

# VALIDATION PACKAGES

## EVERY SUCCESSFUL JOURNEY *STARTS* WITH A PLAN.

Let PinPoint Testing help you plan your next validation to ensure smooth travel from sample prep to final report.



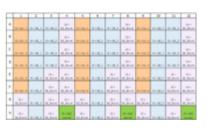
PinPoint's Validation Packages are modeled to meet the stringent requirements outlined in ANSI/ASB 036 Standard, Standard Practices for Method Validation in Forensic Toxicology. 2019. 1st Ed



At PinPoint Testing, we know the cost and adminstrative burden reference materials take on executing a successful validation. We have streamlined the formatting and delivery of these materials, enabling laboratories to begin their validation experiments affordably and without delay. Our validation materials have been meticulously designed and developed over a decade, based on experience validating hundreds of methods in client laboratories and PinPoint's own ISO 17025-accredited and CLIA-certified laboratory.

#### PPT-10033 -VALIDATION REAGENT PACKAGE

- ✓ Validation "A" Plates Designed for conducting comprehensive studies using 96 or 48 well plates, for:
  - Accuracy and Precision
  - LOQ Studies
  - Carry-over
  - · Calibration modeling
  - Measurement Uncertainty
  - Specificity
  - Extract Stability



- ✓ Validation "D" Plates Designed for conducting comprehensive studies using 96 or 48 well plates, for:
  - Ion Suppression & Enhancement
  - Dilution
  - LOD & multi-matrix studies
- ✓ Validation "I" Plates Interference Studies
  - Supplied in 96 well plate(s) with dry residue of drugs at concentrations specified in validation plan.
- Validation Supplemental Supplies
  - Ion Suppression/Enhancement High Level Dilution\*
  - Ion Suppression/Enhancement Low Level Dilution\*

    \*Compliments studies completed with "D" plates
  - High Calibrator Solution prepared for suitability checks & dilution studies



#### Optimization Plates / Reference Library

- 96 well plate with 1ug dry drug residue of parent drugs
- 96 well plate with 1ug dry drug residue of internal standards
- Optimization Solution Set
  - Representative Drug Mix A mixture of drugs from the main panel, separated by 2 AMU, at a concentration of 1  $\mu$ g/mL in methanol.

All reference materials used in validation materials are NIST traceable certified reference materials supplied by ISO 17034 accredited manufacturers. Materials are quality controlled and tested in an ISO 17025 laboratory.



At PinPoint Testing, we offer both virtual and onsite consulting services to streamline and speed up your LC-MS/MS validation process. With experience in developing and implementing hundreds of validations, our team can guide you in avoiding common challenges—many of which we've encountered ourselves. Our approach is both consultative and educational. We aim to empower you and your staff with the knowledge to successfully complete a validation, ensuring you can replicate that success in the future.

#### LABORATORY DISCOVERY

Our consultants will collaborate closely with your team to understand your short- and long-term goals, helping to develop a tailored validation plan designed for lasting success.

#### **OPTIMIZATION & SUITABILITY STUDIES**

Whether virtual or onsite, our team will conduct thorough suitability studies to ensure that your instrumentation is fully equipped for the method(s) you choose to validate.

#### **METHOD SUITABILITY**

PinPoint's ISO 17025-accredited and CLIA-certified laboratory will refine your method. We'll optimize chromatography conditions, instrument specifications, and sample preparation to ensure precise results and limit disruptions in your current operations.

#### **METHOD TRANSFER**

In approximately ten days\*, an industry-trained consultant will transfer the optimized method onto your instrument and run validation experiments using our PinPoint Validation Reagent Package.

#### **DATA ANALYSIS & REPORTING**

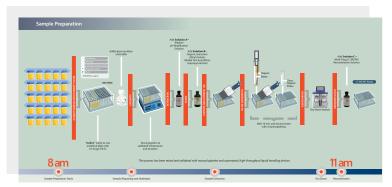
Throughout the process, a dedicated data analyst will support your project, analyzing data and providing comprehensive reports through our proprietary PAVE software.

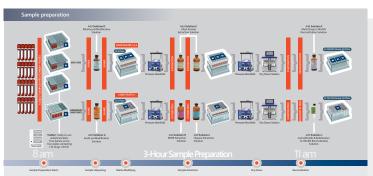
### **ONSITE TRAINING & DOCUMENTATION**

PinPoint consultants offer comprehensive staff training on proper documentation, including SOPs and daily worksheets, as well as training on newly implemented workflows and data processing.

\*10 days is a standard time to transfer one method, validated on one column and one instrument.







PinPoint Testing has built strong partnerships with leading suppliers in the toxicology industry for sample preparation, chromatography, and general laboratory supplies and equipment. We can source these essential materials and provide a consolidated shipment, ensuring everything is ready when your validation begins.

SAMPLE PREPARATION	
PRODUCT	USE
Multi-Drug Extraction Kit - Urine (EXT-101)	Liquid/Liquid Urine Extractions
Multi-Drug Extraction Kit - Blood (SLE) (EXT-201)	Supported Liquid Extraction for Blood
Blank Urine (human-pooled)	Urine validation
Blank Blood (ovine)	Urine validations
Biotage - 400uL Supported Liquid Extraction (SLE) - 96 Well (DE)	Blood validations
Biotage - 1 mL Supported Liquid Extraction (SLE) - 48 well	Blood validations
CHROMATOGRAPHY SUPP	LIES
Phenomenex - Supported Liquid Extraction (SLE) - 96 well Plate (DE)	Blood validations
Phenomenex - Kinetex 2.6 µm PS C18 100 Å, LC Column 50 x 2.1 mm, Ea [00B-4780-AN]	Standard column used for multi-drug separation
Phenomenex - Kinetex® 2.6 μm Phenyl-Hexyl 100 Å, LC Column 50 x 4.6 mm [00B-4495-E0]	Standard column used for multi-drug separation
Phenomenex - Kinetex 2.6 μm C18 100 Å, LC Column 100 x 2.1 mm [00D-4462-AN]	Standard column used for specialized isobaric separation
Column Guards & Holders	·
Mobile Phase Concentrates - Multi-Drug Formulation [PPT-3001]	Concentrated mobile phase solvents for daily use, ensures quality chromatography.
Mobile Phase Concentrates - GHB/Barbiturate Formulation [PPT-3002]	Concentrated mobile phase solvents for daily use, ensures quality chromatography.
Mobile Phase Concentrates - Cannabinoid/Barbiturate Formulation [PPT-3003]	Concentrated mobile phase solvents for daily use, ensures quality chromatography.
Peak Tubing	
GENERAL EQUIPMENT & CONSU	JMABLES
LC-Autosampler Vials	
1250 uL Pipette Tips	
200 uL Pipette Tips	
Large Volume Solvent Reservoirs	Extractions, Waste
Small Volume Reservoirs	Matrix Handling, Extractions, general liquid handling
Blank Plates (96 well & 48 well) w/foil seals	Extractions & Sample Handling
Conical Vials – 5mL	Dilutions & General Mixing
Biotage® SPE Dry 96 Dual Sample Concentrator System	Dry down station for sample preparation
Biotage® PRESSURE+	Positive Pressure manifold for processing blood samples
Incubator/Shaker - 96 well	Mixing / Shaking
Multi-Channel Pipette	
Single-Channel Pipette	
Gloves	



