Abbott
AXSYM
SYSTEM

en
Quinidine
REF 7A73
34-5421/R7

# Quinidine

**Customer Service**
**United States: 1-877-4ABBOTT**
**International: Call your Abbott Representative**

This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

**Read Highlighted Changes**
**Revised May, 2009**

## Key to symbols used

| | | | |
|---|---|---|---|
| REF | List Number | LOT | Lot Number |
| IVD | *In Vitro* Diagnostic Medical Device | | Expiration Date |
| 2°C 8°C | Store at 2-8°C | STANDARD CAL A | Standard Calibrator (A-F) |
| 15°C 30°C | Store at 15-30°C | CONTROL L | Control Low, Medium, High (L, M, H) |
| | Caution, consult accompanying documents | REAGENT PACK | Reagent Pack |
| | Consult instructions for use | REACTION VESSELS | Reaction Vessels |
| | | SAMPLE CUPS | Sample Cups |
| | Manufacturer | EC REP | Authorized Representative |

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

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## NAME
Quinidine

## INTENDED USE
The AxSYM Quinidine assay is a reagent system for the quantitative measurement of quinidine in serum or plasma. The measurements obtained are used in monitoring levels of quinidine to ensure appropriate therapy.

## SUMMARY AND EXPLANATION OF TEST
The AxSYM Quinidine assay utilizes Fluorescence Polarization Immunoassay (FPIA) technology.[1,2] Refer to the AxSYM System Operations Manual, Section 3, under Principles of Operation for a discussion of this technology.

Quinidine is a naturally occurring alkaloid which is used to treat cardiac arrhythmias. It is given orally or parenterally as the sulfate, gluconate, or polygluconate forms of the drug, and intravenously by administering quinidine gluconate by slow infusion.[3-5] Quinidine is used to prevent both atrial and ventricular arrhythmias.[6] Quinidine has a narrow therapeutic index and the therapeutic and toxic effects have been shown to be related to quinidine serum or plasma concentrations.[7,8] Patient response to treatment with quinidine has been noted to vary widely.[9] This is due to patient-to-patient variation in bioavailability, metabolism and elimination.[10] To attain optimum therapy, monitoring of serum levels of quinidine in patients receiving the drug is recommended.

Quinidine is bound to protein, principally albumin, to the extent of 70-80%. Plasma protein binding of the drug is reduced in liver disease.[11] Quinidine is metabolized in the liver. Principle metabolites, as found in serum, are 3-hydroxyquinidine, 2'-oxoquinidine and O-desmethylquinidine.[12] 3-Hydroxyquinidine is reported to have an antiarrhythmic potency possibly equal to that of quinidine.[10]

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

SAMPLING CENTER

- Sample and all AxSYM Quinidine 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 with the processing probe.

PROCESSING CENTER

- A second aliquot of the predilution mixture is transferred to the cuvette along with the Quinidine Antiserum (antibody) and the Quinidine Fluorescein Tracer.
- Quinidine from the sample and the Quinidine 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 Quinidine Reagent Pack (7A73-20)*

- 1 Bottle (14.5 mL) <1% Quinidine Antiserum (Goat, Polyclonal) in Phosphate buffer with protein stabilizers. Preservative: Sodium Azide. (Reagent Bottle 1)
- 1 Bottle (8.6 mL) Pretreatment Solution. Surfactant in TRIS buffer. Contains N,N-Dimethylformamide. Preservative: Sodium Azide. (Reagent Bottle 2)
- 1 Bottle (15.1 mL) <0.01% Quinidine Fluorescein Tracer in TRIS buffer containing surfactant. Preservative: Sodium Azide. (Reagent Bottle 3)

*7A73-99 includes an AxSYM Quinidine Reagent Pack (100 Tests) and Reaction Vessels (100 each). 7A73-20 includes these items for international shipments.

CALIBRATORS

AxSYM Quinidine Standard Calibrators (7A73-01)

6 Bottles (6 mL A, 4 mL each B-F) of AxSYM Quinidine Standard Calibrators contain accurately measured amounts of quinidine prepared in human serum to yield the following concentrations:

| | Quinidine Concentration | |
|---|---|---|
| Bottle | (µg/mL) (mg/L) | (µmol/L) |
| STANDARD CAL A | 0.0 | 0.00 |
| STANDARD CAL B | 0.5 | 1.54 |
| STANDARD CAL C | 1.0 | 3.08 |
| STANDARD CAL D | 2.0 | 6.16 |
| STANDARD CAL E | 4.0 | 12.32 |
| STANDARD CAL F | 8.0 | 24.64 |

Preservative: Sodium Azide

Abbott manufactures internal reference standards using Quinidine (USP Reference Standard) or Quinidine Sulfate (contains not less than 99.0% and not more than 101.0% $(C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4$ on the anhydrous basis). Quinidine calibrators are manufactured gravimetrically and tested against these internal reference standards.

CONTROLS

AxSYM Quinidine Controls (7A73-10)

3 Bottles (8 mL each) of AxSYM Quinidine Controls contain quinidine prepared in human serum to yield the following concentration ranges:

| | Quinidine | | | |
|---|---|---|---|---|
| | Concentration | | Range | |
| Bottle | (µg/mL) (mg/L) | (µmol/L) | (µg/mL) (mg/L) | (µmol/L) |
| CONTROL L | 1.5 | 4.62 | 1.28 - 1.73 | 3.94 - 5.33 |
| CONTROL M | 3.0 | 9.24 | 2.64 - 3.36 | 8.13 - 10.35 |
| CONTROL H | 6.0 | 18.48 | 5.28 - 6.72 | 16.26 - 20.70 |

Preservative: Sodium Azide

The AxSYM Quinidine reporting unit is factory set to µg/mL. An alternate unit (µmol/L or mg/L) may be selected for reporting results (Assay Parameter 45).

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 0.1M Phosphate Buffer. Preservatives: Sodium Azide and Antimicrobial Agents.

## WARNINGS AND PRECAUTIONS
IVD

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[13]. Biosafety Level 2[14] or other appropriate biosafety practices[15,16] should be used for materials that contain or are suspected of containing infectious agents.
- The human serum used in the AxSYM Quinidine Standard Calibrators and AxSYM Quinidine 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.
- The AxSYM Quinidine Pretreatment Solution (Reagent Bottle 2) listed in the **REAGENTS** section of this package insert contains N,N-Dimethylformamide and is classified per applicable European Community (EC) Directives as: Toxic (T). The following are the appropriate Risk (R) and Safety (S) phrases.

| | |
|---|---|
| R61 | May cause harm to the unborn child. |
| S53 | Avoid exposure-obtain special instructions before use. |
| S35 | This material and its container must be disposed of in a safe way. |
| S28 | After contact with skin, rinse immediately with plenty of water. |
| S36/37/39 | Wear suitable protective clothing, gloves, and eye/face protection. |
| S45 | In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). |

Restricted to professional users. Attention - Avoid Exposure - Obtain special instructions before use.

For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.

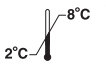
HANDLING PRECAUTIONS

- 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.

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

## STORAGE INSTRUCTIONS

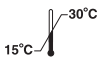
**The AxSYM Quinidine Reagents are light sensitive. When the AxSYM Reagent Pack is not on the AxSYM analyzer, the pack must be stored protected from light.**




The AxSYM Quinidine Reagent Pack, Calibrators and Controls must be stored at 2-8˚C. The AxSYM Quinidine Reagent Pack, Calibrators and Controls may be used immediately after removing them from the refrigerator. Calibrators and controls should be returned to 2-8˚C storage immediately after use. Do not freeze AxSYM Quinidine Reagents.

The AxSYM Quinidine 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, Section 2, for further information on tracking on-board time.

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




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

## INSTRUMENT PROCEDURE

Assay File Installation

The AxSYM Quinidine assay file must be installed on the AxSYM System from one of the following software disks, prior to performing Quinidine assays:

- 8A83-01, or higher (112 hours on-board Stability)
- 3D53-01, or higher (336 hours on-board Stability)

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

AxSYM Quinidine Assay Parameters

The default values for the assay parameters used for the AxSYM Quinidine 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): Quinidine |
| 6 | Abbrev Assay Name (English): Quin |
| 11 | Assay Number: 705 |
| 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: 0.50 |
| 23 | Cal C Concentration: 1.00 |
| 24 | Cal D Concentration: 2.00 |
| 25 | Cal E Concentration: 4.00 |
| 26 | Cal F Concentration: 8.00 |
| 43 | Default Dilution Protocol >UNDILUTED |
| 44 | Default Calibration Method > Standard Calibration |
| 45 | Selected Result Concentration Units > ug/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 | Hi Limit-Normal/Therapeutic Range upper limit > 0.00 |
| 75 | Low Extreme Value > 0.30 |
| 76 | High Extreme Value > 80.00 |
| 91 | Low Range Neat: * |
| 92 | High Range Neat: * |

**Note:** 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.

We recommend that you set General Configuration Parameter, Release Mode, to the “Manual” or “Hold” release mode to ensure that all flagged results are reviewed prior to reporting assay results. Refer to the AxSYM System Operations Manual, Section 2, for a detailed description of Instrument Procedures. If General Configuration Parameter, Release Mode, is configured in the “Automatic” release mode, ensure that all flagged results are reviewed prior to reporting assay results.

## SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

- Serum or plasma (collected in heparin, citrate, EDTA, or oxalate collection tubes) may be used in the AxSYM Quinidine assay. Follow the manufacturer’s processing instructions for serum or plasma collection tubes.
- 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 Quinidine 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).
- 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 (patients, 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 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 federal and international regulations covering the transport of clinical samples and etiologic agents.

*Relative Centrifugal Force.

SAMPLE VOLUME

The sample volume required to perform a single undiluted quinidine test on the AxSYM System varies depending on the type of sample container used. For sample cups, a ROUTINE test requires 150 µL and a STAT test requires 89 µL. For every additional quinidine test performed (ROUTINE or STAT) from the same sample container, an additional 39 µL of sample is required.

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. 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 39 µL of sample.

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 AxSYM Quinidine Calibrators and Controls, hold the bottles **vertically** and dispense 4 drops of each calibrator or control into each respective sample cup.

## AxSYM QUINIDINE PROCEDURE

Materials Provided

- 7A73-99 AxSYM Quinidine Reagent Kit, containing:
  AxSYM Quinidine **REAGENT PACK**
  100 **REACTION VESSELS**

Materials Required But Not Provided

- 7A73-01 AxSYM Quinidine Standard Calibrators
- 7A73-10 AxSYM Quinidine Controls
- 8A46 **SOLUTION 4 LINE DILUENT**
- 9A35-05 AxSYM **PROBE CLEANING SOLUTION**
- 8A76-01 **SAMPLE CUPS**
- Pipettor and pipette tips

**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 can be easily removed for use at the instrument. They 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 STAT sample volume requirements for all ordered tests. It is recommended that this report be referenced when loading samples into sample segments.

**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).
- When only performing FPIA assays, the instrument homes all motors and may display “Error Code 5066 Matrix cell not detected, trap door, processing center”. Select **OK** to proceed with testing the FPIA assays.
- 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 Quinidine 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 Quinidine assay must be calibrated using a Standard Calibration (6-point) procedure.

Standard Calibration

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

Once the AxSYM Quinidine 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 specified 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 Quinidine calibration curve should meet the following criteria:

a) Polarization Error (PERR) -2.00 to +2.00 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.

QUALITY CONTROL

The recommended control requirement for an AxSYM Quinidine assay is a single sample of at least two different quinidine 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 Quinidine 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

AxSYM Quinidine 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, Section 2.

## LIMITATIONS OF THE PROCEDURE

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

SAMPLE DILUTION PROCEDURES

**CAUTION:** The automated dilution protocol **CANNOT BE USED** with the AxSYM Quinidine reagent system.

Manual Dilution Protocol

Patient samples with quinidine concentrations reported as greater than 8.00 µg/mL may be diluted using a manual dilution of 1:6. Add one part of the patient sample to five parts of the AxSYM Quinidine 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 = Reported Concentration x Manual Dilution Factor

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

## EXPECTED VALUES

Many studies have shown a relationship between serum quinidine levels and its therapeutic effectiveness. Optimum therapeutic effects are usually observed when serum levels are between 2 - 5 µg/mL. At concentrations below 2 µg/mL the patient generally experiences little relief from the symptoms of arrhythmia and above 5 µg/mL toxic symptoms of the drug may be manifest. Mild side effects include anorexia, nausea, vomiting and diarrhea. Toxic doses may produce what is termed "cinchonism". This includes gastrointestinal disturbances, tinnitus, hypotension and cyanosis. This condition may lead to death unless it is recognized early and the quinidine treatment interrupted.[17] The Quinidine assay was developed to measure total serum quinidine. A pharmacologically active component of all administered quinidine preparations, dihydroquinidine, is also quantitated by the assay. The level of this quinidine derivative is reported to be less than 10% of the total quinidine level in patient sera.[18] Dihydroquinidine is reported to have antiarrhythmic activity comparable to that of quinidine.[19]

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

## SPECIFIC PERFORMANCE CHARACTERISTICS

PRECISION

Precision was determined as described in National Committee for Clinical Laboratory Standards (NCCLS) protocol EP5-T2[20] using human serum with 1.5, 3.0, and 6.0 µg/mL of quinidine added. Results from these studies typically yielded CV's of less than 6%.

Representative data are shown in the following table.

| | Concentration (µg/mL) | | |
|---|---|---|---|
| Target value (n=80) | 1.5 | 3.0 | 6.0 |
| Mean | 1.42 | 2.91 | 5.67 |
| SD Within Run | 0.06 | 0.09 | 0.20 |
| CV Within Run (%) | 4.0 | 3.2 | 3.6 |
| SD Between Day | 0.04 | 0.06 | 0.13 |
| CV Between Day (%) | 2.9 | 2.2 | 2.3 |
| SD Total | 0.08 | 0.13 | 0.31 |
| CV Total (%) | 5.6 | 4.4 | 5.4 |

ACCURACY BY RECOVERY

Recovery was determined by adding quinidine to human serum and to buffer at concentrations of 0.5, 1.0, 1.5, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0 and 7.0 µg/mL. The concentration of quinidine was determined using the AxSYM Quinidine 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.

| Added Concentration (µg/mL) | Concentration in serum (µg/mL) | Concentration in Buffer (µg/mL) | Percent (%) Recovery |
|---|---|---|---|
| 0.5 | 0.58 | 0.50 | 116.0 |
| 1.0 | 0.94 | 0.95 | 99.0 |
| 1.5 | 1.56 | 1.36 | 114.7 |
| 2.5 | 2.30 | 2.32 | 99.1 |
| 3.0 | 2.88 | 2.68 | 107.5 |
| 3.5 | 3.40 | 3.26 | 104.3 |
| 4.0 | 3.81 | 3.63 | 105.0 |
| 5.0 | 4.84 | 4.58 | 105.7 |
| 6.0 | 5.59 | 6.09 | 91.8 |
| 7.0 | 6.28 | 7.00 | 89.7 |

Average Recovery: 103.3 ± 8.6%

SENSITIVITY

The sensitivity of the AxSYM Quinidine assay was calculated to be 0.20 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 AxSYM Quinidine assay. The reported values were determined with drug-free samples. Percent cross-reactivity = 100 x ("concentration found" divided by "concentration added").

Representative data are shown in the following table.

| Test Compound | Concentration Added (µg/mL) | Concentration Found (µg/mL) | % Cross-Reactivity |
|---|---|---|---|
| Quinidine-N-oxide | 1.00 | 0.52 | 52 |
| | 10.00 | 3.50 | 35 |
| | 100.00 | 13.49 | 13.5 |
| 3-Hydroxy-quinidine | 1.00 | 0.59 | 59 |
| | 10.00 | 2.03 | 20 |
| | 100.00 | 5.75 | 5.8 |

INTERFERENCE

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

| Compound | Concentration Tested | Results |
|---|---|---|
| • Bilirubin | 10 mg/dL | <10% error |
| • Hemoglobin | 1000 mg/dL | <10% error |
| • Triglycerides | 2000 mg/dL | <10% error |
| • Total Protein | 3.6 - 14.4 g/dL | <10% error |

ACCURACY BY CORRELATION

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

| Manufacturer | Number of Observations | Intercept | Slope | Correlation Coefficient |
|---|---|---|---|---|
| Abbott AxSYM Quinidine vs. Abbott TDx/TDxFLx Quinidine | 100 | -0.05 | 1.00 | 0.995 |

Sample Range (AxSYM): 0.37 - 6.41 µg/mL.

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