

ARK™ Methotrexate Assay

Siemens Atellica™ CH Analyzer System

For In Vitro Diagnostic Use

The ARK Methotrexate Assay is a homogeneous enzyme immunoassay 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.

Refer to applicable ARK reagent, calibrator, control and dilution buffer package inserts for intended use, reagent storage, specimen handling, calibration, quality control and other required information. ARK package inserts are available online at www.ark-tdm.com.

MANUFACTURER INFORMATION

ARK Methotrexate reagents, calibrators, controls and dilution buffer are manufactured by ARK Diagnostics, Inc. and sold/distributed by Siemens Healthcare Diagnostics for application on the Siemens Atellica CH Analyzer System.

ARK Diagnostics, Inc.
48089 Fremont Boulevard
Fremont, CA 94538
www.ark-tdm.com

ORDERING INFORMATION

For orders and technical support, contact Siemens Healthcare Diagnostics.

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
Siemens.com/healthineers

Technical Support for USA and Canada:
1-877-229-3711

Ordering for USA:
1-888-588-3916

Ordering for Canada:
1-800-615-2615

In other countries, please contact your local representative.

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Product Name	Product Description	ARK Product Number	Siemens Material Number (SMN)
ARK Methotrexate Assay	R1 16 mL, R2 8 mL	5026-0001-00	10709280
ARK Methotrexate Calibrators	6 x 2 mL	5026-0002-00	10709281
ARK Methotrexate Control	6 x 2 mL; LOW, MID, HIGH, 5, 50, 500 $\mu\text{mol/L}$	5026-0003-00	10709282
ARK Methotrexate Control	3 x 2 mL; LOW, MID, HIGH	5026-0003-01	10709283
ARK Methotrexate Control	3 x 2 mL; 5, 50, 500 $\mu\text{mol/L}$	5026-0003-02	10709284
ARK Methotrexate Dilution Buffer	25 mL	5026-0004-00	10709285
EMPTY reagent pack	4 P1 Packs & 4 P2 Packs	N/A	11097534
Atellica CH EMPTY1	8 P1 Packs	N/A	11538114
Atellica CH EMPTY2	8 P2 Packs	N/A	11538115

PREPARATION OF ASSAY COMPONENTS

The following assay components are ready-to-use liquids as supplied. When not in use, store upright at 2-8°C. Components are stable until the expiration date printed on the label if stored as directed.

Reagent R1: Antibody/Substrate (16 mL) and **Reagent R2:** Enzyme (8 mL). Transfer the respective reagent into the appropriate size reagent bottle (EMPTY Reagent Pack). Mark the label on the bottle with the reagent name and expiration date.

Precaution: Avoid cross-contamination of R1 and R2.

Calibrators, Controls and Dilution Buffer: Supplied separately. Perform assay-specific calibration and quality control as recommended.

EMPTY Reagent Packs: Supplied separately by Siemens. The reagent pack must be manually loaded on the Siemens Atellica CH Analyzer System. Manually fill the EMPTY reagent packs with R1 and R2. Refer to the online help for instructions on loading operator-filled empty reagent packs.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Refer to the ARK Methotrexate Assay package insert for information on specimen collection and preparation.

Dilution Protocol

The measurement range of the ARK Methotrexate Assay is 0.04 – 1.20 $\mu\text{mol/L}$. Specimens and controls containing methotrexate in higher concentrations (>1.20 $\mu\text{mol/L}$) are assayed by dilution of the specimens and controls into the measurement range. Specimens or controls may be diluted by using the ARK Methotrexate Dilution Buffer. Prepare the appropriate ten-fold serial dilution as shown below. Multiply the assayed result by the dilution factor.

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Volume	Sample	Dilution Buffer Volume	Dilution	Dilution Factor
50 µL	Undiluted sample	450 µL	1:10	10
50 µL	1:10 sample	450 µL	1:100	100
50 µL	1:100 sample	450 µL	1:1000	1000
50 µL	1:1000 sample	450 µL	1:10000	10000

ARK Diagnostics, Inc. has validated the auto-dilution procedure on the Siemens Atellica CH Analyzer System. The auto-dilution procedure allows for automatic dilution of the patient specimen by the analyzer and uses deionized (DI) water on board. One level of auto-dilution is possible. ARK validated the use of 1:10 auto-dilution on the analyzer. Higher dilutions require pre-dilution manually with the ARK Methotrexate Dilution Buffer. Specimen dilution is required for concentrations that exceed the assay measurement range 0.04 to 1.20 µmol/L.

IMPORTANT INFORMATION

Siemens does not manufacture the ARK reagents or perform quality control or other tests on individual lots. Siemens cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of ARK reagent, ARK calibrator or ARK control nor changes to analyzer protocols for ARK Assays.

TECHNICAL PERFORMANCE EVALUATION

Performance characteristics on the Siemens Atellica CH Analyzer System were consistent with package insert information for the ARK Methotrexate Assay. All data were obtained on a Siemens Atellica CH Analyzer System. Data available upon request.

INSTRUMENT PARAMETERS: SIEMENS ATELICA CH ANALYZER SYSTEM

The following are parameters for use when performing the ARK Methotrexate Assay on the Siemens Atellica CH Analyzer System. Instrument operating instructions are contained in the Siemens Atellica Operator's Manual.

Contents	Pack Volume	Number of Tests
Reagent 1: Pack 1, Well 1	16 mL	110
Reagent 2: Pack 2, Well 1	8 mL	110

CH Lot and Pack Assay Reagent Calibrations	
LOT CAL INTERVAL	62 Days*
ONBOARD STABILITY	62 Days*
PACK CAL INTERVAL	15 Days*

*Days listed are based on data collected from validation of the ARK Methotrexate Assay on the Siemens Atellica CH Analyzer System. Refer to the ARK Methotrexate Assay package insert for instructions on when to re-calibrate.

Parameter	Atellica
R1 volume	88 µL
R2 volume	44 µL
Serum reac.s.vol	20 µL
predilution.s.vol	50 µL
predilution dil.volume	150 µL

Results

Results are reported as µmol/L or µg/mL.

Assay	TDEF Code	Time to First Result
MTX	8048	7 minutes

Calibration

Prepare a calibration curve by using the calibrators listed in the table below. Run controls. Recalibrate as indicated by control results.

Assay	Cal A	Cal B	Cal C	Cal D	Cal E	Cal F
MTX	0.00 µmol/L	0.05 µmol/L	0.15 µmol/L	0.25 µmol/L	0.50 µmol/L	1.20 µmol/L

Parameter	Atellica
Measurement Times	Seconds
MNRead_x1	339.75
MNRead_x2	348.67
MNRead_x3	357.59
MNRead_x4	366.51

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Reaction time (minutes)	7
Reagent 1 stir	MixerMediumMixCmd
Reagent 2 stir	MixerFastMixCmd
Name	Mtx
Digits	2
Common Unit	μmol/L
SI Unit	μg/mL
M-wave.L.	340 nm
S-wave.L.	410 nm
Analy.mthd	Rate
Calc.mthd	Logit
Caliblevel	CalibLevelWeight
L1	50
L2	10
L3	1
L4	1
L5	1
L6	1
Overrange	Volume (μL)
Overrange.smp.vol 1	10 μL
Overrange Diluent vol 1	90 μL

MNRead_x5	375.43
MNRead_x6	384.35
MNRead_x7	393.27
MNRead_x8	402.19
MNRead_x9	411.11
MNRead_x10	420.03
MNRead_x11	428.95
Calibrator Predilution	μL sample/μL Diluent
CAL A	50/150
CAL B	50/150
CAL C	50/150
CAL D	50/150
CAL E	50/150
CAL F	50/150

Sample Type Serum

Sample Type Plasma

Assay measurement range: 0.04 – 1.20 μmol/L (0.02 – 0.55 μg/mL)

Auto Dilution

An automatic repeat condition for this assay extends the measuring interval to 12.00 μmol/L (5.50 μg/mL) for serum and plasma. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**. This condition applies to specimens containing methotrexate concentrations above the assay measurement range requiring dilution into the measurement range using a 1:10 auto-dilution on the analyzer.

Distributed by:
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Siemens.com/healthineers