



# BIOMARKER & CLINICAL DIAGNOSTIC SERVICES



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Alliance Pharma has industry-recognized expertise in biomarker assay method development, transfer, adaptation of commercial kits, and method validation. Our biomarker team uses the latest scientific innovation and state-of-the-art platforms to support both preclinical and clinical studies during all phases of development.

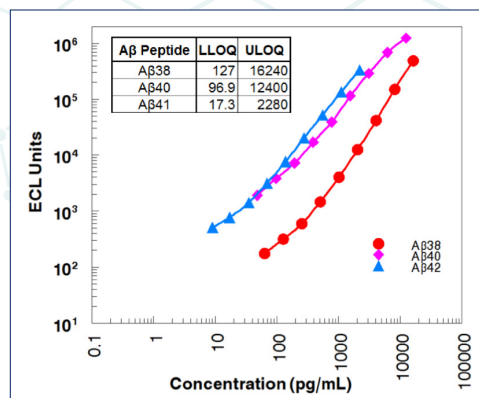
Alliance Pharma is a CLIA-certified<sup>1</sup> COLA-accredited<sup>2</sup> laboratory, and supports clinical research by providing a resource to perform diagnostic biomarker testing at all phases of clinical development.

Our expertise includes the following areas:

- **Regulated (GCP & GLP) and R&D support**
- **Customized method development and fit-for-purpose assay validation**
- **Transfer of proprietary assays**
- **Adaptation of commercial kit-based assays**
- **Sample analyses**
  - All phases (Phase I, II, III, IV) of regulated clinical studies
  - Discovery and preclinical PK/PD studies

### Technology Platforms

- HPLC / UHPLC-MS/MS platform based assays
  - SCIEX API 4000™, 5500, 6500, and 4000 QTRAP
  - Thermo Scientific™ Q Exactive™ Plus
  - Agilent 6545XT AdvancedBio LC/Q-TOF and Orbitrap™ (XL)
  - Agilent 8900 Triple Quadrupole ICP-MS
- ELISA / Ligand-binding assays
- MSD® platform based assays
- Multiplexed assays
- Cell-based assays
- Beckman Coulter AU480 Chemistry Analyzer



**Example:** Adaptation and Validation of a Multiplex Assay Kit for the Quantitative Analyses of Aβ38, Aβ40, and Aβ42 Peptides in Cynomolgus Monkey Plasma





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## Available Biomarker Assays

Analyte	Matrix	Platform
1-Hydroxypyrene	Urine	LC-MS/MS
25-OH-Vitamin D2	Plasma	LC-MS/MS
25-OH-Vitamin D3	Plasma	LC-MS/MS
4 $\beta$ -OH-Cholesterol	Plasma	LC-MS/MS
7-Dehydrocholesterol	Plasma	LC-MS/MS
Acetylcholinesterase	Whole Blood	ELISA
Adiponectin	Serum	ELISA
Amyloid $\beta$ 1-40	CSF, Plasma	ELISA
Amyloid $\beta$ 1-42	CSF, Plasma	ELISA
Butyrylcholinesterase	Whole Blood	ELISA
CFI	Plasma	Cofactor Assay
Chemokine ligand 17 (free & total)	Serum	MSD
Cholesterol	Cell Culture Medium	LC-MS/MS
iC3b	Plasma	ELISA
IFN- $\gamma$	Serum, Plasma	MSD
IL-1 $\beta$	Plasma	MSD
IL-5	Serum	MSD
IL-6	Serum, Plasma	MSD
IL-8	Serum, Plasma	MSD
Mannac	Plasma	LC-MS/MS
MCP-1	Cell Culture Medium	ELISA
Mercaptoethanol	Cell Culture Medium	LC-MS/MS
N-Acetyl-aspartic acid	Plasma, CSF, Brain	LC-MS/MS
Sialic Acid (free) and CMP-Neu5Ac (intact)	Plasma, Buffy Coat Isolation	LC-MS/MS
TNF- $\alpha$	Plasma	MSD
VEGF	Vitreous, Plasma	ELISA

For a full list of assays that demonstrate our wide range of experience and expertise, please visit our website at [www.alliancepharmaco.com/services/biomarker/](http://www.alliancepharmaco.com/services/biomarker/)

<sup>1</sup> CLIA refers to the Clinical Laboratory Improvement Amendments program, administered by the Centers for Medicare and Medicaid Services (CMS), which provides regulatory guidance for quality laboratory testing.

<sup>2</sup> COLA is an independent, non-profit accreditor, recognized by CMS, whose education-based program and standards enable clinical laboratories and staff to meet CLIA and other regulatory requirements.

