



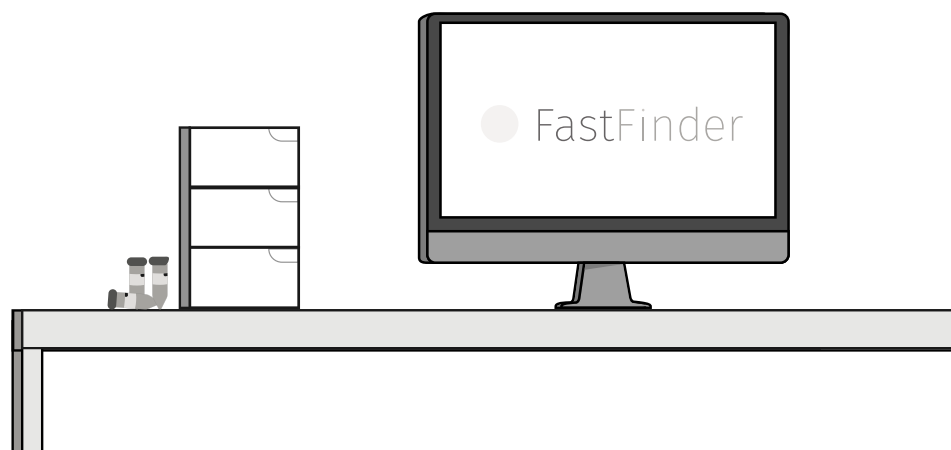
» *Accurate PCR assay results with FastFinder*

Ensuring accuracy of reported results

- » The accuracy of your molecular assays is essential to the quality of service of your lab. As you stand behind the results the molecular research or diagnostics laboratory sends out to referrers and customers, you take great effort to ensure the reported results are reliable.



In this brief overview, we'll discuss how the FastFinder platform supports the lab in making sure the results are accurate and reliable - so that you and your referrers can confidently depend on sent out test reports, resting assured the the interpretation of PCR data is sound, and the underlying lab workflow is validated, reproducible, and audited - from sample to result.



How FastFinder helps ensure your lab's accuracy

- » To ensure accuracy of assay results, every step in your lab workflow has to be evaluated and validated, automated and supported, and monitored and audited. Without adding the burden of additional manual work to the process.

Assay validation

validating the performance of data analysis and interpretation on the assays on your test menu is essential for both commercial off-the-shelf kits as well as for your Lab Developed Tests. For kits, the assays you buy will come with the Ugentec FastFinder Real-Time software containing "assay plug-ins" that have been validated for that specific assay and for the cyclers you use. With a FastFinder Real-Time assay plugin bolted on to your commercial kit, you can rest easy that the algorithms and decision support tools are a perfect fit right off the bat.

For your lab developed tests, bolting on an assay plugin to automate data analysis and interpretation support is easy as well. One of the very first things you'll do together with UgenTec, is provide examples of positive and negative assays, and interpretation SOP - so UgenTec can provide you with assay plugins that perfectly match your assays and thermocyclers. UgenTec not only creates optimal plugins for you, but creates a validation report on key metrics like sensitivity, specificity, positive and negative predictive value (PPV, NPV), false-positive and false-negative rates, and all other metrics to ensure confidence in assay results.

Workflow Automation

a sound, validated analytical pipeline is just the beginning. It is equally essential to maximize use of opportunities to automate the workflow - from sample reception and accessioning to result sign-out. Not just to avoid manual error (think of mistakes in manual data entry, sample swaps, errors in pipetting, plate mixups, wrong assay assignments) but also to avoid that operators such as lab technicians have to spend time on rote, repetitive and sometimes menial tasks. Leave the repetitive work to robots, software and workflow automation tools, so your lab staff will be intellectually engaged, to the benefit of assay result accuracy and quality.

FastFinder automates the workflow on numerous fronts. First of all, the **FastFinder Real-Time** software will automate assignment of samples to plates, will automate the execution of data analysis and interpretation support decision trees. This means the molecular biologist or lab technician will **only have to review exceptions**, in cases the algorithm is unsure of the result - not pile through each and every curve, control, and positive/negative call.

Secondly, **FastFinder Workflow** will support automation of the broader workflow - starting from the work lists imported from your LIMS system, over optimally assigning samples to assays, generating a resource-efficient plate setup, and automatically generating pipetting lists. FastFinder Workflow, moreover, will drive your instrumentation and capture data, and orchestrate the flow of samples, assays, results and reports all the way back into the LIMS or reporting system.

Thirdly, validation of results can be a key way to avoid operator error. FastFinder supports 2-step validation, where a secondary reviewer can be set up to confirm the results of the initial analyst. Supporting review and sign-off, FastFinder supports further clinical validation of the results generated.

Best of class interpretation

Under the hood of the FastFinder platform lives a powerful machine learning engine. Borrowing from Artificial Intelligence methods, FastFinder is able to learn from previous assays to optimize algorithm performance. Based on millions of de-identified historical PCR curves, the software uses smart “features” of curves, not simply Cq values but slopes, angles, noise metrics, and many more - so that even for non-obvious results, the platform uses an unbiased, trained method to assess positives vs. negatives.

Additionally, these smart, learning algorithms are complemented by Decision Trees, which automate the manual and often complex steps of assay interpretation. Diligently executing the Instructions for Use of an assay can be tedious and error prone, so FastFinder Real-Time can take all the rules about how to deal with controls, how to calculate and execute cut-offs, and how to combine results of multiple channels - and wrap these up in a standardized, fixed procedure which is validated and packaged into your assay plugins.

Audit trails

Another essential tool to guarantee quality and accuracy is that when an assay does fail (e.g. an entire run failed, or issues came up with a specific lot of a certain reagent), you have all the tools at hand to figure out where things could have gone wrong. FastFinder natively supports lot-tracking, and has all the capabilities needed to track who does what, when and why - capturing documented exceptions in time-stamped logs. For example, when a biologist corrects a result, she/he can capture a text remark on the reasoning and circumstances behind it. This greatly facilitates root cause analysis when issues arise.

Intelligent analytics

FastFinder brings intelligence to the molecular lab's analysis and interpretation workflow. Firstly, the software is very visual in nature - engaging the user by highlighting the right information graphically and intuitively. But the platform is also packed with intelligence. Through flexible reports, lab directors can get a cross-lab view, identify bottle necks, see usage statistics, turnaround times, etc. Ask UgenTec about what bespoke reports can be generated, to give you true Business Intelligence across your molecular testing workflows.

QC module

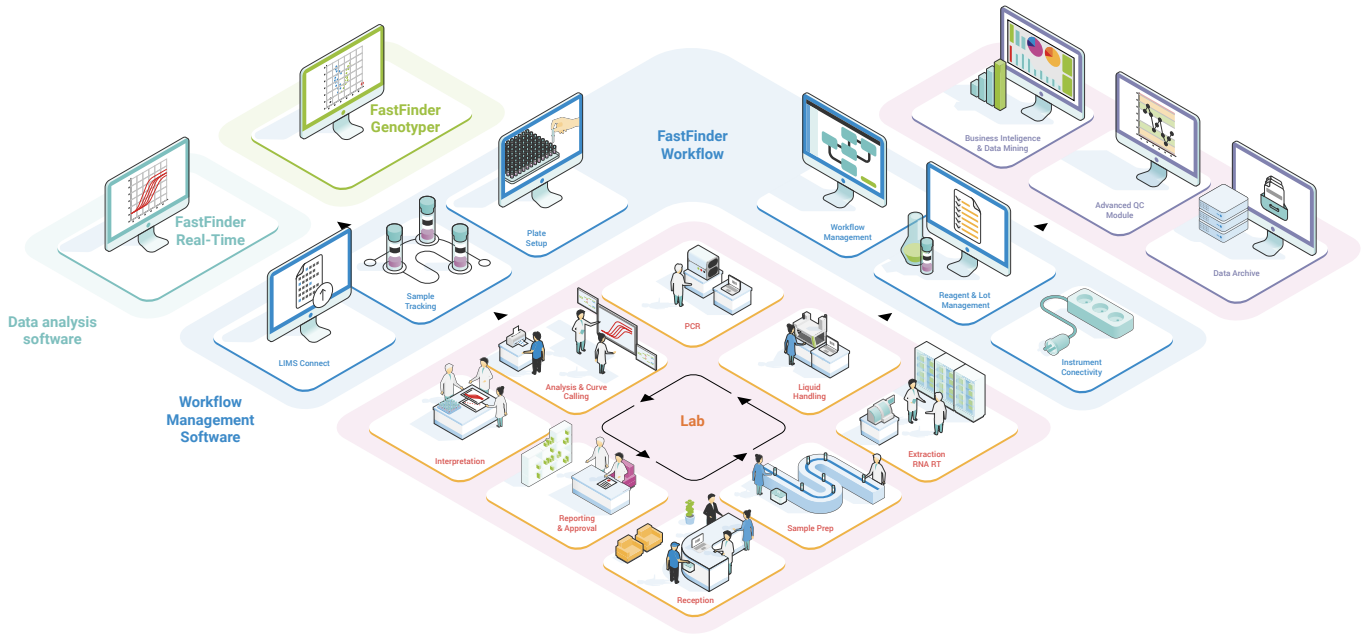
FastFinder Real-Time boasts an extensive QC module, where users can track QC metrics in real time, not after the fact - as is sometimes the case with lab-wide one-size-fits-all QC management software platforms. QC reporting is not an afterthought, and not a tick in the box - it's an essential component of your assay workflow.

With FastFinder Real-Time's QC module, you can track assay performance over time, plot Levy-Jennings curves, configure your lab's own rules on what exceptions are permissible, and see alerts when certain metrics fall out of bounds. To learn more, grab our white paper on QC reporting, or ask for a software demo.

Systems Integration

Lastly, relying on result accuracy requires you avoid clerical errors such as sample result mixups. Whenever manual steps come in, there is a risk of clerical error. That's why the FastFinder platform supports tight integration with lab and hospital LIMS systems. Both inbound, for capturing work lists as well as capturing raw curve data from all commonly used thermocycle instruments, as well as outbound, automatically pushing finished results into the lab's LIMS, EHR or reporting system.

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