Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	MJ DeHaan	**Date**	07/10/2020

A. Requested deviation applies to (Technical Procedure – include specific section):

Forensic Biology Procedure for Direct to DNA Work Flow using the QIACube Section 5.2.5.2

B. Requested deviation:

Replace wording for 5.2.5.2: Toilet paper, tampons, pads, or other similar items contained within the kit will be sampled for processing. Representative cuttings or swabbing will be collected from the item(s). These cuttings or swabbing will be extracted as noted in 5.2.1.

C. Necessity for the deviation:

To streamline the SAK processing within Forensic Biology. This DRF will serve to replace the previously approved DRF to this procedure that was approved on 6/24/20.

D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)
Comments(to include merits and impacts):

Approved	☑	Yes	☐	No	Duration	until next version
Signature	Mackenzie DeHaan Digitally signed by Mackenzie DeHaan DN: C=US, OU=Forensic Biology, O=NCSCL, CN=Mackenzie DeHaan, E=mdehaan@ncdoj.gov Reason: I have reviewed this document Location: Date: 2020-07-10 06:41:19 Foxit PhantomPDF Version: 9.3.0				Date	07/10/2020

E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)

Acceptable within general QA guidelines and good laboratory practice?	☑	Yes	☐	No
Significant negative impact to Crime Laboratory Quality System?	☐	Yes	☑	No

Restrictions/limitations:

☑	Authorized	☐	Rejected	Signature	Jody H. West Digitally signed by Jody H. West DN: cn=Jody H. West, o=DOJ, ou=State Crime Laboratory, email=jwest@ncdoj.gov, c=US Date: 2020.07.10 13:35:37 -04'00'	Date	7/10/20

Form approved for use by: Timothy G. Suggs Digitally signed by Timothy G. Suggs DN: cn=Timothy G. Suggs, o=North Carolina State Crime Laboratory, ou=Quality Manager, email=tsuggs@ncdoj.gov, c=US Date: 2014.12.19 09:01:52 -05'00'

Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	MJ DeHaan	**Date**	03/31/2020

A. Requested deviation applies to (Technical Procedure – include specific section):

Procedure for Direct to DNA Workflow using the QIAcube Section 5.2.3

B. Requested deviation:

Add wording to the section: "If due to sample type or other case information the scientist decides that less than the entirety of the swab needs to be consumed, then the reason and the amount consumed shall be documented in the notes."

C. Necessity for the deviation:

This allows for consistency between Section 5.2.2 and 5.2.3 by allowing the scientist to consume a different amount of the swabs collected with documentation.

D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)
Comments(to include merits and impacts):

In the current version, scientists were given the ability in Section 5.2.2 to consume a differing amount if multiple swabs were taken, this change to Section 5.2.3 allows for the same ability if only a single swab is collected.

Approved	☑	Yes	☐	No	Duration	until next version
Signature	Mackenzie DeHaan Digitally signed by Mackenzie DeHaan DN: C=US, OU=Forensic Biology, O=NCSCL, CN=Mackenzie DeHaan, E=mdehaan@ncdoj.gov Reason: I have reviewed this document Location: Date: 2020-03-31 07:17:02 Foxit PhantomPDF Version: 9.3.0				Date	03/31/2020

E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)

Acceptable within general QA guidelines and good laboratory practice?	☑	Yes	☐	No
Significant negative impact to Crime Laboratory Quality System?	☐	Yes	☑	No

Restrictions/limitations:

☑	Authorized	☐	Rejected	Signature	Jody H. West Digitally signed by Jody H. West DN: cn=Jody H. West, o=DOJ, ou=State Crime Laboratory, email=jwest@ncdoj.gov, c=US Date: 2020.03.31 08:58:42 -04'00'	Date	3-31-20

Procedure for Direct to DNA Work Flow using the QIAcube

1.0 Purpose - This procedure specifies the method for processing a Sexual Assault Evidence Collection Kit (SAECK) and acceptable additional items through Forensic Biology case work analysis.

2.0 Scope - This procedure applies to those Forensic Scientists who have been released to do forensic casework in Forensic Biology. The procedure also applies to trainees.

3.0 Definitions - See Section Definition List

4.0 Equipment, Materials and Reagents - N/A.

5.0 Procedure

5.1 Background – Case scenarios of SAECKs are divided into two types that will guide the work flow determination (See 5.3). SAECKs where evidence is collected more than 5 days after the event will be evaluated for analysis on a case-by-case basis. If a consensual partner is reported up to 5 days prior to the incident, an elimination standard is required. SAECKs will be tested using a direct to DNA approach. Serology testing is not initially performed on direct to DNA items associated with sexual assault kits. Initial testing will include swabs contained within the SAECK as guided by the provided case related information, any relevant reference standards, and underwear and/or a condom if applicable. Supplemental testing of other evidence items may be requested if testing for the SAECK is negative; however, results of the SAECK testing will be reported before any additional testing is commenced.

5.2 Sampling of Items

5.2.1 All swabs/samples collected for the direct to DNA process must be differentially extracted unless details of the case state that contact other than penile penetration occurred.

5.2.2 If multiple swabs are collected from a single location, the swabs shall be tested by removing ½ of each swab collected (by type). If, due to sample type or other case information the scientist decides that more than ½ of each swab needs to be consumed, then the reason and the amount consumed shall be documented in the notes.

5.2.3 If a single swab is collected from a location, the swab shall be tested by removing the entirety of each swab (by type).

5.2.4 Underwear contained inside or outside of SAECK. If multiple pairs are present, the underwear outside the SAECK shall be analyzed according to section procedure for semen analysis for clothing.

5.2.4.1 Examine the underwear using an alternate light source (ALS) for areas of interest.

5.2.4.1.1 If areas of interest are noted, collect a representative swabbing. This swabbing will be extracted as noted in 5.2.1

5.2.4.1.2 If no areas of interest are noted, a representative swabbing from the crotch area (or drainage area) shall be collected. This swabbing will be extracted as noted in **5.2.1**.

5.2.4.2 If penile penetration did not occur (digital only), a representative swabbing shall be collected from area(s) of interest from the underwear as guided by the details of the case. This swabbing will be extracted as noted in **5.2.1**.

5.2.5 Condom contained inside or outside of SAECK

5.2.5.1 Two total swabbings shall be collected from a condom. One shall be collected from the inside of the condom, and one from the outside of the condom. This swabbing will be extracted as noted in **5.2.1**.

5.2.5.2 Toilet paper contained within the kit should not be examined on the initial testing. If present, supplemental testing on toilet paper will be conducted by using the Alternate light source and performing the Acid Phosphatase Test (AP) on areas of interest. AP positive areas may subsequently be cut and taken forward for STR testing.

5.2.5.3 The analyst should use the SWGDAM/NIJ recommended time frames for evidence collection in conjunction with the case information provided for decisions of which samples to process for testing.

Type of Assault	Collection Time
Vaginal	Up to 120 hours (5 days)
Anal	Up to 72 hours (3 days)
Oral	Up to 24 hours (1 day)
Bite marks/saliva on skin	Up to 96 hours (4 days)
Unknown	Collect respective samples within the time frames listed above

5.3 Case Types – as defined for the workflow for Direct to DNA processing of SAECK. All available case information shall be used in guiding the decision of case type. Analysts will use their best judgement when making decisions on Case Type. Analysts should not make decisions on case type based solely on the alcohol or drug use of the individual, this is only one factor in the case details.

5.3.1 Case Type 1 – Cases with a single assailant, no consensual partner, and clear victim recall of events.

5.3.1.1 Only the sample with the best quantification results should be taken forward to STR testing. If more than one sample is sufficient, samples will be chosen based on sample type:

5.3.1.1.1 Orifice swabs shall be chosen first.

5.3.1.1.2 External body swabs shall be chosen second, followed by underwear and condom swabs.

5.3.2 Case Type 2 – Cases with multiple assailants, consensual partners, or lack of clear victim recall, and cases involving a male victim and a male suspect.

5.3.2.1 At least one fraction from each item that meets the requirements for STR testing based on quantification results shall be taken forward (See Procedure for DNA Quantitation Using

Quantifiler Trio). Analysts can make case specific decisions on whether to amplify both Fraction 1 and Fraction 2 from a sample, based on quantitation values, along with item and case details.

6.0 Limitations – Due to the nature of the cases worked by Forensic Biology, it is difficult to cover every possibility with a procedure. Exemptions may be made, in writing, by the Forensic Biology FSM or Supervisors on a case-by-case basis.

7.0 Safety – N/A

8.0 References

Forensic Biology Section Procedure for DNA Extraction using the EZ1 Advanced Biorobot.

Forensic Biology Section Procedure for DNA Quantitation Using Quantifiler Trio.

Forensic Biology Section Procedure for Semen and Sperm Analysis

National Best Practices for Sexual Assault Kits: A Multidisciplinary Approach (https://www.NIJ.gov)

SWGDAM Recommendations for the Efficient DNA Processing of Sexual Assault Evidence Kits

9.0 Records - N/A

10.0 Attachments - N/A

Revision History		
Effective Date	Version Number	Reason
03/09/2020	3	Removed revision history; 5.2.2- added wording to document differing consumption; 5.2.6 – added analysis steps for toilet paper within kit; 5.2.4, 5.3 – updated wording in section