Prolactin

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>List Number</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>⊳</td>
<td></td>
</tr>
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<td>Store at 2-8°C</td>
<td></td>
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<tr>
<td>⊳</td>
<td></td>
</tr>
<tr>
<td>Store at 15-30°C</td>
<td></td>
</tr>
<tr>
<td>!</td>
<td></td>
</tr>
<tr>
<td>Caution</td>
<td></td>
</tr>
<tr>
<td>☟</td>
<td></td>
</tr>
<tr>
<td>Consult instructions for use</td>
<td></td>
</tr>
<tr>
<td>☟</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>☟</td>
<td></td>
</tr>
<tr>
<td>Authorized Representative in the European Community</td>
<td></td>
</tr>
<tr>
<td>☟</td>
<td></td>
</tr>
<tr>
<td>CONTAINS: AZIDE Contains Sodium Azide. Contact with acids liberates very toxic gas.</td>
<td></td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
and its secretion is regulated physiologically by inhibitory and hormone (TRH). The major physiologic action of prolactin is the blood promptly after administration of thyrotropin-releasing factors of the hypothalamus. Prolactin appears in amenorrhea and galactorrhea.

Various factors other than disease states have been found to influence the prolactin levels. Factors which increase prolactin concentrations include: pregnancy, breast stimulation, stress, colitus, administration of estrogens, progesterone, androgens, some psychotropic and antihypertensive drugs, and TRH. Factors which decrease prolactin concentrations include the administration of L-dopa and bromocriptine.

**BIOLOGICAL PRINCIPLES OF THE PROCEDURE**

**SUMMARY AND EXPLANATION OF THE TEST**

Human prolactin (hPRL) is a single chain polypeptide of 199 amino acids and a molecular weight of approximately 23,000 daltons. Its existence as a distinct chemical entity, separate from growth hormone, was established through a series of studies between 1965 and 1971. Prolactin is produced by the anterior pituitary and its secretion is regulated physiologically by inhibitory and releasing factors of the hypothalamus. Prolactin appears in the blood promptly after administration of thyrotropin-releasing hormone (TRH). The major physiologic action of prolactin is the initiation and maintenance of lactation in women. Hyperprolactinemia has been established as a common cause of infertility and gonadal disorders in men and women. Prolactin has been shown to inhibit the secretion of ovarian steroids and to interfere with follicle maturation and the secretion of LH and FSH in the human female. Measurement of elevated serum prolactin levels may provide the first quantitative evidence of pituitary dysfunction. Quantitation of prolactin levels is also of interest in the evaluation and management of patients with amenorrhea and galactorrhea.

Various factors other than disease states have been found to influence the prolactin levels. Factors which increase prolactin concentrations include: pregnancy, breast stimulation, stress, colitus, administration of estrogens, progesterone, androgens, some psychotropic and antihypertensive drugs, and TRH. Factors which decrease prolactin concentrations include the administration of L-dopa and bromocriptine.

**INTENDED USE**

AxSYM Prolactin is a Microparticle Enzyme Immunoassay (MEIA) technology for the quantitative determination of prolactin in human serum or plasma.

**NAME**

Prolactin

**CALIBRATORS**

Prolactin Calibrators (9C07-02)

1 Bottle (4 mL) Prolactin Calibrator A contains: TRIS buffer with antimicrobial agents.
5 Bottles (4 mL each) Prolactin Calibrators B-F contain: Prolactin (human) in TRIS buffer with protein stabilizers.

**CONTROLS**

Prolactin Controls (9C07-11)

3 Bottles (8 mL each) of Prolactin Controls contain prolactin (human) prepared in TRIS buffer with protein stabilizers to yield the following concentration ranges:

**LIMITATIONS OF**

The AxSYM Prolactin assay is an AxSYM Prolactin Reagent Pack (7A62-22)*

1 Bottle (8.3 mL) Anti-Prolactin (Mouse, Monoclonal) Coated Microparticles in TRIS buffer. Preservative: Sodium Azide (Reagent Bottle 1)
1 Bottle (9.0 mL) Anti-Prolactin (Rabbit, Polyclonal): Alkaline Phosphatase Conjugate in TRIS buffer with protein stabilizers. Minimum concentration: 0.1 µg/mL. Preservative: Sodium Azide (Reagent Bottle 2)
1 Bottle (11.4 mL) Assay Diluent, rabbit serum. Preservative: Sodium Azide (Reagent Bottle 3)

*7A62-67 includes an AxSYM Prolactin Reagent Pack (100 tests), reaction vessels (100 each) and matrix cells (100 each).

**SUMMARY AND EXPLANATION OF THE TEST**

Human prolactin (hPRL) is a single chain polypeptide of 199 amino acids and a molecular weight of approximately 23,000 daltons. Its existence as a distinct chemical entity, separate from growth hormone, was established through a series of studies between 1965 and 1971. Prolactin is produced by the anterior pituitary and its secretion is regulated physiologically by inhibitory and releasing factors of the hypothalamus. Prolactin appears in amenorrhea and galactorrhea.

Various factors other than disease states have been found to influence the prolactin levels. Factors which increase prolactin concentrations include: pregnancy, breast stimulation, stress, colitus, administration of estrogens, progesterone, androgens, some psychotropic and antihypertensive drugs, and TRH. Factors which decrease prolactin concentrations include the administration of L-dopa and bromocriptine.

**BIOLOGICAL PRINCIPLES OF THE PROCEDURE**

AxSYM Prolactin is based on Microparticle Enzyme Immunoassay (MEIA) technology. The AxSYM Prolactin Reagents and sample are pipetted in the following sequence:

**SUMMARY AND EXPLANATION OF THE TEST**

**INTENDED USE**

AxSYM Prolactin is a Microparticle Enzyme Immunoassay (MEIA) technology for the quantitative determination of prolactin in human serum or plasma. Quantitation of prolactin levels is also of interest in the evaluation and management of patients with amenorrhea and galactorrhea.

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AxSYM Probe Cleaning Solution (9A35-05)

PROBE CLEANING SOLUTION 2 Bottles (220 mL each) AxSYM Probe Cleaning Solution containing 2½ Tetraethylammonium Hydroxide (TEAH).

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 Pathogens12. Biosafety Level 213 or other appropriate biosafety practices14,15 should be used for materials that contain or are suspected of containing infectious agents.

- 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 Solution 1 (MUP) beyond the expiration date or a maximum of 14 days on-board the AxSYM System. When loading new Solution 1 (MUP) it is important to immediately tighten the instrument cap for MUP to minimize exposure to air. Prolonged exposure of MUP to air may compromise performance.

- Do not use Reagent Pack beyond the expiration date or a maximum of 336 cumulative hours on-board the AxSYM System. Additional safety and handling precautions and limitations for the reagent packs, calibrators, controls, patient samples and other reagents are described in the AxSYM System Operations Manual, Sections 7 and 8.

STORAGE INSTRUCTIONS

The AxSYM Prolactin Reagent Pack must be stored at 2 to 8°C (do not freeze). The Prolactin Calibrators and Controls must be stored at -10°C or colder until use, after thaw at 2-8°C. The AxSYM Prolactin Reagent Pack may be used immediately after removal from the refrigerator. Calibrators and Controls should be returned to 2 to 8°C storage immediately after use. Reagents are stable until the expiration date when stored and handled as directed. The AxSYM Prolactin 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 Appendices, for further information on tracking on-board time.

Solution 1 (MUP) must be stored at 2 to 8°C (do not freeze). It may be used immediately after removing it from the refrigerator. MUP may be on-board the AxSYM System for a maximum of 14 days. After 14 days, it must be discarded.
SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

- Serum (including serum collected in separator tubes) or plasma (collected in sodium heparin or tripotassium EDTA) may be used in the AxSYM Prolactin 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 Prolactin assay.

- Do not test grossly hemolyzed specimens.

- 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.

- For optimal results, samples should be free of fibrin, red blood cells or other particulate matter.

- Patient samples should be mixed and centrifuged after any freeze-thaw cycle to remove red cells or particulate matter.

- Multiple freeze-thaw cycles should be avoided. Samples must be mixed thoroughly after thawing, by LOW speed vortexing or gently inverting, and centrifuged prior to use to remove particulate matter and to ensure consistency in the results.

- Samples may be stored for up to 24 hours at 2 to 8°C prior to testing. 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). Samples have been stored frozen at -10°C or colder for 12 months and no performance difference was seen.

- To minimize the effects of evaporation, all samples (patient samples, 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 federal and international regulations covering the transport of clinical samples and etiologic agents.

SAMPLE VOLUME

The sample volume required to perform a single Prolactin test on the AxSYM System varies according to the different sample containers. For sample cups, a ROUTINE test requires 150 µL and a STAT test requires 146 µL. For every additional Prolactin test performed (ROUTINE or STAT) from the same sample container, an additional 96 µL of sample will be required.

The sample cup minimum volume for both STAT and ROUTINE tests is calculated by the AxSYM System. It will be displayed on the Order screen at the time the test(s) is(are) ordered, and printed in the Order list report. When using Host Order Query the Order screen information and Order list 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/reflex, 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 an additional 96 µL sample. Refer to the AxSYM System Operations Manual, Section 2, for details on Automatic Sample Retest Configuration.

To obtain the recommended volume requirements for the Prolactin Calibrators and Controls, hold the bottles vertically and dispense 6 drops of each Calibrator or 4 drops of each Control into each respective sample cup.

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

AxSYM PROLACTIN PROCEDURE

Materials Provided

- 7A62-67 AxSYM Prolactin Reagent Kit, containing:
  - AxSYM Prolactin REAGENT PACK
  - 100 REACTION VESSELS
  - 100 MATRIX CELLS

Materials Required But Not Provided

- AxSYM System
- 9C07-11 Prolactin Controls
- 9C07-02 Prolactin Calibrators
- 8A47-04 SOLUTION 1 HTR
- 8A81-04 SOLUTION 3 MATRIX CELL WASH
- 8A46 SOLUTION 4 LINE DILUENT
- 9A35-05 AxSYM PROBE CLEANING SOLUTION
- 8A76-01 SAMPLE CUPS
- Pipettes/pipette tips (optional) to deliver the volumes specified on the Order screen.

CAUTION:

- When manually dispensing sample into sample cups, verify that the dispensing equipment does not introduce cross contamination and delivers the specified sample volume.

- 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 these 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 matrix cells, bulk solutions and waste levels are acceptable.

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.

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 (RV’s).

- 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 Prolactin Reagent Pack are removed from the Sampling Center to maximize the on-board reagent pack use. Store at 2 to 8°C.

SAMPLE DILUTION PROCEDURES

Automated Dilution Protocol

Prolactin samples CANNOT be diluted automatically on the System.

Manual Dilution Protocol

Patient samples with prolactin concentrations reported as greater than 200 ng/mL may be diluted using a manual dilution of sample with the Prolactin Calibrator A (0 ng/mL). The dilution should be performed so that the diluted test results read greater than the sensitivity of the assay (0.6 ng/mL). Perform 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.
QUALITY CONTROL PROCEDURES

CALIBRATION

The AxSYM Prolactin Assay must be calibrated using a Standard Calibration (6-point) procedure. The use of a particular calibration procedure is dependent on individual laboratory policy.

Standard Calibration

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

Once the AxSYM Prolactin 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 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.

QUALITY CONTROL

The recommended control requirement for an AxSYM Prolactin Assay is a single sample of all prolactin 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 REAGENTS, CONTROLS section of this package insert for Prolactin 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.

At the discretion of the laboratory, selected quality control rules may be applied to the quality control data.

Fluorescence Background Acceptance Criteria

Quality Control with regards to the MUP substrate blank is automatically determined by the instrument and checked under Assay Parameter 64 Max Intercept-Max MUP intercept each time a test result is calculated. If the MUP intercept value is greater than the maximum allowable value, the result is invalid. The test request will be moved to the Exceptions List where it will appear with the message “1064 Invalid test result, intercept too high” and the calculated intercept value. Refer to the AxSYM System Operations Manual, Section 10, when this error message is obtained.

Refer to the AxSYM System Operations Manual, Section 2, for further information on this parameter.

RESULTS

AxSYM Prolactin utilizes a four parameter logistic curve fit (4PLC) data reduction method to generate a standard calibration curve.

Alternate Result Units

The default result unit for AxSYM Prolactin is ng/mL. When selecting the alternate result unit, mIU/L, the conversion factor used by the AxSYM System is 21.2. When selecting the alternate result unit, µg/L, the conversion factor used by the AxSYM System is 1.

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, Sections 1 and 2.

LIMITATIONS OF THE PROCEDURE

- Prolactin levels have been found to be influenced by various factors other than the disease states. Refer to the SUMMARY AND EXPLANATION OF THE TEST section in this assay package insert. For diagnostic purposes, the AxSYM Prolactin results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunossays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.
- Prolactin may exist in alternate structural forms (e.g., macroprolactin) which may exhibit variable levels of physiological activity. In patients with elevated prolactin results, additional information may be required for diagnosis.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies. These specimens should not be assayed with the AxSYM Prolactin assay.
- HIGH DOSE HOOK

Samples with prolactin concentrations up to 10,000 ng/mL can be assayed without experiencing a High Dose Hook effect. In some rare pathological conditions, prolactin concentrations may exceed 10,000 ng/mL. These specimens may read lower than the highest calibrator and should be diluted prior to pipetting the sample into the sample well (see Manual Dilution Protocol).

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

EXPECTED VALUES

The suggested normal range for AxSYM Prolactin is 3.24-29.12 ng/mL. This range represents the prolactin values obtained by testing serum specimens from 256 apparently healthy individuals. These results are provided in the following table.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Prolactin Value (ng/mL)</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>130</td>
<td>7.93</td>
<td>3.28-19.68</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>126</td>
<td>9.72</td>
<td>3.24-29.12</td>
<td></td>
</tr>
</tbody>
</table>

It is recommended that each laboratory establish its own normal range.

SPECIFIC PERFORMANCE CHARACTERISTICS

PRECISION

Precision was determined as described in Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) protocol EP5-T. A three member buffered protein based panel was assayed, using a single lot of reagents, in replicates of 2 at two separate times per day for twenty days. Data from this study are summarized in the following tables.
The AxSYM Prolactin assay demonstrated the stated interference in the presence of the following at 13-58 ng/mL of prolactin:

- **Bilirubin**: <11% interference at 20 mg/dL
- **Hemoglobin**: <10% interference at 750 mg/dL
- **Triglycerides**: <10% interference at 1000 mg/dL

### ACCURACY BY CORRELATION

The AxSYM Prolactin assay was compared to the ARCHITECT Prolactin assay. The results of the specimen testing are shown in the following table.

<table>
<thead>
<tr>
<th>Correlation</th>
<th>Number of Manufacturer</th>
<th>Observations</th>
<th>Intercept</th>
<th>Slope</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott AxSYM</td>
<td>223</td>
<td>-0.05</td>
<td>0.96</td>
<td>0.997</td>
<td></td>
</tr>
<tr>
<td>vs. Abbott ARCHITECT</td>
<td>Prolactin</td>
<td>Prolactin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In this evaluation, serum samples tested ranged from 2.81 to 397.20 ng/mL by AxSYM Prolactin. The correlation was evaluated by Passing-Bablok Linear Regression, a linear regression method with no special assumptions regarding the distribution of the samples and the measurement errors.23

### BIBLIOGRAPHY


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