

ASSAYS IN VALIDATION

- + Amantadine
- + Monomethyl fumarate

ASSAYS IN DEVELOPMENT

- + Acridinium bromide
- + Artemether and lumefantrine*
- + Axitinib
- + Diazoxide
- + Droxidopa
- + Eluxadoline
- + Eslicarbazepine
- + Ezogabine (retigabine)
- + Fluticasone and vilanterol*
- + Ibrutinib
- + Idelalisib
- + Indacaterol Maleate
- + Olodaterol and tiotropium*
- + Pirfenidone and nintedanib*
- + Regorafenib/regorafenib N-oxide
- + Sacubitril (prodrug), LBQ657 and valsartan*
- + Toremfene
- + Trientine
- + Umeclidinium bromide and vilanterol*

* combination assays



At PPD® Laboratories bioanalytical lab, we have a 1:1 ratio of mass specs to bioanalytical scientists

FOR A COMPLETE LISTING OF OUR VALIDATED TEST METHODS, PLEASE [CLICK HERE](#)



Trending of Bioanalytical Assay Performance

Rapid, accurate assay results to keep your study on track

PPD's experience with more than 2,000 proprietary and non-proprietary validated assays and ongoing and real-time trending of these methods is fundamental to our commitment to providing the highest-quality data.

The trending of assay performance starts with but is not limited to:

- + Watching for abnormally high failure rate to proactively identify issues
- + Monitoring incurred sample reproducibility (ISR) failures to ensure data quality
- + Evaluating assay performance post method validation to ensure consistent assay performance for sample analysis
- + Ongoing evaluation of analyst proficiency with the method to ensure data integrity

Client benefits include:

- + Robust, high-performing methods with maximum uptime
- + On-time, high-quality data submissions to help inform critical decisions
- + Accurate project and sample analysis timelines to keep projects on track

Bioanalytical Assay Performance

GENERICS SNAPSHOT - DECEMBER 2017



PERFORMANCE OF KEY LC-MS/MS METHODS

MOMETASONE FUROATE

- + 125,000+ samples analyzed
- + 97.0% average run acceptance rate
- + 95.7% average ISR acceptance rate

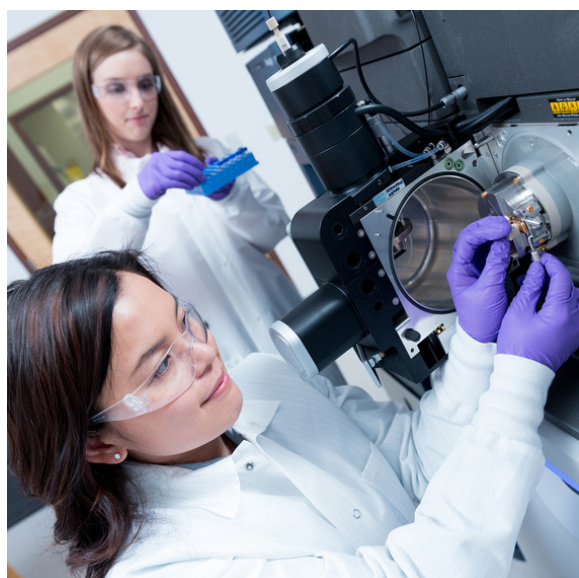
BUDESONIDE

- + 61,000+ samples analyzed
- + 91.1% average run acceptance rate
- + 92.3% average ISR acceptance rate

FORMOTEROL

- + 22,000+ samples analyzed
- + 85.5% average run acceptance
- + 90.9% average ISR run acceptance

CHROMATOGRAPHIC SCIENCES EXPERTISE



STATE-OF-THE-ART INSTRUMENTATION

- + 100+ LC/MS systems including triple quadrupole and high resolution
- + 28 UHPLC systems
- + Multiplexing (Thermo Scientific Aria®)
- + Hamilton® robotics: Microlab™ STAR, STARlet, Nimbus
- + KingFisher™ Flex Purification System

HIGH THROUGHPUT

- + Average 52,500 samples per month
- + Approximately 12 validations per month
- + Added 45-50 new non-prop assays per year over past three years
- + More than 1,800 currently active LC-MS/MS assays

EXTENSIVE SMALL MOLECULE EXPERIENCE

- + Ultra-sensitive methods (inhaled delivery products)
- + Chiral assays (150,000+ samples assayed)
- + Protein binding assays with equilibrium dialysis
- + Unusual matrices (variety of tissues)
- + Difficult compounds (reactive, endogenous)

ABOUT PPD LABORATORIES

PPD Laboratories combines world-class scientific expertise with state-of-the art technologies supported by a commitment to exceptional quality. Our clients benefit from comprehensive lab services spanning bioanalytical, biomarkers, central lab, GMP and vaccine sciences. Our laboratory services accelerate pharmaceutical development for small molecules and biologics, allowing clients to make faster decisions about their compounds.

CONTACT US TO LEARN MORE ABOUT HOW ASSAY PERFORMANCE TRENDING CAN IMPROVE YOUR NEXT PROGRAM

For more information about our capabilities watch our new bioanalytical lab tour video, visit our website or contact our generics business development representative.

Jason McPherson

Senior Account Director, PPD Laboratories
Bioanalytical lab, global generics
Mobile/text: +1 443 979 3072
Email: Jason.Mcpherson@ppdi.com



[CLICK HERE TO WATCH THE VIDEO](#)