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Sample Flow Intelligence.

» WHITE PAPER

Navigating the EU IVDR: UgenTec as a knowledgeable partner

Learn how the FastFinder software platform and UgenTec team enable your lab's compliance efforts in routine PCR testing.

"The EU IVDR puts specific requirements on labs – spanning GSPR compliance, performance validation, and documenting and justifying the lab's approach. FastFinder helps labs comply on all fronts."

K. HENSEN | REGULATORY & QUALITY

WHAT YOU'LL LEARN

The main aim of the new European In Vitro Diagnostic Medical Devices Regulation (IVDR) is to improve patient safety. It replaces the old IVD Directive and brings clarity to the requirements for laboratories and kit manufacturers that run assays in routine practice.

Additionally, it adds new requirements to domains previously not touched.

Labs confronted with the new IVD Regulation have questions on how their Lab Developed Tests (LDTs, also called in-house devices) will be impacted; whether or not they should move parts of their assay portfolio to closed systems or commercial off-the-shelf assays; what the implications are of either approach – and how they can stay compliant.

With UgenTec as a knowledgeable partner, you can be confident on compliance as you implement these new regulations. In this white paper, you will learn how the UgenTec team and the FastFinder software platform allow you to ideally position your lab for the new IVD Regulation, ensuring compliance and continuity.

INTRODUCTION – THE NEW EU IVD REGULATION … AND HOW UGENTEC HELPS.

The new In Vitro Diagnostic Regulation outlines requirements for labs and kit manufacturers, and adds new requirements to domains the old Directive did not touch. With UgenTec as a partner, you can be confident on compliance as you implement these new regulations.

A KNOWLEDGEABLE PARTNER

UgenTec works side by side with labs and manufacturers on compliance with the new IVD Regulation. Our expert regulatory team helps you with the right experience and expertise – as well as with tangible assets, such as document templates, check lists, and a full-fledged validation package.

UgenTec works alongside your team to shorten the time for your transition to the IVDR.

FACILITATING PERFORMANCE VALIDATION

The FastFinder platform is ideally positioned to support and ease performance validation efforts. To this end, the UgenTec regulatory team provides labs with a comprehensive validation package.

This set of tools will guide you through performance validation efforts, and help you put together the validation report for PCR assays with real test cases, document templates, and guidelines. See page 7 for a detailed description of the validation package.

SOFTWARE BUILT FROM THE GROUND UP FOR RESULT CONSISTENCY

Consistency is key in a routine clinical setting, regardless of the regulatory context. The FastFinder software is built from the ground up to ensure assay analysis and interpretation happens in a consistent way.

This means the platform is packed with tools geared at reducing user error, optimizing data management, and executing analysis and interpretation rules independent of technician level of experience, expertise, and training.

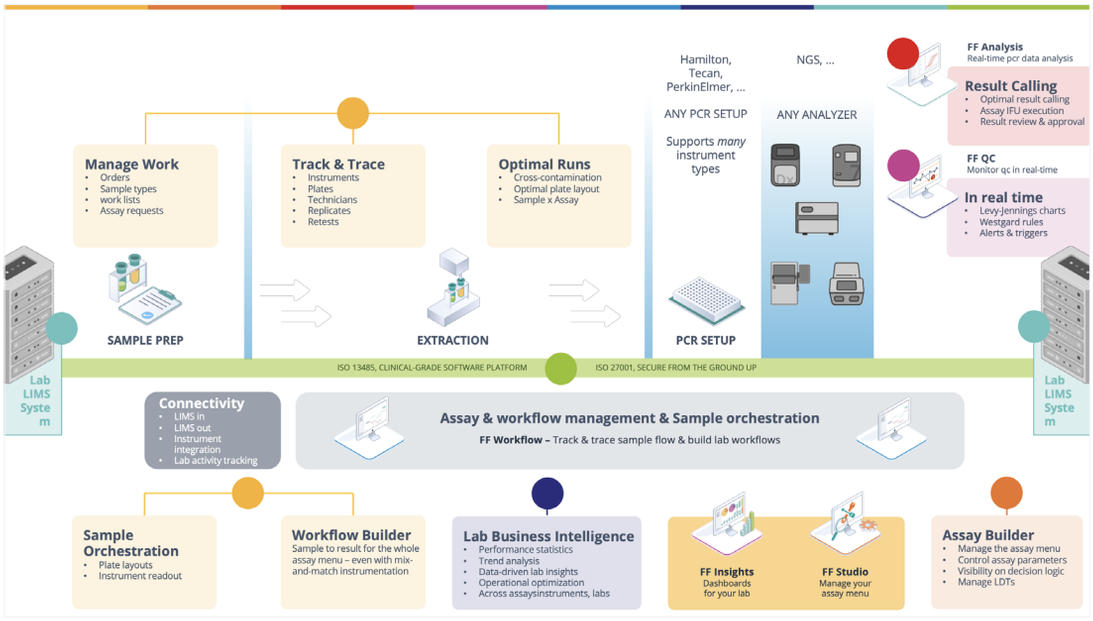

Figure 1 – overview of the lab workflow and the FastFinder platform components – Analysis, Workflow, QC, Insights, and Studio.

FastFinder has different components (in which each component contributes to improved efficiency and quality of result generation) – Figure 1 shows an overview of the platform. At its core, ***FastFinder Analysis*** automates the manual steps of analysis and interpretation. This way, standardizing assay instructions for use (IFU's) leads to fewer mistakes and less repetitive work, often removing secondary result review needs.

With ***FastFinder Workflow***, you'll be tracking and tracing manual steps, with software tools providing instructions for lab personnel, and software automation and integration guaranteeing full audit trails and track-and-trace of how samples flow through the lab, and integrating instruments, lab information management systems (LIMS), and lab result reporting.

With ***FastFinder QC***, you'll get real-time insights in key QC metrics, keeping tabs on the behavior of controls, visualizing Levy-Jennings charts, and triggering exceptions on industry-standard quality rules.

With the knowledge on result calling and reporting locked into software logic rather than people's minds, labs can rely more easily on junior staff and on lab technicians rather than involving highly-trained molecular biologists in every result call. With uncertain calls flagged for review and with real-time insights on assays, samples and controls, labs can rest assured they are not missing results that don't meet QC criteria.

OPERATING AT SCALE REQUIRES OPERATIONAL & PERFORMANCE INSIGHTS

Once you've transitioned assays to IVDR, you will want to run them at scale in a routine diagnostic setting. The UgenTec FastFinder platform allows you to fulfill accreditation and validation requirements, as well as effectively operate at scale once implemented.

In addition to the assays that a lab runs frequently, the more sporadic and exceptional assays are equally run in a controlled manner – with a validated result calling workflow providing consistency across the board, eased with software.

If you are processing samples with in-house devices in a clinical diagnostic setting, you will need to monitor and optimize performance. Through the QC module or optionally through custom FastFinder Insights dashboards, you have this information readily available.

BEYOND OFF-THE-SHELF PERFORMANCE

Labs often contribute their own expertise into optimizing the performance of an assay. For example, labs use their experience and insights into how assays work to enhance and improve on the data analysis and interpretation – allowing the lab to increase performance over the standard data analysis and result calling protocol that comes with the assay. In other cases, labs wish to improve on an assay design, based on their domain knowledge on diagnostic markers, or the clinical requirements for a specific demographic they serve.

Labs improving on assays in this way will find FastFinder is a great fit to support these in-house device assays.

INDEPENDENCE – SO THE LAB STAYS IN CONTROL

Labs often choose to adopt systems from multiple vendors, implementing a range of thermocyclers, combining open and closed systems, procuring assays from a multitude of commercial assay vendors as well as building in-house LDTs for specific applications.

This results in a complex ecosystem of systems, assays, sample flows, and approaches. At first sight, a heterogeneous setup further complicates IVDR implementation and compliance. With FastFinder, however, labs don't need to maintain, train and validate a wide range of vendor-specific software solutions. Rather, FastFinder provides a single environment for the lab technician, molecular biologist and lab director regardless of assay, sample type, thermocycler, file format, chemistry, or technology.

PARTNERING FOR COMPLIANCE

Through partnering with UgenTec, you'll be able to manage compliance efforts effectively, support performance evaluation and performance validation efforts, and run IVDR assays at scale.

Moreover, with UgenTec you'll ease and accelerate the ISO 15189 accreditation and validation requirements – limiting cost and effort, ensuring compliance, and maintaining the highest level of quality your physicians, referrers and customers rely on you for.

PART 1 – KEY REQUIREMENTS WITH THE IVDR

AN OVERVIEW OF THE KEY FOCUS AREAS OF ARTICLE 5 (5)

A key focus for labs and MDx providers alike is the compliance to requirements in Article 5 (5) of IVDR. Compliance can be broken down into 4 major areas to focus on, and we'll outline below how UgenTec supports you with each.

KEY REQUIREMENTS		
1	GSPR compliance	The EU IVDR outlines general safety and performance requirements (GSPR)
2	ISO 15189 compliance	ISO 15189 compliance outlines requirements for quality and competence for medical laboratories
3	Documented justification	Labs are required to document and justify assay manufacturing, modification and use
4	Device transfer	Devices are not allowed to be transferred between your legal entities

1. GSPR Compliance

The EU IVDR specifies General Safety and Performance Requirements (GSPRs). As it turns out, there is a very significant overlap between the rules set out by GSPR and ISO 15189, which labs typically already are accredited for.

To facilitate and bridge the gap between ISO and GSPR, UgenTec contributes expertise and tools along the way. For example, UgenTec provides a GSPR checklist for the Assay plugins to demonstrate compliance of an Assay Plugin.

During your journey to compliance, UgenTec will provide an Assay Plugin for every assay you automate, as well as the needed Summary of Technical Documentation (STED). Moreover, the UgenTec team can support your performance validation efforts with a report on validation.

2. ISO 15189

The EU IVDR stipulates ISO 15189 compliance as required – a standard that outlines requirements for quality and competence for medical laboratories.

FastFinder can help you with your ISO 15189 accreditation and maintenance in profound ways. This is where the FastFinder platform shines:

RESULT CONSISTENCY

Using FastFinder ensures consistent assay interpretation. The way FastFinder works is by automating the decision process on calling assay results. This means FastFinder provides state-of-the art curve calling, but also covers all complexities on dealing with controls, replicates, multiplexing, combining markers, thresholding, and more. This approach ensures automation and consistent assay interpretation.

Through automation, result interpretation becomes independent of experience, expertise, seniority, and training level of a technician. Adherence to Standard Operating Procedure (SOPs) is optimized with software.

Two clear benefits follow:

- Result repeatability. Regardless of the analyst executing the assay, assay result calling workflows are repeatable and results are reproducible.
- Onboarding and unburdening staff. Expertise is not locked in the minds of molecular experts or hidden in paper SOPs, but coded in software, de-risking user error, speeding up onboarding, and supporting staff of all expertise levels. Experts can focus on test design rather than burdensome and repetitive manual result calling.

REDUCED USER ERROR

Automation removes the rote, repetitive task of curve review for lab technicians – by taking away this error-prone work and having molecular experts and lab technicians only focus on curves that require attention, the risk of oversights and calling errors is greatly reduced.

ENHANCED PERFORMANCE

FastFinder can enhance assay performance. Instrument vendor software only goes so far in terms of capabilities of optimizing the result calls. The flexibility and capability of FastFinder goes far beyond what these vendor software systems can deliver, allowing labs to get maximum performance from assays.

With the molecular biologist in control, and the power and flexibility of rule automation and AI-based curve calling, many labs and assay developers have demonstrated performance gains over the standard approaches to analysis and calling by this way increasing patient safety.

CENTRAL, PERMANENT, QUERYABLE DATA MANAGEMENT

With a full lab result repository, validation efforts are eased to a great extent. Moreover, troubleshooting becomes traceable and manageable because data is readily queryable. And audit readiness is greatly enhanced, since the audit trail isn't paper based – it's available in real-time through dashboards and search tools.

3. Justification & Documentation Requirements

Under IVDR, labs are required to document and justify their assay manufacturing, modification, and use. When labs have better tools at hand to automate the results of their assay optimization efforts and 'code' the SOPs for assay result calling on a software platform that automates consistent analysis and result calling, they can prove this leads to better performance and assays can be enhanced.

UgenTec can deliver lab-specific documentary support for you to underscore this rationale. Specifically, UgenTec provides you with a validation package, minimizing the residual effort to comply with documentation requirements.

PLUGINS: A SMART FOUNDATION TO COMPLIANCE

The way the software platform is built, allows labs to have a repeatable, consistent assay data analysis and interpretation workflow. In FastFinder, an "Assay Plugin" is a stand-alone, well-documented, self-contained packet that represents everything about your assay – from markers, channels and dyes to interpretation rules and algorithm parameters. It uniquely describes how an assay will go from raw data to called result. Since Assay Plugins have a lifecycle independent of the FastFinder platform, you can upgrade the platform and leverage new features without affecting the validated state of your Assay Plugin.

VALIDATION PACKAGE

UgenTec delivers an Assay Plugin, representing the assay specifics, algorithm, and interpretation logic in a self-contained bundle. All the lab has to do, is configure the specific settings for this pre-set Plugin.

Every Assay Plugin (AP) comes with its **validation package**.

① – **AP handbook** that comes with the Assay Plugin, serving as a manual to its use

② – Documented suggestions to the **optimal validation approach** for the assay – with clear steps and guidelines on how to progress from initial use to final production assay

③ – A **pre-populated document** template for your specific assay plugin, outlining requirements and specifications

④ – **Test cases** for your validation report, in close collaboration with the lab

4. Device Transfer

Labs that span sites or organization structures don't always have a singular legal entity. Under IVDR, devices are not allowed to be transferred between your legal entities – depending on how you are organized, it may be impactful for your lab or the labs you collaborate with. To fulfill the requirement, UgenTec can provide your different Legal Entities with separate Assay Plugins so that you are implementing the same best practice efforts across different labs – including streamlined documentation. This unifies the performance across entities making use of the assay. While each individual lab will still need to validate individually, the process is streamlined and predictable.

THE LAB'S DIFFERENT USE CASES – LABS VARY IN TESTING APPROACH. FIND HOW UGENTEC FITS YOURS.

Whether you use commercial assays, lab developed tests, or both – FastFinder is the ideal software platform to orchestrate your lab workflow from sample coming in to result sign-out:

- Track and trace what happens to a sample
- Clearly, explicitly represent and execute interpretation and decision rules for result calling
- Confidence in results through real-time, in the moment QC tracking
- Validate assays more easily with standardized, uniform approach to result calling – across assays, instruments and technologies

I am using commercial off-the-shelf assay kits. How does FastFinder help?

FastFinder can reflect your interpretation rules and processes in a repeatable, white-box software workflow. You will find FastFinder to be the ideal companion to standardize and automate your SOP and reduce training. Documented, traceable, audit-trailed, and automated.

I am using commercial kits, and I optimize them for improved performance.

You have started from a commercial kit, and improved on its performance. For example, you may be using a commercial assay for a very specific clinical scenario to which you have optimized its performance. Or you've optimized it for performance on a specific demographic cohort. Or perhaps your process and expertise in general improved on the performance of an existing kit and it's standard IFU.

FastFinder can be an ideal solution to ensure you can standardize and streamline your own interpretation logic which you implement to optimize performance of your assays. This way, using a commercial kit in an in-house context is readily supported.

I am using lab developed, 'in-house' tests. How does FastFinder help?

FastFinder has the capabilities needed to track assay performance, guard consistency in assay execution and interpretation, and ensuring full traceability on sample flow and result calling.

With an in-house assay in place, adding a software component to ensure the interpretation and result calling are standardized and automated, greatly simplifies the lab process, and evidence of consistent performance becomes readily available.

FastFinder is built from the ground up for clinical use. FastFinder readily supports implementing the requirements of IVDR article 5 (5) – as outlined previously. Moreover, our approach can ease your path to compliance:

- The IVDR requires you follow sound assay development lifecycle principles. With FastFinder bolted on to your assay, you can rest easy: FastFinder is built on ISO 13485 Quality Management System (QMS) principles – foundationally.
- Labs manage LDT activities in a QMS, which covers QC and risk management. On the software side, UgenTec can provide input on the required risk reports for the Assay Plugin. So you do not have to worry about creating risk reports from scratch.
- Performance assessment of an assay is greatly facilitated when you include result calling automation software in the process that has built-in QC, a database repository to maximize the quality of your results, and can feed relevant assay info into your LDT validation & verification files.
- UgenTec is ISO 13485 and ISO 27001 certified, clearing the hurdle of your manufacturer compliance requirements.

CURIOUS TO LEARN MORE?

There is much more we can help with – if you are interested to learn more, please watch our IVDR webinar (available through www.ugentec.com or upon e-mail request) or reach out to our team (info@ugentec.com) to set up a conversation with our regulatory experts on how to ensure your LDT is all it can be.

In short, UgenTec helps you ensure you have an appropriate QMS, minimizing the time it takes you to comply with GSPR, and providing review experience from clinical use.

UgenTec

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