Idaho State Police Forensic Services Validation Form

Section 1: Initial Validation Approval

Validation Title: Internal Validation of PowerPlex® Fusion 6C for Casework and Direct Amplification Samples on Applied Biosystems® 3500 Genetic Analyzer using GeneMapper® ID-X v1.6 Analysis Software

Analytical Method(s): Biology/DNA Casework Analytical Methods

Requestor/Discipline: Taylor Maichak, DNA/Biology

Primary Staff Involved:
Promega Corporation, Taylor Maichak, Eric Seat, other DNA analysts as needed

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/Biology 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™ 3500 Genetic Analyzer.

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

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

Discipline Approval to Proceed

Discipline Lead/Signature: Taylor K Maichak
Title/Discipline: Forensic Scientist 3 – DNA Technical Lead

Date: 4/15/2022

Quality Approval to Proceed

Quality Approver/Signature: Jason Crowe
Title: Quality Manager
Date: 4/27/2022

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)

The PowerPlex® Fusion 6C System was evaluated using the GeneAmp® PCR System 9700 thermal cycler and was run following the recommendations in the technical manual for amplification of extracted DNA in a 25µl reaction volume. The amplified product was run using a 1.2kv, 15 second injection on the Applied Biosystems® 3500 Genetic Analyzer. An analytical threshold of 70 RFU was chosen for the validation with 29 cycles. A stochastic threshold of 400 RFU was determined for 29 cycles. The results showed that the system was capable of producing reliable and reproducible results. The precision of the system was within the recommended range. 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 use in a forensic casework laboratory.

The PowerPlex® Fusion 6C System was evaluated using the GeneAmp® PCR 9700 thermal cycler and was run following the recommendations in the technical manual for direct amplification in a 12.5µl reaction volume. The amplified product was run using a 1.2kV injection for 15 or 10 seconds on an Applied Biosystems® 3500 Genetic Analyzer. An analytical threshold of 75 RFU in conjunction with a 20% global filter was chosen for the validation with 26 cycles. A stochastic threshold of 250 RFU was determined for 26 cycles. The results showed that the system was capable of producing 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 laboratory.

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

See “Idaho State Police, PowerPlex® Fusion 6C System Casework Report” and “Idaho State Police, PowerPlex® Fusion 6C System Direct Samples Report”.

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

The studies completed for the Casework validation were sensitivity and stochastic studies, precision, accuracy, known and mock evidence samples, mixture samples, and contamination assessment. The studies completed for the Direct Amplification portion were sensitivity and stochastic studies, known samples, precision, accuracy, and contamination assessment. See the "Idaho State Police, PowerPlex® Fusion 6C System Casework Report" and "Idaho State Police, PowerPlex® Fusion 6C System Direct Samples 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?)

Yes, those who did not participate in the validation to the extent of their involvement in casework will also complete a practical competency test. All analysts will complete a virtual training from Promega.

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:

Taylor Maichak, Kira Hughes, Jade Miller, Eric Seat, Katie Dace, and Kelsey Price (technician duties)

The analyst below performed tasks which cover the relevant aspects that they will be authorized to perform on direct amplification samples, thereby acting as their practical competency test for this procedure:

Taylor Maichak

Discipline Lead Approval

Discipline Leader/Signature: Taylor K Maichak
Title: DNA Technical Lead
Date: 1/5/2023

Quality Approval

Quality Approver/Signature: Corinna C Owsley
Title: Acting Quality Manager
Date: 1-9-2023