

Independent Forensics
Rapid Stain Identification
Of Human Semen (RSID®-Semen)
Validation Summary Page

[Laboratory Name]

[Laboratory Address]

Test Evaluated: **RSID®-Semen**

Validation for: Detection of Human Semen

Number of sample types tested: _____

Number of samples run: _____ [minimum 5 samples]

Technique summary: Semen; vaginal swabs; swabs from stained surfaces; cuttings from fabric; punches from fabric; _____; _____
[circle and/or add as required] were extracted and tested as per protocol (see RSID® -Semen, *Suggested Protocols*).

Precision and Sensitivity: Pass / Fail [circle one]

Accuracy and Reproducibility: Pass / Fail [circle one]

Result: Technique passes. Results within acceptable limits.
 Analyst Initials _____ Date: ___/___/___

Approved by: _____ Date: _____
 QA/QC Supervisor

Reviewed by: _____ Date: _____
 Technical Leader

Date of Release: _____

VALIDATION DESCRIPTION

RSID®-Semen, Human Semen Detection

Introduction

Validation is the process of testing and documenting procedures and reagents to verify that laboratory protocols used for sample analysis will provide results that are precise, accurate and reproducible.

Rationale

The presence of human semen on forensic exhibits can be probative for both legal and scientific reasons and thus test results used to identify semen must be scientifically robust and legally admissible.

Material, Reagents and Equipment

_____ [Laboratory Name] used _____ [insert number] samples for RSID®-Semen validation studies. The samples used included swabs / extracts from semen, semen swabs, swabs from stained surfaces, cuttings from fabric, punches from fabric, _____, _____ [circle and/or add as required]. RSID®-Semen was used to detect human semen from these samples.

Procedure

The presence of human semen on questioned stains and exhibits can be tested in order to determine if sufficient biological material is present for DNA-STR analysis. The method uses sampling of exhibits (using a moistened swab or similar) to test for the presence of human semenogelin. The assay is capable of detecting as little as 1 µl human semen from an aqueous extract. Semenogelin is assayed using a dual monoclonal immunochromatographic lateral flow strip test. Test results are simple to interpret (is there one or two visible lines) and uses a minimal amount of material. The testing procedure can be integrated into DNA-STR analysis or can be used as a 'stand-alone' assay for human semen. The basis of the assay, serological detection in a lateral flow format, is well established in forensic practice - the laboratory can demonstrate that the assay results conform to known standards and subsequently use the test for all questioned samples.

Validation Criteria

The ability of the test to detect semen from the types of samples commonly encountered in the forensic laboratory, (e.g. vaginal swabs, swabs from stained surfaces, cuttings from fabric, punches from fabric) is tested and confirmed, as is the background signal from samples without human semen. The test should perform to 100% accuracy (i.e., no false positives) and to the threshold of detection acceptable to the laboratory.

Validation Results

The RSID®-Semen test can readily measure at least 1 µl of human semen from a variety of surfaces and samples. No interference from human blood, saliva, breast milk, or urine was detected.

Discussion

This validation study demonstrates that RSID®-Semen can be used to determine the presence of human semen from samples routinely encountered in case work. The method is reproducible, accurate, and sufficiently sensitive to meet laboratory standards for the results to be incorporated into case work and reported. RSID®-Semen testing can be used as an adjunct to triaging samples and exhibits for DNA-STR analysis at the discretion of the laboratory.