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

<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>Caution, consult accompanying documents</td>
</tr>
<tr>
<td>2°C</td>
<td>Store at 2-8°C</td>
</tr>
<tr>
<td>15°C</td>
<td>Store at 15-30°C</td>
</tr>
<tr>
<td>30°C</td>
<td>Store at 30°C</td>
</tr>
<tr>
<td>🔍</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>Matrix Cells</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>⏰</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>STANDARD CAL A</td>
<td>Standard Calibrator (A-F)</td>
</tr>
<tr>
<td>CONTROL L</td>
<td>Control Low, Medium, High (L, M, H)</td>
</tr>
<tr>
<td>REAGENT PACK</td>
<td>Reagent Pack</td>
</tr>
<tr>
<td>SAMPLE CUPS</td>
<td>Sample Cups</td>
</tr>
<tr>
<td>MASTER CAL 1</td>
<td>Master Calibrator (1, 2)</td>
</tr>
<tr>
<td>REACTION VESSELS</td>
<td>Reaction Vessels</td>
</tr>
<tr>
<td>EC REP</td>
<td>Authorized Representative</td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
Human luteinizing hormone (LH, lutropin) is a glycoprotein hormone with two dissimilar subunits (α and β). LH has a molecular weight of approximately 30,000 daltons. The α-subunit of LH contains 92 amino acid residues and is essentially identical to the α-subunits of follicle stimulating hormone (FSH, follitropin), thyroid stimulating hormone (TSH, thyrotropin), and human chorionic gonadotropin (hCG). The β-subunit of LH contains 112 amino acid residues and is considerably different from that of FSH and TSH. However, the β-subunits of LH and hCG are very similar. The structural similarities between LH and hCG are responsible for the observed similarity in biological properties.

LH, together with FSH, is secreted by the gonadotroph cells in the pituitary, which in turn regulate the menstrual cycle in females. When the follicle, and the ovum contained within it, reach maturity, a surge of LH causes the follicle to rupture releasing the ovum. The follicular remnant is transformed into a corpus luteum which secretes progesterone and estradiol. During the follicular and luteal phases, LH concentrations are much lower than the levels observed at the time of the LH surge. During the follicular and luteal phases, the estrogens exert a negative feedback on the release of LH. Shortly before the mid-cycle surge in LH, ovarian steroids, specifically, estradiol, exert a positive feedback on LH release.

Determination of the concentration of LH is essential for the prediction of ovulation, in the evaluation of infertility, and the diagnosis of pituitary and gonadal disorders. Increasing concentrations of LH precede ovulation and in cases in which the period of optimal fertility needs to be defined for the timing of intercourse or artificial insemination, daily concentrations of LH are important for the prediction of ovulation. More frequent sampling is required if the precise time of follicular rupture is needed for egg aspiration for in vitro fertilization.

At menopause, or following ovarectomy in women, concentrations of estrogens decline to low levels. The lowered concentrations of estrogens result in a loss of the negative feedback on gonadotropin release. The consequence is an increase in the concentrations of LH and FSH.

The primary role of LH in the male is to stimulate the production of testosterone by the Leydig cells. LH, through the production of testosterone by the Leydig cells, regulates spermatogenesis in the Sertoli cells of the seminiferous tubules of the testes. Testosterone exerts a negative feedback on the release of LH.

In sexually mature adults, gonadotropin deficiency is usually an early indication of the development of panhypopituitarism. Low concentrations of LH, FSH, and steroids are observed with this disorder. In contrast, gonadotropin secreting tumors of the hypophalamus and pituitary result in elevated concentrations of LH and FSH.

Gonadal failure, a cause of infertility, is indicated by elevated concentrations of LH and FSH accompanied by low concentrations of gonadal steroids. In the female, elevated concentrations of LH can indicate primary amenorrhea, menopause, premature ovarian failure, polycystic ovarian syndrome, hypergonadotrophic hypogonadism. In the male, elevated concentrations of LH can result from primary testicular failure, seminiferous tubule dysgenesis (Klinefelter’s syndrome), Sertoli cell failure, anorchia, or hypergonadotrophic hypogonadism.
AxSYM LH Standard Calibrators (7A61-02)

6 Bottles (4 mL each) of AxSYM LH Standard Calibrators. Standard Calibrator A is calf serum. Standard Calibrators B-F contain pituitary LH (human) prepared in calf serum to yield the following concentrations:

<table>
<thead>
<tr>
<th>Bottle</th>
<th>LH Concentration (mIU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STANDARD CAL.A</strong></td>
<td>0</td>
</tr>
<tr>
<td><strong>STANDARD CAL.B</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>STANDARD CAL.C</strong></td>
<td>10</td>
</tr>
<tr>
<td><strong>STANDARD CAL.D</strong></td>
<td>25</td>
</tr>
<tr>
<td><strong>STANDARD CAL.E</strong></td>
<td>100</td>
</tr>
<tr>
<td><strong>STANDARD CAL.F</strong></td>
<td>250</td>
</tr>
</tbody>
</table>

Preservative: Sodium Azide.

The LH calibrators are manufactured gravimetrically and referenced to the World Health Organization (W.H.O.) Luteinizing Hormone (LH) Human, Pituitary 2nd International Standard 80/552 at each concentration.

**CONTROLS**

AxSYM LH Controls (7A61-12)

3 Bottles (8 mL each) of AxSYM LH Controls contain pituitary LH (human) prepared in processed bovine serum to yield the following concentration ranges:

<table>
<thead>
<tr>
<th>Bottle</th>
<th>LH Concentration (mIU/mL)</th>
<th>Range (mIU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONTROL L</strong></td>
<td>5</td>
<td>3.5 - 6.5</td>
</tr>
<tr>
<td><strong>CONTROL M</strong></td>
<td>40</td>
<td>30 - 50</td>
</tr>
<tr>
<td><strong>CONTROL H</strong></td>
<td>80</td>
<td>57 - 103</td>
</tr>
</tbody>
</table>

Preservative: Sodium Azide.

**OTHER REAGENTS**

Solution 1 (MUP) (8A47-04)

**SOLUTION 1 [MUP]**

4 Bottles (230 mL each) Solution 1 (MUP) containing 4-Methylumbelliferyl Phosphate, 1.2 mM, in AMP buffer. Preservative: Sodium Azide.

Solution 3 (Matrix Cell Wash) (8A81-04)

**SOLUTION 3 [MATRIX CELL WASH]**

4 Bottles (1000 mL each) Solution 3 (Matrix Cell Wash) containing 0.3 M Sodium Chloride in TRIS Buffer. Preservatives: Sodium Azide and Antimicrobial Agents.

Solution 4 (Line Diluent) (8A46)

**SOLUTION 4 [LINE DILUENT]**

1 Bottle (10 L) Solution 4 (Line Diluent) containing 4 M Phosphate Buffer. Preservatives: Sodium Azide and Antimicrobial Agent.

AxSYM Probe Cleaning Solution (9A35-05)

**PROBE CLEANING SOLUTION**

2 Bottles (220 mL each) AxSYM Probe Cleaning Solution containing 2% Tetraethylammonium Hydroxide (TEAH).

**WARNINGS AND PRECAUTIONS**

**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 Pathogens15. Biosafety Level 216 or other appropriate biosafety practices23,24 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.

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 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.
- 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 LH Reagent Pack must be stored at 2-8°C (do not freeze). The AxSYM LH Calibrators and Controls must be stored at 2-8°C. The AxSYM LH 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. Reagents are stable until the expiration date when stored and handled as directed.

**NOTE:** The AxSYM LH Master Calibrators, Standard Calibrators and Controls are shipped on dry ice and should be stored at 2-8°C after receipt.

The AxSYM LH 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 2-8°C (do not freeze). It may be used immediately after removing it from the refrigerator. It may be on-board the AxSYM System for a maximum of 14 days. After 14 days, it must be discarded.

**INSTRUMENT PROCEDURE**

Assay File Installation

The AxSYM LH Assay File must be installed on the AxSYM System from one of the following software disks, prior to performing LH assays:

- 3D51-02, or higher (336 hours on-board Stability)
- 3D51-05 (304 hours on-board Stability)
- 3D51-07 (352 hours on-board Stability)

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

AxSYM LH Assay Parameters

The default values for the assay parameters used for the AxSYM LH assay are listed below. 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 that can be edited contain a (> ) symbol.
SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

- Human serum (including serum collected in serum separator tubes) or plasma (collected in sodium heparin or tripotassium EDTA) may be used in the AxSYM LH assay. Follow the manufacturer’s processing instructions for serum or plasma collection tubes.
- Ensure that complete clot formation has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- For optimal results, specimens should be free of fibrin, red blood cells or other particulate matter.
- Patient specimens should be mixed and centrifuged after any freeze-thaw cycle or to remove red cells or particulate matter.
- Multiple freeze-thaw cycles should be avoided. Specimens must be mixed thoroughly after thawing, by LOW speed vortexing or gently inverting, and centrifuged prior to use to remove particulate matter.

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 those procedures.

AxSYM LH PROCEDURE

Materials Provided
- AxSYM LH Reagent Kit, containing:
  - AxSYM LH REAGENT PACK
  - REAGENT VESSELS
  - MATRIX CELLS

Materials Required But Not Provided
- AxSYM System
- AxSYM LH Controls
- AxSYM LH Standard Calibrators
- AxSYM LH Master Calibrators
- SOLUTION(MUP)
- SOLUTION 3 MATRIX CELL WASH
- SOLUTION 4 LINE DILUENT
- AxSYM PROBE CLEANING SOLUTION
- SAMPLE CUPS

- Pipettes/pipette tips (optional) to deliver the volumes specified on the Order screen.

NOTE: Parameter 45 can be edited to an alternate result unit (IU/L).

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

Sample Volume

The sample volume required to perform a single LH test on the AxSYM System varies according to the different sample containers. For sample cups, both a ROUTINE and a STAT test requires 150 μL. For every additional LH test performed (ROUTINE or STAT) from the same sample container, an additional 100 μL of sample will be required.

To obtain the recommended volume requirements for the AxSYM LH 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.

Materials Provided
- 7A61-67 AxSYM LH Reagent Kit, containing:
  - AxSYM LH REAGENT PACK
  - 100 REAGENT VESSELS
  - 100 MATRIX CELLS

Materials Required But Not Provided
- AxSYM System
- 7A61-12 AxSYM LH Controls
- 7A61-02 AxSYM LH Standard Calibrators
- 7A61-32 AxSYM LH Master Calibrators
- 8A47-04 SOLUTION(MUP)
- 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.
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 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.

When using Host Order Query, the Orderlist report is not available. Refer to the AxSYM System Operations Manual, Section 5, Ordering Patient Samples, 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 (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 LH Reagent Pack are removed from the Sampling Center to maximize the on-board reagent pack use. Store at 2-8°C.

SAMPLE DILUTION PROCEDURES
Automated Dilution Protocol
LH specimens CANNOT be diluted automatically on the System.

Manual Dilution Protocol
Patient specimens with LH concentrations reported as greater than 250 mIU/mL may be diluted using a manual dilution of specimen with the AxSYM LH Standard Calibrator A (0 mIU/mL) or AxSYM LH Master Calibrator 1 (0 mIU/mL). A 1:2 dilution is adequate for most specimens. The dilution should be performed so that the diluted test results read greater than the sensitivity of the assay (0.5 mIU/mL). Perform the test using this manually diluted specimen. The concentration reported by the AxSYM System must be multiplied by the manual dilution factor to obtain the final specimen concentration.

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

QUALITY CONTROL PROCEDURES

CALIBRATION
The AxSYM LH Assay must be calibrated using either a Master Calibration (2-point), or a Standard Calibration (6-point) procedure. The use of a particular calibration procedure is dependent on individual laboratory policy.

Master Calibration
Each AxSYM LH Reagent Pack is shipped with a bar coded label insert that contains the Master Curve information for that specific lot of reagents. When using a lot number for the first time, the bar coded Master Curve information must be entered into the AxSYM System. Refer to the AxSYM System Operations Manual, Section 6, for additional information on entering Master Curve bar codes. Once this bar code information is entered, a Master Calibration must be performed. To perform an AxSYM LH Master Calibration, test Master Calibrators 1 and 2 in duplicate. A single sample of all levels of LH controls must be tested as a means of evaluating the assay calibration.

Standard Calibration
The Standard Calibration procedure may be used without prior entry of the bar coded Master Curve information. To perform an AxSYM LH Standard Calibration, test Standard Calibrators A, B, C, D, E, and F in duplicate. A single sample of all levels of LH controls must be tested as a means of evaluating the assay calibration. Once the AxSYM LH 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 LH Assay is a single sample of all LH control levels tested once every 24 hours each day of use. Controls may be placed in any position in the Sample Carousel. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow those procedures.

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

Ensure that assay control values are within the concentration ranges specified in the package insert. Refer to the REAGENTS, CONTROLS section of this package insert for AxSYM LH 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 LH Assay utilizes a four parameter logic data reduction method (4PLC) to generate a calibration curve. The Master Calibration uses Linear Transformation Techniques to adjust the Master Curve. Refer to the AxSYM System Operations Manual, Appendix F, for further information.

Flags
Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the AxSYM System Operations Manual, Section 2.

LIMITATIONS OF THE PROCEDURE
For diagnostic purposes, the AxSYM LH results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.

Red blood cell interference will cause depressed results.

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.20,28 These specimens should not be assayed with the AxSYM LH assay.

Refer to the SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS section in this package insert.
EXPECTED VALUES
Specimens were drawn from 19 normal males, 26 post-menopausal females and daily from 26 normal cycling females. For this study, the follicular phase was defined as the period of time from 12 days to 4 days prior to the mid-cycle peak. The luteal phase was defined as the period of time from 4 days to 11 days following the mid-cycle peak. Cycle days were synchronized to the mid-cycle peak, the day on which the LH concentration was most elevated.

A summary of the data, using the AxSYM LH assay, for the expected normal ranges, is presented in the following table:

<table>
<thead>
<tr>
<th>Sample</th>
<th>LH Value (mIU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n Mean Range</td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>19 5 2 - 12</td>
</tr>
<tr>
<td>Normally Menstruating Females</td>
<td></td>
</tr>
<tr>
<td>Follicular Phase</td>
<td>96 6 1 - 18</td>
</tr>
<tr>
<td>Mid-Cycle Peak</td>
<td>21 44 24 - 105</td>
</tr>
<tr>
<td>Luteal Phase</td>
<td>92 5 0.4 - 20</td>
</tr>
<tr>
<td>Post-menopausal Females</td>
<td>26 34 15 - 62</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 National Committee for Clinical Laboratory Standards (NCCLS) protocol EPS-T2.27 A three member bovine serum 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 table.

**PANEL MEMBER 1**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean Conc. Value (mIU/mL)</th>
<th>n</th>
<th>Within Run CV(%)</th>
<th>Between Run CV(%)</th>
<th>Between Day CV(%)</th>
<th>Total Run CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4.61 80 0.21 4.57 0.09 1.88 0.08 1.73 0.24 5.23</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4.41 80 0.18 4.15 0.18 4.00 0.16 3.72 0.30 6.88</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>4.85 80 0.22 4.50 0.21 4.33 0.09 1.79 0.32 6.49</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>4.12 80 0.27 6.64 0.28 6.39 0.00 0.00 0.38 9.21</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PANEL MEMBER 2**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean Conc. Value (mIU/mL)</th>
<th>n</th>
<th>Within Run CV(%)</th>
<th>Between Run CV(%)</th>
<th>Between Day CV(%)</th>
<th>Total Run CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>39.88 80 1.71 4.28 0.99 2.49 1.43 3.56 2.44 6.11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>36.32 80 2.04 5.62 1.78 4.90 0.16 3.72 0.30 6.88</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>43.18 80 1.94 4.44 2.87 6.93 0.00 0.00 3.41 8.23</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>34.97 80 1.96 4.46 1.41 4.03 0.74 2.13 2.23 6.38</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PANEL MEMBER 3**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean Conc. Value (mIU/mL)</th>
<th>n</th>
<th>Within Run CV(%)</th>
<th>Between Run CV(%)</th>
<th>Between Day CV(%)</th>
<th>Total Run CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>79.11 80 3.56 4.61 0.00 0.00 3.11 3.93 4.73 5.98</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>70.98 80 3.53 4.98 2.54 3.58 2.24 3.16 4.90 6.80</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>81.65 80 5.48 6.71 6.07 7.43 0.00 0.00 8.17 10.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>67.83 80 4.56 6.71 2.67 3.93 1.74 2.56 5.56 8.19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RECOVERY

Known concentrations of LH were added to 5 human serum samples. The concentration of LH was determined using the AxSYM LH assay and the resulting percent recovery was calculated.

<table>
<thead>
<tr>
<th>Sample</th>
<th>LH Added (mIU/mL)</th>
<th>Value Obtained (mIU/mL)</th>
<th>Percent Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endogenous Level (mIU/mL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>32.90 22</td>
<td>53.20</td>
<td>92</td>
</tr>
<tr>
<td>2</td>
<td>0.51 40</td>
<td>37.00</td>
<td>91</td>
</tr>
<tr>
<td>3</td>
<td>1.80 89</td>
<td>81.70</td>
<td>90</td>
</tr>
<tr>
<td>4</td>
<td>4.10 142</td>
<td>139.80</td>
<td>96</td>
</tr>
<tr>
<td>5</td>
<td>18.90 200</td>
<td>228.00</td>
<td>105</td>
</tr>
</tbody>
</table>

Average Percent Recovery: 94.8%

**SENSITIVITY**

The sensitivity of the AxSYM LH Assay was calculated to be 0.5 mIU/mL (n = 51 runs in replicates of 10). This sensitivity is defined as the concentration at 2 standard deviations from the AxSYM LH Calibrator A (0 mIU/mL) and represents the lowest measurable concentration of LH that can be distinguished from zero.

**SPECIFICITY**

Serum specimens, containing low levels of LH, were supplemented with human chorionic gonadotropin (hCG), follicle stimulating hormone (FSH), or thyroid stimulating hormone (TSH) at specific levels. The results follow.

<table>
<thead>
<tr>
<th>Potential Cross Reactant</th>
<th>Concentration Range Tested</th>
<th>Mean Cross Reactivity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>hCG</td>
<td>1 x 10⁶ (mIU/mL)</td>
<td>0.02</td>
</tr>
<tr>
<td>FSH</td>
<td>2000 (mIU/mL)</td>
<td>0.00</td>
</tr>
<tr>
<td>TSH</td>
<td>2000 (μIU/mL)</td>
<td>3.50</td>
</tr>
</tbody>
</table>

**INTERFERENCE**

The AxSYM LH assay demonstrated the stated interference in the presence of the following:

- Bilirubin - < 10% interference at 20 mg/dL
- Hemoglobin - < 10% interference at 1000 mg/dL
- Triglycerides - < 5% interference at 1000 mg/dL

**ACCURACY BY CORRELATION**

The AxSYM LH assay was compared to a commercially available diagnostic kit. The results of the specimen testing are shown in the following table.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Number of Observations</th>
<th>Intercept</th>
<th>Slope</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott AxSYM</td>
<td>vs.</td>
<td>100</td>
<td>0.16</td>
<td>0.99</td>
</tr>
<tr>
<td>Abbott AxSYM</td>
<td>1st IRP</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In this evaluation, serum specimens tested ranged from 1.97 to 211.76 mIU/mL by AxSYM LH 2nd International Standard referenced materials.

**BIBLIOGRAPHY**


AxSYM is a trademark of Abbott Laboratories in various jurisdictions.