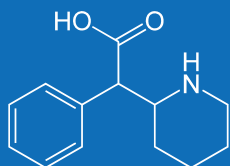


# ARK™ Methylphenidate Metabolite Assay



The ARK Methylphenidate Metabolite Assay is intended for the qualitative and/or semiquantitative determination of methylphenidate metabolite in human urine at a cutoff concentration of 100 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers.

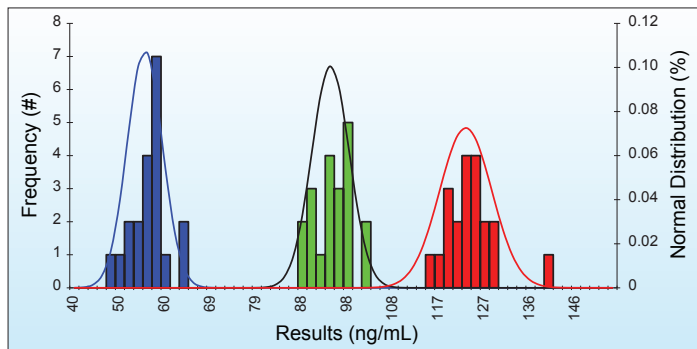


## KEY POINTS

- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- Qualitative and/or semiquantitative applications available for clinical chemistry systems
- 0 – 1,000 ng/mL calibration range; 100 ng/mL cutoff
- Excellent sensitivity and specificity for detection of ritalinic acid (metabolite of Ritalin®) in human urine
- Nonhazardous preservatives

*Next Generation Assays*

## QUALITATIVE PRECISION



Qualitative Control Precision vs 100.0 ng/mL Cutoff Calibrator

## ACCURACY – SPIKED URINE SAMPLES

Theoretical Concentration (ng/mL)	Mean Recovered Concentration (ng/mL)	Percent Recovery (%)	N
60.0	62.6	104.3	6
140.0	140.2	100.2	6
250.0	254.6	101.8	6
350.0	342.4	97.8	6
700.0	678.1	96.9	6

## SEMIQUANTITATIVE PRECISION

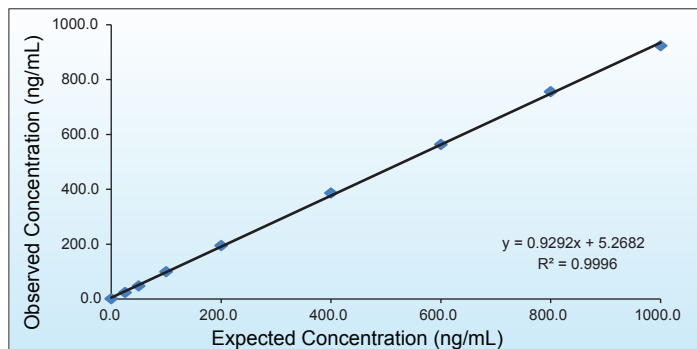
Urine Spiked Samples N=160			WITHIN-RUN		TOTAL	
Methylphenidate Metabolite (ng/mL)	% Cutoff	Mean (ng/mL)	SD	CV (%)	SD	CV (%)
50.0	-50	51.7	3.58	6.9	4.84	9.4
75.0	-25	74.8	4.59	6.1	6.35	8.5
100.0	Cutoff	99.6	5.37	5.4	7.48	7.5
125.0	+25	125.2	5.50	4.4	8.15	6.5
150.0	+50	149.2	7.03	4.7	9.31	6.2
200.0	+100	201.1	7.75	3.9	11.34	5.6

Pooled Human Urine Samples containing methylphenidate metabolite were assayed in quadruplicate twice a day for 20 days. CLSI Guideline EP5-A3.

## CROSS-REACTIVITY AND INTERFERENCE

- No cross-reactivity with psychostimulant and antidepressant drugs at concentrations tested.
- No cross-reactivity with parent compound methylphenidate at concentration tested.
- Endogenous substances do not interfere at concentrations tested
- 80 % cross-reactivity to *d-threo*-ritalinic acid (metabolite of Focalin®)

## LINEARITY



ARK Methylphenidate Metabolite Assay Calibrator Range: 0 to 1,000 ng/mL

## METHOD COMPARISON

		LC-MS/MS	
		(+)	(-)
ARK Methylphenidate Metabolite Assay (100 ng/mL Cutoff)	(+)	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

## SAFETY AND STABILITY

### Reagent on-board stability

Up to at least 60 days

### Shelf Life of Reagents, Calibrators, and Controls

18 months from date of manufacturing

### Safety

Nonhazardous preservatives

Contains sodium azide ≤ 0.09%

Results shown are typical and may vary among laboratory analyzers.

## ORDERING INFORMATION

ARK™ Methylphenidate Metabolite Assay	5042-0001-00
ARK™ Methylphenidate Metabolite Calibrator	5042-0002-00
ARK™ Methylphenidate Metabolite Calibrator A (Negative)	5042-0002-01
ARK™ Methylphenidate Metabolite Calibrator B (Cutoff)	5042-0002-02
ARK™ Methylphenidate Metabolite Control	5042-0003-00

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