Idaho State Police Forensic Services Validation Form

Section 1: Initial Validation Approval

Validation Title: Internal Validation of PowerPlex® Fusion 6C for Database Samples on Applied Biosystems® 3500xL Genetic Analyzer

Analytical Method(s): DNA Database Analytical Methods

Requestor/Discipline: Taylor Maichak, DNA/Biology

Primary Staff Involved:
Promega Corporation, Taylor Maichak, Jodie Carney, Lorianne Welch

Resources/Materials Needed:
Refer to Promega document "Pre-validation Checklist".

Safety Considerations:
Laboratory safety practices are addressed in the ISP Forensic Services Health and Safety Manual. No additional hazards are expected to be encountered during this validation.

Technical Justification/Benefit of Validation:
The DNA database section is upgrading to a 6-dye chemistry for amplification. The newer 6-dye amplification kits are, in general, more sensitive and offer additional loci when compared to the current 5-dye kit being used at ISP. These improvements are beneficial as we expand our services to include touch DNA items and move to the Applied Biosystems™ 3500xL Genetic Analyzer.

Validation Proposal and References:
See documentation from Promega, "Internal Validation Experimental Design of PowerPlex® Fusion 6C for Database Samples".

Suitability and Performance Requirements/Criteria:
To meet the Quality Assurance Standards, the following studies will be conducted and evaluated: known database-type samples, precision and accuracy studies, sensitivity and stochastic studies, and contamination assessment studies. See documentation from Promega, "Internal Validation Experimental Design of PowerPlex® Fusion 6C for Database Samples" for more information.

Discipline Approval to Proceed

Discipline Lead/Signature: Taylor K Maichak
Title/Discipline: Forensic Scientist 3 – DNA Technical Lead
Date: 10/19/2022

Quality Approval to Proceed

Quality Approver/Signature: Corinna C Owsley
Title: Acting Quality Manager
Date: 10/20/2022

Section 2: Progress Reports

(Optional Section: Document any intermediate progress, obstacles, changes in the plan, timeframe, etc)

Section 3: Completed Validation Approval

Validation Executive Summary: (add information here or attach files)

Processing of all FTA® card samples was performed following the instructions described in the PunchSolution™ Kit technical manual. For each sample, 10µl of PunchSolution™ Reagent was combined with one 1.2mm punch in a 96-well reaction plate and incubated at 70°C for 30 minutes or until wells were completely dry.

DNA amplification was performed on a GeneAmp® PCR System 9700 following the cycling parameters described in the PowerPlex® Fusion 6C System technical manual for direct amplification of DNA from storage card punches in a 12.5µl reaction volume. The cycling protocol is as follows using the Max mode ramp speed: 96°C for 1 minute, 25 cycles of 96°C for 5 seconds and 60°C for 1 minute, followed by 60°C for 10 minutes and a 4°C soak. Twenty-five cycles were utilized unless otherwise noted.

The results showed that the system could produce reliable and reproducible results. The studies performed in this validation meet the criteria for an internal validation and have shown that the PowerPlex® Fusion 6C System is suitable for direct amplification of reference samples in a forensic DNA databasing laboratory.

Validation Write-Up: (add information here or attach files)

See "Idaho State Police PowerPlex® Fusion 6C System Amplification Kit on the Applied Biosystems® 3500xL Genetic Analyzer using GeneMapper® ID-X v1.6 Analysis Software Database Validation Report".

Suitability and Performance Assessment (provide assessment of how the validation met the requirements and criteria set forth in Section 1):

The studies completed were sensitivity and stochastic studies, known samples, precision, accuracy, and contamination assessment. See "Idaho State Police PowerPlex® Fusion 6C System Amplification Kit on the Applied Biosystems® 3500xL Genetic Analyzer using

GeneMapper® ID-X v1.6 Analysis Software Database Validation Report" for more information.

Uncertainty of Measurement: (address any UM considerations based on the completed validation)

N/A

Competency: (new or additional competency needed upon completion?)

The analysts below performed tasks which cover the relevant aspects that they will be authorized to perform on casework, thereby acting as their practical competency tests for this procedure:

Jodie Carney, Lorianne Welch

Discipline Lead Approval

Discipline Leader/Signature:
Title: DNA Technical Lead
Date: 7/13/2023

Quality Approval

Quality Approver/Signature:
Title: Lab Improvement Manager
Date: 8/14/2023