Abbott AXSYM SYSTEM

en

Tricyclic Antidepressants

REF 3B34

34-6046/R09

Read Highlighted Changes
Revised September 2010

Tricyclic Antidepressants

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

REF	List Number
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
2°C–8°C	Store at 2-8°C
15°C–30°C	Store at 15-30°C
	Consult instructions for use
	Caution
EC REP	Authorized Representative in the European Community
	Manufacturer
	Expiration Date
CAL A	Calibrator (A-F)
ASSAY NO.	Assay Number
CHECKSUM	Checksum
CONTROL L	Control Low, Medium, High (L, M, H)
SAMPLE CUPS	Sample Cups
REAGENT PACK	Reagent Pack
REACTION VESSELS	Reaction Vessels
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

Abbott

NAME

Tricyclic Antidepressants

INTENDED USE

The AxSYM Tricyclic Antidepressants assay is a semi-quantitative reagent system for the measurement of tricyclic antidepressants in human serum or plasma. Measurements obtained are used in the diagnosis and treatment of tricyclic antidepressants overdose.

SUMMARY AND EXPLANATION OF TEST

The AxSYM Tricyclic Antidepressants assay utilizes Fluorescence Polarization Immunoassay (FPIA) technology. Refer to the AxSYM System Operations Manual, Section 3, under Principles of Operation for a discussion of this technology.

Depression is one of the most common human maladies. Tricyclic antidepressants (TCA) are widely used for the treatment of depressive illness. The most common tricyclic antidepressant drugs include imipramine, desipramine, amitriptyline and nortriptyline. Deliberate self-poisoning with TCA has become a major medical problem due to the widespread use of these drugs and the severity of the side effects. Patients with TCA overdose may develop a variety of symptoms and signs of intoxication. Detection of the drug concentration in the plasma or serum of patients with suspected drug overdose is helpful in confirming the diagnosis and selecting the appropriate treatment.[1-3]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The AxSYM Tricyclic Antidepressants assay is based on Fluorescence Polarization Immunoassay (FPIA) technology. The AxSYM Tricyclic Antidepressants Reagents and sample are pipetted in the following sequence:

SAMPLING CENTER

- Sample and all AxSYM Tricyclic Antidepressants Reagents required for one test are pipetted by the sampling probe into various wells of the Reaction Vessel (RV).
- Sample and Solution 4 (Line Diluent) are pipetted into one well of the RV.
- An aliquot of the prediluted sample, pretreatment and Solution 4 (Line Diluent) are transferred to the cuvette of the RV.

The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center with the processing probe.

PROCESSING CENTER

- A second aliquot of the predilution mixture is transferred to the cuvette along with the AxSYM Tricyclic Antidepressants Antiserum (antibody) and AxSYM Tricyclic Antidepressants Fluorescein Tracer.
- Tricyclic Antidepressants from the sample and the AxSYM Tricyclic Antidepressants Fluorescein Tracer compete for binding sites on the antibody molecule.
- The intensity of polarized fluorescent light is measured by the FPIA optical assembly.

For further information, refer to the AxSYM System Operations Manual, Section 3.

REAGENTS

REAGENT PACK, 100 TESTS

AxSYM Tricyclic Antidepressants Reagent Pack (3B34-20)*

- 1 Bottle (5.0 mL) < 0.01% Tricyclic Antidepressants Fluorescein Tracer in buffer with surfactant and protein stabilizer. Preservative: Sodium Azide. (Reagent Bottle 1)
- 1 Bottle (4.7 mL) < 25% Tricyclic Antidepressants Antiserum (Rabbit) in buffer with protein stabilizer and human serum. Preservative: Sodium Azide. (Reagent Bottle 2)
- 1 Bottle (4.4 mL) Pretreatment Solution with surfactant and protein stabilizer. Preservative: Sodium Azide. (Reagent Bottle 3)

*3B34-99 includes an AxSYM Tricyclic Antidepressants Reagent Pack (100 tests) and reaction vessels (100 each). 3B34-20 includes these items for international shipments.

CALIBRATORS

XSYSTEMS Tricyclic Antidepressants Calibrators (9681-02)

6 Bottles (2.5 mL each) of XSYSTEMS Tricyclic Antidepressants Calibrators. Calibrator A contains human serum and Calibrators B-F contain imipramine in human serum, to yield the following concentrations:

	Imipramine Concentration	
Bottle	(ng/mL)	(nmol/L)
CAL A	0	0.00
CAL B	75	267.45
CAL C	150	534.90
CAL D	300	1069.80
CAL E	600	2139.60
CAL F	1000	3566.00

Preservative: Sodium Azide.

Abbott manufactures internal reference standards for Tricyclic Antidepressants using Imipramine HCl (not less than 98% purity by TLC). Tricyclic Antidepressants calibrators are manufactured gravimetrically and tested against these internal reference standards.

CONTROLS

XSYSTEMS Tricyclic Antidepressants Controls (9681-11)

3 Bottles (2.5 mL each) of XSYSTEMS Tricyclic Antidepressants Controls contain imipramine in human serum to read within the following ranges:

	Imipramine Concentration		Range	
Bottle	(ng/mL)	(nmol/L)	(ng/mL)	(nmol/L)
CONTROL L	100	356.60	62.56 - 137.44	223.09 - 490.11
CONTROL M	200	713.20	141.19 - 258.81	503.48 - 922.92
CONTROL H	500	1783.00	398.93 - 601.07	1422.58 - 2143.42

Preservative: Sodium Azide.

OTHER REAGENTS

AxSYM Probe Cleaning Solution (9A35-05)

PROBE CLEANING SOLUTION 2 Bottles (220 mL each) AxSYM Probe Cleaning Solution containing 2% Tetraethylammoniumhydroxide (TEAH).

Solution 4 (Line Diluent) (8A46)

SOLUTION 4 LINE DILUENT 1 Bottle (10 L) Solution 4 (Line Diluent) containing 0.1 M Phosphate Buffer. Preservative: Sodium Azide and Antimicrobial Agent.

WARNINGS AND PRECAUTIONS

- **IVD**
- For *In Vitro* Diagnostic Use
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

SAFETY PRECAUTIONS

- ⚠ **CAUTION:** This product contains human sourced and/or potentially infectious components. Refer to the **REAGENTS** section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens[4]. Biosafety Level 2[5] or other appropriate biosafety practices[6,7] should be used for materials that contain or are suspected of containing infectious agents.
- The human serum used in the Tricyclic Antidepressants Antiserum, Calibrators and Controls is nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HCV and anti-HIV-1/HIV-2.
- This product contains sodium azide. For a specific listing, refer to the **REAGENTS** section. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

HANDLING PRECAUTIONS

- Do not use kits beyond the expiration date or a maximum of 336 cumulative hours on-board the AxSYM System.
- Do not mix reagents from different reagent packs regardless of lot number.

Refer to the AxSYM System Operations Manual, Sections 7 and 8, for a more detailed discussion of safety and handling precautions during system operation.

STORAGE INSTRUCTIONS

The AxSYM Tricyclic Antidepressants Reagent Pack, XSYSTEMS Tricyclic Antidepressants Calibrators and XSYSTEMS Tricyclic Antidepressants Controls must be stored at 2-8°C. They may be used immediately after removing them from the refrigerator. XSYSTEMS Calibrators and XSYSTEMS Controls should be returned to 2-8°C storage immediately after use.

Reagents are stable until the expiration date when stored and handled as directed.

The AxSYM Tricyclic Antidepressants Reagent Pack may be on-board the AxSYM System for a maximum of 336 cumulative hours; for example, 42 eight hour shifts. Recalibration may be required to obtain maximum on-board reagent stability. More frequent use of controls may be required to monitor reagent performance within the same lot. Refer to the AxSYM System Operations Manual, Sections 2, 5, and Appendix C for further information on tracking on-board time.

The AxSYM Probe Cleaning Solution and Solution 4 (Line Diluent) must be stored at 15-30°C.

INSTRUMENT PROCEDURE

Assay File Installation

The AxSYM Tricyclic Antidepressants Assay File must be installed on the AxSYM System from the software disk, 3D54-04, or higher (336 hours on-board Stability), prior to performing Tricyclic Antidepressants assays.

Refer to the AxSYM System Operations Manual, Section 2, for proper installation procedures.

NOTE: AxSYM Tricyclic Antidepressants Version 2.00.1 or higher must only be run with AxSYM(s) Software Version 3.00 or higher.

AxSYM Tricyclic Antidepressants Assay Parameters

The default values for the assay parameters used for the AxSYM Tricyclic Antidepressants assay are listed below. Assay parameters that can be edited contain a (>) symbol. These parameters can be displayed and edited according to the procedure in the AxSYM System Operations Manual, Section 2. In order to obtain values for the parameters with an asterisk (*), review the specific Assay Parameter Screen. Press **PRINT** to print the assay parameters.

Assay Parameters	
1	Long Assay Name (English): Tricyclics
6	Abbrev Assay Name (English): TCA
11	Assay Number: 555
12	Assay Version: *
13	Calibration Version: *
14	Assay file Revision: *
15	Assay Enabled > ON
17	Assay Type: FPIA
18	Standard Cal Reps > 2
21	Cal A Concentration: 0.00
22	Cal B Concentration: 75.00
23	Cal C Concentration: 150.00
24	Cal D Concentration: 300.00
25	Cal E Concentration: 600.00
26	Cal F Concentration: 1000.00
43	Default Dilution Protocol: > UNDILUTED
44	Default Calibration Method > Standard Cal
45	Selected Result Concentration Units > ng/mL
46	Selected Result Decimal Places > 2
62	Blank I-Max background intensity: *
63	Min Tracer-Min net intensity: *
73	Low Limit - Normal/Therapeutic Range lower limit > 0.00
74	High Limit - Normal/Therapeutic Range upper limit > 0.00
75	Low Extreme Value > 0.00
76	High Extreme Value > 0.00
91	Low Range Undiluted: *
92	High Range Undiluted: *

NOTE: Parameter 45 can be edited to the alternate result unit µg/mL or nmol/L.

Refer to the AxSYM System Operations Manual for a detailed description of Instrument Procedures.

SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

- Human serum or plasma (collected in heparin, citrate, EDTA, or oxalate collection tubes) may be used in the AxSYM Tricyclic Antidepressants assay. Other anticoagulants have not been tested with the AxSYM Tricyclic Antidepressants assay. Follow the manufacturer's processing instructions for serum or plasma collection tubes.
- **For optimal results, samples must be free of fibrin, red blood cells, or other particulate matter.**
- The AxSYM System does not provide the capability of verifying sample type. It is the responsibility of the operator to verify the correct sample type(s) is (are) used in the Tricyclic Antidepressants assay.
- Samples may be stored for up to 24 hours at 2-8°C prior to being tested. If testing will be delayed more than 24 hours, serum or plasma should be separated from the clot or red blood cells and stored frozen (-10°C or colder).
- Inspect all samples for bubbles. Remove bubbles prior to analysis.
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Refer to the AxSYM System Operations Manual, Section 5, for a detailed discussion of on-board sample storage constraints.

SAMPLE VOLUME

The minimum sample volume required to perform a single tricyclic antidepressants test from a sample cup is 150 µL for a ROUTINE test or 100 µL for a STAT test on the AxSYM System. An additional 50 µL of sample is required for every tricyclic antidepressants test performed (ROUTINE or STAT) from the same sample cup.

The sample cup minimum volume for both ROUTINE and STAT tests is calculated by the AxSYM System. It is displayed on the Order screen at the time the test(s) is (are) ordered. The STAT sample cup minimum volume is printed on the Orderlist Report.

When using Host Query, the Order screen information and Orderlist Report are not available. Refer to the AxSYM System Operations Manual, Section 5, for a description of the Host Order Query option.

If the assay is configured for auto retest, the additional sample volume needed for the retest will not be displayed on the Order screen at the time the test(s) is (are) ordered. Therefore, the total sample volume should include the additional sample volume stated above.

For sample volume requirements in primary or aliquot tubes, and calibrator and control requirements for multiple reagent lots, refer to the AxSYM System Operations manual, Section 5.

AxSYM TRICYCLIC ANTIDEPRESSANTS PROCEDURE

Materials Provided

- 3B34-99 AxSYM Tricyclic Antidepressants Reagent Kit containing:
  - AxSYM Tricyclic Antidepressants **REAGENT PACK**
  - 100 **REACTION VESSELS**

Materials Required But Not Provided

- 9681-02 XSYSTEMS Tricyclic Antidepressants Calibrators
- 9681-11 XSYSTEMS Tricyclic Antidepressants Controls
- 8A46 **SOLUTION 4 LINE DILUENT**
- 9A35-05 AxSYM **PROBE CLEANING SOLUTION**
- 8A76-01 **SAMPLE CUPS**
- Pipettes/Pipette tips (optional) to deliver the volume specified on the order screen

CAUTION: For optimal performance it is important to follow the routine maintenance procedures defined in the AxSYM System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Assay Procedure

Sections 5 and 6 of the AxSYM System Operations Manual contain detailed steps for performing assay calibration and sample testing procedures. Prior to ordering tests, confirm that the System inventory of Reaction Vessels and Solution 4 (Line Diluent) is sufficient.

The Orderlist Report contains sample placement information and sample cup volume requirements for all ordered tests. It is recommended that this report be referenced when loading samples into sample segments. When using Host Order Query, the Orderlist Report is not available. Refer to the AxSYM System Operations Manual, Section 5, for a description of the Host Order Query option.

CAUTION: When operating the AxSYM System, always observe the following:

- The System status must be WARMING, PAUSED, READY, or STOPPED before adding or removing sample segments, reagent packs or Reaction Vessels (RVs).
- An "Error Code 5066 Matrix cell not detected, trap door, processing center" may be displayed when the instrument homes the motors. If performing only FPIA (and/or REA) assays, select OK to proceed with testing.
- Do not open the Interior Waste Door or the AxSYM Processing Center Cover while any test is in process. If opened, all processing will stop. Tests in process will be terminated and must be repeated.
- When testing is completed, it is recommended that samples and the AxSYM Tricyclic Antidepressants Reagent Pack are removed from the Sampling Center to maximize the on-board reagent pack use. Store Reagent Pack at 2-8°C.

QUALITY CONTROL PROCEDURES

CALIBRATION

To review the detailed results of a calibration curve, refer to Section 6 of the AxSYM System Operations Manual.

To perform an AxSYM Tricyclic Antidepressants Calibration, test XSYSTEMS Tricyclic Antidepressants Calibrators A, B, C, D, E and F in duplicate. A single sample of all levels of controls must be tested to evaluate the assay calibration.

Once the AxSYM Tricyclic Antidepressants calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

- A reagent pack with a new lot number is used
- Control values are out of their specific range

Refer to the AxSYM System Operations Manual, Section 6, for:

- Setting up an assay calibration
- When recalibration may be necessary
- Calibration verification

The AxSYM System verifies that the results of an assay calibration meet the specifications assigned to selected validity parameters. An error message occurs when the calibration fails to meet a specification. Refer to the AxSYM System Operations Manual, Section 10, for an explanation of the corrective actions for the error code. Refer to the AxSYM System Operations Manual, Appendices, for an explanation of the calibration validity parameters that may be used by the AxSYM System.

Operator Verification

An acceptable AxSYM Tricyclic Antidepressants calibration curve should have all controls within the acceptable ranges.

QUALITY CONTROL

The recommended control requirement for an AxSYM Tricyclic Antidepressants assay is a single sample of at least two control levels tested once every 24 hours, each day of use. Controls may be placed in any position in the Sample Carousel.

If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow those procedures.

To achieve maximum on-board reagent stability, more frequent use of controls may be required to monitor reagent performance within the same lot.

Ensure that assay control values are within the concentration ranges specified in the package insert. Refer to the **REAGENTS**, CONTROLS section of this package insert for XSYSTEMS Tricyclic Antidepressants Control ranges.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and require retesting. Assay recalibration may be indicated. Refer to the AxSYM System Operations Manual, Section 10, Subsection: Observed Problems, for further troubleshooting information.

The AxSYM System has a capability to generate a Levey-Jennings plot of each assay's quality control performance. Refer to the AxSYM System Operations Manual, Section 5 for further information. At the discretion of the laboratory, selected quality control rules may be applied to the quality control data.

RESULTS

A Four Parameter Logistics Fit method (4PLC, Y weighted) is used to generate the AxSYM Tricyclic Antidepressants calibration curve. The calibration curve is stored in memory and concentrations of drug in controls and unknown samples are calculated from this curve using polarization values generated.

Alternate Result Units

The default unit for AxSYM Tricyclic Antidepressants is ng/mL. When selecting the alternate result unit, nmol/L the conversion factor used by the AxSYM System is 3.566. When selecting alternate result unit µg/mL, the conversion factor used by the AxSYM System is 0.001.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the AxSYM System Operations Manual, Section 1.

LIMITATIONS OF THE PROCEDURE

The AxSYM Tricyclic Antidepressants assay is primarily for the detection of the four major tricyclic antidepressants: amitriptyline, nortriptyline, imipramine and desipramine. Refer to the Specificity section in this assay insert for additional information on other tricyclic antidepressants which may cross-react with this assay.

The serum or plasma sample result is only an estimation of the total amount of tricyclic antidepressants and their demethylated metabolites present. Accurate quantitation of total tricyclic antidepressants or individual tricyclic antidepressants should be determined by a confirmatory assay methodology such as HPLC. Samples containing toxic concentrations of phenothiazines such as perphenazine, or other drugs structurally related to tricyclic antidepressants, such as cyclobenzaprine, may show interference in the assay. Refer to the Specificity section in this assay insert for additional information.

As with all analyte determinations, the tricyclic antidepressants value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

Serum samples with a background intensity greater than the allowable value are flagged with "Error Code 1065 Invalid test results, background intensity too high, (#)." These samples MUST NOT BE DILUTED AND RERUN.

SAMPLE DILUTION PROCEDURES

CAUTION: The automated dilution protocol, as described in the AxSYM System Operations Manual, Section 5, CANNOT BE USED with the AxSYM Tricyclic Antidepressants assay.

Manual Dilution Protocol

If a numerical value is desired for patient samples reported as > 1000 ng/mL, the serum or plasma sample may be manually diluted with XSYSTEMS Tricyclic Antidepressants Calibrator A and repeated on the AxSYM System. The concentration reported by the AxSYM System must be multiplied by the manual dilution factor to obtain the final sample concentration.

$$\text{Final Sample Concentration} = \text{Reported Concentration} \times \text{Manual Dilution Factor}$$

$$\text{Manual Dilution Factor} = \frac{\text{(Volume of Sample + Volume of Dilution Reagent)}}{\text{Volume of Sample}}$$

EXPECTED VALUES

Pharmacokinetic studies have shown there is a marked individual variation in the therapeutic and toxic response to tricyclic antidepressants at similar blood concentrations.[8] Cardiac effects have been demonstrated with TCA blood levels as low as 50.00-100.00 ng/mL. With levels greater than 500.00 ng/mL, the incidence of serious cardiac toxicity increases significantly. Above 1000.00 ng/mL, severe, sometimes fatal, cardiac and other side effects often occur.[9] In order to give effective treatment, blood levels as well as clinical symptoms should be continuously monitored if an overdose is suspected.

SPECIFIC PERFORMANCE CHARACTERISTICS

PRECISION

Precision was determined as described in National Committee for Clinical Laboratory Standards (NCCLS) Protocol EP5-T2.[10] A three member serum panel was assayed in duplicate, using a single lot of reagents and a single calibration, on two separate times per day for 20 days. Data from this study yielded %CVs of less than 10%. Representative data follow.

Control	Target Conc.	Mean Conc. Value	Within Run		Total Run	
Levels	(ng/mL)	(ng/mL)	SD	%CV	SD	%CV
Low	100	111.66	6.81	6.10	7.47	6.69
Medium	200	225.14	9.78	4.34	10.71	4.76
High	500	510.23	21.09	4.13	23.76	4.66

ACCURACY BY RECOVERY

Two sets of calibrators and controls were prepared by adding known quantities of imipramine to human serum and AxSYM Solution 4 (Line Diluent) to levels of 75, 100, 150, 200, 300, 500 and 600 ng/mL. The analyzer was calibrated with serum calibrators and both sets of calibrators and controls were assayed relative to this calibration. Percent recovery = 100 x ("concentration in Solution 4 (Line Diluent)" divided by "concentration in serum "). Representative data follow.

Added Concentration (ng/mL)	Concentration in serum (ng/mL)	Concentration in Solution 4 (ng/mL)	Percent (%) Recovery
75.00	72.80	77.74	106.79
100.00	93.55	101.57	108.57
150.00	151.04	153.14	101.39
200.00	201.08	212.09	105.47
300.00	287.12	291.77	101.62
500.00	536.33	536.51	100.03
600.00	610.80	611.63	100.14

Average Recovery = 103.43 ± 3.46%

SENSITIVITY

The sensitivity of the AxSYM Tricyclic Antidepressants assay was calculated to be 20.00 ng/mL. This sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with at least 95% confidence.

SPECIFICITY

Cross-reactivity was tested for tricyclic antidepressants and metabolites. The following compounds **cross-react** above the sensitivity (20.00 ng/mL) of the AxSYM Tricyclic Antidepressants assay:

COMPOUND	CONCENTRATION TESTED (ng/mL)
Amitriptyline	100
Clomipramine	400
Desipramine	100
Dibenzepin	2,950
Dothiepin	300
Doxepin	898
cis-10-Hydroxynortriptyline	689
2-Hydroxydesipramine	998
2-Hydroxyimipramine	700
Imipramine-N-oxide	700
Lofepramine	30,042
Nordoxepin	999
Nortriptyline	100
Opipramol	192
Protriptyline	999
Trans-10-Hydroxyamitriptyline	1,000
Trans-10-Hydroxynortriptyline	999
Trimipramine	1,000

Cross-reactivity was also tested for other antidepressants. The following compounds **cross-react** above the sensitivity (20.00 ng/mL) of the AxSYM Tricyclic Antidepressants assay:

COMPOUND	CONCENTRATION TESTED (ng/mL)
Maprotiline	1,000
Mianserin	420

Cross-reactivity was also tested with compounds that have similar chemical structure or are used concurrently. The following compounds **cross-react** above the sensitivity (20.00 ng/mL) of the AxSYM Tricyclic Antidepressants assay:

COMPOUND	CONCENTRATION TESTED (ng/mL)
Carbamazepine	29,972
Carbamazepine-10, 11-Epoxide	14,969
Chlorpromazine	2,000
Perphenazine	90
Phencyclidine	101
Prochlorperazine	999
Quetiapine Fumarate	2,484
Thioridazine	5,194

The following compounds **do not cross-react** above the sensitivity (20.00 ng/mL) of the AxSYM Tricyclic Antidepressants assay:

COMPOUND	CONCENTRATION TESTED (ng/mL)
Acetaminophen	251
Amoxapine	1,002
Amphetamine	999
Bupropion HCl	3,000
Citalopram HBr	599
Clonazepam	160
Clozapine	905
Diazepam	5,016
Ethchlorvynol	100,340
Fluoxetine	3,461
Fluphenazine	40
Flurazepam	500
Fluvoxamine Maleate	2,760
Lorazepam	998
Loxapine	60
Methaqualone	1,600
Mirtazapine	675
Morphine	499
Nefazodone	3,003
Nordiazepam	5,014
Olanzapine	300
Paroxetine HCl	1,000
Pimozide	150
Propoxyphene	1,601
Risperidone	362
Secobarbital	21,480
Sertraline	600
Temazepam	5,027
Thiothixene	100
Trazodone	5,022
Venlafaxine	299
Ziprasidone	660

INTERFERENCE

The following compounds resulted in less than 10% error in detecting added drug (200 ng/mL) when assayed with the AxSYM Tricyclic Antidepressants assay.

Compound	Concentration Tested	
Anticoagulants		
Citrate	4	mg/mL
EDTA	2	mg/mL
Heparin	20	Units/mL
Oxalate	2	mg/mL
Sodium Fluoride	8	mg/mL
Bilirubin	10	mg/dL
Hemoglobin	1	g/dL
Total Protein	9.6	g/dL
Triglycerides	1	g/dL

ACCURACY BY COMPARISON WITH REFERENCE ASSAY

The AxSYM Tricyclic Antidepressants assay was compared to TDx/TDxFLx and to HPLC. Samples were analyzed on-site at Abbott Laboratories and at a reference lab in Dallas,Texas. Representative data follows.

Manufacturer	Number of Observations	Slope	Y-Intercept	Correlation Coefficient
AxSYM Tricyclic Antidepressants vs. TDx/TDxFLx Tricyclic Antidepressants	81	0.95	2.61	0.990

For the AxSYM to TDx/TDxFLx comparison, samples were evaluated on the AxSYM to be within the range of 11.68 - 591.21 ng/mL and on the TDx/TDxFLx to be within the range of 19.68 - 606.44 ng/mL.

Sample Type	Conc. Range (ng/mL)	Number of Observations AxSYM	Number of Observations TDx/TDxFLx	Number of Observations HPLC
All Tricyclic Antidepressants	0 - 99	40	38	42
	100 - 199	26	29	14
	200 - 299	10	7	7
	≥ 300	7	9	20

For the AxSYM to TDx/TDxFLx comparison, samples were evaluated on the AxSYM to be within the range of 0 - 591.21 ng/mL and on the TDx/TDxFLx to be within the range of 0 - 606.44 ng/mL. For the AxSYM to HPLC comparison, samples were evaluated on the AxSYM to be within the range of 0 - 591.21 ng/mL and on the HPLC to be within the range of 0 - 674 ng/mL.

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