ARK Diagnostics, Inc.

CE

ARK™ Methotrexate Assay

Dimension Vista® 500, Dimension Vista® 1000T, Dimension Vista® 1500, Dimension Vista® 3000T Systems with software version 3.2.1 or higher

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.

Please review **IMPORTANT INFORMATION** below. Refer to applicable package inserts for information regarding intended use, reagent storage, specimen handling, calibration, quality control and other required information. ARK package inserts for reagent, calibrator, control and dilution buffer 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 Dimension Vista Systems.

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

1-800-227-8994 in the USA
1-800-264-0083 in Canada
Outside the USA and Canada, call your local Siemens representative.

Product Name	ARK Product Number	Siemens Material Number (SMN)
ARK Methotrexate Assay (R1 x 16 mL / R2 x 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 µmol/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 µmol/L)	5026-0003-02	10709284
ARK Methotrexate Dilution Buffer (25 mL)	5026-0004-00	10709285
EMPTY Flex® Reagent Cartridge	N/A	KS999

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PREPARATION OF ASSAY COMPONENTS

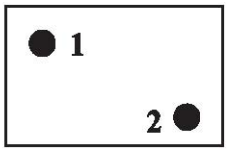
The following assay components are ready-to-use liquids as supplied. When not in use, store upright at 2-8°C. Components are stable until the expiration date printed on the label if stored as directed.

Reagent R1: Antibody/Substrate and **Reagent R2:** Enzyme.

Preparation of the Flex® Reagent Cartridge

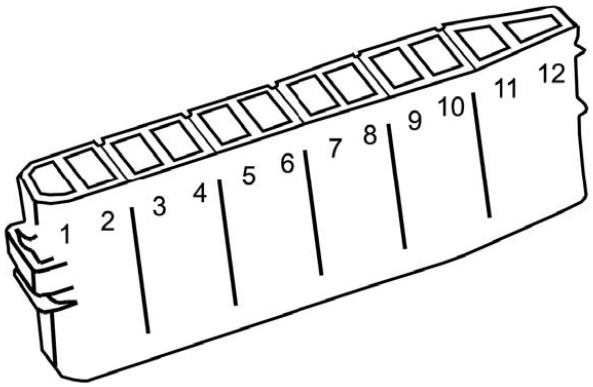
Venting the Flex®

The Flex® well must be vented before filling with reagent. To vent a Flex® well, puncture the film at a corner of the well (1) and then fill the well from the opposite corner (2). Care must be taken to minimize the size of the vent and fill holes without tearing the film.



Filling the Flex®

Transfer reagent into an empty, vented Flex® according to the table below.



Reagent	Wells	Volume per Well	Tests Per Well	# of Tests/flex
Reagent R2	1 and 2	0.8 mL	10	20
Reagent R1	11 and 12	1.4 mL	10	20

Flex Cartridge Configuration

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Well number	1	2	3 to 10	11	12
Component	(R2) 0.8 mL	(R2) 0.8 mL	EMPTY	(R1) 1.4 mL	(R1) 1.4 mL
Number of tests	10	10		10	10
Well Life (hours)	24	24		24	24
Calibrate Time (days)	14	14		14	14

A pre-filled Flex® is stable when taped and stored at 2-8ºC for up to 7 days. Remove this covering before loading the Flex® on the analyzer.

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

SPECIMEN COLLECTION AND PREPARATION

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 µmol/L. Specimens and controls containing methotrexate in higher concentrations (>1.20 µmol/L) are assayed by dilution of the specimen 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

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 reagents, any variation between lots of ARK reagents, ARK calibrators or ARK controls nor changes to analyzer protocols for the ARK Methotrexate Assay.

Each laboratory is responsible for validating assay performance on their system. The parameters provided should be verified with additional testing as applicable before reporting diagnostic results.

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The following are parameters for use when performing the ARK Methotrexate Assay on Siemens Dimension Vista automated chemistry analyzers. Instrument operating instructions are contained in the Siemens Dimension Vista series operator's manuals.

Instrument Parameters

Note: Auto-dilution feature is not available on the instrument.

Name: XMTX	**Units: µmol/L**	**Mode:** Photometric

Execution Screen

Delivery	**Time**	**Component 1**		**Remix**	**Component 2**	**Remix**	**Chase**	**Mix**
D1	-21	**R1**	**100 µL**	None	None	None	**0 µL**	None
S1	0	**S**	**6 µL**	None	None	None	**4 µL**	Gentle
D2	82	**R2**	**50 µL**	None	None	None	**10 µL**	Moderate

D3 and S2 Delivery are not used

Reagent Screen

For each well, enter the appropriate values for the reagent that will be added.

Well 1

Reagent	R2
Tests	10
Life (hours)	24

Well 2

Reagent	R2
Tests	10
Life (hours)	24

Well 11

Reagent	R1
Tests	10
Life (hours)	24

Well 12

Reagent	R1
Tests	10
Life (hours)	24

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Calculation Screen

Format: Rate
Measuring: 340 nm
Blank: 600 nm

Photometer	Time	Dilution	
P1	138 sec.	1.00	IOD < 100
P2	224 sec.	1.00	FOD >1800

P3 and P4 are not used

Errors √

Check 700
Read 1 138
Read 2 224
Trigger > 15
Select Absorbance
Click Add. The absorbance calculation appears.

Calibration Screen

Std. Curve:	**Logit**
Interval (days)	**14**
C4:	**0.500**

Calibrator Levels:

Level 1 to 6
Weight 1
Replicates 3

Sample Screen

Serum: √

Assay Range
Low 0.04
High 1.20
Reference Range
Low *
High *
Expiration 120 (minutes)
Predilute and Autodilution are not used

Plasma: √

Assay Range
Low 0.04
High 1.20
Reference Range
Low *
High *
Expiration 120 (minutes)
Predilute and Autodilution are not used

***User Defined**

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