celerion

Translating Science to Medicine

Global List of Validated Bioanalytical Tobacco Assays (BTA)

For further information on our validated assays, please contact your business development representative or via info@celerion.com.

Exposure Marker Assays

Assay	Exposure Component	Measured Analyte	Method of Analysis	LLOQ	Matrix
Total 1-OHP	Pyrene	1-Hydroxypyrene	LC-MS/MS	10.0 pg/mL	Urine
Total 3-OH BaP	Benzo[a]pyrene	3-Hydroxybenzo[a]pyrene	LC-MS/MS	25.0 fg/mL	Urine
Mercapturic Acids	Acrolein	3-Hydroxypropylmercapturic Acid (3-HPMA)	LC-MS/MS	20.0 ng/mL	Urine
	Acrolein	2-Hydroxypropylmercapturic Acid (2-HPMA)	LC-MS/MS	2.50 ng/mL	Urine
	Crotonaldehyde	3-Hydroxy-1-methylpropylmercapturic Acid (HMPMA)	LC-MS/MS	20.0 ng/mL	Urine
	Acrylonitrile	2-Cyanoethyl-mercapturic acid (CEMA)	LC-MS/MS	0.200 ng/mL	Urine
MHBMA	1,3-Butadiene	Monohydroxybutenylmercapturic Acid	LC-MS/MS	100 pg/mL	Urine
Trace Nicotine	Nicotine	Nicotine	LC-MS/MS	0.200 ng/mL	Plasma (K_2EDTA)
	Nicotine	Cotinine	LC-MS/MS	1.00 ng/mL	Plasma (K_2EDTA)
	Nicotine	*trans*-3'-hydroxycotinine	LC-MS/MS	1.00 ng/mL	Plasma (K_2EDTA)
Trace Nicotine	Nicotine	Nicotine	LC-MS/MS	0.200 ng/mL	Plasma (Heparin)
	Nicotine	Cotinine	LC-MS/MS	1.00 ng/mL	Plasma (Heparin)
	Nicotine	*trans*-3'-hydroxycotinine	LC-MS/MS	1.00 ng/mL	Plasma (Heparin)
Nicotine (High Dose)	Nicotine	Nicotine	LC-MS/MS	1.00 ng/mL	Plasma (K_2EDTA)
Nicotine	Nicotine	Nicotine	LC-MS/MS	0.500 ng/mL	Plasma (K_3EDTA)
Nicotine	Nicotine	Nicotine	LC-MS/MS	0.500 ng/mL	Serum
	Nicotine	Cotinine	LC-MS/MS	1.00 ng/mL	Serum
High Speed Trace	Nicotine	Nicotine	LC-MS/MS	0.200 ng/mL	Plasma (K_2EDTA)
	Nicotine	Cotinine	LC-MS/MS	1.00 ng/mL	Plasma (K_2EDTA)
High Speed Nic	Nicotine	Nicotine	LC-MS/MS	1.00 ng/mL	Plasma (K_2EDTA)
	Nicotine	Cotinine	LC-MS/MS	1.00 ng/mL	Plasma (K_2EDTA)
High Speed Nic	Nicotine	Nicotine	LC-MS/MS	1.00 ng/mL	Plasma (K_2EDTA)
	Nicotine	Cotinine	LC-MS/MS	5.00 ng/mL	Plasma (K_2EDTA)
High Speed Nic	Nicotine	Nicotine	LC-MS/MS	1.00 ng/mL	Plasma (K_2EDTA)
	Nicotine	Cotinine	LC-MS/MS	5.00 ng/mL	Plasma (K_2EDTA)
	Nicotine	*trans*-3'-hydroxycotinine	LC-MS/MS	5.00 ng/mL	Plasma (K_2EDTA)
Nicotine Equivalents	Nicotine	Nicotine	LC-MS/MS	10.0 ng/mL	Urine
	Nicotine	Cotinine	LC-MS/MS	10.0 ng/mL	Urine
	Nicotine	*trans*-3'-hydroxycotinine	LC-MS/MS	10.0 ng/mL	Urine
	Nicotine	Nicotine-*N*-glucuronide	LC-MS/MS	10.0 ng/mL	Urine
	Nicotine	Cotinine-*N*-glucuronide	LC-MS/MS	20.0 ng/mL	Urine
	Nicotine	*trans*-3'-hydroxycotinine-*O*-glucuronide	LC-MS/MS	50.0 ng/mL	Urine
Nicotine Equivalents	Nicotine	Nicotine	LC-MS/MS	50.0 ng/mL	Urine
	Nicotine	Cotinine	LC-MS/MS	50.0 ng/mL	Urine
	Nicotine	*trans*-3'-hydroxycotinine	LC-MS/MS	50.0 ng/mL	Urine
	Nicotine	Nicotine-*N*-glucuronide	LC-MS/MS	50.0 ng/mL	Urine

Exposure Marker Assays

Assay	Exposure Component	Measured Analyte	Method of Analysis	LLOQ	Matrix
	Nicotine	Cotinine-*N*-glucuronide	LC-MS/MS	200 ng/mL	Urine
	Nicotine	*trans*-3'-hydroxycotinine-*O*-glucuronide	LC-MS/MS	200 ng/mL	Urine
Total NNAL	Tobacco specific nitrosamines	4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanol	LC-MS/MS	5.00 pg/mL	Urine
Total NNN	Tobacco specific nitrosamines	*N*-Nitrosonornicotine	LC-MS/MS	0.200 pg/mL	Urine
Total NAT/NAB	Tobacco specific nitrosamines	*N*-Nitrosanabasine	LC-MS/MS	2.00 pg/mL	Urine
	Tobacco specific nitrosamines	*N*-Nitrosanatabine	LC-MS/MS	5.00 pg/mL	Urine
S-PMA	Benzene	S-Phenyl mercapturic acid	LC-MS/MS	25.0 pg/mL	Urine
HEMA	Ethylene dioxide	Hydroxyethyl mercapturic acid	LC-MS/MS	0.1 ng/mL	Urine
o-Toluidine	o-Toluidine	o-Toluidine	LC-MS/MS	20 pg/mL	Urine
Aromatic Amines	Aromatic Amines	1-Aminonaphthalene (1-AM)	LC-MS/MS	2.0 pg/mL	Urine
	Aromatic Amines	2-Aminonaphthalene (2-AM)	LC-MS/MS	2.0 pg/mL	Urine
	Aromatic Amines	3-Aminobiphenyl (3-ABP)	LC-MS/MS	0.500 pg/mL	Urine
	Aromatic Amines	4-Aminobiphenyl (4-ABP)	LC-MS/MS	1.0 pg/mL	Urine

Biomarker Assays

Assay	Exposure Component	Measured Analyte	Method of Analysis	LLOQ	Matrix
11-dTXB2	Platelet activation in cardiovascular disease	11-dehydro Thromboxane B_2	LC-MS/MS	5.00 pg/mL	Urine
11-dTXB2	Platelet activation in cardiovascular disease	11-dehydro Thromboxane B_2	LC-MS/MS	25.00 pg/mL	Urine
iPF2a-III	Oxidative stress	Isoprostaglandin $F_{2\alpha}$ (type III)	LC-MS/MS	25.0 pg/mL	Urine
iPF2a-VI	Oxidative stress	Isoprostaglandin $F_{2\alpha}$ (type VI)	LC-MS/MS	25.0 pg/mL	Urine
Creatinine	Kidney function	Creatinine	ELISA	30.0 ug/mL	Urine
COHb (Carboxyhemoglobin)		COHb	Spectrophotometric	0.02 mm Hg	Whole Blood

Celerion Solution

Over 15 years of experience

conducting smoking, tobacco or nicotine-related research. Celerion scientists have designed, conducted, consulted on, or analyzed data for more than 60 tobacco product-related studies

Global presence with purpose-built facilities

custom designed to the needs of tobacco-related research including infrastructure for confined smoking periods, technology for smoking data collection and proven procedures for managing the potential hazards of cross contamination, common to nicotine sample management. Celerion has three clinical facilities with over 600 beds, two bioanalytical laboratories, in addition to a global network of audited partner sites in North America, Europe, South Korea and Singapore

Extensive experience

designing studies to capture events and endpoints commonly evaluated in tobacco studies, performing statistical analysis, interpreting data and providing written reports describing the results. This full-service approach delivers quality data, while saving clients' time and cost

Highly qualified scientists

stay abreast of industry trends and regulatory guidelines in addition to attending key scientific conferences. This enables Celerion to deliver on clients' scientific objectives, and ensure the data meets regulatory requirements

Bioanalytical services

at world leading laboratories offering extensive expertise in the assessment of tobacco exposure markers, having analyzed over 200,000 samples in the past three years

Regulatory experience

assists clients to navigate the evolving regulatory pathway toward product approval. Celerion has experience working with the FDA, EMA and MHRA, as well as other regulatory authorities