

Document Title: Validation of New Serological Tests

Controlled: Yes, with red stamp present

Controlled By: Quality Manager

Prepared By: _____ Date: _____

Approved By: _____ Date: _____

A. PURPOSE:

To validate published tests and procedures to be used by the Forensic Biology Section.

B. RESPONSIBILITY:

Forensic Science Examiners 1 and 2 in the Forensic Biology Section.

C. SAFETY:

Use appropriate measures for the proper handling of biological materials and chemicals according to SOP-GL-2 (Safety Manual).

D. PROCEDURE:

1. A positive control and a negative control will be run with the new test.
2. Sensitivity and/or specificity will be validated with the new test. If the new test is similar to or is replacing a current test, the new test will be compared to the current test.
3. Examiners in the Forensic Biology Section will be trained with a preliminary protocol to perform the new test.
4. Case samples will be analyzed with the new test. If there is a current test, both tests will be run concurrently.
5. All validation paperwork (procedures and results) and reference articles will be placed in a notebook.
6. The validation will be reviewed and approved by the Quality Manager.
7. When the new test is approved, a final SOP to perform the test and a SOP to perform quality control of the chemical(s)/reagent(s) used in the test will be created. These SOP's will be added to the current Forensic Biology Section SOP's and the master list.
8. A log sheet will be created for the new test and added to the Chemical/Reagent Log notebook.
9. The chemical(s)/reagent(s) for the new test will be added to the Chemical Inventory. If new equipment is involved with the new test, the equipment will be added to the Equipment Inventory.
10. Examiners in the Forensic Biology Section will have to perform a competency test with the final SOP prior to reporting out case sample results. It should be noted that the examiner(s) validating the new test shall be considered competent and will not be required to complete a competency test.

- D. 11. A memo will be generated by the Supervisor of the Forensic Biology Section, or designee, stating that the final SOP is now in use and it's effective date.