DXC (STCX) TRICYCLICS SERUM

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PURPOSE

To provide instruction for the semiquantitative determination of tricyclic antidepressants in human serum on the DXC 600/800.

PRINCIPLE

The DRI Tricyclic Serum Tox Assay is intended for the semiquantitative determination of tricyclic antidepressants in human serum.

BACKGROUND

Clinical Significance

Amitriptyline, imipramine, and related compounds are tricyclic antidepressants that are widely used for the treatment of depression. Metabolites of amitriptyline and imipramine (nortriptyline and desimipramine, respectively) also possess antidepressant activity, but are less effective than the parent compounds. The most frequent side effects associated with the use of tricyclic antidepressants include dry mouth, constipation, dizziness, palpitations and urinary retention. Acute toxicity due to tricyclic antidepressants may lead to coma, cardiac arrhythmia, respiratory depression and death. Tricyclics have become the most common drug overdose case admitted to intensive care units. Detecting the presence of the drugs and determining its concentration in serum from patients suspected of drug overdose can assist the physician in diagnosing and treating the patient.

Methodology

The DRI Tricyclics Serum Tox Assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents. Specific tricyclic antibodies were used to detect most tricyclic antidepressants in serum. The test is based on the competition of as enzyme, glucose-6-phosphate dehydrogenase (G6PDH), labeled-drug and the drug from the sample for a fixed amount of specific antibody binding sites. In the absence of the drug from the sample, the specific antibody binds the enzyme-labeled drug and the enzyme activity is inhibited. The phenomenon creates a direct relationship between drug concentration in the sample and the enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide dinucleotide (NAD) to NADH.

RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
J-F-CH0826	DXC 800 Calibrators

M-F-CH0820 Chemistry Controls
M-F-CH0826 Chemistry Calibrators

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine are not recommended for use as a sample.

Specimen Storage and Stability

Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• 8 hours at 18-26**°C** • 48 hours at 2-8**°C**

NOTE: the LIS code to order this test is TTCA, the Beckman Coulter test name is STCX.

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

User-defined DRI Tricyclics Serum Tox Assay- Microgenics (STCX)

Beckman Coulter Kit product number- A45325. ThermoScientific kit product number- 1128.

Reagent Preparation

The reagents are ready for use.

Into a user-defined cartridge, pipette all 25 mL of Antibody/Substrate Reagent into the “A” compartment. Pipette all 8 mL of Enzyme Conjugate Reagent into “B” compartment.

The on-board expiration of the reagent is 60 days.

NOTE: For high volume testing, add **X2** Antibody/Substrate Reagent and Enzyme Conjugate Reagents into the specific compartments.

DRI Tricyclics Serum Tox Assay for SYNCHRON Systems	Compartment A of user defined cartridge	Compartment B of user defined cartridge
Antibody/Substrate Reagent	All 25 mls or 2 - 25 mls bottles for high volume use	
Enzyme Conjugate Reagent		All 8 mls or 2 – 8ml bottles for high volume use

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria.

Reagent Storage and Stability

STCX reagent when stored unopened at +2°C to +8°C will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable at +2°C to +8°C for 60 days. Do not use past the manufacturers expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

Microgenics DRI Serum Tox Negative Calibrator
Microgenics DRI Serum Tox Cal 1 (150 ng/mL)
Microgenics DRI Serum Tox Cal 2 (300 ng/mL)
Microgenics DRI Serum Tox Cal 3 (500 ng/mL)
Microgenics DRI Serum Tox Cal 4 (1000 ng/mL)

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the Microgenics DRI Serum Tox Calibrators should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable. Do not use beyond the manufacturer expiration dates.

Calibration Information

1. The system must have valid calibration factors in memory before controls or patient samples can be run.

2. Under typical operating conditions the STCX reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result.

ANTICOAGULANT TEST RESULTS

Anticoagulants such as heparin, citrates, oxalates and EDTA, were found not to interfere with the assay. Plasma samples collected with these anticoagulants may be used although a fresh serum sample is preferred.

PERFORMANCE CHARACTERISTICS

Reference Range

Reporting	Range
Theraputic range	0-300 ng/mL
Supratheraputic range	300-500 ng/mL
Toxic	>500 ng/mL Reported as 500-600 ng/mL 600-700 ng/mL 700-800 ng/mL >800 ng/mL

Reporting results outside the Analytical Range

Result	Report As
Results below 300 ng/mL	0-300 ng/mL
Results >800 ng/mL	>800 ng/mL

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for STCX determination is 40 ng/mL.

LIMITATIONS

Do not dilute samples since this is a semi- quantitative assay.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

Beckman DXC 800 Operations Manual

Microgenics DRI Tricyclics Serum Tox Assay Insert

DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Standardized formatting using small tables. Added new header.			
Committee Approval Date	☒ Date: 1/8/2015 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 7/30/15