

Application guide for FastFinder Standalone

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1. About this application guide

This application guide for the FastFinder Standalone software (UgenTec NV, Hasselt, Belgium) describes how to apply assay plugins with FastFinder Standalone within the AltoStar® Workflow.

For general information on intended purpose, intended user, operating environment, FastFinder Standalone access and installation, product characteristics, and performance characteristics, refer to the instructions for use of FastFinder Standalone.

For specific information on altona Diagnostics (RT-)PCR products, including performance data, refer to the respective instructions for use.

2. Login

1. Access FastFinder Standalone through a web browser on the AltoStar® Automated Analysis PC by accessing <http://fastfinder/>.
2. Select your user name.

NOTE



Only the user FAS (field application specialist) is set up as default. Other users must be created by an admin.

3. Enter your password.

The start screen is displayed. All open and authorized analyses can be accessed.

For further information on access and installation, refer to the instructions for use of FastFinder Standalone.

3. Description of the user interface

In the following chapters the different menu items of the FastFinder Standalone user interface are described.

3.1 Analyses

In the menu **Analyses** all open and authorized analyses can be accessed. All analyses can be viewed by all users.

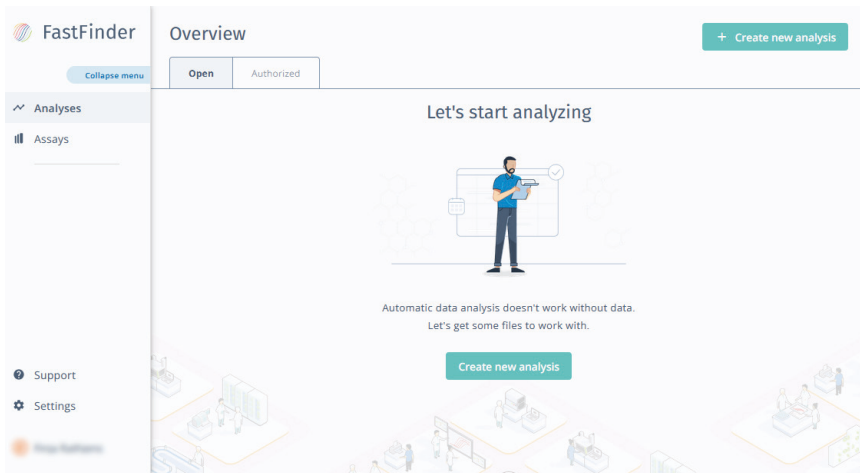


Figure 1: Start screen of FastFinder Standalone

Clicking on a specific analysis, the tabs **PCR setup**, **Summary** and **Details** are displayed (see figure 2). The tab **Summary** opens by default.

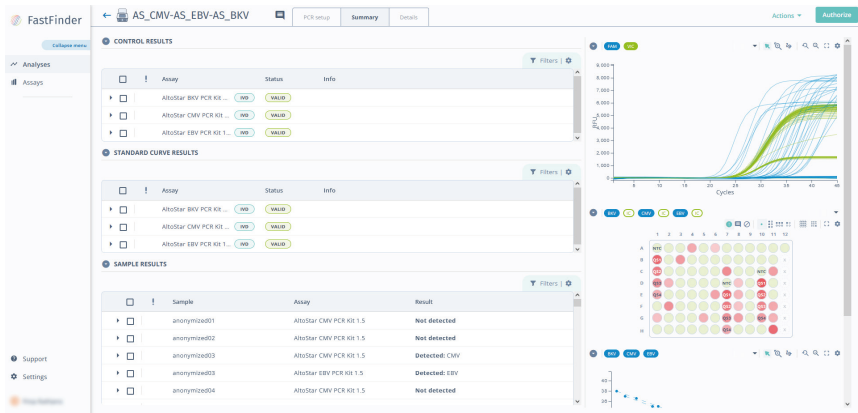


Figure 2: Tab Summary of an analysis

3.1.1 Analysis overview

PCR setup

In the tab **PCR setup** the plate configuration and assigned assays are displayed. The plate configuration is generated automatically. No user interaction is required.

Summary

In the tab **Summary** an overview of all results is displayed (control results, standard curve results and sample results). In addition, the PCR signals for all wells, a graphical representation of the PCR plate and if applicable the standard curve are displayed.

Details

In the tab **Details** the specifics (e.g., dye, C_q value, concentration or well) for every single sample can be accessed. In addition, the PCR signals for all wells, a graphical representation of the PCR plate and if applicable the standard curve are displayed.

3.1.2 Creating a new analysis

1. Click the **Create new analysis** button in the upper-right corner of the **Analyses** menu.
2. Browse for the PCR run file to be analyzed and select it by clicking the **Open** button. Only .pcrd files generated with the CFX96™ Deep Well Dx System (Bio-Rad) are supported.

NOTE



It is highly recommended to analyze only one PCR data file (.pcrd) at once instead of analyzing multiple PCR runs in batches.

The file is uploaded and analyzed automatically without further user interaction. After the analysis is finished the status **Ready for review** is displayed (see figure 3).

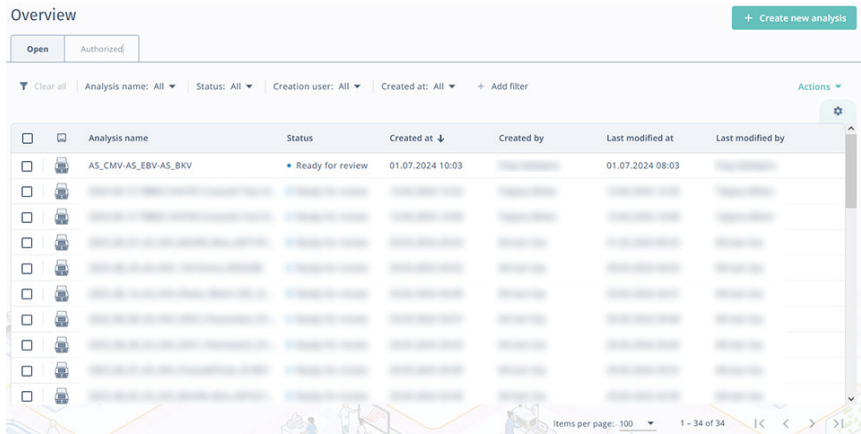


Figure 3: Start screen: Status of an analysis

Different statuses can be displayed and are shown in table 1.

Table 1: Different statuses of an analysis

Status	Description
New	A new PCR run file is uploaded.
Analyzing	The PCR run file is being analyzed.
Ready for review	The PCR run file was uploaded and analyzed. The user can review the results.
Analysis failed	The analysis failed. Contact altona Diagnostics technical support (see chapter 6. Technical support).
File is not supported	A file type that is not supported has been used or the PCR setup was not performed using the AltoStar® Automation System AM16. Repeat the PCR setup using the AltoStar® Workflow or analyze the results manually with the CFX Manager™ Dx software. For further information, refer to the instructions for use of the respective altona Diagnostics (RT-)PCR product.
Manual PCR setup required	No assay has been detected in the PCR run file for which an assay plugin is available. Analyze the results manually with the CFX Manager™ Dx software. For detailed information, refer to the instructions for use of the respective altona Diagnostics (RT-)PCR product.

3.1.3 Reviewing and authorizing analyses

1. In the **Analyses** menu, click on the analyzed PCR run file to start the review process.

NOTE










If a PCR run contains an assay for which there is no assay plugin available, this assay will not be displayed in the analysis. For information on whether an assay plugin is available or not, refer to the instructions for use of the respective altona Diagnostics (RT-)PCR product.

The tab **Summary** is displayed by default.



A graphical representation of the PCR plate is displayed on the right side of the window. The wells are marked with different colors and symbols, which are explained in table 2.

Table 2: Explanation of colors and symbols on the graphical representation of the PCR plate

Symbol	Explanation
	Negative result, target was not detected.
	Positive result, target was detected. The intensity of the color corresponds to the C_q value.
	Inconclusive result, user marked the result as inconclusive.
	Error
	Warning
	Retesting required.
	Well not used.

2. Check the results of all analyzed controls and samples. Check in particular for warnings and errors indicated by the respective symbols shown in table 3.

Table 3: Symbols requiring user attention

Symbol	Explanation
	Error
	Warning

Detailed information on the error/warning is displayed via mouse over (e.g., "Error: Uncertain result").

3. Resolve any error messages for individual samples. Runs with errors cannot be authorized. All errors need to be resolved by the user before a run can be authorized and the user can proceed in FastFinder Standalone. Runs with warnings can still be authorized. For detailed information on resolving errors, refer to chapter 4. Use cases.
4. Authorize the analysis.

After clicking the **Authorize** button the analysis is automatically exported to a predefined directory (LIMS) if this was set up during installation.

NOTE



The export file can only be accessed after authorization.

3.1.4 Generation of PDF reports and download of results

Usually, results are automatically saved in a predefined directory upon authorization of the run. If not defined, it is possible to manually download results or to generate PDF reports by accessing the **Analyses** menu. After selecting the **Authorized** tab, all authorized analyses are listed. Results can be downloaded only from authorized analyses.

1. Click on the respective analyses for which a PDF report shall be generated or for which results shall be downloaded manually.
2. Click the **Actions** button in the upper right corner and select **Generate PDF Export**.

A PDF file will be generated in case it is needed.

3. Click on the **Actions** button and hover over **Downloads**. All files that can be downloaded are displayed.
4. Choose the file of interest for download.

The following file types are available for download:

- Analysis PDF (only if previously generated)
- Analysis CSV (data format not compatible with the LIMS interface description provided by altona Diagnostics)
- All CSV export: The All CSV export contains different CSV files: The CSV file contained in the archive starting with the run name is compatible with the LIMS interface description provided by altona Diagnostics. For each well group (assay) a separate file is created. The CSV file including the results is named "run name - Quantification Cq Results_0". It is recommended to use this CSV file for the LIMS export. Additional information on the PCR run and the devices used is stored in the CSV file ending with "Run information".

For more information on the different file types and on LIMS integration, contact altona Diagnostics technical support (see chapter 6. Technical support).

3.2 Assays

In the menu **Assays** all available assay plugins for which data analysis and automated result interpretation is possible are displayed. Only the user FAS is able to change non-active assays to active and vice versa.

3.3 Support

In the menu **Support** information on the FastFinder Standalone version, the user documentation and the support address can be found.

3.4 Settings

In the menu **Settings** different adjustments can be made:

- **Analysis:** Retest reasons which will be exported in the analysis results can be defined.
- **Team** (admins only): Users can be managed here and roles (Authorizer/Admin) can be assigned to them.
- **Export** (FAS only): Export options can be managed here.

3.5 User

Click on your user name to log out.

4. Use cases

The following chapters describe different scenarios in which errors and warnings can occur and how they can be resolved.

4.1 Errors in an analysis

Errors are indicated by a red bordered number. Errors can be resolved in the tab **Summary** (see figure 4) and in the tab **Details** (see figure 5). Detailed information about the error is displayed in the mouse over.

Sample	Assay	Result
03306827	AltoStar HSV PCR Kit 1.5	Detected: HSV-1
03313539	AltoStar HSV PCR Kit 1.5	Detected: HSV-2
03321057	AltoStar HSV PCR Kit 1.5	Not detected

Figure 4: Tab Summary: errors in an analysis

In the following, the process how to resolve an error is shown. In the selected example, the error is an uncertain result.

1. In the tab **Details**, click on the exclamation mark in the table header to sort the samples by error messages. Alternatively, use filters to only show samples with errors.
2. Click on the arrow to the left of the sample flagged with an error to get more detailed information.

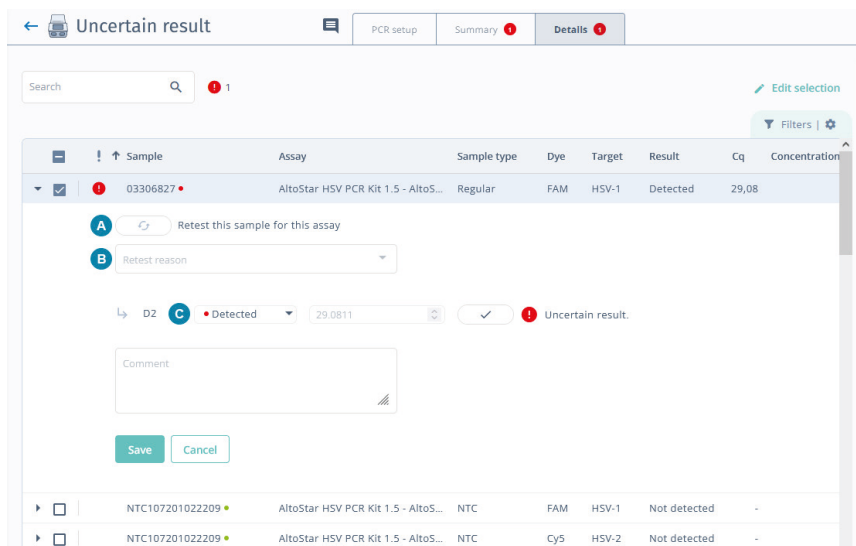


Figure 5: Details on the sample with an error

- Resolve the error according to the error message. Different options to resolve an error are available:
 - Confirm the result by clicking on the check mark next to the result and click the **Save** button. No comment is required to confirm results. A warning is displayed, but the result for this sample is included in the LIMS export.
 - Change the status of the result to the opposite status (Detected or Not detected) (C). A comment is required to save the changes. The result for this sample is included in the LIMS export.
 - Change the status of the result to **Inconclusive** (C). A comment is required to save the changes. The result for this sample is excluded from the LIMS export. Re-extract and re-test the sample.
 - Mark the sample for retesting (A). Select a reason for retesting (B) and click the **Save** button. Reasons for retesting are set up during installation of FastFinder Standalone. No comment is required to save the changes. The result for this sample is excluded from the LIMS export. Re-extract and re-test the sample.

4. After resolving an error, the audit trail symbol appears in the line for the sample. Information on modifications is displayed via mouse over. In addition, comments and reasons for retesting are displayed.

NOTE



Information from the audit trail are not included in the LIMS export.

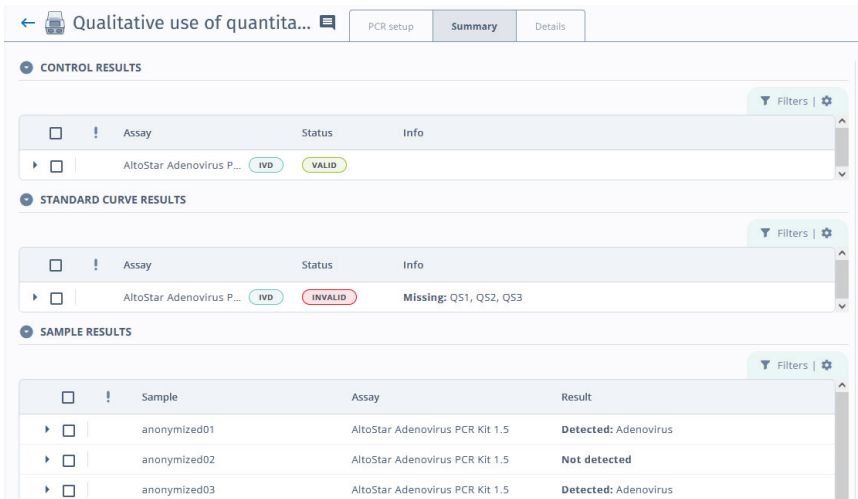
5. Resolve all errors in the analysis.
6. Authorize the analysis.

4.2 Invalid standard curve

4.2.1 Qualitative use of assays provided with Quantification Standards

Some assays provided with Quantification Standards can be used for quantitative and qualitative analysis. For detailed information, refer to the instructions for use of the respective Altona Diagnostics (RT-)PCR product.

When using an assay with Quantification Standards for qualitative detection, FastFinder Standalone marks the standard curve results as invalid (see figure 6).



The screenshot displays the 'Qualitative use of quantita...' tab with three sections:

- CONTROL RESULTS:** A table with columns 'Assay', 'Status', and 'Info'. One row shows 'AltoStar Adenovirus P...' with a status of 'VALID'.
- STANDARD CURVE RESULTS:** A table with columns 'Assay', 'Status', and 'Info'. One row shows 'AltoStar Adenovirus P...' with a status of 'INVALID' and 'Info' containing 'Missing: Q51, Q52, Q53'.
- SAMPLE RESULTS:** A table with columns 'Sample', 'Assay', and 'Result'. Three rows are shown for 'anonymized01', 'anonymized02', and 'anonymized03', all using 'AltoStar Adenovirus PCR Kit 1.5'. Results are 'Detected: Adenovirus', 'Not detected', and 'Detected: Adenovirus' respectively.

Figure 6: Tab Summary: qualitative use of an assay provided with Quantification Standards

If the assay provided with Quantification Standards can be used for quantitative and qualitative analysis, there are no warnings. If errors are included, resolve them as described in chapter 4.1 Errors in an analysis.

After resolving all errors, authorize the analysis. The results for all samples assigned for qualitative analysis are exported to the LIMS.

4.2.2 Invalid standard curve in a quantitative PCR run

For a quantitative analysis all 4 Quantification Standards (QS) are needed. If less than 4 QS are used, FastFinder Standalone marks the standard curve as invalid. In the tab **Summary**, all quantitatively assigned samples are marked with a warning (see figure 7).

The screenshot displays the 'Invalid standard curve' tab in the Summary section. It is divided into three main sections:

- CONTROL RESULTS:** Contains a table with one row for 'AltoStar EBV PCR Kit 1...' with a status of 'VALID'.
- STANDARD CURVE RESULTS:** Contains a table with one row for 'AltoStar EBV PCR Kit 1...' with a status of 'INVALID' and info 'Missing: QS2, QS3'.
- SAMPLE RESULTS:** Contains a table with three rows for 'anonymized01', 'anonymized03', and 'anonymized08', all with a status of 'Invalid: EBV'.

Figure 7: Tab Summary: missing QS in standard curve results

Since this is an improper use of quantitative assays, the analysis of the results is not possible. Repeat PCR setup and PCR run with 4 QS. For detailed information, refer to the instructions for use of the respective altona Diagnostics (RT-)PCR product.

The warnings can not be resolved, but the analysis can be authorized. The results of all samples assigned for quantitative analysis are excluded from the LIMS export.

4.3 Invalid controls

Both the No Template Control (NTC) and the Positive Control (PC) can be marked as invalid.

In case an invalid control signal has been detected, the control and all samples which were tested with the respective assays are marked with a warning in the tab **Summary** (see figure 8). In the tab **Details**, an error is displayed. How to deal with this issue is illustrated for an analysis including an invalid PC.

The screenshot displays the 'Invalid PC' summary tab. At the top, there is a navigation bar with 'PCR setup', 'Summary' (selected), and 'Details'. Below this, the 'CONTROL RESULTS' section shows 1 warning (yellow triangle) for the assay 'AltoStar SARS-CoV-2 R...'. The status is 'INVALID' (red box). The info field indicates 'Invalid: SARS-CoV-2 PC | 131111902302 (PC)'. The 'SAMPLE RESULTS' section shows 54 warnings (yellow triangles) for four anonymized samples (01-04). All samples used the 'AltoStar SARS-CoV-2 RT-PCR Kit 1.5' assay and resulted in 'Invalid: E gene, 5 gene'.

Assay	Status	Info
AltoStar SARS-CoV-2 R...	INVALID	Invalid: SARS-CoV-2 PC 131111902302 (PC)

Sample	Assay	Result
anonymized01	AltoStar SARS-CoV-2 RT-PCR Kit 1.5	Invalid: E gene, 5 gene
anonymized02	AltoStar SARS-CoV-2 RT-PCR Kit 1.5	Invalid: E gene, 5 gene
anonymized03	AltoStar SARS-CoV-2 RT-PCR Kit 1.5	Invalid: E gene, 5 gene
anonymized04	AltoStar SARS-CoV-2 RT-PCR Kit 1.5	Invalid: E gene, 5 gene

Figure 8: Tab Summary: invalid PC

In the tab **Details**, the error is displayed for the well of the PC. The software displays information on why the error occurs (see figure 9).

The screenshot displays the 'Invalid PC' details view. At the top, there is a search bar and a 'Details' tab. Below the search bar, there is a table with columns: Sample, Assay, Sample type, Dye, Target, Result, Cq, and Well. The selected row is 'SARS-CoV-2 PC | 1311119023...' with 'AltoStar SARS-CoV-2 RT-PCR Kit...' as the assay, 'PC' as the sample type, 'FAM' as the dye, 'E gene' as the target, and 'Not detected' as the result. Below the table, there is a 'Comment' field and 'Save' and 'Cancel' buttons. The error message 'Expected reaction did not occur in control.' is displayed next to the result.

Sample	Assay	Sample type	Dye	Target	Result	Cq	Well
SARS-CoV-2 PC 1311119023...	AltoStar SARS-CoV-2 RT-PCR Kit...	PC	FAM	E gene	Not detected	-	C8
SARS-CoV-2 PC 1311119023...	AltoStar SARS-CoV-2 RT-PCR Kit...	PC	Cy5	S gene	Not detected	-	C8
NTC 131201902302	AltoStar SARS-CoV-2 RT-PCR Kit...	NTC	FAM	E gene	Not detected	-	A1
NTC 131201902302	AltoStar SARS-CoV-2 RT-PCR Kit...	NTC	Cy5	S gene	Not detected	-	A1

Figure 9: Details on the error for the PC well

1. Check the results and the PCR curve for the PC.
2. Confirm the results or change the status. The results for all samples tested with the respective assay are excluded from the LIMS export. Repeat the PCR run.
3. Authorize the analysis.

NOTE



For general information on how to deal with incorrect results for the controls refer to the instructions for use of the respective altona Diagnostics (RT-)PCR product.

5. LIMS export

For detailed information on consequences of errors and warnings on the LIMS export, refer to table 4.

Table 4: Consequences for LIMS export

Scenario	Error/warning	Consequence for LIMS export
Invalid NTC or invalid PC	Possible contamination	All samples tested with the respective assay are excluded from LIMS export.
	IC not detected	
	Expected reaction did not occur in control	
Invalid standard curve	Missing QS	All quantitatively assigned samples are excluded from LIMS export while all qualitative results are still exported.
	Invalid QS	
	R ² value	
Sample marked inconclusive*	N/A	The complete well will be excluded from LIMS export.
Sample marked for retest*	N/A	
Invalid sample	IC invalid	

* This scenario is assigned by the user.

6. Technical support

For customer support, contact altona Diagnostics technical support:

e-mail: support@altona-diagnostics.com











phone: +49-(0)40-5480676-0

7. Revision history

Table 5: Revision history

Date of issue [month/year]	Modifications
09/2024	Initial release

8. Symbols

Symbol	Explanation
	Error
	Warning
	Warning for a well
	Information
	Audit trail
	Retesting required
	Well not used
	Valid control or standard curve result
	Invalid control or standard curve result
	The assay is an IVD product.

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