RAPID IMMUNOASSAY FOR URINE

17.1 PURPOSE

17.1.1: To identify Tamm-Horsfall Protein (RSID™-Urine) in Forensic samples.

17.1.2: To quality control new RSID™-Urine rapid immunoassay kits.

17.2 RESPONSIBILITY

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

17.2.2: 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.

17.3 SAFETY

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

17.4 DEFINITIONS

A. RSID™: Rapid Stain Identification

B. THP: Tamm-Horsfall Protein

17.5 TEST PROCEDURE

A. This 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. Do not use this test with samples containing fecal material, refer to FB SOP-18 (Test for Fecal Material).

17.5.1: Materials

A. RSID™-Urine Buffer

B. RSID™-Urine test cassettes

C. Centrifuge tubes and spin baskets

D. Micropipet and tips

E. Wooden sticks

F. Ultrasonic bath

G. Shaker

H. Centrifuge

17.5.2: Procedure:

A. Record the lot numbers of the test and buffer used on the General Reagent Sheet (FBQR-09).

B. Undiluted urine should not be used with this test, a stain of the questioned urine sample should be made instead and dried overnight.

C. Extract a portion of the questioned sample or stain in a centrifuge tube with 150ul of RSID™-Urine Buffer and mix with a wooden stick.

D. Place the sample in an ultrasonic bath for fifteen (15) minutes and then place on the shaker for one (1) hour and forty-five (45) minutes at room temperature for a total extraction time of two (2) hours.

E. If necessary, the sample may be extracted overnight at 4°C after the sonication step.

F. If the sample was refrigerated, bring to room temperature for approximately ten (10) minutes before testing.

G. Place the sample in a spin basket, return to tube and centrifuge for approximately ten (10) minutes. The centrifuge will be set at approximately 13,000 rpm.

H. Label the RSID™ cassette with the case and item number.

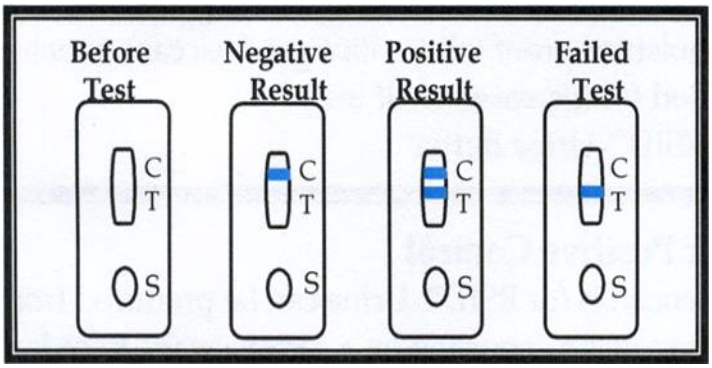
I. Using a micropipet, add 100µl of extract to well 'S' of the cassette. Note the time immediately after adding the sample.

J. Monitor progress of test results for a fifteen (15) minute period. Record final result at fifteen (15) minutes. DO NOT record any changes that occur after fifteen (15) minutes. Any change in the test results after fifteen (15) minutes is invalid.

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

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

17.5.3: Results and *Suggested Report Statements*



A. Negative

A visible blue line at the Control 'C' position only, indicates a negative result. No Tamm-Horsfall Protein detected.

1. "High Dose Hook Effect" refers to weak positive or false negative results due to the presence of a high concentration of the target in the sample.

2. Under standard laboratory testing and relevant urine concentration ranges, the "High Dose Hook Effect" is not observed with the RSID™-Urine Test.

3. *An immunological test for the presence of Tamm-Horsfall protein, a component of urine, was performed on [ ]. Urine was not detected with this test.*

B. Positive

Visible blue lines at both the Control 'C' and Test 'T' positions indicate a positive result. Tamm-Horsfall Protein detected.

[ ] gave a positive result(s) with an immunological test for the presence of Tamm-Horsfall protein, a component of urine.

C. Inconclusive

1. Not able to determine a blue line at the Test 'T' position.

   An immunological test for the presence of Tamm-Horsfall protein, a component of urine, was performed on [ ]. 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. Failed (Invalid)

1. No visible blue line at the Control 'C' position.

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

   An immunological test for the presence of Tamm-Horsfall protein, a component of urine, was performed on [ ]. 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.

17.6 QC PROCEDURE

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

17.6.1: Lot QC

A. Test the new lot before use according to the test procedure and the RSID™ - Urine Reagent Log Sheet. Record the 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 the provided buffer bottles. Store according to manufacturer's instructions.

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

17.6.2: Buffer QC

A. Buffer will be tested prior to use with each case but no more often than once a week, by adding 100µl directly to the RSID™ cassette (see steps I and J in section 17.5.2 above).

B. Record the results on the Buffer Log Sheet (see section 17.5.3 above).

C. Notify the Unit Lead if the expected results are not obtained, remove from service and replace.

17.7 REFERENCES

A. Independent Forensics, Rapid Stain Identification of Urine (RSID™ - Urine) Technical Information and Protocol sheet.
B. Old, Dr. Jennifer, Reich, Dr. Karl, Developmental Validation of RSID™ - Urine, p1-19.
C. Connecticut State Forensic Science Laboratory, RSID™ - Urine Internal Validation, 2012.

D. GL-2 (Safety Manual)
E. GL-6 (Purchasing)
F. Safety Data Sheets