



LC/MS/MS Bioanalysis Research Grade Assays

- Proprietary diagnostic probes
- 3 day turnaround for standard assays
- Menus of fit-for-purpose assays

B E T T E R D A T A F A S T E R

Agilux Laboratories is offering “2nd Generation” Research Grade Assays (RGAs) to support non-GLP, research and discovery applications, drawing upon the more than 50 years of collective experience among its founders and the needs and expectations of pharma and biotech clients. Sensitive to the necessary throughput and financial requirements, Agilux offers a menu of enhanced, standardized, fit-for-purpose assays capable of generating data satisfying experimental objectives in the shortest possible time with minimum transactional overhead and maximum contractual flexibility.

Our “2nd Generation” RGA assays incorporate a proprietary and standardized series of diagnostic probes into each and every assay providing surrogate measures of assay performance and indicators of potential liabilities. Taken together, the resulting data enables an improved understanding of sample data set quality attributes and acceleration of technical troubleshooting, when required, at no additional cost and turnaround time. Future enhancements include data visualization tools to improve the accuracy, effectiveness and efficiency of data review.

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Attribute	Parameter	RGA Level 1	RGA Level 2	RGA Level 3
Pre-Study Assay Qualification		No	No	Yes
Analytical Reference Materials	Characterization (Analyte)	% Purity & salt content	% Purity & salt content	Identity, % purity, salt content, moisture; CofA Preferred
	Characterization (ISTD)	Salt content	Salt content	Identity, % purity, salt content, moisture
	Chemical Structure (Analyte & ISTD)	Not necessary, prefer elemental comp., alternately MW	Not necessary, prefer elemental comp., alternately MW	Preferred or functional groups, minimally elemental comp.
	Identity (ISTD)	Generic ISTD(s) and/or Chemotype analog	Generic ISTD(s) and/or Chemotype analog	Close chemotype, structural analog or stable label, if available
	Minimum Quantity (Analyte & ISTD)	Pre-weigh, stock solution or 1 mg	Pre-weigh, stock solution or 1 mg	Analyte: > 5 mg, > 10 mg preferred ISTD: Pre-weigh, stock solution or 1 mg
Methodology	Intra-Assay Diagnostics	Yes	Yes	Yes
	Extraction	Default - protein precipitation	Default - protein precipitation	Protein precipitation, liq.-liq. or SPE
	Extraction volume	Default - 10 µL biofluid	Default - 10 µL biofluid	As required for purpose, e.g. LLOQ
	Chromatography	Generic reversed phase gradient	Generic reversed phase gradient	Optimized and specific for application
	Non-Principle Matrix Samples, e.g. tissues	Assayed diluted in plasma/serum or vs matrix matched cal. curve	Assayed diluted in plasma/serum or vs matrix matched cal. curve	Assayed versus matrix matched calibration standards & QCs
Calibration Curves (bracketing, n=2)	Conc. Range	1.0 – 5,000 ng/mL	1.0 – 5,000 ng/mL	Client/assay defined
	Number Standards	> 9	> 9	> 6.
	Preparation	Modified serial dilution, < 1% organic	Modified serial dilution, < 1% organic	As required for purpose, < 1% organic
	Accuracy	> 75% STDs < + 30%	> 75% STDs < + 25%	> 75% STDs pass; < + 15% except < + 20% at LLOQ
QC Standards	Inclusion	NA	Yes	Yes
	Concentrations.	NA	Low-, mid- & high	LLOQ, Low-, Mid-, High & Dilution
	Preparation	NA	Cal Std stock	> 2 weighings
	Precision (%CV)	NA	< 25% all levels	< 15% Low-, Mid- & High < 20% LLOQ
	Accuracy	NA	> 67% all QCs < + 25%, > 50% at each level	> 67% all QCs pass, < + 15% Low-, Mid-, High- & Dilution, < + 20% LLOQ; > 50% at each level
Specificity		NA	NA	Response < 33% LLOQ in 3 lots, duplicates
Carryover		NA	NA	< 33% LLOQ
Stability (QC-Mid)	Matrix F/T	NA	NA	3 F/T, triplicates
	Matrix RT	NA	NA	24 h, triplicates
	Processed Sample	NA	NA	Batch reinjection
Recovery/Suppression		NA	NA	Spike and extract vs solution Std, QC-Mid, triplicate
Deliverable	Report & Data	EXCEL file summary	EXCEL file summary	Abbreviated report with methodology