

ARK™ Methotrexate Assay

The ARK™ Methotrexate Assay Test is a highly specific homogeneous enzyme immunoassay for the quantitative determination of methotrexate in human serum or plasma. The Assay helps to provide reliable results for the monitoring of methotrexate levels and to ensure safe, effective and personalized drug therapy.

Assay Characteristics

- Very low cross reactivity to 7-Hydroxymethotrexate ($\leq 0.07\%$)
- Well suited for the detection of MTx in the low ranges, limit of detection 0.02 $\mu\text{mol/L}$, limit of quantification 0.04 $\mu\text{mol/L}$
- Dilution protocols available to extend concentration range up to 1000 $\mu\text{mol/L}$
- Convenient, liquid-stable, ready-to-use format
- Applications available for all major automated clinical chemistry analysers
- Excellent calibration range
- Calibration curve stable from 3 days to up to 6 weeks, depending on instrument type and work load
- Non-hazardous preservatives do not contain sodium azide

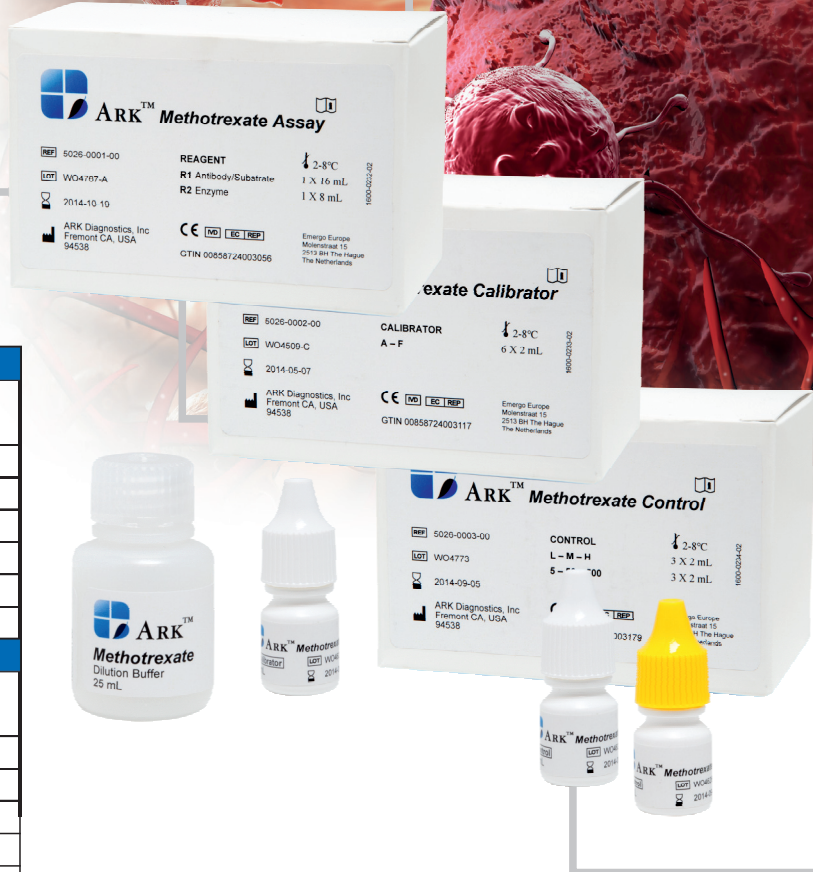
Background

Methotrexate inhibits the growth of rapidly reproducing cells, such as cancer, skin or bone marrow cells, by interfering with the folic acid metabolism. As an antimetabolite and antifolate drug, it is used for high-dose therapy in combined anti-cancer drug regimens and the low-dose treatment of severe psoriasis, Morbus Crohn, rheumatoid arthritis and other auto-immune diseases.

Treatment with methotrexate may lead to major toxic effects, such as hepatic, pulmonary, renal and bone marrow abnormalities. These may be life threatening, especially in high dose therapy.

With the ARK™ Methotrexate Assay, Specialty Diagnostix offers a reliable tool for the monitoring of serum methotrexate concentrations, thus helping to reduce toxicity and to optimize patient-specific dose adjustment.



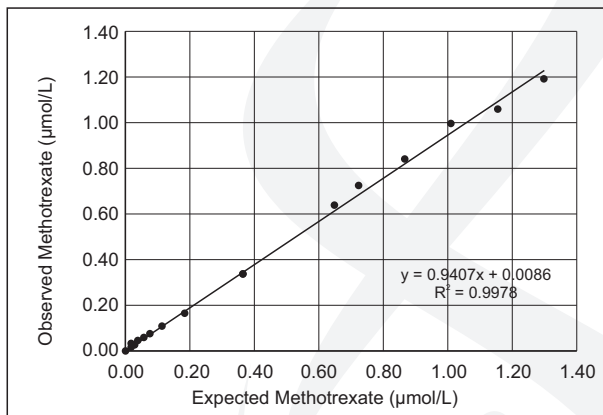


Precision

ARK™ Methotrexate						
Sample	N	Mean (µmol/L)	Within Run		Total	
			SD	CV (%)	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						
Sample	N	Mean (µmol/L)	Within Run		Total	
			SD	CV (%)	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

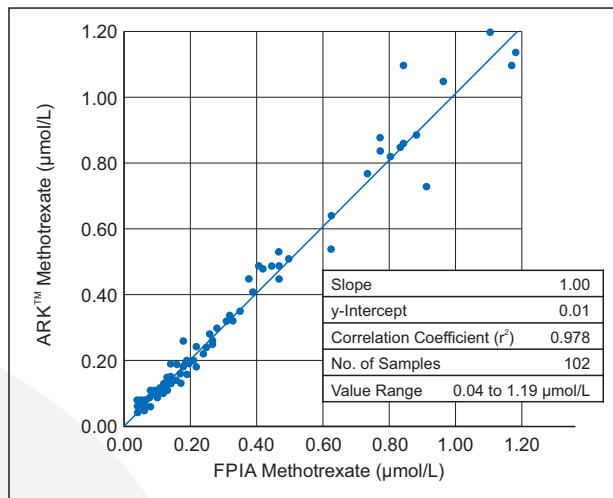
Precision was performed according to (CLSI) Guideline EP5-A2.

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.

Method Comparison



Ordering Information

Reagents	Size	Order No.
ARK™ Methotrexate Assay	16 mL R1 & 8 mL R2	5026-0001-00
Calibrators		
ARK™ Methotrexate Calibrators	6 x 2 mL	5026-0002-00
Controls		
ARK™ Methotrexate Controls (LOW, MID, HIGH, 5, 50, 500 µmol/L)	6 x 2 mL	5026-0003-00
ARK™ Methotrexate Controls (LOW, MID, HIGH)	3 x 2 mL	5026-0003-01
ARK™ Methotrexate Controls (5, 50, 500 µmol/L)	3 x 2 mL	5026-0003-02
Dilution Buffer		
ARK™ Methotrexate Dilution Buffer	25 mL	5026-0004-00

Specialty Diagnostix

Specialty Diagnostix GmbH
Sailerwöhr 16
94032 Passau, Germany
Phone +49 (0)851 988 4930 0
Fax +49 (0)851 988 4930 8
info@specialtydiagnostix.de
www.specialtydiagnostix.de