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.

Key to symbols used

REF
Lot Number

LOT
List Number

IVD
In Vitro Diagnostic Medical Device

Store at 2-8°C

Store at 15-30°C

Caution, consult accompanying documents

Consult instructions for use

Manufacturer

STANDARD CAL
Standard Calibrator

(A-B)

CONTROL
Control Low, Medium, High

(L, M, H)

REAGENT PACK
Reagent Pack

REACTION VESSELS
Reaction Vessels

SAMPLE CUPS
Sample Cups

EC REP
Authorized Representative

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

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patient-to-patient variation in bioavailability, metabolism and elimination.\textsuperscript{10} Related to quinidine serum or plasma concentrations.\textsuperscript{7,8} Patient response index and the therapeutic and toxic effects have been shown to be is metabolized in the liver. Principle metabolites, as found in serum, are 3-hydroxyquinidine, 2’-oquinoquinine and D-dehydroquinidine.\textsuperscript{12} 3-Hydroxyquinidine is reported to have an antiarrhythmic potency possibly equal to that of quinidine.\textsuperscript{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 sample probe into various wells of a Reaction Vessel (RV).

**Parameter 45**
- An aliquot of the predilution mixture, predilution 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)\textsuperscript{10}
- 1 Bottle (14.5 mL): Quinidine Antiserum (Goat, Polyclonal) in Phosphate buffer with protein stabilizers. Preservative: Sodium Azide. (Reagent Bottle 1)
- 1 Bottle (8.8 mL): Predilution Solution. Surfactant in TRIS buffer. Contains N,N-Dimethylformamide. Preservative: Sodium Azide. (Reagent Bottle 2)
- 1 Bottle (15.1 mL): Quinidine Fluorescein Tracer in TRIS buffer containing surfactant. Preservative: Sodium Azide. (Reagent Bottle 3)

\textsuperscript{10}7A73-99 includes an AxSYM Quinidine Reagent Pack (100 Tests) and Reaction Vessels (100 each). 7A73-20 includes these forms for international shipments.
INSTRUMENT PROCEDURE

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

- BA03-01, or higher (112 hours on-board Stability)
- DD03-01, or higher (336 hours on-board Stability)

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

SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

- Serum or plasma (collected in heparin, citrate, EDTA, or platelet poor 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 clotforms, 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 RCP x 10 minutes).
- Samples may be stored for up to 24 hours at 2-8°C prior to being tested.
To obtain the recommended volume requirements for AxSYM Quinidine System Operations Manual, Section 5, and control requirements for multiple reagent lots, refer to the AxSYM include the additional 39 μL of sample. The test(s) is (are) ordered. Therefore, the total sample volume should be referenced when loading samples into sample segments. 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.

**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.

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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 testcots 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 Sample Washes

**Materials Required But Not Provided**

- 7A73-01 AxSYM Quinidine Standard Calibrators
- 7A73-10 AxSYM Quinidine Controls
- 8A46 SOLUTIONS LINE SILVERN
- 9A35-05 AxSYM PRIME 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 OrderSet 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 READY, STOPPED before adding or removing sample segments, reagent packs or Reaction Vessels (RVA).
- When only performing FPIA assays, the instrument homes all motors and may display "Error Code 508B Matrix cell not detected, keep door, processing center". Select OK to proceed with testing the FPIA assay.
- 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 the AxSYM Quinidine Reagent Pack 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 (5-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

**AxSYM System**

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, Appendixes, 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) -0.50 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 these 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 (4PL, 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.

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Concentration Tested

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration Tested</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>10 mg/dL</td>
<td>&lt;10% error</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1000 mg/dL</td>
<td>&lt;10% error</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>2000 mg/dL</td>
<td>&lt;10% error</td>
</tr>
<tr>
<td>Total Protein</td>
<td>3.6 - 14.4 g/dL</td>
<td>&lt;10% error</td>
</tr>
</tbody>
</table>

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.

ACCURACY BY RECOVERY

Recovery was determined by adding quinidine to human serum and to buffer at concentrations of 2.5, 5.0, 10.0, 15.0, 20.0, 30.0, 40.0, 50.0, 60.0 and 70.0 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.
BIBLIOGRAPHY


RELATED READING