



Singleplex Biomarker Assay Development and Sample Testing Services

Create Sensitive, Robust Assays and Obtain High-Quality Sample Testing Data

Key Benefits



Extensive assay development and analysis **experience**



Services performed under MSD's **Quality Management System**



Industry-leading **technology** platform



Personalized assay development and support at every step

Highlights

- MSD offers a structured process to develop high-quality assays with transparent pricing
- MSD has a track record of success with top biotech and pharmaceutical clients
- Biomarker assay development projects can include secreted or intracellular protein immunoassays
- Personalized services include regular progress updates, interactive discussions on project status, and consultative decision making
- Projects can range from method development to full method validation
- Packages B, C, and D include the seamless transfer of assays to MSD's Bioanalytical Lab for exploratory, GLP, or GCLP sample analysis

Package	Cat. No.	Description	Estimated Duration
Package A	S05BA	Method Development	6 weeks
Package B	S05BB	Method Development and Method Qualification; Sample Analysis (up to 480 Samples)	9 weeks; 4 weeks ¹
Package C	S05BC	Method Development and Method Validation; Sample Analysis, GLP/GCLP (up to 960 Samples)	14 weeks; 4 weeks ¹
Package D ²	S05BD	Method Validation; Sample Analysis, GLP/GCLP (up to 960 Samples)	9 weeks; 4 weeks ¹
Add-on	S05CR	Critical Reagents Identification (Antibody Screening)	3 weeks

¹ Turnaround time for sample analysis.

² Package D can be purchased separately at a later time to supplement Package A.

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Package Components	A	B	C	D
Consultation and Planning Session	✓	✓	✓	
Assay Platform Selection: R-PLEX® or S-PLEX® Singleplex Assays	✓	✓	✓	
Method Development: Biotin Capture Antibody Conjugation	✓	✓	✓	
Method Development: SULFO-TAG™ or TURBO-BOOST® Detection Antibody Conjugation	✓	✓	✓	
Method Development: Assay Protocol Development and Optimization for One Sample Type	✓	✓	✓	
Method Development: Spike Recovery and Dilution Linearity Analysis of Up to 10 Samples	✓	✓	✓	
Method Development: LLOQ Estimation	✓	✓	✓	
Method Development: Assay Protocol and Method Development Report	✓	✓	✓	
Lot Build: Antibody Sets, Calibrators and Controls		✓	✓	✓
Method Qualification: Accuracy and Precision, Limits of Quantitation		✓	✓	✓
Method Validation: Validation Plan			✓	✓
Method Validation: Donor Target Range and Sample Panel			✓	✓
Method Validation: Selectivity and Hook Effect			✓	✓
Method Validation: Specificity and Interferences			✓	✓
Method Validation: Short-Term Stability			✓	✓
Method Validation: Long-Term Stability			✓	✓
Method Validation: Analytical Method Validation Report			✓	✓
Sample Analysis: Data Transfer Specifications			✓	✓
Sample Analysis: Bioanalytical Report (end of study)			✓	✓
Sample Analysis: Duplicate Measurements Per Sample		Up to 480 samples	Up to 960 samples (GLP/GCLP)	Up to 960 samples (GLP/GCLP)

Ask us how we can help;
Schedule a call with our team:

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