OVERVIEW FOR THE AU480/AU680/ AU5800 AND DxC 700 AU CLINICAL CHEMISTRY SYSTEMS

Since the 1970s, the therapeutic drug monitoring (TDM) assay has been used to help physicians monitor and maintain drug levels within a specific therapeutic range.[1] The therapeutic range is the concentration range in which a drug exerts its clinical effect with minimal adverse effects for most patients.[2]

For some drugs, maintaining this steady state can be difficult, because each person absorbs, metabolizes, utilizes and eliminates drugs differently. Additionally, therapeutic drug-monitoring rates may change over time—even on a daily basis—depending on disease states and interactions with other medications.

TDM assays can also assist in determining the patient's noncompliance (e.g., when the person does not take a prescribed medication regularly) and the effect of drug interactions, which may cause higher- or lower-than-expected drug concentrations at a given dosage.[3] In short, drug monitoring helps personalize a dose to fit the specific needs of the patient.

Overview:

An effective TDM program requires a comprehensive, broad menu of high-quality assays to support testing laboratories' goals. SYVA® Enzyme Multiplied Immunoassay Technique (EMIT®) TDM panel offers a comprehensive menu of reliable assays with ready-to-use reagents for effective testing on the AU480, AU680, AU5800 and DxC 700 AU analyzers. SYVA EMIT assays can provide accurate, efficient analysis of anticonvulsants, antiarrhythmics, aminoglycoside antibiotics and antiasthmatics.

AU5800

AU680

AU480

DxC 700 AU

BECKMAN COULTER

Product Benefits

Beckman Coulter offers a comprehensive panel of TDM assays, allowing greater consolidation of testing on one system. Beckman Coulter's SYVA EMIT TDM assays also deliver high-quality performance, giving technologists confidence in reported results.

In addition, SYVA EMIT TDM combines the specificity and sensitivity of immunoassay with the convenient speed and reproducibility of enzyme measurements. These high-quality assays help to improve patient care, while meeting the routine TDM assays combine requirements of the laboratory. Furthermore, SYVA EMIT helps optimize laboratory operations for clinical and operational efficiency.

SYVA EMIT DAT assays feature:

- Ready-to-use, all-liquid reagents, controls and calibrators with convenient storage at 2–8° C (36–46° F)
- Prefilled, ready-to-use AU barcoded reagent cartridges
- Enhanced formulation—eliminates interferences from hemolysis, lipemia and bilirubin
- Common sample types—serum and plasma

Methodology:

SYVA EMIT TDM chemistry utilizes a homogenous enzyme immunoassay method. The assay is based on competition between the drug in the specimen and the drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Since enzyme activity decreases upon binding to the antibody, the drug concentration is measured in terms of enzyme activity.

Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH—the reduced form of NAD—resulting in an absorbance change that is measured spectrophotometrically at 340 nm. Endogenous G6PDH does not interfere, because the coenzyme NAD functions only with the bacterial (i.e., *Leuconostoc mesenteroides*) enzyme employed in the assay.

Semiquantitative results are calculated through the use of multiple calibrator levels to provide an approximate cumulative concentration of the drugs and metabolites detected by the reagent. The results obtained during this screen provide a reliable estimate of the drug concentration, which can be used to prepare an appropriate dilution for gas chromatography and mass spectrometry (GC/MS) confirmatory testing. Semiquantitative drug screening reagents can be a valuable tool to evaluate drug treatment plan compliance and drug overdose medical emergencies.

EXPANDED TDM MENU OFFERING

- Acetaminophen
- Amikacin*
- Caffeine*
- Carbamazepine
- Digoxin
- Disopyramide*
- Ethosuximide*
- Gentamicin
- Lidocaine*
- Methotrexate*
- N-Acetylprocainamide
- Phenobarbital
- Phenytoin
- Primidone*
- Procainamide
- Quinidine
- Salicylic Acid
- Theophylline
- Tobramycin
- Valproic Acid
- Vancomycin

*Siemens SYVA® EMIT® off-the-shelf kits are NOT packaged in AU bottles.

For more information on TDM assays for the Beckman Coulter AU Clinical Systems, please visit www.siemens.com/bci-applications or contact your local sales representative today.

1. Touw, DJ et al. "Cost-effectiveness of Therapeutic Drug Monitoring: A Systematic Review." Ther Drug Monit, vol. 27. 2005, pp. 10-7.

2. Birkett, DJ et al. "Therapeutic Drug Monitoring." Aust Prescr, vol. 20. 1997, pp. 9-11.

3. Tange, SM et al. "Therapeutic Drug Monitoring in Pediatrics: A Need for Improvement." J Clin Pharmacol, vol. 34. 1994, pp. 200-14.

National Institute on Drug Abuse, Nationwide Trends, June 2015, https://www.drugabuse.gov/publications/drugfacts/nationwide-trends#asterisk. Accessed 25 Oct. 2017

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