Methotrexate II Assay

Advancing personalized methotrexate treatment

Atellica DT 250 Analyzer and Atellica CH 930 and Atellica CI* Analyzers

Methotrexate Monitoring in Oncology and Autoimmune Disorders

On-label uses of methotrexate (MTX) include treatment of some types of solid tumors, blood cancers, and lymphomas. In 2019, approximately 200,000 patients worldwide had a need for high-dose MTX therapy.[1] High-dose MTX therapy can be highly cytotoxic and carries risk of severe or fatal damage to the kidneys, liver, heart, GI tract and skin.[2] In addition, low-dose MTX is considered a first line of treatment for many autoimmune inflammatory disorders such as rheumatoid arthritis and systemic lupus erythematosus.[3]

From high- to low-dose MTX therapy, laboratory testing plays a critical role in patient care.

Methotrexate II Assay Benefits

- Provides fully validated and supported Alliance Application of the Methotrexate II Assay for the Atellica DT 250 Analyzer, Atellica CH 930 Analyzer, and Atellica CI* Analyzer, using trusted EMIT-like technology.
- Monoclonal antibodies provide high specificity with strong precision, linearity, and sensitivity.
- Extended range† enables faster high-dose MTX monitoring with fewer manual dilutions, while sensitive low-level detection supports accurate clearance assessment and safer patient management.
- Lower cross-reactivity† with structurally related 7-hydroxymethotrexate (≤0.01%) helps prevent false-positive results.
- Contains liquid-stable, ready-to-use reagents, eliminating the need for manual preparation, dilution, and complex mixing.

Clinical Utility

The duration of methotrexate exposure is a key determinant of toxicity. Direct monitoring of methotrexate levels in serum or plasma is therefore essential to prevent harmful accumulation.[4,5,6,7]

Individualized treatment regimens improve therapeutic target achievement in acute lymphoblastic leukemia patients.

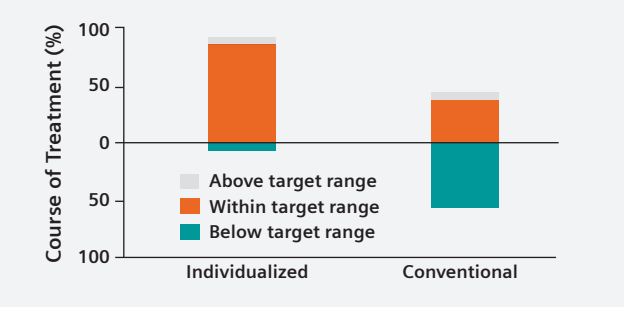


Figure 1. Percentage of treatment courses falling above, within, and below the targeted clearance range in individualized vs. conventional therapy.[8]

Higher rate of remission in patients receiving individualized treatment

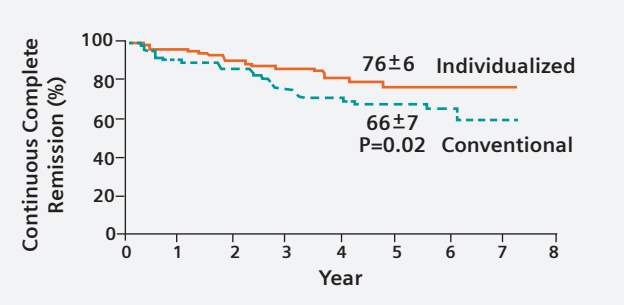


Figure 2. Kaplan-Meier curve demonstrated greater rate of continuous complete remission in individualized vs. conventional treatment regimens.[8]

**Validated application on the Atellica CI Analyzer pending upcoming software release.*
†Compared to ARK Methotrexate Assay

SIEMENS Healthineers

Healthcare Impact

Essential monitoring for treatment

Methotrexate monitoring prevents harmful toxicity and results in patient compliance.[1]

Enhanced assay performance

Improved on-board stability† helps improve operational efficiency, minimize costs, and ensure result accuracy.

Making methotrexate monitoring routine

Simplifies integration into your clinical laboratory workflow.

Assay Specifications‡

	Atellica DT 250 Analyzer	Atellica CH 930 System
Assay principle	Homogenous Enzyme Immunoassay Technique (HEIA)	Homogenous Enzyme Immunoassay Technique (HEIA)
Sample types	Serum or plasma	Serum or plasma
Sample volume	8 µL	17.5 µL
Analytical measuring range	0.030 – 1.300 µmol/L	0.030 – 1.300 µmol/L
Limit of blank	0.006 µmol/L	0.001 µmol/L
Limit of detection	0.010 µmol/L	0.003 µmol/L
Limit of quantitation	0.030 µmol/L	0.030 µmol/L
Reagent onboard stability	30 days	60 days
Calibration Stability	14 days	14 days
Time to first result	10 minutes	7 minutes

Ordering Information

Material Description	SMN No.	Contents
ARK MTX II Assay Kit 16 mL	11834726	R1 16 mL / R2 8 mL
ARK MTX II Calibrators Kit	11834728	6 x 4 mL
ARK MTX II Complete Control Set	11834729	3 x 4 mL; 3 x 2 mL
ARK MTX II Low-Medium-High Control	11834730	3 x 4 mL
ARK MTX II 5-50-500 High Control	11834731	3 x 2 mL
ARK MTX II Dilution Buffer	11834732	25 mL

†Compared to ARK Methotrexate Assay
‡Application manufactured by third party, distributed by Siemens Healthineers.

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