

ARK™ Methotrexate II Assay

The ARK™ Methotrexate II Assay is a homogeneous enzyme immunoassay for the quantitative determination of methotrexate in human serum or plasma on automated clinical chemistry analyzers. The measurements obtained are used in monitoring levels of methotrexate to help ensure appropriate therapy.

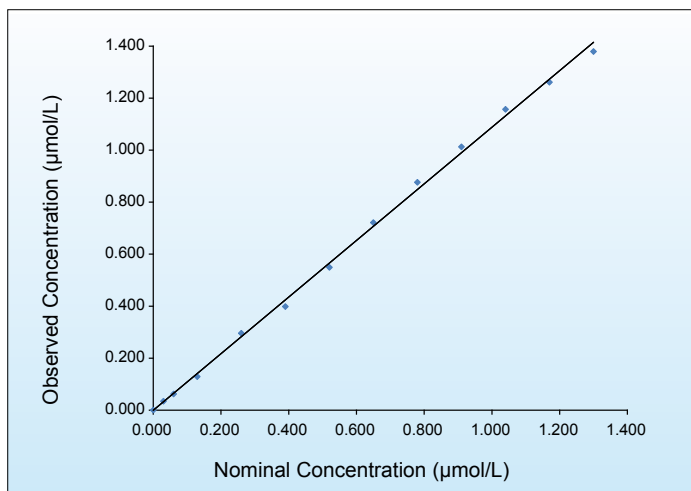


KEY POINTS

- Improved sensitivity, precision, linearity, and stability
- Expanded assay range
- Lower cross-reactivity to 7-hydroxymethotrexate ($\leq 0.01\%$)
- Homogenous enzyme immunoassay
- Applicable to many automated clinical chemistry analyzers
- Convenient, liquid-stable, ready-to-use

Next Generation Assays

LINEARITY



ARK™ Methotrexate II Assay Measurement Range: 0.030 - 1.300 µmol/L. Specimens containing methotrexate in higher concentrations (>1.300 µmol/L) are assayed by dilution of the specimen into the measurement range.

ACCURACY

Target (µmol/L)	Mean (µmol/L)	SD	CV (%)	Recovery (%)
0.060	0.063	0.002	3.14	104.4
0.100	0.105	0.002	1.74	105.2
0.300	0.322	0.005	1.48	107.2
0.600	0.628	0.007	1.12	104.7
1.000	1.079	0.047	4.33	107.9
1.200	1.293	0.053	4.06	107.8

PRECISION

Calibration Range Control Levels							
Sample	N	Mean (µmol/L)	Within Run SD	Within Run CV (%)	Between Day SD	Between Day CV (%)	Total (Within Lab)
Control Low	160	0.069	0.002	2.84	0.001	1.23	0.002 3.00
Control Mid	160	0.411	0.006	1.40	0.002	0.43	0.006 1.40
Control High	160	0.811	0.014	1.79	0.008	0.97	0.017 2.05
Serum Low	160	0.070	0.002	2.50	0.001	1.49	0.002 2.88
Serum Mid	160	0.404	0.008	1.86	0.003	0.65	0.008 1.92
Serum High	160	0.846	0.016	1.93	0.008	0.95	0.017 2.06

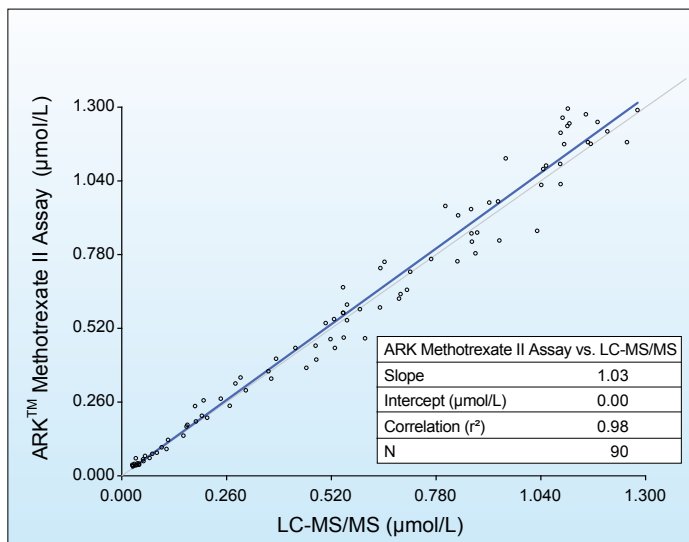
High Range Control Levels							
Sample	N	Mean (µmol/L)	Within Run SD	Within Run CV (%)	Between Day SD	Between Day CV (%)	Total (Within Lab)
Control 5	160	4.868	0.070	1.44	0.036	0.74	0.077 1.58
Control 50	160	49.660	1.108	2.23	0.397	0.80	1.141 2.30
Control 500	160	493.769	8.012	1.62	2.483	0.50	8.012 1.62
Serum 5	160	5.247	0.076	1.45	0.028	0.54	0.078 1.49
Serum 50	160	51.614	0.723	1.40	0.285	0.55	0.777 1.51
Serum 500	160	507.988	7.632	1.50	4.240	0.83	8.538 1.68

Precision was performed according to (CLSI) Protocol EP5-A3.

LIMIT OF BLANK, LIMIT OF DETECTION, AND LOWER LIMIT OF QUANTITATION

Limit of Blank: 0.000 µmol/L
 Limit of Detection: 0.004 µmol/L
 Limit of Quantitation: 0.030 µmol/L

METHOD COMPARISON



SAFETY AND STABILITY

Reagent on-board stability

Up to at least 60 days

Shelf Life of Reagents, Calibrators, Controls, and Dilution Buffer

18 months from date of manufacturing

Safety

Nonhazardous preservatives

Contains sodium azide ≤0.09%

PROFICIENCY SAMPLES

CAP Survey		
Sample ID	Consensus Mean (µmol/L)	ARK Value (µmol/L)
CHM-06 (2022)	8.003	7.253
CHM-07 (2022)	0.209	0.218
CHM-08 (2022)	2.161	2.347
CHM-09 (2022)	9.838	9.393
CHM-10 (2022)	0.278	0.311

ORDERING INFORMATION

ARK™ Methotrexate II Assay (R1 x 16 mL / R2 x 8 mL)	5071-0001-00
ARK™ Methotrexate II Calibrators (6 x 4 mL)	5071-0002-00
ARK™ Methotrexate II Controls (3 x 4 mL; LOW, MID, HIGH / 3 x 2 mL; 5, 50, 500 µmol/L)	5071-0003-00
ARK™ Methotrexate II Controls (3 x 4 mL; LOW, MID, HIGH)	5071-0003-01
ARK™ Methotrexate II Controls (3 x 2 mL; 5, 50, 500 µmol/L)	5071-0003-02
ARK™ Methotrexate II Dilution Buffer (25 mL)	5071-0004-00

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