Fact Sheet

ARK™ Methylphenidate Metabolite Assay

The ARK™ Methylphenidate Metabolite Assay is a homogeneous enzyme immunoassay for the qualitative and/or semi-quantitative determination of methylphenidate metabolite in human urine on automated clinical chemistry analyzers, at a cut-off concentration of 100 ng/mL.

Assay Characteristics

- Highly specific detection of methylphenidate abuse
- Fast and efficient routine monitoring for the methylphenidate metabolite – Ritalinic Acid
- Liquid, ready-to-use reagents, calibrators and controls
- Storage at 2-8°C
- On-board stability for at least 60 days
- Does not contain any harmful preservatives, only ≤ 0.09% sodium azide

Background

Methylphenidate (Ritalin®) is a mild central nervous system stimulant used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). According to the United States Controlled Substances Act, Methylphenidate is a Schedule II substance and has a high potential for abuse, due to its pharmacological properties which are similar to those of amphetamines and cocaine. Methylphenidate appears to activate the brain stem arousal system and cortex to produce its stimulant effect. In some clinical settings it may improve cognitive function.

The drug is usually consumed orally in form of tablets, sniffed as a powder or dissolved in water and injected. The stimulating effect lasts for approx. 4 hours. During this time, concentration and performance are enhanced, and the body loses the ability to perceive exhaustion. At the moment, there are no reliable figures available regarding the prevalence of consumption.

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Properties of Methylphenidate

Dose	Dosage is individualized, according to patient requirements & responses; average dosing is 20 to 30 mg/day.
Bioavailability	10.5% to 52.5%
Peak level	1 to 2 hours after dosing
Protein binding	Low (10% to 33%)
Excretion	78% to 97% of the Methylphenidate dose is excreted in urine within 48 to 96 hours in form of metabolites, 80% of the dose is excreted in urine as ritalinic acid, less than 11% as unchanged methylphenidate
Metabolism	Hepatic metabolization
Elimination half-time	3 to 4 hours

Assay Precision – semi-quantitative

Human Urine (ng/mL)	Cut-off (%)	# of Determinations	Mean (ng/mL)	Results	Repeatability (Within-Run Precision)		Within Laboratory (Total Precision)	
					SD	%CV	SD	%CV
0.0	-100	160	1.2	160 neg	1.22	NA	1.76	NA
50.0	-50	160	51.7	160 neg	3.58	6.9	4.84	9.4
75.0	-25	160	74.8	160 neg	4.59	6.1	6.35	8.5
100.0	Cut-off	160	99.6	92 neg / 68 pos	5.37	5.4	7.48	7.5
125.0	+25	160	125.2	160 pos	5.50	4.4	8.15	6.5
150.0	+50	160	149.2	160 pos	7.03	4.7	9.41	6.2
200.0	+100	160	201.1	160 pos	7.75	3.9	11.34	5.6

Method Comparison

ARK Methylphenidate Metabolite Assay (100 ng/mL Cutoff)		LC-MS/MS (+)	LC-MS/MS (-)
	(+)	64	1*
	(-)	0	54

*Discordant Result

Sample ID Number	ARK Qualitative Result	ARK Semiquantitative Result	LC-MS/MS Result
11P	Positive	123.7 ng/mL	94 ng/mL

Order Information

Product Description	Size	Order No.
ARK™ Methylphenidate Metabolite Assay	28 mL R1 & 14 mL R2	5042-0001-00
ARK™ Methylphenidate Metabolite Calibrator	5 x 4 mL	5042-0002-00
ARK™ Methylphenidate Metabolite Control	4 x 4 mL	5042-0003-00

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