RAPID IMMUNOASSAY FOR SEMEN

15.1 PURPOSE

15.1.1: To identify p30 (ABAcard®) in Forensic samples.

15.1.2: To quality control new p30 rapid immunoassay kits.

15.2 RESPONSIBILITY

15.2.1: Forensic Science Examiners from the Division of Scientific Services who have been trained in the discipline of rapid immunoassay tests for semen according to FB SOP-26 (Training Manual and Checklist).

15.2.2: Forensic Science Examiners in the Forensic Biology Unit. Ordering information is maintained in a log book in the Forensic Biology Unit. New kits are purchased according to GL-6 (Purchasing). For additional information, refer to the Biological Inventory in Appendix 2.

15.3 SAFETY

Use appropriate measures for the proper handling of biohazardous material according to GL-2 (Safety Manual) and the Safety Data Sheets.

15.4 DEFINITIONS

A. ABAcard®: Rapid Immunoassay

B. RSID™: Rapid Stain Identification

15.5 TEST PROCEDURE

A. The p30 ABAcard® test will be performed at the discretion of the examiner, with input from the Unit Lead(s), based on the submitting agency requests, case information and the condition of the evidence.

B. A sample heavily stained with fecal-type material or if the presence of breast milk is suspected (based on case information), the sample is considered compromised. Therefore, the p30 test should not be conducted but the sample may be forwarded for DNA analysis, at the discretion of the examiner, with input from the Unit Lead(s).

15.5.1: Materials

A. Extracted samples

B. ABAcard® test device and enclosed dropper

D. Spot plates

E. Micropipet and tips

15.5.2: Procedure

A. Record the test lot number used on the General Reagent Sheet (FBQR-09).

B. The sample should be at room temperature before testing.

C. Label the ABAcard® devise with the case and item number.

D. Using the enclosed dropper, add 6-7 drops or using a pipet add ~200µl of supernatant to well "S" of the test device. Note the time immediately after adding the sample.

E. Monitor progress of test results for a 10-minute period.
   a. Record final result at 10 minutes.
   b. If positive, record the time elapsed when a positive result was first observed.

   DO NOT record any changes which occur after 10 minutes. Any change in test results after 10 minutes is invalid.

F. If the internal control fails (see Invalid Test under results below), review the test procedure and, if the quantity of sample allows retesting, repeat the test with a new device. If the test does not yield the appropriate results again, then inform the Unit Lead, determine the root cause and correct.

G. Record the results of the control(s) and sample(s) on the appropriate Quality Record Worksheet.

15.5.3: Results and *Suggested Report Statements*

A. Positive
   If there are two pink lines, one each in the test area 'T' and in the control area 'C',the test result is positive and indicates that the p30 level is present at or above 4ng/ml.

   This/these extract(s) gave a positive result(s) with an immunological test for the presence of p30, a component of semen.

B. Negative
   If there is only one pink line in the control area 'C', the test result is negative. This may indicate that no p30 is present, the p30 level is below 4ng/ml or the presence of the "High Dose Hook Effect".

1. Presence of "High Dose Hook Effect" may give false negative results due to the presence of a high concentration of p30 in the sample.

2. "High Dose Hook Effect" may be suspected when a strong positive Acid Phosphatase reaction was observed and a negative p30 result was obtained. The extract may be diluted 1:20 and rerun with the ABAcard® Procedure.

3. *An immunological test for the presence of p30, a component of semen, was performed on this/these extract(s). Semen was not detected with this test.*

C. Inconclusive

1. If a pink line in the test area 'T' could not be determined.

   An immunological test for the presence of p30, a component of semen, was performed on this/these extract(s). Due to indeterminate results and/or substrate interference, this/these test(s) was/were determined to be inconclusive.

2. Record the reason a result is determined to be inconclusive on the appropriate Quality Record Worksheet.

D. Invalid (Failed)

1. If there is no pink line visible in the control area 'C'.

2. If there is not enough sample to repeat the test then no conclusion is possible.

   An immunological test for the presence of p30, a component of semen, was performed on this/these extract(s). Due to the failure of this/these test(s), no conclusion(s) is/are possible.

3. Record the reason the test failed on the appropriate Quality Record Worksheet.

15.6 QC PROCEDURE

Manufacturer's expiration dates with only month and year indicated (i.e. 04/2014) expire the last day of the month noted.

A. Test the new lot before use according to the test procedure above, FB SOP-13 (Extraction of Samples) and the ABAcard® p30 Reagent Log Sheet. Record required information.

B. If the appropriate results are not obtained, review the procedure and repeat the test. If the test still does not yield the appropriate results, then inform the Unit Lead, determine the root cause and correct.

C. If the lot is suitable for use, record the date received, date opened and examiner's initials on each box and store according to the manufacturer's instructions.

D. Discard according to the manufacturer's expiration date.

15.7 REFERENCES

A. Abacus Diagnostics' OneStep ABAcard® p30 Test For The Forensic Identification of Semen, provided Technical Information and Protocol sheet.
B. Connecticut State Forensic Science Laboratory, ABAcard® p30 Internal Validation, 1998.
C. Connecticut State Forensic Science Laboratory, RSID™ - Semen Internal Validation, 2010.
D. Independent Forensics, RSID™ - Universal Buffer Technical Information and Protocol sheet.
E. Connecticut State Forensic Science Laboratory, RSID™ - Universal Buffer Internal Validation, 2011.
F. Abacus Diagnostics' OneStep ABAcard p30 Test For The Forensic Identification of Semen provided Technical Information and Protocol sheet.
G. Connecticut State Forensic Science Laboratory, ABAcard p30 Internal Validation, 1998.
H. GL-2 (Safety Manual)
I. GL-6 (Purchasing)
J. Safety Data Sheets