



# FastFinder

Automated PCR analysis

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## Instructions for use

Software release FastFinder  
Lab management 1.0  
Analysis 4.0

IFU Version 1.0



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# Intended Purpose

FastFinder is UgenTec's UgenTec's software platform that transforms the molecular lab into a digital, connected lab. FastFinder is intended to be used by trained laboratory professionals and has multiple components. Each FastFinder component is intended to cover a different need:

Components, owned by UgenTec in scope of this IFU:

- **FastFinder Analysis** is the user interface component, where the results generated by the FastFinder Assay Plugins are visualized and reported. This component does not contribute to the result generation of a specific assay or examination, rather, it merely provides a user interface, result visualization and reporting functionality.
- **FastFinder Lab Management** is a component that enables central assay plugin, instrument, workflow and user management by the end-user.

Components owned by another legal manufacturer and **NOT** in scope of this IFU.

- **FastFinder Assay Plugins** are intended to be used as decision-support software for the analysis and interpretation of the results of a qualitative amplification qPCR assay or end point detection PCR assay, generated on a particular PCR cyclers. An Assay Plugin contains an assay specific algorithm and decision mechanism that allows conversion of the PCR raw data into test results with minimal manual intervention. The FastFinder Assay Plugins are developed in order of a molecular assay developer or laboratory and considered the analysis software component of a particular molecular assay. Only in combination with that particular assay, they can turn into a system for automating PCR analysis interpretation for a specific assay. The *Assay details* view indicates who is the legal manufacturer of each Assay Plugin and with which assay and in which domain the assay plugin can be used (Clinical Diagnostics (IVD) or Research (RUO), AgBio, Food, Veterinary).

# Intended User

The intended user of FastFinder is a professional with the necessary clinical and/or laboratory background or education and relevant experience in molecular biology.

# Qualification, classification and QMS certification

All components of FastFinder, except for the FastFinder Assay Plugins, are qualified as **general laboratory use** software, since they do not contain any functionality which contributes to the Assay result generation.

The general laboratory use of FastFinder components (FastFinder Analysis, FastFinder Workflow, FastFinder LabManagement), which can be used in combination with *in vitro diagnostic* medical device FastFinder Assay Plugins in clinical laboratories are developed under a ISO13485 compliant Quality Management System to ensure that the safety and performance of the Assay Plugins, which are intended to be used in combination with other FastFinder components, is not impaired.

Since the FastFinder Assay Plugins are considered the analysis software component of a particular molecular assay, the qualification and classification of the FastFinder Assay Plugins in a jurisdiction is identical to the qualification and classification of the related Assay and determined by the legal manufacturer of the Assay Plugin, which can be found in the Assay details view of FastFinder. ***A non-IVD Assay Plugin cannot be used for diagnostic purposes unless its compliance with the local safety and performance requirements is demonstrated by the health institution that is using this software in combination with the related (Lab Developed) Assay.***

## Use in Combination with other devices

### **Molecular Assay**

As described in the Intended Purpose section, the UgenTec owned FastFinder components can be used in combination with a molecular assay and corresponding FastFinder Assay Plugin, owned by the Assay Manufacturer, specified in the Assay details view. All Assay specific details, such as the type of specimens required, the test principle, the needed reagents and controls, a list of materials provided or needed, any storage and handling conditions, ..., can be found in the Assay Instructions for Use. ***All final results, generated by IVD assay plugins, should be interpreted according to the Assay IFU and in conjunction with the patient's clinical signs and symptoms, medical history and other laboratory data available to the physician.***

## Assay Plugin compatibility

Assay Plugins designed for FastFinder Analysis 3.x are not supported on the FastFinder release in scope of this document.

# Operating Environment

## Minimum System Requirements

- Processor: 2 GHz CPU, 2 GB RAM
- Internet Connection Cable or DSL
- Screen resolution: min. 1366 x 768 pixels, max. 1920 x 1080 pixels
- Supported browsers:
  - Microsoft Edge (last 3 versions)
  - Mozilla Firefox (last 3 versions)
  - Google Chrome (last 3 versions)

## Recommended IT Security Requirements

FastFinder provides the following default IT system security hardening measurements:

- Role based user access management: FastFinder supports two specific roles that can be assigned to each user in the Settings - Team page:
  - Authorizer: only users with this role can authorize analyses
  - Admin: only users with this role can access and edit the Lab configuration (Assays, Instruments, Workflow setup) and manage Settings (General, Team)
  - All other functionalities are available to all users.
- Password complexity measures
- Audit trails to support non-repudiation of data
- Data encryption in-transit and at-rest

It is recommended to use all of the above IT security measures to protect against unauthorised access and run the software as intended.

Besides the above listed measures, it is recommended to apply also adequate cybersecurity best practices to maintain the security status of the operating environment, such as

- Physical security measures to prevent unauthorized physical access
- Malware and anti-virus protection on workstations to prevent unauthorised code execution
- Security awareness training for personnel
- Exclusive use of genuine software and ban of all illegitimate software and applications

***It is important to understand that any invalidated modification of the software or use outside the intended operational environment can adversely affect system performance or safety in unpredictable ways.***

***The users of FastFinder should adhere to any national and EU regulations with regards to data protection.***

## FastFinder Access and Installation

### **Access and Initial Installation**

There is no installation needed on the client's side. FastFinder can be accessed directly by logging in with your unique username and password at <https://customer.fastfinder.app>, where customer is your unique customer name.

### **Patch Management**

If needed UgenTec will deploy software patches to restore the software conform its original specifications and/or to install additional security measurements.

## Data Storage

Controls for handling data corruptions, rollbacks, disaster recovery and archiving include

- Isolation of tenant-specific data in tenant-specific data repositories
- SQL databases can be geo-restored from a different Microsoft data center in case of disaster, within 24 hours and with a maximal data loss of 1 hour
- SQL databases are archived as a whole every month, and archives can be kept for up to 10 years

- File storage is immutable & append-only, while being replicated in at least 3 physical locations

All data storage has been configured to be encrypted at rest, covering both file storage, as the underlying data storage of databases. Together with the strong protection layers that are in place for data in transit, and the strong isolation of a laboratory's data, we ensure data is handled by our system in a safe & secure way.

## Product Characteristics

### Supported Analysis types

- Qualitative amplification curve analysis
- End point analysis

### Supported Devices and File Types

Device	File Type(s)
Abbott m2000	.sds
Agilent AriaDx	.amxd
Agilent AriaMx	.amxd
Applied Biosystems ABI 7500 (fast) (Dx)	.sds (software v1.x) .eds (software v2.x)
Applied Biosystems ViiA7	.eds
Applied Biosystems QuantStudio 3 (seen as QS5) and QuantStudio 5	.eds
Applied Biosystems QuantStudio 5 Dx	.eds
Applied Biosystems QuantStudio 7	.eds

Applied Biosystems QuantStudio 12K Flex	.eds
BioRad CFX (CFX 96, CFX 384)	.pcrd
BMS micPCR	.micrun
GeneTrac Cyclor	.gtrun
RIDACYCLER	.cyclerrun
LGC IntelliQube	.csv
LGC Araya	.csv
Qiagen Rotor-gene 6000 & Q	.rex
Roche Cobas z 480	.ixo, .xml
Roche LightCycler 480 Type I & II	.ixo, .xml
Roche LightCycler 96	.lc96p

## Analysis Exports

When authorizing an analysis, FastFinder automatically creates a standard CSV export. This can be used as input for any other system to e.g. establish a LIMS connection. The standard CSV export is verified and validated as part of FastFinder. Contact [support@ugentec.com](mailto:support@ugentec.com) if you need the technical specifications of this CSV export.

***It is the end user's responsibility to validate a LIMS connection before clinical use. Exports can be modified manually after generation outside of FastFinder and hence do not necessarily represent the actual state of the data in the FastFinder database at time of generation. The content of exports is the sole responsibility of the user.***

## Traceability

Changes done by a user that may impact the final result (e.g. editing results, modifying assay settings...) are audit trailed and logged, and can be accessed by other users at all times.

## Warnings and Errors

FastFinder warnings and errors, which require user attention, are displayed in the user interface.

Warnings are indicated by an orange symbol, errors by a red symbol. It is the responsibility of the user to handle each operation correctly for which warnings are raised. In case of errors, the user first needs to resolve the error before proceeding in FastFinder.

## Performance Characteristics

FastFinder cannot demonstrate clinical effectiveness as standalone software. Analytical and clinical performance can only be demonstrated in combination with a molecular assay. The (clinical) performance characteristics of the molecular assay, analysed with the FastFinder Assay Plugins can be found in the molecular assay IFU.

## Support

FastFinder contains in-app user guides on all functionalities. If you need additional support or assistance with setting up and operating your FastFinder laboratory environment or in case of malfunctioning and/or data security events, please visit our support center

<https://support.ugentec.com/> or contact support@ugentec.com.

Any incidents with the FastFinder software need to be reported to our support center










<https://support.ugentec.com/> or support@ugentec.com. ***Serious incidents in relation to FastFinder need to be reported to the competent authority of the country in which the end user and/or patient is established.***



## Document Version

Version	Description	Date
1.0	New document	Oct 12, 2020

## Appendix A - Symbols used in FastFinder

	In-app user guide
	Overview of guides
	Error
	Warning
	Audit trail
	Mark for retest
	Date of manufacture
	Manufacturer
	Settings