VALIDATION OF NEW SEROLOGICAL METHODS

25.1 PURPOSE

To validate published methods/procedures, prior to the implementation for casework in the Forensic Biology Unit.

25.2 RESPONSIBILITY

Personnel qualified to perform Forensic Biology duties.

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 validation of a new method/procedure will generally be initiated by a Forensic Biology Technical Lead or designee. A validation plan describing the proposed methodology and experiments planned to evaluate the new method/procedure will be provided to the Assistant Director, Deputy Director and Director for approval. If not initiated by a Technical Lead, then the Technical Lead may also approve it. Approval may be documented by signing and dating this plan.

1. If a change to the plan is required, at minimum, the change plan will be approved by the Deputy Director and Director.

2. A DSS Laboratory Method Validation Summary Form from Qualtrax will be completed for each validation.

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, at a minimum, each day of the validation testing.

D. Sensitivity, specificity and reproducibility will be validated with the new method. Experiments may also include but are not limited to, inhibition and substrate studies.

Known samples typically encountered in casework shall be examined to demonstrate any potential limitations of the new method/procedure and to determine if the procedure generates acceptable results.

E. If they are similar, the new method and the current method may be compared to each other.

F. New equipment utilized with the new method will be validated with the new method.

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

H. A validation summary will be provided to the Assistant and/or Deputy Director and Director for approval.

I. If the new method is approved, a draft SOP will be generated. If approved by the Director, the final SOP will be added to the current Forensic Biology SOPs in QMS.

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

K. If necessary, appropriate log sheets will be created for the new method/equipment and added to the Chemical/Reagent/Equipment Logs located in Appendix 2.

L. New chemical(s)/reagent(s) for the validated 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 3.

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 a Forensic Biology Lead stating that the SOP for the new method is in use for case work and its effective date.

O. For additional information, see GL-22 (Policy on Validation and Performance Checks).

25.5 REFERENCES

A. GL-2 (Safety Manual)
B. GL-22 (Policy on Validation and Performance Checks)
C. Safety Data Sheets