Datasheet

VEROGEN

Verogen Validation Services

Increase your operational efficiency with guided workflows.

Highlights

- Demonstrated time savings
  Reduce your validation timeline by as much as one year.
- Flexible service offerings
  Choose a plan that meets your laboratory resouces, budget, and other plans.
- Hands-on assistance from Verogen
  Get expert advice along each step in the validation process.

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 laboratories require internal validation to verify optimal system performance and 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).

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. Figure 2 presents the validation service workflow.

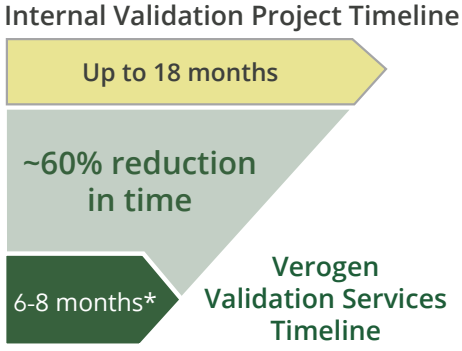

Figure 1: Managing an internally developed validation project on your own can take up to 18 months. Using any of the Verogen validation service options can take you from planning to completion in approximately 6–8 months*.

*Completion time depends on lab readiness and chosen product workflow.

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: Key features of validation service options

Feature	Planned	Assisted	Full
Validation plan and study design documentation	✓	✓	✓
Onsite FAS assistance		✓ Up to one week to get started	✓ Up to four weeks for FAS to complete all runs
Reagent bundle for studies	✓	✓	✓
Data analysis and internal validation report		✓	✓
Validation data teach-back		✓ Remote calls	✓ 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 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.

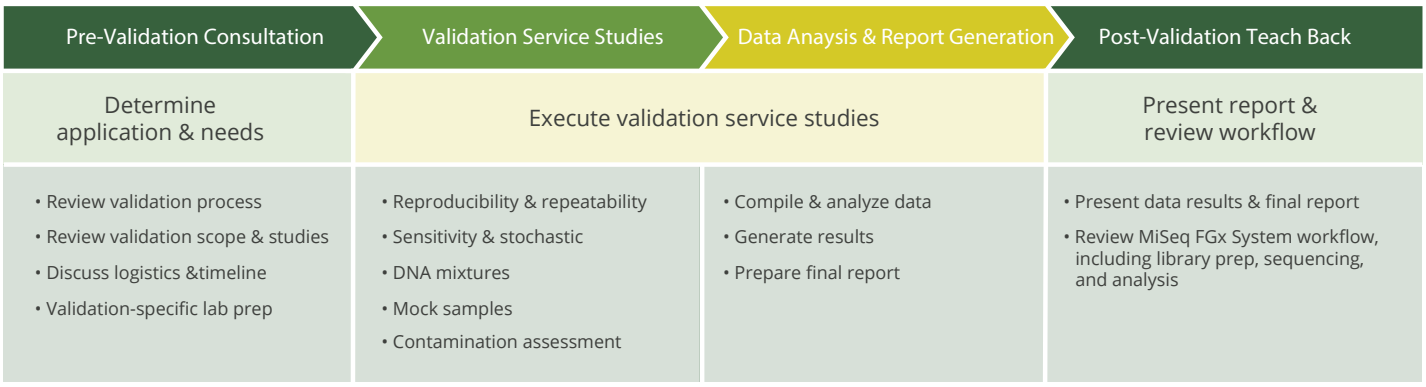

Figure 2: A Verogen validation service begins with a personalized consultation to understand your laboratory use case and needs, and ends with a personalized consultation to present data, review the final report, and review the MiSeq FGx System workflow.

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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 system ability 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 MainstAY Workflow—Validate a gDNA workflow designed to generate profiles of 27 autosomal STR and 25 Y-STR markers compatible with regional database requirements for routine casework.
- ForenSeq mtDNA Control Region Workflow—Validate a workflow designed to evaluate the highly mutated control region of the mtDNA maximizing variant detection in challenging forensic samples.
- 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

Validation Service	Part Number
ForenSeq DNA Signature	
Planned Validation Service	V16000090
Assisted Validation Service	20004426
Full Validation Service	20004427
ForenSeq MainstAY	
Planned Validation Service	V16000174
Assisted Validation Service	V16000175
Full Validation Service	V16000176
ForenSeq mtDNA Control Region	
Planned Validation Service	V16000177
Assisted Validation Service	V16000178
Full Validation Service	V16000179
ForenSeq mtDNA Whole Genome	
Planned Validation Service	V16000122
Assisted Validation Service	V16000123
Full Validation Service	V16000124

Product documentation is available for download at verogen.com/services/validation/

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