



Citylabs 2.0

## Supporting QIAGEN with a Fully Integrated and Automated Platform for Their End-to-End miRNA Companion Diagnostic Assays in Targeted Therapies

### INTRODUCTION

At the heart of QIAGEN's business is a vision for making improvements in life possible. QIAGEN delivers on this promise by providing differentiating Sample to Insight solutions that help customers to unlock valuable molecular insights encoded in the building blocks of life.

Even with best developed practices, there are pinch points in day-to-day processing. In IVD development, QIAGEN needs to maintain traceability from start-to-end, across multiple independent databases and across multiple workflow steps. Experimental information is recorded in great detail but on paper worksheets and the bioinformatics systems need manual triggering which can delay reporting.

QIAGEN was interested in an integrated and automated solution for this end-to-end process.

### METHOD

QIAGEN selected L7|ESP to automate the entire laboratory workflow, from sample to insight, and selected the miRNA NGS assay development as the lead project to assess the integration of experimental workflows, instrumentation and bioinformatics analysis. The miRNA CDx workflow chain begins with the registration of plasma samples and subsequent extraction of miRNA using the miRNeasy Serum Plasma Advanced Kit. L7|ESP guides the user through the process by means of digitized protocols and provides a choice of QC methods (TapeStation, BioAnalyzer, Qubit, and qPCR) to determine the quality of the extract.

At library preparation, L7|ESP handles the sample traceability as libraries are prepared and sample specific indexes are assigned. After performing the necessary QC steps, the libraries are diluted and pooled to prepare for next generation sequencing.

These steps are summarized in the workflow summary in Figure 1.

## RESULTS

For sequencing, L7|ESP generates the sample sheet to be used on the Illumina NextSeq. Once complete, L7|ESP automatically registers the generated FastQ files for each library, while also scrutinizing important sequencing run metrics to assess the quality of the run. The user may then submit a bioinformatics analysis job to the QIAGEN CLC Genomics Server at the click of a button. L7|ESP receives the results and displays the output of the secondary analysis back to the user.

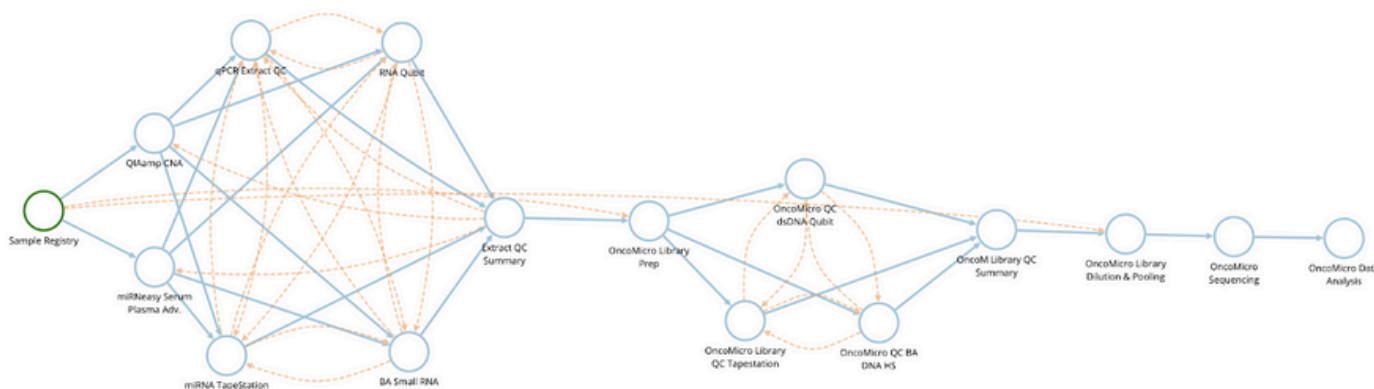


Figure 1. Experimental workflow for miRNA CDx development

## CONCLUSION

L7|ESP digitizes paper workflows and provides user management. L7|ESP also provides a complete chain of custody for the experimental process and offers an electronic guide for the user via the use of digitized protocols.

L7|ESP provides a solution that integrates data from laboratory equipment, databases, and bioinformatic tools while creating a central resource for storage and organization of sample metadata.

*“L7|ESP is an adaptable and customizable platform that streamlines process execution, provides a complete chain of custody from sample to report, and enables management of complex workflows.”*

**- Simon Hughes, Associate Director, CDx Assay Development QIAGEN**