

ARK™ Methotrexate Assay

The ARK™ Methotrexate Assay is intended 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.

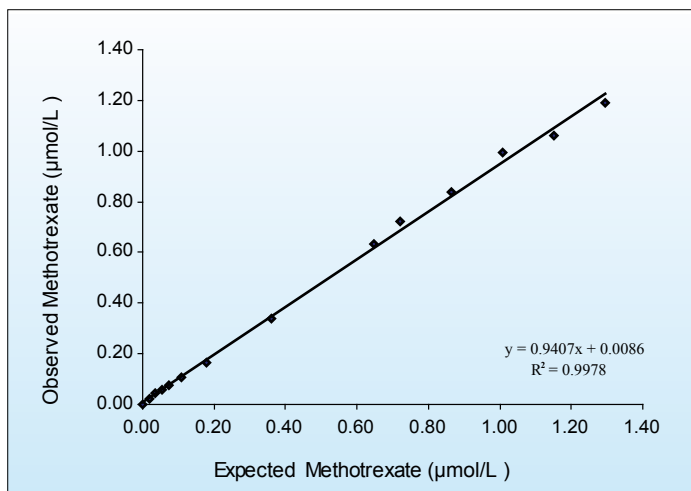


KEY POINTS

- Homogeneous enzyme Immunoassay
- Applications available for automated clinical chemistry analyzers
- Convenient, liquid-stable, ready-to-use
- Excellent calibration range
- Very low cross reactivity to 7-Hydroxymethotrexate ($\leq 0.07\%$)
- Nonhazardous preservatives (contains no sodium azide)

Next Generation Assays

LINEARITY



ARK™ Methotrexate Assay Measurement Range: 0.04 - 1.20 µmol/L
Specimens containing methotrexate in higher concentrations (>1.20 µmol/L) are assayed by dilution of the specimen into the measurement range.

ACCURACY

Target Concentration (µmol/L)	Mean Concentration (µmol/L)	Percent Recovery N = 6
0.06	0.07	111.1
0.10	0.10	100.0
0.30	0.30	98.3
0.60	0.61	102.2
1.00	0.99	98.8

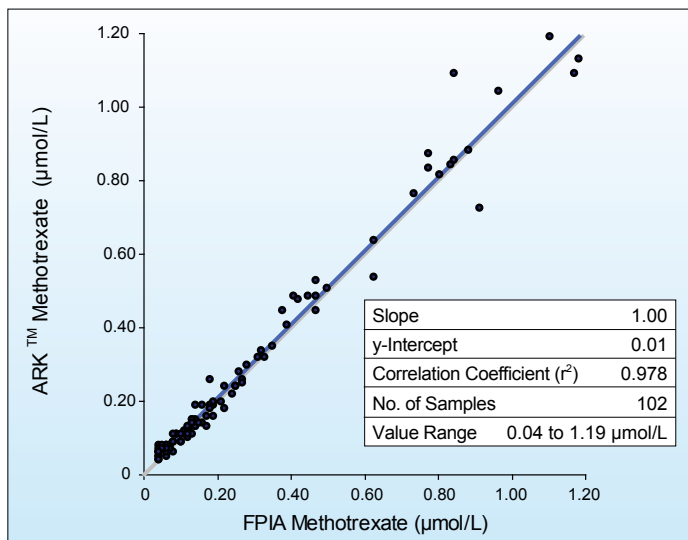
Mean percent recovery: 102.1

PRECISION

ARK™ METHOTREXATE CONTROL						
Sample	N	Mean (µmol/L)	Within Run SD	CV (%)	Total SD	CV (%)
LOW	160	0.06	0.005	8.1	0.007	10.6
MID	160	0.37	0.011	3.1	0.014	3.8
HIGH	160	0.76	0.039	5.1	0.048	6.4
5	160	4.8	0.13	2.8	0.19	4.1
50	160	48	1.40	2.9	2.71	5.6
500	160	470	15.63	3.3	33.35	7.0
PATIENT POOL						
Sample	N	Mean (µmol/L)	Within Run SD	CV (%)	Total SD	CV (%)
LOW	160	0.07	0.006	9.1	0.008	11.7
MID	160	0.41	0.013	3.3	0.030	7.2
HIGH	160	0.82	0.037	4.5	0.057	6.9
5	160	4.6	0.14	3.1	0.24	5.3
50	160	45	1.31	2.9	2.92	6.5
500	160	460	11.55	2.5	29.63	6.4

Precision was performed according to (CLSI) Guideline EP5-A2.

METHOD COMPARISON



LIMIT OF DETECTION AND LOWER LIMIT OF QUANTITATION

Limit of Detection: 0.02 µmol/L

Limit of Quantitation 0.04 µmol/L

CAP SURVEY SAMPLE

Sample ID	Mean (µmol/L)	SD (µmol/L)
CAP Survey - Consensus		
CHM01	35.174	2.558
CHM02	8.123	0.457
ARK Methotrexate Assay		
CHM01	32.17	0.983
CHM02	7.67	0.427

ORDERING INFORMATION

ARK™ Methotrexate Assay (R1 x 16 mL / R2 x 8 mL)	5026-0001-00
ARK™ Methotrexate Assay (Roche c-pack) (R1 x 16 mL / R2 x 8 mL)	5026-0001-02
ARK™ Methotrexate Calibrators (6 x 2 mL)	5026-0002-00
ARK™ Methotrexate Controls (6 x 2 mL; LOW, MID, HIGH, 5, 50, 500 µmol/L)	5026-0003-00
ARK™ Methotrexate Controls (3 x 2 mL; LOW, MID, HIGH)	5026-0003-01
ARK™ Methotrexate Controls (3 x 2 mL; 5, 50, 500 µmol/L)	5026-0003-02
ARK™ Methotrexate Dilution Buffer (25 mL)	5026-0004-00

ARK Diagnostics, Inc.

48089 Fremont Boulevard
Fremont, CA 94538
Tel: 510-270-6270 Fax: 510-270-6298

For Customer Support:

Call toll free: 877-869-2320
customersupport@ark-tdm.com
www.ark-tdm.com