Forensic Rapid DNA Guidelines		
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Forensic Rapid DNA Guidelines

1 Purpose:

1.1 Rapid DNA is the fully automated (hands-free) process of developing a CODIS acceptable STR profile from a casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection, and allele calling without human intervention.

1.2 A rapid DNA cartridge (also known as a chip) is a pre-assembled set of reagents and other analytical components designed for use in a Rapid DNA instrument for the automated extraction, amplification, and separation of DNA samples.

2 General Guidelines:

2.1 Rapid DNA was approved for use by the Commission on Forensic Science on the ANDE 6C Rapid DNA System on buccal swabs from reference samples collected via the manufacturer's recommended protocol for mass disaster victims and missing persons identification.

2.1.1 See Section 5 for Policy & Workflow Overview.

2.2 The Forensic Rapid DNA Program under the Department of Forensic Biology is using the following NDIS approved Rapid DNA Instrument/System:

2.2.1 Name of Rapid DNA Instrument: ANDE 6C DNA Rapid System

2.2.2 Typing Kit: FlexPlex 27

2.2.3 Cartridge: A-chip, catalog #A0210001057

2.2.4 Instrument Software: ANDE System Software v2.0.6

2.2.5 Expert System Software: ANDE Expert System 2.0.5

2.3 The Forensic Rapid DNA Program under the Department of Forensic Biology will be operating the Rapid DNA Instrument/System in the laboratory. The Rapid DNA Instrument/System is maintained in areas outside of rooms containing amplified DNA.

2.4 The Rapid DNA Instrument/System will not be operated in a mobile/temporary facility or outside of the room in the DNA laboratory space.

2.5 The Forensic Rapid DNA Program under the Department of Forensic Biology does not operate in conjunction with a Rapid DNA partner agency. Therefore, there is no Forensic Rapid DNA Administrator, Forensic Rapid DNA Lead Operator, or Forensic Rapid DNA Operator.

3 Staff Roles and Responsibilities:

3.1 For the list of duties and responsibilities of the staff roles refer to the DNA Technical Leader Forensic Biology Administrative Manual, Forensic Biology CODIS Manual, and the Staff Roles and Responsibilities Forensic Biology Administrative Manual.

3.2 Nuclear Technical Leader

3.2.1 The Nuclear Technical Leader shall have authority over the operations and/or the Forensic Rapid DNA Program.

3.3 CODIS Administrator

3.3.1 The Casework CODIS Administrator shall have authority over the CODIS operations of the Forensic Rapid DNA Program.

3.4 Technical Reviewer

3.4.1 A Criminalist trained and currently qualified to review the generated reports based on the profiles of casework reference samples generated by the Rapid DNA instrument/System. Technical Reviewers do not interpret or analyze the profiles.

3.5 Analyst

3.5.1 A Criminalist trained and currently qualified to review the profiles of casework reference samples generated by the Rapid DNA instrument/System to generate reports. Analysts do not interpret or analyze the profiles.

3.6 Technician

3.6.1 A Criminalist trained and currently qualified to operate a Rapid DNA instrument/System with casework reference samples. DNA Technicians do not interpret data to reach conclusions on typing results or prepare final reports.

4 Training:

4.1 Refer to the training module M29 ANDE Rapid DNA Forensic Biology Training Manual

5 Policy & Workflow Overview

5.1 Sample selection, collection, and consumption

5.1.1 Two samples will be collected from every sample donor: one using a sterile cotton tipped applicator and one using the ANDE® swab.

5.1.2 ANDE® swabs used to collect buccal samples are consumed upon testing. Ensure a second buccal sample from the donor is collected using a sterile cotton tipped applicator for non-Rapid DNA testing.

5.1.2.1 For details regarding the submission and storage of these samples, refer to the Evidence Control section of the Forensic Biology Evidence and Case Management manual.

5.1.3 Buccal swabs from reference samples collected using the ANDE® swab and/or sterile cotton tipped applicator can be collected by personnel who regularly collect reference samples (i.e. law enforcement or medical examiner's personnel).

5.1.3.1 For specifics, refer to the ANDE® Rapid DNA – Sample Collection, Preparation & Exam section of the Forensic Biology Evidence and Case Management manual.

5.2 Sample processing

5.2.1 After sample collection, Rapid DNA testing with the ANDE® swab will be conducted by a Rapid trained technician. If the sample processed through Rapid DNA testing does not produce a passing profile, the buccal reference samples collected with the sterile cotton tipped applicator will be cut and sent for DNA testing.

5.2.1.1 For specifics, refer the ANDE® Rapid DNA – Sample Collection, Preparation & Exam of the Forensic Biology Evidence and Case Management manual and the ANDE® Rapid DNA section of the Forensic Biology Protocols for Forensic STR Analysis manual.

6 Consumables & Instrument Specifications

6.1 As per ANDE specifications, the ANDE® chips are stable at 5°C to 25°C (41°F to 77°F) for up to 6 months; no refrigeration is required. Once the ANDE® chip is removed from its packaging, use within 30 minutes.

6.1.1 As per ANDE specifications, the operating condition of the instrument is at 10°C to 40°C (50°F to 104°F) with 20% to 80% relative humidity, non-condensing.

7 Samples and Data Storage

7.1 Sterile cotton-tipped applicators and ANDE® swabs will be stored at room temperature.

7.1.1 For details regarding the submission and storage of these samples, refer to the Evidence Control Forensic Biology Evidence and Case Management manual.

7.2 Data generated by the Rapid instrument is exported to a USB drive and decrypted by the FAIRS software on the ANDE computer.

7.3 Following decryption, the system generates an Excel file, as well as .PNG, .FSA, and .XML files, which are then stored on the OCME network drive.

7.3.1 The Excel file contains the Allele Table for all samples.

7.3.2 The Allelic Ladder should have a .PNG and .FSA file.

7.3.2.1 Instances where a ladder fails are indicated in the header of the ladder's .PNG file.

7.3.3 The samples should have a .PNG, .FSA, and .XML file.

7.3.3.1 The .XML file may not be present if the sample failed.

8 Use of Rapid Data and CODIS

8.1 Only passing samples with complete profiles will be used for comparison or be eligible for CODIS.

9 Nonconformities

9.1 Refer to Control of Non-Conforming Work Forensic Biology Quality Assurance/Quality Control Manual.

10 QC Procedures

10.1 Refer to QC375 – ANDE A Chip, QC370 – ANE 6C Rapid DNA Maintenance and Troubleshooting, and QC380 – NIST SRM Testing of a Positive Control for Rapid DNA Forensic Biology Quality Assurance QC Procedures.