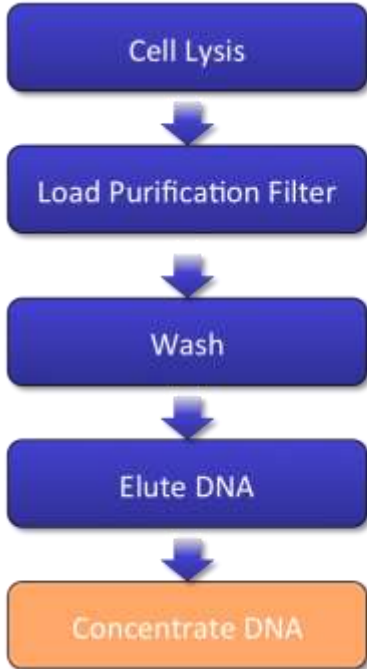
Module 1: DNA Purification. Cells on the swab are lysed, and DNA is purified using a guanidinium and silica binding-based approach. The Cassette is designed to generate DNA analysis results without the need for DNA quantitation, provided that the sample collection instructions are followed. The purification modules of the HDC and LDC BCSs have variations in their purification processing steps, as shown below:

HDC Cassette DNA Purification Module Process Flow:

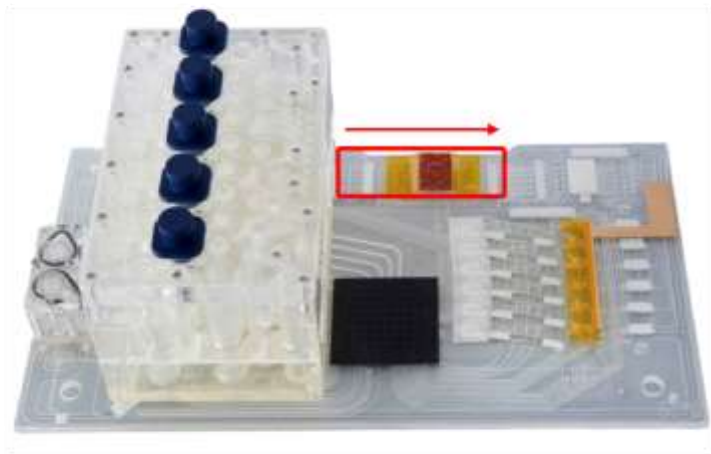
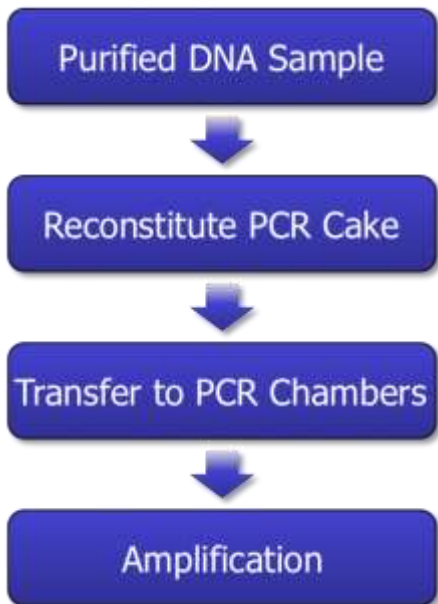


The LDC BioChipSet Cassette purification module has been optimized to achieve high purification efficiency and has an additional process step that concentrates the eluted DNA to maximize the amount of DNA moving forward for STR amplification. Post-purification, the LDC and HDC processing steps are identical.

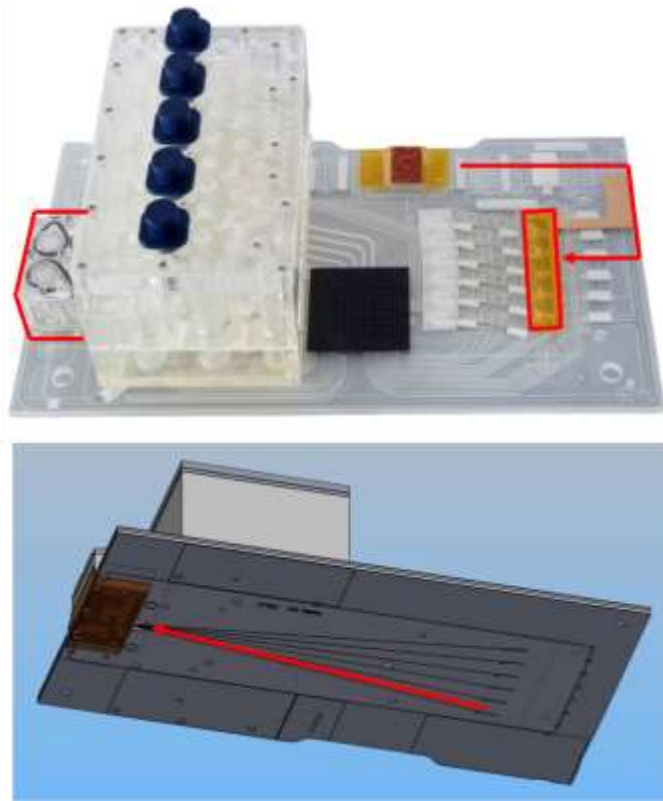
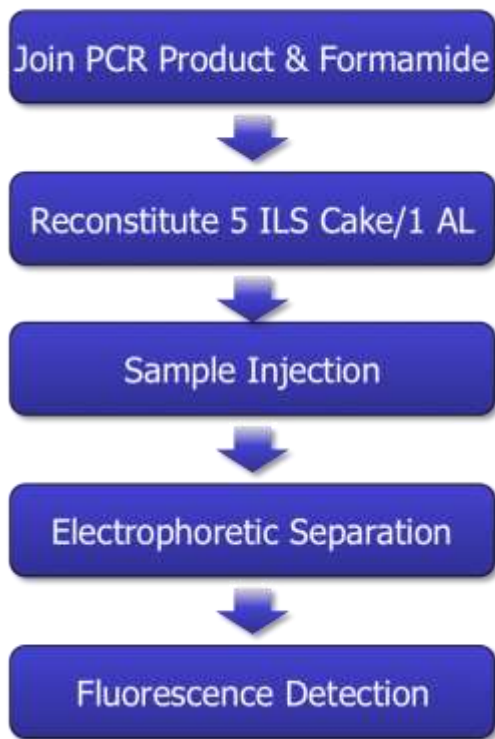
LDC Cassette DNA Purification Module Process Flow:



Module 2: STR Amplification. Purified DNA is subjected to Polymerase Chain Reaction (PCR) to amplify and fluorescently label the targeted loci. See section 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.



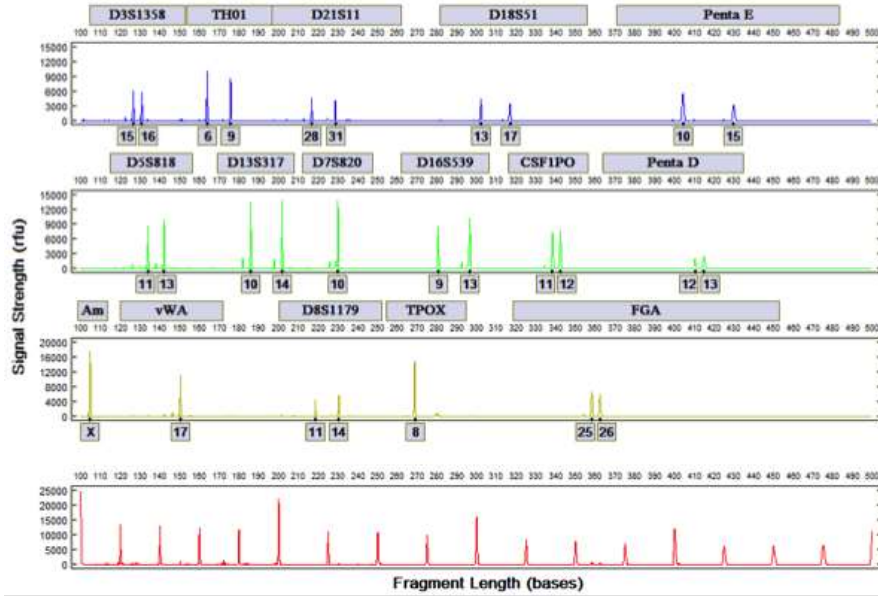
Once sample processing is complete, the raw optical data generated during the detection process is processed, allowing the Expert System software to perform data analysis and convert the electrophoretic traces to CODIS/NDIS compatible STR profiles. The Expert System software generates a data package for each sample consisting of four files:

- .png for visualization of the electropherogram with all allele calls.
- .fsa for comparison using other commercially available allele calling software programs.
- .xml in Common Message Format (CMF) for upload to CODIS-like databases.
- .csv file in the form of a Microsoft® Excel® compatible allele table that lists all loci and the associated allele calls for each of the samples.

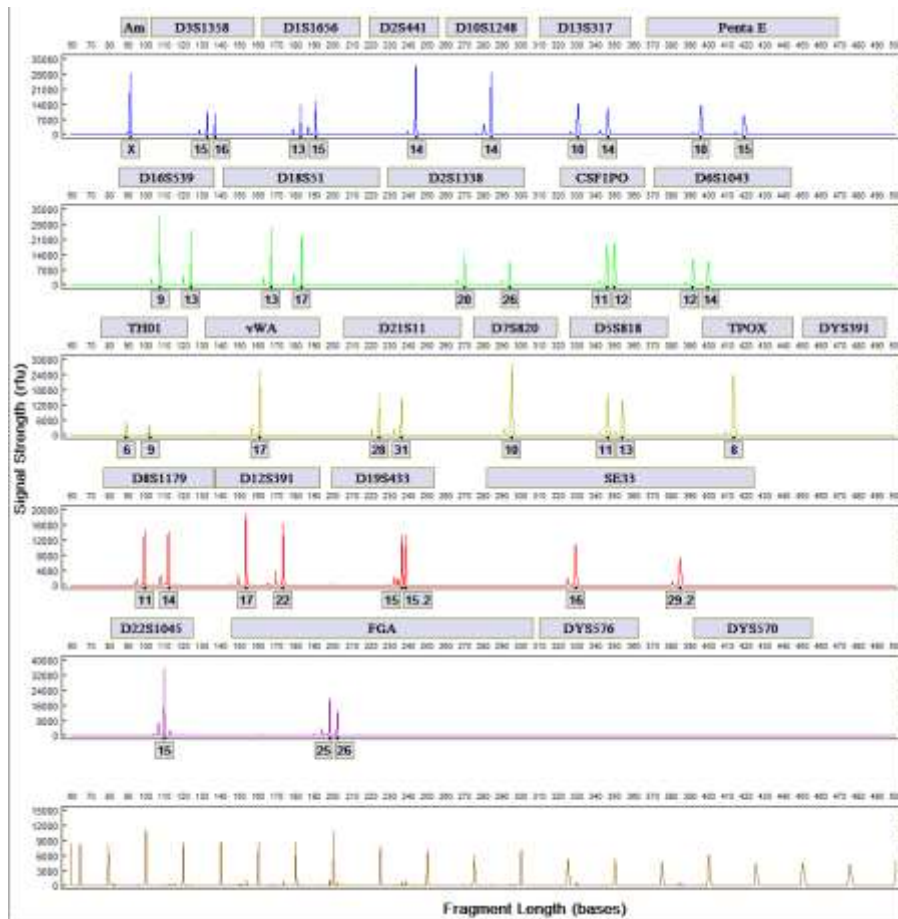
3.2.2. Multiplexed STR amplification assays

BioChipSet Cassettes are available with two multiplexed STR amplification assays: (1) PowerPlex® 16 that assay 16 STR loci, including core the CODIS 13 loci, and (2) Flexplex™ 27, an expanded 27-locus STR assay that incorporates both international, CODIS 13, and CODIS 20 loci.

PowerPlex 16 Female DNA Fingerprint Generated by the ANDE Rapid DNA Analysis System



FlexPlex 27 Female DNA Fingerprint Generated by the ANDE Rapid DNA Analysis System



3.2.3. Reagents

The Cassettes contains all reagents required to perform DNA analysis and is stable at 5–25°C for 6 months; no refrigeration is required. The User is not required to load or handle reagents, and reagents never come in contact with the instrument. There are a combination of liquid, gel, and lyophilized (freeze-dried) reagents at different locations on the Cassette. The table below lists the reagents on-board the Cassettes and summarizes for each reagent the function, location, storage form, and stability.

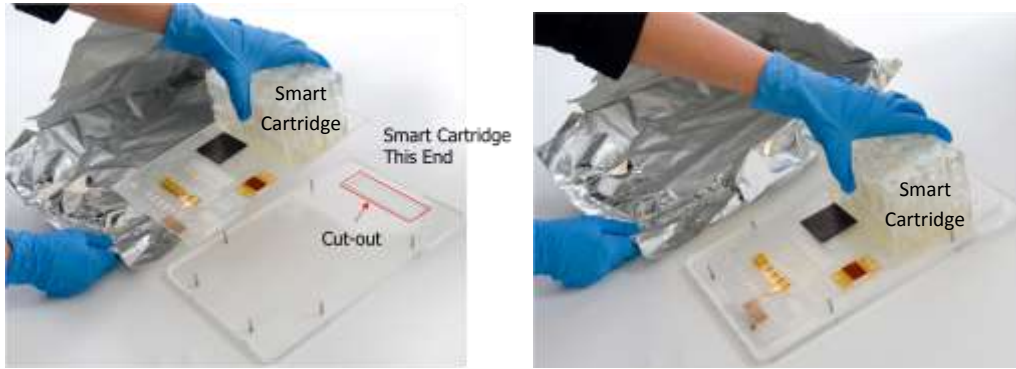
Reagent	Function	Location on BioChipSet	Storage Form
Lysis solution	purification	Smart Cartridge	liquid
Ethanol	purification	Smart Cartridge	liquid
Wash solution	purification	Smart Cartridge	liquid
Elution solution	purification	Smart Cartridge	liquid
PP 16 or FlexPlex STR Assay	amplification	Integrated Biochip	lyophilized
Internal Lane Standard (ILS)	sizing	Integrated Biochip	lyophilized
Allelic ladder	sizing	Integrated Biochip	lyophilized
Formamide	electrophoresis	Smart Cartridge	liquid
Separation matrix	electrophoresis	Gel Smart Cartridge	gel
Electrophoresis buffer	electrophoresis	Gel Smart Cartridge	liquid

Refer to the individual reagent MSDS for more detailed information. For additional information on the STR loci assayed using the ANDE 6C System, see section 10. *STR Loci Assayed on the BioChipSet Cassettes*.

3.2.4. Sample Loading Fixture

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





The BioChipSet Cassette Sample Loading Fixture is supplied with the ANDE 6C instrument.

3.3. BioChipSet Swab

The ANDE system includes the BioChipSet Swab for sample collection. The BioChipSet Swab has been specially designed for the ANDE system with features that allow for automated input of the sample ID and tracking of sample placement within the BioChipSet.

BioChipSet Swab



BioChipSet Swab Barcode for Automated Sample ID Input: The BioChipSet Swab cap has a 2D barcode sticker embedded with a 1D barcode that when read by the ANDE 6C instrument's integrated RFID/Barcode reader automatically inputs the 1D barcode as the Sample ID. The 2D barcode sticker on the swab cap also has a 4-letter designation that allows the user to visually identify the swab that is in the process of being loaded.

BioChipSet Swab RFID for Automated Sample Tracking: The BioChipSet Swab cap contains an RFID chip that is first read by the ANDE 6C instrument's integrated RFID/Barcode reader during the sample loading process. The initial scan allows the sample ID entered into the instrument to be linked with the swab containing the sample. Then, once all samples have been loaded and the BioChipSet is inserted into the instrument, a second RFID reader located inside the instrument reads the RFID chips in each of the swab caps to identify where each swab has been placed within the BioChipSet and thus what lane will contain the profile for that particular sample.

To read the 2D barcode and RFID chip, the User simply placed the swab cap near the integrated RFID/Barcode reader on the front of the instrument when prompted to do so by the on-screen instructions. The integrated RFID/Barcode reader will automatically scan the swab cap, input the Sample ID, and at the same time read the RFID chip and link it to the sample ID.



BioChipSet Swab Cap Locks into the Swab Chambers: The BioChipSet swab has a locking cap that secures the swab inside the Swab Chamber of BioChipSet Cassette to ensure the sample cannot be removed once it has been loaded and the Swab Chamber is sealed in order to contain the reagents that will be released during the analysis process so they do not come in contact with the instrument.



NOTICE

The ANDE 6C System can process other swab types. NetBio protocols must be adhered to when doing so. Contact NetBio Technical Support for protocols and instructions.



NOTICE

BioChipSet Swabs are certified to be free of detectable amplified human DNA, detectable DNase, and detectable RNase.