Phenytoin

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
- **i**: Consult instructions for use
- **STANDARD CAL**: Standard Calibrator (A-F)
- **CONTROL L**: Control Low, Medium, High (L, M, H)
- **REAGENT PACK**: Reagent Pack
- **REACTION VESSELS**: Reaction Vessels
- **MATRIX CELLS**: Matrix Cells
- **SAMPLE CUPS**: Sample Cups
- **CONTAINS AZIDE**: Contains Sodium Azide. Contact with acids liberates very toxic gas.
- **EC REP**: Authorized Representative in the European Community

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

**INTENDED USE**
The AxSYM Phenytoin assay is a reagent system for the quantitative measurement of phenytoin, an anticonvulsant drug, in serum or plasma. The measurements obtained are used in monitoring levels of phenytoin to ensure appropriate therapy.

**SUMMARY AND EXPLANATION OF THE TEST**
The AxSYM Phenytoin assay uses Fluorescence Polarization Immunoassay (FPIA) technology. Refer to the AxSYM System Operations Manual, Section 3, under Principles of Operation, for a discussion of this technology.

Phenytoin (Dilantin) is one of the most widely prescribed anticonvulsants and is occasionally used as a myocardial antiarrhythmic. In the treatment of epilepsy, phenytoin is indicated for grand mal epilepsy (major motor) and is occasionally used as a myocardial antiarrhythmic. In the treatment of epilepsy, phenytoin is indicated for grand mal epilepsy (major motor) and cortical focal seizures and temporal lobe epilepsy.

The main pathway (about 90%) for disposition of phenytoin is by excretion of the glucuronide of para-hydroxyphenylhydantoin (HPPH) in the urine. It is hydroxylated in the liver and eliminated. The metabolic conversion to HPPH is a saturable process and in many cases small increments in dosage can cause a large increase in phenytoin plasma level. Because of the narrow therapeutic index and the wide interindividual variability in the rate of phenytoin metabolism and clearance, the determination of blood levels of phenytoin for patients receiving therapy is essential.

**BIOLOGICAL PRINCIPLES OF THE PROCEDURE**
The AxSYM Phenytoin assay is based on Fluorescence Polarization Immunoassay (FPIA) technology. The AxSYM Phenytoin Reagents and sample are pipetted in the following sequence:

**SAMPLING CENTER**
- Sample and all AxSYM Phenytoin Reagents required for one test are pipetted by the sampling probe into various wells of a Reaction Vessel (RV).
- Sample and Solution 4 (Line Diluent) are pipetted into one well of the RV.
- An aliquot of the predilution mixture, pretreatment solution 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 by the Processing Probe.

**PROCESSING CENTER**
- A second aliquot of the predilution mixture is transferred to the cuvette along with the Phenytoin Antiserum (antibody) and the Phenytoin Fluorescein Tracer.
- Phenytoin from the sample and the Phenytoin 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 Phenytoin Reagent Pack (7A67-201*
- 1 Bottle (14.5 mL) <5% Phenytoin Antiserum (Sheep, Polyclonal) in normal saline with protein stabilizers. Preservative: Sodium Azide. (Reagent Bottle 1)
- 1 Bottle (8.6 mL) Pretreatment Solution. Surfactant in Phosphate buffer. Preservative: Sodium Azide. (Reagent Bottle 2)
- 1 Bottle (15.1 mL) >0.01% Phenytoin Fluorescein Tracer in Phosphate buffer containing surfactant. Preservative: Sodium Azide. (Reagent Bottle 3)

*7A67-99 includes an AxSYM Phenytoin Reagent Pack (100 Tests) and Reaction Vessels (100 each). 7A67-20 includes these items for international shipments.

**CALIBRATORS**
AxSYM Phenytoin Standard Calibrators (7A67-01)
6 Bottles (6 mL A, 4 mL each B-F) of AxSYM Phenytoin Standard Calibrators contain accurately measured amounts of phenytoin prepared in human serum to yield the following concentrations:

<table>
<thead>
<tr>
<th>Bottle</th>
<th>Concentration (µg/mL)</th>
<th>(µmol/L)</th>
<th>Range</th>
<th>(µg/mL)</th>
<th>(µmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STANDARD CAL A</td>
<td>0.0</td>
<td>0.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STANDARD CAL B</td>
<td>2.5</td>
<td>9.90</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STANDARD CAL C</td>
<td>5.0</td>
<td>19.80</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STANDARD CAL D</td>
<td>10.0</td>
<td>39.60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STANDARD CAL E</td>
<td>20.0</td>
<td>79.20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STANDARD CAL F</td>
<td>40.0</td>
<td>158.40</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Preservative: Sodium Azide


**CONTROLS**
AxSYM Phenytoin Controls (7A67-10)
3 Bottles (8 mL each) of AxSYM Phenytoin Controls contain phenytoin prepared in human serum to yield the following concentration ranges:

**SAFETY PRECAUTIONS**
- **IVD:**
- **For In Vitro Diagnostic Use Only**

**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. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

- The human serum used in Standard Calibrators A-F and the Controls is nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.
- 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 Reagent Packs beyond the expiration date or a maximum of 336 cumulative hours on-board the AxSYM System.
- Do not mix reagents from different Reagent Packs.

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

STORAGE INSTRUCTIONS

The AxSYM Phenytoin Reagents are light sensitive. When the AxSYM Reagent Pack is not on the AxSYM Analyzer, the pack must be stored protected from light.

Reagents are stable until the expiration date when stored and handled according to the procedure in the AxSYM System Operations Manual, Sections 2, 5, and Appendix C for further information on tracking on-board time. Refer to the AxSYM System Operations Manual, Sections 2, 5, and Appendix C for further information on tracking on-board time.

Reagents are stable until the expiration date when stored and handled according to the procedure in the AxSYM System Operations Manual, Sections 2, 5, and Appendix C for further information on tracking on-board time.

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The AxSYM Phenytoin 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.

To obtain values for the parameters with an asterisk (*), review the specific Assay Parameter screen. Press PRINT to print the assay parameters.

SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

Samples from patients receiving fosphenytoin should be drawn at least 2 hours following IV administration and 4 hours following IM administration per the recommendations of the manufacturer. The change in the phenytoin concentration is dependent on the amount of time that has elapsed since the administration of fosphenytoin.

- Human serum or plasma (collected in sodium heparin, citrate, EDTA, or oxalate collection tubes) may be used in the AxSYM Phenytoin assay. Other anticoagulants have not been tested with the AxSYM Phenytoin assay. Follow the manufacturer’s processing instructions for serum or plasma collection tubes.
- Serum separator tubes (SSTS) are not recommended for blood collection in phenytoin monitoring. A reduction in phenytoin concentration has been shown with SST samples. Concentration changes were dependent on the time the samples remained in the SSTs prior to testing.
- The AxSYM System does not provide the capability of verifying sample type. It is the responsibility of the operator to verify the correctness of the assay type(s) used in the AxSYM Phenytoin assay.
- Ensure that complete clot formation has taken place prior to centrifugation. Some samples, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the sample is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- Specimens containing particulate matter or red blood cells may give inconsistent results and should be centrifuged before testing (recommended 8,000-10,000 RCF x 10 minutes).
- For optimal results, specimens should be free of fibrin, red blood cells, or other particulate matter.
- Samples may be stored for up to 24 hours at 2-8°C prior to being tested.
- To minimize the effects of evaporation, all samples (patient specimens, controls, and calibrators) should be tested within 3 hours of being placed on-board the AxSYM System. Refer to the AxSYM System Operations Manual, Section 5, for a more detailed discussion of on-board sample storage constraints.
- Inspect all samples for bubbles. Remove bubbles prior to analysis.
- When shipped, samples must be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical samples and infectious substances.
- Performance has not been established using cadaver specimens or body fluids other than human serum or plasma.
- Specimens with obvious microbial contamination should not be used.
- AxSYM Phenytoin Calibrators and Controls should be mixed by gentle inversion prior to use.

*Relative Centrifugal Force. SAMPLE VOLUME

The sample volume required to perform a single undiluted phenytoin test on the AxSYM System varies depending on the type of sample container used. For sample cups, a ROUTINE or STAT test requires 180 µL. For every additional AxSYM Phenytoin test performed (ROUTINE or STAT) from the same sample container, an additional 130 µL of sample is required.

TABLE 1: AxSYM Phenytoin Assay Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspended</td>
<td>False</td>
</tr>
<tr>
<td>Time</td>
<td>720.8</td>
</tr>
<tr>
<td>Value</td>
<td>100.0</td>
</tr>
<tr>
<td>Value</td>
<td>100.0</td>
</tr>
<tr>
<td>Value</td>
<td>100.0</td>
</tr>
<tr>
<td>Value</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Note: Parameter #44 is not editable. Parameter #45 can be edited to the alternate result unit μmol/L or mg/L.

VALUES ASSOCIATED WITH THE LOW AND HIGH EXTREME FLAGS, ASSAY PARAMETERS #75 AND 76, ARE ASSAY SPECIFIC AND SHOULD NOT BE EDITED.
The sample cup minimum volumes for both ROUTINE and STAT tests (undiluted or diluted) are calculated by the AxSYM System. They are displayed on the Order screen at the time the test(s) is(are) ordered and printed on the Orderlist Report. When using Host Order 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/auto dilution 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 130 µL of sample. Refer to the AxSYM System Operations Manual, Section 2, for details on Automatic Sample Retest Configuration.

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.

To obtain the recommended volume requirements for the AxSYM Phenytoin Calibrators, hold the bottles vertically and dispense 6-8 drops of each calibrator into each respective sample cup.

To obtain the recommended volume requirements for the AxSYM Phenytoin Controls, hold the bottles vertically and dispense 8-10 drops of each control into each respective sample cup.

AxSYM PHENYTOIN PROCEDURE

Materials Provided

- 7A67-99 AxSYM Phenytoin Reagent Kit, containing:
  - AxSYM Phenytoin REAGENT PACK
  - 100 REACTION VESSELS

Materials Required But Not Provided

- AxSYM System
- 7A67-01 AxSYM Phenytoin Standard Calibrators
- 7A67-10 AxSYM Phenytoin Controls
- 8A46 SOLUTION [LINE DILUENT]
- 9A35-05 AxSYM PROBE CLEANING SOLUTION
- 8A76-01 SAMPLE CUPS
- Pipettes and pipette tips (optional) to deliver the volumes 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.
- When manually dispensing sample into sample cups, verify that dispensing equipment does not introduce cross contamination and delivers the specified sample volume. Use a separate pipette tip for each sample. Use accurately calibrated equipment.

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 bulk solutions and waste levels are acceptable. The Orderlist Report contains sample placement information and sample cup volume requirements for all tests ordered. 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 Phenytoin Reagent Pack are removed from the Sampling Center to maximize the on-board reagent pack use. Store Reagent Pack protected from light at 2-8°C.

QUALITY CONTROL PROCEDURES

CALIBRATION

The AxSYM Phenytoin assay must be calibrated using a Standard Calibration (6-point) procedure.

Standard Calibration

To perform a Standard Calibration, test the AxSYM Phenytoin Standard Calibrators A, B, C, D, E, and F in duplicate. A single sample of all levels of Phenytoin controls must be tested as a means of evaluating the assay calibration.

Once the AxSYM Phenytoin 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 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, Appendix E, for an explanation of the calibration quality control parameters that may be used by the AxSYM System.

Operator Verification

An acceptable AxSYM Phenytoin calibration curve should meet the following criteria:

a) Polarization Error (PERR) 0.00 to +3.00 for all calibrators.

b) Root Mean Squared Error (RMSE) less than or equal to 2.00.

c) L, M and H controls are all within the acceptable ranges.

NOTE: PERR’s and RMSE’s are to be used as guidelines only. If controls are within specified ranges, the calibration curve is acceptable.

QUALITY CONTROL

The recommended control requirement for the AxSYM Phenytoin assay is a single sample of at least two different Phenytoin control levels, which span the medical decision range, 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 this package insert. Refer to the REAGENTS, CONTROLS section of this package insert for AxSYM Phenytoin Control ranges.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

When a Phenytoin 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, 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

CALCULATION

AxSYM Phenytoin assay utilizes a Four Parameter Logistic Curve Fit method (4PLC, Y weighted) to generate a calibration curve. This curve is stored in memory and concentrations of drug in controls and unknown samples are calculated from this curve using polarization values generated.

Flags

Some results may contain information in the Flags field. Samples flagged as low extreme values (LL), Assay Parameter #75, must be reviewed prior to reporting assay results. Results at or near the assay sensitivity should be verified prior to reporting drug concentrations.

For a description of the other flags that may appear in this field, refer to the AxSYM System Operations Manual, Sections 1 and 2.
LIMITATIONS OF THE PROCEDURE
Uremic specimens may exhibit a positive bias with the Phenytoin assay.16
Samples from patients receiving fosphenytoin should be drawn at least 2 hours following IV administration and 4 hours following IM administration according to the recommendations of the manufacturer. Phenytoin concentrations measured before complete conversion of fosphenytoin will not reflect phenytoin concentrations ultimately achieved.

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

Refer to the SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS section in this package insert for additional information.

SAMPLE DILUTION PROCEDURES

Automated Dilution Protocol

Patient samples with phenytoin concentrations reported as greater than 40.00 µg/mL may be diluted using an automated dilution protocol. The AxSYM System automatically calculates the concentration of the diluted sample and reports the result. Refer to the AxSYM System Operations Manual, Section 5, for additional information on ordering sample dilutions.

Manual Dilution Protocol

Patient samples with phenytoin concentrations reported as greater than 160.00 µg/mL by the Automated Dilution Protocol may be diluted using a manual dilution of 1:10. Add one part of the patient sample to nine parts of the AxSYM Phenytoin Calibrator A. Repeat the test using this manually diluted sample. The concentration reported by the AxSYM System must be multiplied by the manual dilution factor to obtain the final sample concentration.

Final Sample Concentration = Printed Concentration x Manual Dilution Factor

Manual Dilution Factor = (Volume of Sample + Volume of Dilution Reagent) / Volume of Sample

EXPECTED VALUES

Strong correlations have been shown between serum levels and both therapeutic effect and toxicity.14 Clinical observations indicate that toxicity of phenytoin is increased in patients with renal disease.16 Phenytoin toxicity primarily affects the central nervous system. Toxic levels can lead to nystagmus, vertigo, ataxia, psychoses and even convulsions.7 Chronic treatment leads to hyperplasia of gums,11 anemia12 and osteomalacia.13 The frequency and severity of dose-dependent toxic effects increases as the serum level rises above 20 µg/mL. Most patients will receive maximum seizure control when serum levels of phenytoin are in the range of 10-20 µg/mL.14,16

Refer to the drug manufacturer’s package insert or the Physicians’ Desk Reference (PDR) for proper drug dosage and for phenytoin measurement sampling times.

SPECIFIC PERFORMANCE CHARACTERISTICS

PRECISION

Precision was determined as described in National Committee for Clinical Laboratory Standards (NCCLS) protocol EP5-T215 using human serum with 7.5, 15.0, and 30.0 µg/mL of phenytoin added. Results from these studies typically yielded CV’s of less than 5%.

Representative data are shown in the following table.

<table>
<thead>
<tr>
<th>Added Concentration (µg/mL)</th>
<th>Concentration in serum (µg/mL)</th>
<th>Concentration in Buffer (µg/mL)</th>
<th>Percent (%) Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>2.69</td>
<td>2.50</td>
<td>107.6</td>
</tr>
<tr>
<td>4.0</td>
<td>4.18</td>
<td>4.00</td>
<td>104.5</td>
</tr>
<tr>
<td>8.0</td>
<td>8.09</td>
<td>8.38</td>
<td>96.5</td>
</tr>
<tr>
<td>12.0</td>
<td>11.84</td>
<td>11.93</td>
<td>99.2</td>
</tr>
<tr>
<td>16.0</td>
<td>16.63</td>
<td>16.60</td>
<td>100.2</td>
</tr>
<tr>
<td>20.0</td>
<td>19.78</td>
<td>19.63</td>
<td>100.8</td>
</tr>
<tr>
<td>30.0</td>
<td>30.97</td>
<td>29.36</td>
<td>105.5</td>
</tr>
<tr>
<td>36.0</td>
<td>36.86</td>
<td>37.81</td>
<td>98.0</td>
</tr>
</tbody>
</table>

Average Recovery: 101.5 ± 3.9%

SENSITIVITY

The sensitivity of the AxSYM Phenytoin assay was calculated to be 0.50 µg/mL. This sensitivity is defined as the lowest measurable concentration that can be distinguished from zero with 95% confidence.

SPECIFICITY

Cross-reactivity was tested for compounds whose chemical structure or concurrent usage could cause potential interference with the Phenytoin assay. Cross-reactivity was tested in the presence of phenytoin for the phenytoin major metabolites, 5-(4-hydroxyphenyl) -5-phenylhydantoin (p-HPPH) and p-HPPH glucuronide. p-HPPH (5 µg/mL) showed less than a 3 µg/mL change in drug concentration when tested at the low and high ends of the phenytoin therapeutic range (10-20 µg/mL) and p-HPPH-glucuronide (100 µg/mL) showed less than a 7 µg/mL change in drug concentration when tested at the low and high ends of the phenytoin therapeutic range (10-20 µg/mL).

Mephenytoin and its major metabolite, 5-Ethyl-5-phenyl-hydantoin, tested at concentrations that correspond to high plasma levels in epileptic patients, showed phenytoin concentrations below the assay sensitivity.

Oxaprozin showed less than 1% cross-reactivity when tested with the Phenytoin assay.

Fosphenytoin, a phosphate ester of the anti-convulsant phenytoin, cross-reacts with the Abbott Phenytoin assays due to its structural similarity. However, cross-reactivity is not an issue with the Abbott Phenytoin assays if patient samples are drawn at least 2 hours following IV administration and 4 hours following IM administration. See SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS and LIMITATIONS OF THE PROCEDURE sections for further information.

INTERFERENCE

The compounds listed below, added to human serum, resulted in less than 10% error in detecting added drug when assayed with the AxSYM Phenytoin assay.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration Tested</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>15 mg/dL</td>
<td>&lt; 5% error</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1.0 g/dL</td>
<td>&lt; 5% error</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>900 mg/dL</td>
<td>&lt; 5% error</td>
</tr>
<tr>
<td>Total Protein</td>
<td>10.0 g/dL</td>
<td>&lt; 10% error</td>
</tr>
</tbody>
</table>

ACCURACY BY RECOVERY

Recovery was determined by adding phenytoin to human serum and to buffer at concentrations of 2.5, 4.0, 8.0, 12.0, 16.0, 20.0, 30.0 and 36.0 µg/mL. The concentration of phenytoin was determined using the AxSYM Phenytoin assay, and the resulting % recovery was calculated according to the following equation:

% Recovery = ("serum concentration" divided by "buffer concentration") x 100.

Representative data are shown in the following table.

<table>
<thead>
<tr>
<th>Added Concentration (µg/mL)</th>
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<td>8.0</td>
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<td>8.38</td>
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</tr>
<tr>
<td>12.0</td>
<td>11.84</td>
<td>11.93</td>
<td>99.2</td>
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<td>29.36</td>
<td>105.5</td>
</tr>
<tr>
<td>36.0</td>
<td>36.86</td>
<td>37.81</td>
<td>98.0</td>
</tr>
</tbody>
</table>

Average Recovery: 101.5 ± 3.9%

ACCURACY BY CORRELATION

The Abbott AxSYM Phenytoin assay was compared to a Fluorescence Polarization Immunoassay. The results of the specimen testing are shown in the following table.

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<tr>
<th>Compound</th>
<th>Concentration Tested</th>
<th>Results</th>
</tr>
</thead>
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<td>Hemoglobin</td>
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</tr>
<tr>
<td>Triglycerides</td>
<td>900 mg/dL</td>
<td>&lt; 5% error</td>
</tr>
<tr>
<td>Total Protein</td>
<td>10.0 g/dL</td>
<td>&lt; 10% error</td>
</tr>
</tbody>
</table>

ACCURACY BY RECOVERY

Recovery was determined by adding phenytoin to human serum and to buffer at concentrations of 2.5, 4.0, 8.0, 12.0, 16.0, 20.0, 30.0 and 36.0 µg/mL. The concentration of phenytoin was determined using the AxSYM Phenytoin assay, and the resulting % recovery was calculated according to the following equation:

% Recovery = ("serum concentration" divided by "buffer concentration") x 100.

Representative data are shown in the following table.

<table>
<thead>
<tr>
<th>Added Concentration (µg/mL)</th>
<th>Concentration in serum (µg/mL)</th>
<th>Concentration in Buffer (µg/mL)</th>
<th>Percent (%) Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>2.69</td>
<td>2.50</td>
<td>107.6</td>
</tr>
<tr>
<td>4.0</td>
<td>4.18</td>
<td>4.00</td>
<td>104.5</td>
</tr>
<tr>
<td>8.0</td>
<td>8.09</td>
<td>8.38</td>
<td>96.5</td>
</tr>
<tr>
<td>12.0</td>
<td>11.84</td>
<td>11.93</td>
<td>99.2</td>
</tr>
<tr>
<td>16.0</td>
<td>16.63</td>
<td>16.60</td>
<td>100.2</td>
</tr>
<tr>
<td>20.0</td>
<td>19.78</td>
<td>19.63</td>
<td>100.8</td>
</tr>
<tr>
<td>30.0</td>
<td>30.97</td>
<td>29.36</td>
<td>105.5</td>
</tr>
<tr>
<td>36.0</td>
<td>36.86</td>
<td>37.81</td>
<td>98.0</td>
</tr>
</tbody>
</table>

Average Recovery: 101.5 ± 3.9%
BIBLIOGRAPHY


Related Reading


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