VALIDATION OF NEW SEROLOGICAL METHODS

25.1 PURPOSE

To validate published methods and procedures to be used by the Forensic Biology Unit.

25.2 RESPONSIBILITY

Forensic Science Examiners in the Forensic Biology Unit.

25.3 SAFETY

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

25.4 PROCEDURE

A. The examiner(s) in the Forensic Biology Unit will generate a validation plan that will be approved by the Forensic Biology Unit Lead or designee and Deputy Director, initialed and dated.

B. The examiner(s) in the Forensic Biology Unit conducting the validation will review the manufacturer's protocol and technical information prior to starting the new validation.

C. Positive and negative controls will be run with the new method.

D. Sensitivity and/or specificity will be validated with the new method.

E. If the new method is similar to a current method, the new method will be compared to the current method.

F. During validation, a certain number of case samples will be run with the new method. If there is a current method, both methods will be run on the case samples concurrently.

G. All validation paperwork (procedures and results) and reference articles will be placed in a notebook.

H. The results of the validation will be reviewed by the Forensic Biology Lead or designee, Deputy Director and a member of the Quality Section for approval.

I. If the new method is approved, a draft SOP will be generated. If approved, the final SOP will be added to the current Forensic Biology SOP's in Qualtrax.

J. If necessary, the new method will be added to the appropriate Quality Records in located in Appendix 1.

K. If necessary, an appropriate log sheet will be created for the new method and added to the Chemical/Reagent Log Notebook and Appendix 2.

L. The chemical(s)/reagent(s) for the new method will be added to the Chemical Inventory. If new equipment is involved with the new method, the equipment will be added to the Equipment Inventory. The Chemical Inventory and Equipment Inventory are located in Appendix 2.

M. Examiners in the Forensic Biology Unit must pass a competency test with the new method prior to reporting out case sample results.

It should be noted that the examiner(s) validating the new method shall be considered competent and will not be required to complete a competency test.

N. Notification will be generated by the Forensic Biology Lead stating that the SOP for the new method is in use for case work and its effective date.

25.5 REFERENCES

A. GL-2 (Safety Manual)
B. Safety Data Sheets