Verogen Validation Services

Increase your operational efficiency with guided workflows.

Introduction

Verogen offers a diverse portfolio of services to support a broad range of forensic genomic applications. Backed by proven next-generation sequencing (NGS) technology and informed by collaboration with a global network of scientific experts, Verogen provides high-quality services to empower your success.

Many forensic labs require internal validation to verify optimal system performance and to meet quality assurance guidelines. Verogen validation studies comprehensively evaluate each workflow component to confirm operation and performance in accordance with casework needs. Validation studies align with the latest forensic guidelines defined by the Scientific Working Group on DNA Analysis Methods (SWGDAM).

To assist with the requirements and workload that internal validation procedures demand, Verogen offers tiered Validation Service options to meet laboratory needs.

Time-Saving Benefits

Designing and executing an entire validation process for a new application can be a time-consuming and resource-intensive process. A validation project managed by the Verogen team of NGS validation specialists expedites the process with an estimated time savings of 60%.

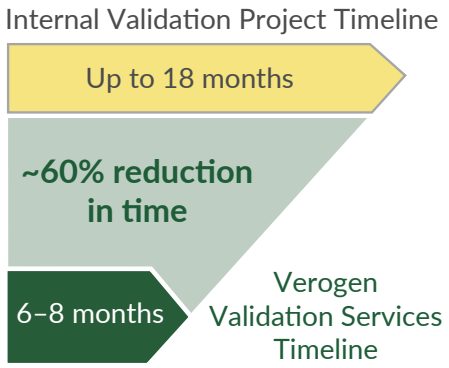


Figure 1: Managing an internally developed validation project on your own can take up to 18 months. Using any of the Verogen Validation Service options can take you from planning to completion in approximately 6–8 months.

Verogen Validation Services include an optimized study design plan, step-by-step protocols, reagents needed to execute studies, flexible options for wet lab execution, data analysis, and reporting assistance. Table 1 describes the key features for each validation service option.

Tiered Validation Service Options

Effective validation planning requires balancing current laboratory resources and availability, price, and turnaround time. Verogen offers flexibility with tiered validation options to meet your laboratory needs. These options range from a self-service out-of-the-box plan to comprehensive execution with onsite support that prepares you with confidence for implementation and audits.

- **Planned—A practical self-service option**
  Verogen provides a roadmap and reagents to complete your validation, eliminating the need to plan where to begin and how to proceed. Instead, you can focus on gaining familiarity and expertise through hands-on validation.
- **Assisted—Hands-on experience with Verogen support**
  You perform the pre-planned studies and Verogen experts assist with final data analysis and reporting. With the support of expert guidance and advice throughout the process, you efficiently master NGS technology.
- **Full—White-glove service from Verogen**
  Verogen experts plan, perform, and complete the studies, analysis, and reporting, allowing you to focus on daily casework. Upon conclusion, Verogen provides training to ensure your in-depth understanding of the validation report and protocols.

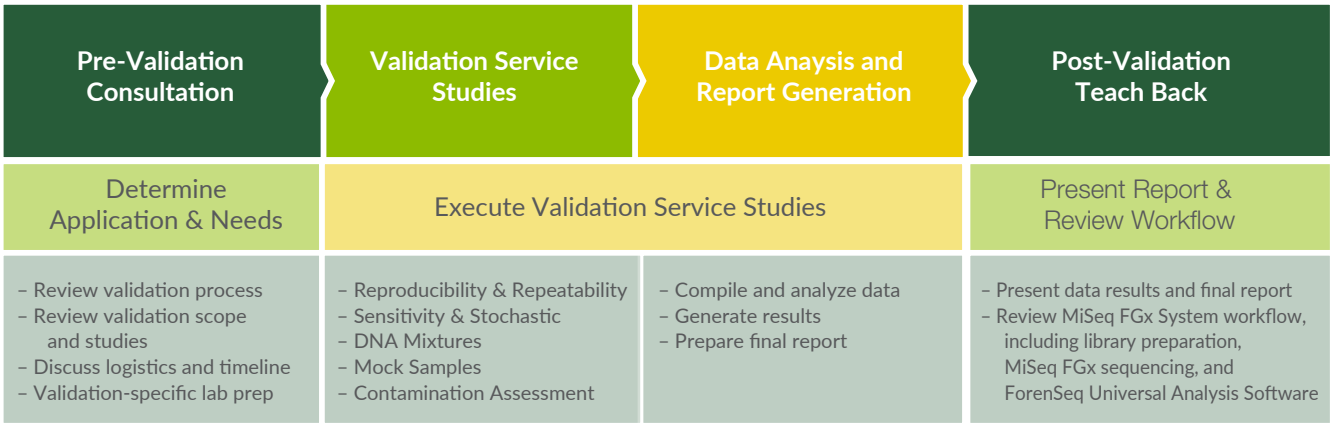
Table 1: Validation Service Options Key Features

Feature	Planned	Assisted	Full
Validation plan and study design documentation	✓	✓	✓
Onsite FAS assistance		✓ Up to one week to get started	✓ Up to four weeks to perform all runs
Reagent bundle for studies	✓	✓	✓
Data analysis and internal validation report		✓	✓
Validation data teach back		✓ Remote call	✓ One week onsite
NIST SRM DNA*		✓	✓

* The National Institute of Standards and Technology (NIST) ensures exact and compatible measurements through the generation, certification, and issuance of Standard Reference Materials (SRM).

Validation Service Workflow

The Verogen Validation Service begins with a personalized consultation to understand your laboratory use case and needs, and ends with a personalized consultation to present data, review the final report, and review the MiSeq FGx System workflow.



Validation Services Studies

Verogen validation studies are designed according to published, international Quality Assurance Guidelines, such as those provided by SWGDAM. Table 2 describes each of the validation studies.

Table 2: Verogen Validation Studies

Study	Description
Reproducibility and Repeatability	Evaluate consistency of results across multiple replicates and multiple runs
Sensitivity and Stochastic	Determine limit of detection and ideal DNA input target range
DNA Mixtures	Evaluate ability of the system to detect and resolve mixtures
Mock Samples	Evaluate system performance with various case type samples
Contamination Assessment	Detect and evaluate potential exogenous DNA

Validation Services Workflow Types

Each Validation Service offering addresses one workflow. Select the workflow suited to your laboratory needs:

- **ForenSeq DNA Signature Workflow**—Validate a gDNA workflow designed to evaluate up to 230 STRs and SNPs, which eliminates the need to prioritize one analysis type over another and reduces iterative testing.
- **ForenSeq mtDNA Whole Genome Workflow**—Validate a workflow designed to evaluate the entire mitochondrial genome, which expands options for challenging samples and population studies.

Getting started has never been easier.

Accelerate your implementation process and "go live" date with Verogen Validation Services. Verogen offers several easily accessible avenues to take advantage of these tools.

To get started, visit: verogen.com/services/validation.

Ordering Information

Table 3: Validation Services

Validation Service	Part Number
Planned Validation Service: ForenSeq DNA Signature	V16000090
Assisted Validation Service: ForenSeq DNA Signature	20004426
Full Validation Service: ForenSeq DNA Signature	20004427
Planned Validation Service: ForenSeq mtDNA Whole Genome	V16000122
Assisted Validation Service: ForenSeq mtDNA Whole Genome	V16000123
Full Validation Service: ForenSeq mtDNA Whole Genome	V16000124

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