

ARK Methotrexate Calibrator – Traceability Statement

ARK Methotrexate Calibrator

REF	Product Description		Quantity/Volume
5026-0002-00	ARK Methotrexate Calibrators Methotrexate, buffer, bovine serum albumin, and preservatives		Dropper vials
	A	0.00 µmol/L	1 X 2 mL
	B	0.05 µmol/L	1 X 2 mL
	C	0.15 µmol/L	1 X 2 mL
	D	0.25 µmol/L	1 X 2 mL
	E	0.50 µmol/L	1 X 2 mL
	F	1.20 µmol/L	1 X 2 mL

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Traceability and Value Verification

A master calibrator lot is prepared volumetrically using a certified solution of methotrexate. The ARK Methotrexate Calibrator is traceable to a certified methotrexate solution and the uncertainty in the methotrexate concentration is 5% relative to the concentration in the certified solution.

The concentration of methotrexate in the certified solution is traceable to HPLC; the purity of methotrexate in the certified solution is determined by HPLC and other spectral procedures as performed by the supplier of the certified solution.

Bulk solutions of the ARK Methotrexate Calibrator are prepared volumetrically using the certified solution of methotrexate. The concentration of methotrexate in the respective bulk solution must agree within 5% of its corresponding master calibrator.

Value Verification: Testing is performed with the ARK Methotrexate Assay on the Beckman Coulter AU680 automated clinical chemistry analyzer. Two calibrated runs are performed using the Master Calibrator. In each run, five replicates of Master Lot (reference) and Test Lot are tested as matched pairs for each calibrator level. Mean values for ten replicates are calculated. Test Lot mean values are expected to match the Master Lot mean values within 5% allowance. Target values for the six levels of calibrator are 0.00 $\mu\text{mol/L}$, 0.05 $\mu\text{mol/L}$, 0.15 $\mu\text{mol/L}$, 0.25 $\mu\text{mol/L}$, 0.50 $\mu\text{mol/L}$ and 1.2 $\mu\text{mol/L}$.

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Figure 1. Traceability Chain of Calibrator

