SCIENTIST II /SUPERVISOR

Professional Overview

To utilize my passion and experience in IVD development to benefit new technologies that will have a great impact on the quality of patient care and the future of healthcare. Highly adaptive, experienced, and self-driven *12 years IVD assay development experience *Experienced with: *feasibility, assay design and formulation determination *Troubleshooting *manufacturing transfer and QC specification *instrument integration *V&V *DSOPs *Regulatory communications *Management and leadership experience *Team player *Development of 5 CE and FDA approved IVD assays

Core Qualifications

- GLP, GMP, GCP,
- Target Capture, Transcription Mediated Amplification (TMA), Real-Time TMA, Hybridization Protection Assay (HPA) technology; RNA / DNA Isolation, PCR, rt(reverse transcriptase )-PCR, RT (real-time) -PCR, SSCP, RFLP, Southern Blot, Western Blot, Gel Electrophoresis, RNA / DNA Quantitation, Restriction Digests, ELISA, Microscopy, Aseptic Technique, UV / mass spec quantiation, Sequence Analysis, Genotyping Analysis, ABI 377 Series Sequencers, Tissue Culture;
- MS Word, Excel , PowerPoint
- Geneious, JMP, TableCurve, DOE,
- Panther Real-Time Assay analysis tool
- Instrument:
- TIGRISÂ® DTSÂ® System, PANTHERÂ® DTSÂ® System

Accomplishments

- DTS 400, 402, and 802 instrument systems: Tecan EVO, SB100, LEADER HC+ Cas-1200 liquid handling system QIAxcel Fast Analyzer Stratagene instrument with MxPro software Clinical Diagnostic Assays: Gen-Probe: Aptima HSV 1 & 2, Aptima HPV, Aptima ATV, Aptima HPV 16, 18/45 GT Assays, PROGENSA PCA3 assayÂ

Education

01/2002

Bachelors of Science : Molecular Biology Chemistry California State University ï¼ State Molecular Biology Chemistry

Experience

04/2014 to Current

Scientist II /Supervisor Thermo Fisher Scientific Inc. ï¼ Madison , WI

- Design, manage, and oversee completion of all studies necessary to complete development of assay; process transfer and QC release of assay; automated instrument assay integration; and CE/FDA submissions for Aptima HSV 1 & 2 (AHSV) assay.
- Provide assistance, training, and present to outside groups in support of AHSV Assay.
- Collaborate with other R&D groups, other functional areas, and external groups on project-related issues or studies to meet project requirements.
- Contribute to the development of technical strategies to address project requirements.
- Analyze associated lines of investigation and devise and recommend methods to resolve problems.
- Design and develop assay, write DSOPs, develop sequencing analysis method, and assist with LIMS data management system development for composite PCR sequencing assay to support AHSV clinical trial.

04/2011 to 04/2014

Scientist I Planet Pharma ï¼ Pittsburgh , PA

- Lead and managed efforts to perform feasibility for AHSV diagnostics assay incorporating both old and new company specific technology on instrument platforms.
- Lead and executed complex V&V studies by writing protocols, completing statistical analysis of study data, and writing reports to support submissions to the FDA and other regulatory bodies for the Aptima HPV (AHPV) assay.
- Lead efforts to design and validate sequence analysis method and successfully lead analysis of over 40,000 individual viral RNA sequences to fulfill FDA requirements -Work with clinical affairs department to operate as a site for Aptima TV (ATV) clinical trial and process and test over 5,000 clinical samples.
- Regularly operate and maintain complex lab equipment including proprietary robotic instrumentation and develop and implement DSOPs for use of instrumentation - Present experimental findings and study results at department meetings.
- Train and manage laboratory personnel.

03/2008 to 04/2011

Research Associate III City Of Hope ï¼ Yorba Linda , CA

- Design and execute complex experiments to support CE mark and PMA submission for the Aptima HPV assay.
- Write protocols, reports to support CE and PMA submission, and maintain accurate detailed documentation of experimental findings.
- Operate and maintain complex lab equipment including robotic instrumentation.
- Train personnel on DTS 400, 402, and 802 manual assay formats and use of TIGRIS instrumentation.
- Regularly present data and project status to supervisor, team or department.

02/2005 to 03/2008

Research Associate II Gen-Probe Inc ï¼ City , STATE

- Assist in development of APTIMA HPV assay and Progensa PCA3 assay.
- Design and execute complex experiments to contribute to optimization and troubleshoot HPV multiplex system.
- Design and execute complex experiments to contribute to optimization of Progensa (PCA3 / PSA) assay -Analyze data and incorporate findings to future experiments for further assay optimization.
- Regularly give presentations on data and project status to supervisor and team.
- Operate and maintain complex lab equipment including robotic instrumentation.
- Write protocols, reports, and maintain accurate detailed documentation of experimental findings.
- Train laboratory personnel.
- Maintained detailed and accurate record of experimental findings.

Publications

Paul D. Swenson, Azza El-Sabaeny, Vanessa Thomas-Moricz, Megan Allen, Anabel Groskopf, Alice Jiang, Damon Getman: "Evaluation of a transcription mediated amplification assay for detection of herpes simplex virus types 1 and 2 mRNA in clinical specimens." J. Clin. Virology 80 (2016) 62-67.

Skills

Aseptic Technique, data management, DTS, DNA, documentation, ELISA, experiments, functional, GCP, GMP, GLP, LIMS, mark, meetings, Excel, PowerPoint, MS Word, optimization, PCR, personnel, presentations, protocols, real-time, robotic, statistical analysis, supervisor, TV, Transcription, troubleshoot, UV