

qPCR at PRA's Laboratories for Drug Development

Introduction

We see new drug types being studied more and more, such as cell and gene therapies. For some of these drug types, qPCR is a valuable technology to better understand their behavior. In addition, qPCR is a powerful tool for biomarker measurements. Hence, PRA recently invested in a qPCR laboratory at its Lenexa, KS, laboratory. The first studies were successfully completed in 2020.

Innovation

The regulatory guidance for qPCR assays is currently unclear. We are developing Standard Operating Procedures (SOPs) and templates to validate the assays and perform quality control of the assays in the spirit of the international Bioanalytical Method Validation guidelines. Depending on the Context of Use (CoU) for the assay, we can flexibly adjust the requirements.

Capabilities & Equipment

Our capabilities include assay transfer, custom method development, qualification, validation, and sample analysis of the following assays types:

- Gene expression
- Genotyping/SNP detection
- Copy number variation
- RNA biomarkers
- Pathogen detection
- CAR-T cell monitoring and RCR assays
- Nucleic acid extraction and banking

Our equipment consists of:

- Applied BioSystems QuantStudio 7 Flex
- King Fisher Flex nucleic acid extraction system
- Hamilton Starlet automated liquid handler
- Veriti Thermal Cycler
- Nanodrop 8000 for nucleic acid quantitation
- Qubit 4 Fluorometer for nucleic acid quantitation
- E-gel Power Snap Electrophoresis system



Capacity and People

Our newly built 48,000 sq. ft. laboratory in Lenexa, Kansas, was built with launching our qPCR service in-mind. Our qPCR space is set up with proper engineering controls that allow for minimizing contamination risk throughout the process, including a designated master mix room with directional airflow and pressure control, dead air box stations with UV decontamination, extraction platforms housed in a 100% exhausted enclosure, isolated areas for templating, designated instrumentation areas, and fridge/freezer storage with temperature monitoring systems.

Experience

PRA's experienced staff of scientists, analysts, and project managers collectively have years of experience with nucleic acid isolation, primer design, RT-qPCR (Sybr Green and Taqman), and qPCR, among others. Our experienced staff have the expertise to evaluate the needs and requirements and provide the best assay design for study support.

Contact Our Expert

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Director of Bioanalytical Sciences in the Lenexa, KS, Bioanalytical Laboratory with experience developing qPCR assays for clinical study support, including gene expression, genotyping, and biomarker assays.

Equipment



QuantStudio 7 Flex



King Fisher Flex nucleic acid extraction system



Veriti Thermal Cycler