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ARK Diagnostics Immunoassay for Methotrexate on Beckman Coulter DXC Chemistry Analyzer Replaces Abbott TDx Assay

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Effective June 13, 2012, methotrexate moved from the Abbott TDx analyzer to the ARK Diagnostics methotrexate assay on the Beckman Coulter DXC chemistry analyzer in the 24 Hour Services Lab.

Abbott Diagnostics had announced in 2010 that they would no longer support the TDx analyzer of 30 years, and had given a grace period of 12-15 months, thus the need to change the assay to another platform.

Method

The ARK Diagnostics methotrexate immunoassay is a homogenous enzyme immunoassay based on competition between drug in the specimen and methotrexate labeled with glucose-6-phosphate dehydrogenase activity measured spectrophotometrically. The assay was evaluated on the Beckman Coulter DXC chemistry analyzer.

Method validation showed good agreement between the TDx assay and ARK diagnostic immunoassay on the Beckman DXC chemistry analyzer. The assay showed good linearity across the range of 0.1 - 1.2 µmol/L. The limit of quantitation was 0.04 µmol/L. Patient comparisons between the TDx analyzer and ARK diagnostic assay on the DXC chemistry analyzer showed a difference (bias) of 0.054 µmol/L at 1.0 µmol/L which is equivalent to less than 5%. No clinically significant interference was observed.

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Background

Methotrexate is an antineoplastic agent that acts by inhibiting the enzyme dihydrofolate reductase, which stops the synthesis of tetrahydrofolate, disrupting the purine synthesis thus inhibiting DNA synthesis. It is an effective treatment for malignancies with rapid cell proliferation such as acute lymphoblastic leukemia and choriocarcinoma, and also effective in treating psoriasis, rheumatoid arthritis and other autoimmune diseases. Administration of high-dose methotrexate followed by leucovorin rescue is an important component of the treatment. Following therapy, monitoring serum methotrexate levels is useful to assess if the drug is being cleared effectively and non-toxic levels are achieved.

The Test

Specimen: Serum, minimum volume requirement 0.5 mL
Neonate minimum volume requirement 150 µL

Performed: 24 hours daily

Reference Value: Nontoxic drug concentration after 48 hrs: < 0.2µmol/L
Nontoxic drug concentration after 72 hrs: < 0.1µmol/L

Increased Risk of Toxicity: >10 µmol/L post infusion concentration after 24 hrs.
>1.0 µmol/L post infusion concentration after 48 hrs.
>0.1 µmol/L post infusion concentration after 72 hrs

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