ARK Diagnostics, Inc.

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ARK™ Methotrexate Assay Application
Ortho Clinical Diagnostics VITROS® XT 7600 Integrated System, VITROS® 5600 Integrated System and VITROS® 4600 Chemistry System

Reference No. 5026000100

Intended for the Quantitative Determination of Methotrexate in Human Serum or Plasma.

For In Vitro Diagnostic Use Only

Intended 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. Specimens from patients who have received glucarpidase (carboxypeptidase G2) as a high dose methotrexate rescue therapy should not be tested with the ARK Methotrexate Assay.

The information provided in this application sheet is intended as a supplement to the package insert. 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.

For package inserts, **visit www.orthoclinicaldiagnostics.com> Technical Documents > MicroTip Partnership Assays (MPA).**

Ordering Information

Please place your order with Ortho Clinical Diagnostics. Ordering information available on **www.orthoclinicaldiagnostics.com.**

Item	Reference Number	Configuration
MTX 88t/kit	5026000100	R1: 1 x 16 mL R2: 1 x 8 mL
MTX Cal	5026000200	6 x 2 mL
MTX Ctrl (Cal and Hi Range)	5026000300	6 x 2 mL
MTX Ctrl (Cal Range)	5026000301	3 x 2 mL
MTX Ctrl (Hi Range)	5026000302	3 x 2 mL
MTX Diluent	5026000400	1 x 25 mL

Technical Support Information

Contact Ortho Clinical Diagnostics for technical support. Contact information available on www.orthoclinicaldiagnostics.com.

Manufacturer Information

ARK Methotrexate reagents, calibrators, controls and dilution buffer are manufactured by ARK Diagnostics, Inc.

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

Reagent Pack Storage

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.

Reagents stored in UDxx reagent packs onboard the analyzer are stable for 60 days and have a calibration interval of 25 days.

The following assay components are ready-to-use liquids as supplied.

Reagent R1: Antibody/Substrate (16 mL) and **Reagent R2:** Enzyme (8 mL).

Precaution: Avoid cross-contamination of R1 and R2.

R1 (mL) in UDxx/A	R2 (mL) in UDxx/B	Tests/pack
16.0	8.0	88

1 UDxx reagent packs would be able to perform approximately 88 tests

It is recommended that the reagents be split into 2 UDxx reagent packs containing a sufficient volume for a 60-day period of testing, based on anticipated utilization. The recommended fill volumes for each of the 2 UDxx reagent packs are as follows: R1 (8 mL) and R2 (4 mL) with 38 tests per UDxx pack

Calibrators, Controls and Dilution Buffer

Supplied separately.

ARK™ Methotrexate Calibrator Concentrations	
Calibrator	**µmol/L**
A	0.00 µmol/L
B	0.05 µmol/L
C	0.15 µmol/L
D	0.25 µmol/L
E	0.50 µmol/L
F	1.20 µmol/L

ARK™ Methotrexate Control Concentrations
µmol/L
0.07 µmol/L (LOW)
0.40 µmol/L (MID)
0.80 µmol/L (HIGH)
5 µmol/L
50 µmol/L
500 µmol/L

Dilution Protocol

The measurement range of the ARK Methotrexate Assay is 0.04 – 1.20 µmol/L. Specimens and controls containing methotrexate in higher concentrations (>1.20 µmol/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.

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. and Ortho have validated the 1:10 auto-dilution procedure on the VITROS® 5600 System and VITROS® 4600 System*. The auto-dilution procedure allows for automatic dilution of the patient specimen by the analyzer and uses ARK Methotrexate Dilution Buffer on board. One level of auto-dilution is possible. Higher dilutions require pre-dilution manually with the ARK Methotrexate Dilution Buffer. Specimen dilution is required for concentrations that exceed the assay measurement range of 0.04 to 1.20 µmol/L.

UDDL: Methotrexate Dilution Buffer (16 mL)

Dilution Buffer stored in UDDLx dilution pack onboard the analyzer was stable for 60 days based on supporting data.

*Performance characteristics for the VITROS® 5600 System are applicable to the VITROS® XT 7600 System.

Auto Dilution Parameters

Configuring Dilution Parameters on the VITROS® Systems using ARK Methotrexate Dilution Buffer as a User Defined Diluent

1. Define a new user defined diluent (MTX DIL) – Touch Options, Configure Assays, User Defined Diluents. Add the information for the new diluent and touch Save.

2. Once the diluent (MTX DIL) is established, begin defining a new User Defined Assay and inputting the application.

Configuring Dilution Parameters on the VITROS® System

3. Touch Dilutions Parms at the bottom of the Review/Edit Assay screen.

   a. Enabling reflex dilution is suggested. Reflex dilution enables the VITROS® System to automatically dilute and re-assay samples with out-of-range results.

b. Type reflex dilution factor 10. This reflex dilution factor will be used for samples requiring dilution at the reflex metering station.

Special Reagent Packs for User Defined Assays
(Please order from Ortho Clinical Diagnostics)

Reference No.	Description	Quantity
6802246	UD01 Packs (Empty)	1 BOX/6PKS
6802247	UD02 Packs (Empty)	1 BOX/6PKS
6802248	UD03 Packs (Empty)	1 BOX/6PKS
6802249	UD04 Packs (Empty)	1 BOX/6PKS
6802250	UD05 Packs (Empty)	1 BOX/6PKS
6802251	UD06 Packs (Empty)	1 BOX/6PKS
6802252	UD07 Packs (Empty)	1 BOX/6PKS
6802253	UD08 Packs (Empty)	1 BOX/6PKS
6802254	UD09 Packs (Empty)	1 BOX/6PKS
6802255	UD10 Packs (Empty)	1 BOX/6PKS
6844449	UD11 Packs (Empty)	1 BOX/6PKS
6844448	UD12 Packs (Empty)	1 BOX/6PKS
6844445	UD13 Packs (Empty)	1 BOX/6PKS
6844442	UD14 Packs (Empty)	1 BOX/6PKS
6844447	UD15 Packs (Empty)	1 BOX/6PKS
6844444	UD16 Packs (Empty)	1 BOX/6PKS
6844441	UD17 Packs (Empty)	1 BOX/6PKS
6844446	UD18 Packs (Empty)	1 BOX/6PKS
6844443	UD19 Packs (Empty)	1 BOX/6PKS
6844440	UD20 Packs (Empty)	1 BOX/6PKS
6802256	UDDL1 PACKS (EMPTY) BX/6PACKS	BOX or BX
6802257	UDDL2 PACKS (EMPTY) BX/6PACKS	BOX or BX

Note: Once the individual UDxx pack number is selected for use during the protocol programming, it is the only UDxx pack number to use for this protocol.

Note: If using the ARK Methotrexate Diluent, it must be transferred into a UDA Diluent Pack (6802256 or 6802257).

ARK™ Methotrexate Assay – Quantitative
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System and VITROS® 4600 System Parameters

Configure Assay

Full Assay Name: Methotrexate

Version Date: MM/DD/YYYY

Short Assay Name: MTX

Fluid Type: Serum

Assay Model Type: 2 Point Rate

Template: *2PT R1-S-R2

Cal Model Type: Logit/Log 4

Calibrator Bottles: 6 Reagent Reps per Cal: 2

Reagent Lot Information

On-Board Stability: 60 Days

Reagent Lot Num. *Kit Lot*

Shelf Exp. Date: *Kit Exp Date*

Edit Dilution Parameters

Diluent: MTX DIL Standard Dilution Factor: 1.0

Reflex Dilution: On Dilution Factor: 10.0

Reduction Factor: 1.0

Edit Result Parameters

Units: µmol/L

Reference Interval: 0.00 to 900000000

Significant Digits: 3 Precision Digits: 2

Supplementary: 0.00 to 900000000

User Adjusted Parameters

Reportable Range: 0.04 to 1.20

Slope: 1.00 Intercept: 0.00

Edit Additional Parameters

Cuve Tip Exp Time: 35 Temp Sens : No

Initial Abs. Limits: -0.200 to 3.500

Second Abs. Limits: -0.200 to 3.500

Edit Protocol Parameters

	Step	Volume	Pack ID	Seconds	Wavelength
1.	Reagent (R1)	150.0 uL	UDxx /A		
2.	Incubation			0.00	
3.	Sample	8.5 uL			
4.	Incubation			304	
5.	Reagent (R2)	75.0 uL	UD xx/B		
6.	Incubation			76	
7.	Read				340 nm
8.	Incubation			76	
9.	Read				340 nm

ARK™ Methotrexate Assay – Quantitative
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System and VITROS® 4600 System Parameters

Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: *Cal Kit lot*
1	1.0	0.20000	Cal value: 0.00
2	1.0	0.20000	Cal value: 0.05
3	1.0	0.20000	Cal value: 0.15
4	1.0	0.20000	Cal value: 0.25
5	1.0	0.20000	Cal value: 0.50
6	1.0	0.20000	Cal value: 1.20

Edit Additional Calibration Parameters

Monotonicity: Increase

Max Resp High: 5.000	Min. Resp. High: 5.000	Cal Fit Goodness Limit: 0.990
Max Resp. Low: -5.000	Min Resp. Low: -5.000	Calibration Interval: 999 Days

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	0.04	0.05
Critical Conc.:	0.62	8.00 %
Reportable Max.:	1.20	8.00 %