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

This package insert must be read carefully before product use. 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>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td></td>
<td>Expiration Date</td>
</tr>
<tr>
<td></td>
<td>Store at 2-8°C</td>
</tr>
<tr>
<td>SN</td>
<td>Serial Number</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
</tr>
<tr>
<td>REACTION VESSELS</td>
<td>Reaction Vessels</td>
</tr>
<tr>
<td>SAMPLE CUPS</td>
<td>Sample Cups</td>
</tr>
<tr>
<td>SEPTUM</td>
<td>Septum</td>
</tr>
<tr>
<td>REPLACEMENT CAPS</td>
<td>Replacement Caps</td>
</tr>
<tr>
<td>REAGENT LOT</td>
<td>Reagent Lot</td>
</tr>
<tr>
<td>ASSAY CD-ROM</td>
<td>Assay CD-ROM</td>
</tr>
<tr>
<td>CONTROL NO.</td>
<td>Control Number</td>
</tr>
</tbody>
</table>

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.
NAME
ARCHITECT DHEA-S

INTENDED USE
ARCHITECT DHEA-S is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of dehydroepiandrosterone sulfate (DHEA-S) in human serum and plasma on the ARCHITECT i System.

SUMMARY AND EXPLANATION OF TEST
Dehydroepiandrosterone sulfate (DHEA-S) is the most abundant adrenal androgen and also functions as a neurosteroid that is produced by the adrenal cortex. DHEA-S is an excellent indicator of adrenal androgen production. DHEA-S exhibits only weak androgenic activity but can be metabolized to more active androgens such as testosterone and androstenedione. Serum concentrations decline with age and can serve as a prognostic factor in both critical illnesses and breast cancer progression. Elevated levels of DHEA-S are found in the plasma of patients with adrenal tumors or congenital adrenal hyperplasia. DHEA-S may also be slightly elevated in patients with polycystic ovaries. Tumors in men that produce hCG may lead to increased levels of testicular DHEA-S.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE
The ARCHITECT DHEA-S assay is a delayed one-step immunoassay for the quantitative determination of DHEA-S in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex. Sample, assay diluent, and anti-DHEA-S coated paramagnetic microparticles are combined. DHEA-S is present in the sample binds to anti-DHEA-S coated microparticles. After incubating, DHEA-S acridinium-labeled conjugate is added to the reaction mixture and binds to unoccupied binding sites of the anti-DHEA-S microparticles. After a second incubation and washing, pre-trigger and trigger solutions are added and the resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of DHEA-S in the sample and the RLUs detected by the ARCHITECT System optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS
Reagent Kit, 100 Tests
NOTE: Some kit sizes are not available in all countries; please contact your local distributor.
ARCHITECT DHEA-S Reagent Kit (8K27)
• MICROPARTICLES 1 or 4 Bottle(s) (6.6 mL each) Anti-DHEA-S (mouse monoclonal) coated microparticles in TRIS buffer. Preservative: sodium azide.
• CONJUGATE 1 or 4 Bottle(s) (5.9 mL each) DHEA-S acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer. Preservative: sodium azide.
• ASSAY DILUENT 1 or 4 Bottle(s) (10.0 mL each) DHEA-S Assay Diluent containing MES buffer with protein (bovine) stabilizer. Preservative: sodium azide.

Other Reagents
ARCHITECT / Pre-Trigger Solution
• PRE-TRIGGER SOLUTION Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.
ARCHITECT / Trigger Solution
• TRIGGER SOLUTION Trigger Solution containing 0.35 M sodium hydroxide.
ARCHITECT / Wash Buffer
• WASH BUFFER Wash Buffer containing phosphate buffered saline solution. Preservative: antimicrobial agent.

WARNINGS AND PRECAUTIONS

Safety Precautions
• CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
• 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.
• For information on the safe disposal of sodium azide and a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Handling Precautions
• Do not use reagent kits beyond the expiration date.
• Do not pool reagents within a reagent kit or between reagent kits.
• Before loading the ARCHITECT DHEA-S Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend the microparticles that have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
• Septums MUST be used to prevent reagent evaporation and contamination, and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.
  • To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
  • Once a septum has been placed on an open reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.
  • Over time, residual liquids may dry on the septum surface. These are typically dried salts, which have no effect on assay efficacy.
• For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Storage Instructions
• The ARCHITECT DHEA-S Reagent Kit must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
• When stored and handled as directed, reagents are stable until the expiration date.
• The ARCHITECT DHEA-S Reagent Kit may be stored on board the ARCHITECT / System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.
• Reagents may be stored on or off the ARCHITECT / System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.
Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The ARCHITECT DHEA-S assay file must be installed on the ARCHITECT i System from the ARCHITECT i Assay CD-ROM Addition E before performing the assay. For detailed information on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.
- The default result unit for the ARCHITECT DHEA-S assay is μg/dL. An alternate result unit, μmol/L or μg/mL, may be selected for reporting results by editing assay parameter “Result concentration units” to μmol/L or μg/mL. The conversion factor used by the system is 0.02714 or 0.01, respectively.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen collection tubes listed below were verified to be used with the ARCHITECT DHEA-S assay.
- Human serum (including serum collected in serum separator tubes)
- Human plasma collected in:
  - Potassium EDTA
  - Sodium Citrate
  - Sodium Heparin
- Use of Lithium and Ammonium Heparin may result in a shift of normal ranges.
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimen.
- The ARCHITECT i System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the ARCHITECT DHEA-S assay.

Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed (> 500 mg/dL)
  - obvious microbial contamination
  - cadaver specimens or any other body fluids
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells or other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- For optimal results, inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Preparation for Analysis

- Follow the tube manufacturer’s processing instructions for serum and plasma collection tubes. Gravity separation is not sufficient for specimen preparation.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at ≥ 10,000 RCF (Relative Centrifugal Force) for 10 minutes before testing if they contain fibrin, red blood cells, or other particulate matter, or they require repeat testing.
- Transfer clarified specimens to a sample cup or secondary tube for testing.
- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimens without the lipemic material.

Storage

- Specimens may be stored on or off the clot, red blood cells, or separator gel for up to 8 days refrigerated at 2-8°C.
- If testing will be delayed more than 8 days, remove serum or plasma from the clot, red blood cells, or separator gel and store frozen.
- Specimens stored frozen for 8 weeks showed no performance difference. Avoid more than 5 freeze/thaw cycles for serum, and more than 2 freeze/thaw cycles for plasma specimens.

Shipping

- Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel.
- When shipping specimens, package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Specimens may be shipped ambient, on wet ice, or on dry ice. Do not exceed the storage time limitations listed above.

PROCEDURE

Materials Provided

- 8K27 ARCHITECT DHEA-S Reagent Kit

Materials Required but not Provided

- ARCHITECT i System
- 1L65 ARCHITECT i ASSAY CD-ROM - US - Addition E
- 1L66 ARCHITECT i ASSAY CD-ROM - WW (excluding US) - Addition E
- 8K27-01 ARCHITECT DHEA-S Calibrators
- 8K27-10 ARCHITECT DHEA-S Controls
- ARCHITECT i PRE-TRIGGER SOLUTION
- ARCHITECT i TRIGGER SOLUTION
- ARCHITECT i WASH BUFFER
- ARCHITECT i REACTION VESSELS
- ARCHITECT i SAMPLE CUPS
- ARCHITECT i SEPTUM
- ARCHITECT i REPLACEMENT CAPS
- Pipettes or pipette tips (optional)

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.
**Assay Procedure**

- Before loading the ARCHITECT DHEA-S Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend the microparticles that have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
  - **Invert the microparticle bottle 30 times.**
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles remain adhered to the bottle, continue inverting the bottle until the microparticles have been completely resuspended.
  - If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.
  - Once the microparticles have been resuspended, place a septum on the bottle. For instructions on placing septums on bottles, refer to the **Handling Precautions** section of this package insert.

- Load the ARCHITECT DHEA-S Reagent Kit on the ARCHITECT System.
  - Verify that all necessary assay reagents are present.
  - Ensure that septums are present on all reagent bottles.
  - Order calibration, if necessary.
  - For information on ordering calibration, refer to the ARCHITECT System Operations Manual, Section 6.

- Order tests
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.

- The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present before running the test.
  - **Priority:** 70 μL for the first ARCHITECT DHEA-S test plus 20 μL for each additional ARCHITECT DHEA-S test from the same sample cup.
  - **≤ 3 hours on board:** 150 μL for the first ARCHITECT DHEA-S test plus 20 μL for each additional ARCHITECT DHEA-S test from the same sample cup.
  - **> 3 hours on board:** additional sample volume is required. For additional information on sample evaporation and volumes, refer to the ARCHITECT System Operations Manual, Section 5.
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.

- Prepare calibrators and controls.
  - Mix ARCHITECT DHEA-S Calibrators and Controls by gentle inversion before use.
  - To obtain the recommended volume requirements for the ARCHITECT DHEA-S Calibrators and Controls, hold the bottles vertically and dispense 5 drops of each calibrator or 5 drops of each control into each respective sample cup.

- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
  - Press RUN.
  - For additional information on principles of operation, refer to the ARCHITECT Operations Manual, Section 3.
  - For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. When a laboratory requires more frequent maintenance, follow those procedures.

**Specimen Dilution Procedures**

Specimens with a DHEA-S concentration > 1500.0 μg/dL (> 40.71 μmol/L) will be flagged as “>1500.0”(“>40.71”) and may be diluted with the Manual Dilution Procedure.

- Manual dilutions should be performed as follows:
  - The suggested dilution for the ARCHITECT DHEA-S assay is 1:2.
  - Add 75 μL of the patient specimen to 75 μL of ARCHITECT DHEA-S Calibrator A.
  - The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The result (before dilution factor is applied) should be greater than 3 μg/dL (0.08 μmol/L).

- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

**Calibration**

- To perform an ARCHITECT DHEA-S calibration, test calibrators A, B, C, D, E, and F in replicates of two. A single sample of each ARCHITECT DHEA-S control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the control package insert. Calibrators should be priority loaded.
  - Calibration Range: 0.0 – 1500.0 μg/dL (0.00 – 40.71 μmol/L).
  - Once an ARCHITECT DHEA-S calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
    - A reagent kit with a new lot number is used.
    - Controls are out of range.

- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

**QUALITY CONTROL PROCEDURES**

The recommended control requirement for the ARCHITECT DHEA-S assay is a single sample of each control to be tested once every 24 hours each day of use. If laboratory quality control procedures require more frequent use of controls to verify test results, follow those procedures.

The ARCHITECT DHEA-S Control values must be within the acceptable ranges specified in the control package insert. Calibrators should be priority loaded.

- For detailed information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Appendix B.
- The ARCHITECT DHEA-S assay belongs to method group 1. Use ARCHITECT DHEA-S Calibrators in place of MasterCheck as described in the ARCHITECT System Operations Manual, Appendix B.

**RESULTS**

**Calculation**

The ARCHITECT DHEA-S assay uses a 4 Parameter Logistic Curve fit (4PLC, Y-weighted) data reduction method to generate a calibration curve.

**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 ARCHITECT System Operations Manual, Section 5.

**Measurement Range (Reportable Range)**

The measurement range for the ARCHITECT DHEA-S assay is 3.0 μg/dL to 1500.0 μg/dL.

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**Measurement Range**

The measurement range for the ARCHITECT DHEA-S assay is 3.0 μg/dL to 1500.0 μg/dL.
LIMITATIONS OF THE PROCEDURE

- If the ARCHITECT DHEA-S results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, the ARCHITECT DHEA-S assay results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Specimens from patients with adrenal tumors or congenital adrenal hyperplasia may exhibit elevated levels of DHEA-S.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA).
- Specimens containing HAMA may produce anomalous values when tested with assay kits (such as ARCHITECT DHEA-S) that employ mouse monoclonal antibodies.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. 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.
- It cannot be excluded that rheumatoid factor present in human serum can interfere with any in vitro immunoassay.

EXPECTED VALUES

It is recommended that each laboratory establish its own reference range, which may be unique to the population it serves depending on the geographical, dietary, or environmental factors. A reference range study was conducted testing a total of 246 samples from female individuals, a total of 240 samples from male individuals and a total of 100 samples from children at one site. These samples gave the following values for the age groups summarized in the following table.*

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Females:</th>
<th></th>
<th></th>
<th>Males:</th>
<th></th>
<th></th>
<th>Children:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>50th percentile</td>
<td>5-95th percentile</td>
<td>50th percentile</td>
<td>5-95th percentile</td>
<td>50th percentile</td>
<td>5-95th percentile</td>
<td></td>
<td>50th percentile</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>μmol/L</td>
<td>μg/dL</td>
<td>μmol/L</td>
<td>μg/dL</td>
<td>n</td>
<td>μmol/L</td>
<td>μg/dL</td>
</tr>
</tbody>
</table>

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT DHEA-S assay is designed to have precision of ≤ 10% total CV. A study was performed with the ARCHITECT DHEA-S assay based on guidance from the Clinical and Laboratory Standards Institute, document NCCLS Protocol EP5-A15. Multiple ARCHITECT DHEA-S control lots were assayed using two lots of reagents in replicates of two at two separate times per day for 20 days on four instruments. A third reagent lot was tested in replicates of two at two separate times per day for 10 days on one instrument. Each reagent lot used a single calibration curve throughout the study. Data from this study are summarized in the following table.*

<table>
<thead>
<tr>
<th>Sample</th>
<th>n</th>
<th>Mean Concentration (μg/dL)</th>
<th>Within Run CV</th>
<th>Total CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Control</td>
<td>2178</td>
<td>10.7</td>
<td>0.45</td>
<td>4.24</td>
</tr>
<tr>
<td>Medium Control</td>
<td>2178</td>
<td>104.8</td>
<td>1.45</td>
<td>1.38</td>
</tr>
<tr>
<td>High Control</td>
<td>2178</td>
<td>984.5</td>
<td>16.54</td>
<td>1.68</td>
</tr>
</tbody>
</table>

* Total assay variability contains within run, run to run and day to day variability.
* Representative performance data are shown. Results obtained at individual laboratories may vary.

Recovery

The ARCHITECT DHEA-S assay is designed to have a mean recovery of 100 ± 10%. A study was performed where known concentrations (20, 60, 180, 540, 1080 μg/dL) of DHEA-S were added to 10 aliquots of human serum with endogenous levels ranging from 10.6 to 173.1 μg/dL. The concentration of DHEA-S and the percent recovery was calculated for each sample. The percent recovery of the ARCHITECT DHEA-S assay resulted in a mean of 102%. Data are representative performance data, but results obtained at individual laboratories may vary.

Dilution Linearity

The ARCHITECT DHEA-S assay is designed to recover diluted specimens within ± 10% of the expected result. A dilution linearity study was performed using specimens with undiluted values that ranged between 132.1 and 386.5 μg/dL. These specimens were diluted manually using normal human serum free of DHEA-S at various dilution factors to result in 10 to 90% of the endogenous DHEA-S level. Data from this study are summarized in the following tables.*

<table>
<thead>
<tr>
<th>Sample</th>
<th>Dilution Factor</th>
<th>Observed Values (μg/dL)</th>
<th>% Mean Recovery a</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>undiluted</td>
<td>287.4</td>
<td>…</td>
</tr>
<tr>
<td></td>
<td>0.1 to 0.9</td>
<td>266.8 to 29.5</td>
<td>103</td>
</tr>
<tr>
<td>2</td>
<td>undiluted</td>
<td>142.3</td>
<td>…</td>
</tr>
<tr>
<td></td>
<td>0.1 to 0.9</td>
<td>126.0 to 15.9</td>
<td>101</td>
</tr>
<tr>
<td>3</td>
<td>undiluted</td>
<td>362.0</td>
<td>…</td>
</tr>
<tr>
<td></td>
<td>0.1 to 0.9</td>
<td>327.5 to 36.3</td>
<td>98</td>
</tr>
</tbody>
</table>

In addition, a dilution study was performed using specimens with different high and low DHEA-S concentration values ranging from 27.7 to 707.1 μg/dL. The low level sample was used to dilute the high level sample to different concentrations.

* Representative performance data are shown. Results obtained at individual laboratories may vary.
<table>
<thead>
<tr>
<th>Sample Pair</th>
<th>Undiluted Concentration Level (μg/dL)</th>
<th>Diluted Concentration Range (μg/dL)</th>
<th>% Mean Recovery&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low 27.7</td>
<td>High 490.7</td>
<td>154.4 to 382.0</td>
</tr>
<tr>
<td>2</td>
<td>Low 34.6</td>
<td>High 540.1</td>
<td>162.9 to 406.8</td>
</tr>
<tr>
<td>3</td>
<td>Low 47.7</td>
<td>High 602.7</td>
<td>179.6 to 453.1</td>
</tr>
</tbody>
</table>

<sup>a</sup> % Recovery = \( \frac{\text{Observed Value (μg/dL)}}{\text{Expected Value (μg/dL)}} \times 100 \)

% Mean Recovery = Mean of % Recovery of all dilutions of a sample

* Representative performance data are shown. Results obtained at individual laboratories may vary.

**Sensitivity**

The ARCHITECT DHEA-S assay is designed to have an analytical sensitivity of \( \leq 3.0 \) μg/dL. Analytical sensitivity is defined as the concentration at two standard deviations above the calibrator A (0.0 μg/dL). In a study \((n = 6 \text{ runs}, 20 \text{ replicates of calibrator A using three instruments and two reagent lots})\), the analytical sensitivity was calculated to be 1.8 μg/dL at a 95% level of confidence.

Representative performance data are shown. Results obtained at individual laboratories may vary.

**Specificity**

The specificity of the ARCHITECT DHEA-S assay is designed to have \( \leq 10\% \) cross-reactivity when tested with structurally similar compounds listed in the table below. A study was performed with the ARCHITECT DHEA-S assay based on guidance from the Clinical and Laboratory Standards Institute, document NCCLS Protocol EP7-A. An aliquots of calibrator A, containing essentially no residual DHEA-S, were supplemented with potential cross-reactants at the concentrations listed and tested for DHEA-S. Data from this study are summarized in the following table.*

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration Cross Reactant (μg/dL)</th>
<th>% Cross Reactivity&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHEA</td>
<td>4000</td>
<td>-0.002</td>
</tr>
<tr>
<td>Cortisol</td>
<td>10000</td>
<td>0.000</td>
</tr>
<tr>
<td>Aldosterone</td>
<td>5000</td>
<td>-0.004</td>
</tr>
<tr>
<td>Estradiol</td>
<td>5000</td>
<td>0.001</td>
</tr>
<tr>
<td>Testosterone</td>
<td>2000</td>
<td>0.000</td>
</tr>
<tr>
<td>5-dihydrotestosterone</td>
<td>5000</td>
<td>-0.011</td>
</tr>
<tr>
<td>Androstenedione</td>
<td>1000</td>
<td>0.003</td>
</tr>
<tr>
<td>Androsterone</td>
<td>2000</td>
<td>-0.021</td>
</tr>
<tr>
<td>Andro-Glucuronide</td>
<td>2000</td>
<td>-0.002</td>
</tr>
<tr>
<td>Estril</td>
<td>5000</td>
<td>0.008</td>
</tr>
<tr>
<td>Estrone</td>
<td>5000</td>
<td>0.001</td>
</tr>
<tr>
<td>19-hydroxyandrostenedione</td>
<td>1000</td>
<td>0.025</td>
</tr>
<tr>
<td>Progesterone</td>
<td>5000</td>
<td>0.003</td>
</tr>
<tr>
<td>Androsterone Sulfate</td>
<td>5000</td>
<td>0.034</td>
</tr>
<tr>
<td>Estrone-3-Sulfate</td>
<td>5000</td>
<td>0.065</td>
</tr>
<tr>
<td>DHEA Glucuronide</td>
<td>5000</td>
<td>0.006</td>
</tr>
</tbody>
</table>

<sup>a</sup> % Cross Reactivity = \( \frac{\text{Mean Value spiked (μg/dL)}}{\text{Mean Value non spiked (μg/dL)}} \times 100 \)

* Representative performance data are shown. Results obtained at individual laboratories may vary.

**Interference**

Potential interference in the ARCHITECT DHEA-S assay from hemoglobin, bilirubin, triglycerides, and protein at the levels indicated below is designed to be \( \leq 10\% \). Interference was demonstrated by a study based on guidance from the Clinical and Laboratory Standards Institute, document NCCLS Protocol EP7-A. There was no significant interference observed since the % mean recovery is within \( \pm 10\% \) of the expected value. Data from this study are summarized in the following table.*

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
<th>% Mean Recovery&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>500 mg/dL</td>
<td>95</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>20 mg/dL</td>
<td>100</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>5000 mg/dL</td>
<td>102</td>
</tr>
<tr>
<td>Protein low</td>
<td>4 g/dL</td>
<td>94</td>
</tr>
<tr>
<td>Protein high</td>
<td>12 g/dL</td>
<td>100</td>
</tr>
</tbody>
</table>

<sup>a</sup> % Recovery = \( \frac{\text{Observed Value (μg/dL)}}{\text{Expected Value (μg/dL)}} \times 100 \)

% Mean Recovery = Mean of % Recovery of all samples

* Representative performance data are shown. Results obtained at individual laboratories may vary.

**Method Comparison**

The ARCHITECT DHEA-S assay is designed to have a slope difference of \( \pm 15\% \) and a correlation coefficient of \( \geq 0.90 \) when compared to a commercially available diagnostic kit. A study was performed with the ARCHITECT DHEA-S assay, where regression analysis was performed using the Passing-Bablok and Least Squares regression methods. Data from this study are summarized in the following table and graph.*

**ARCHITECT DHEA-S vs. Comparison Assay**

<table>
<thead>
<tr>
<th>Method</th>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passing-Bablok&lt;sup&gt;a&lt;/sup&gt;</td>
<td>550</td>
<td>1.08</td>
<td>1.77</td>
<td>0.98</td>
</tr>
<tr>
<td>Least Squares</td>
<td>550</td>
<td>1.04</td>
<td>9.34</td>
<td>0.98</td>
</tr>
</tbody>
</table>

<sup>a</sup> A linear regression method with no special assumptions regarding the distribution of samples and measurement errors.

A bias analysis of the ARCHITECT DHEA-S vs. the comparison assay was performed on the same 550 serum specimens. The average % Bias of ARCHITECT DHEA-S vs. the comparison assay in this study was 22.8%. The 95% confidence interval of that average percent bias is -202.5% to 248.0%.

The following graph demonstrates the % Bias between the two assays.*
In this evaluation, specimen concentrations range from 4.3 μg/dL to 820.0 μg/dL with the ARCHITECT DHEA-S assay and from 0.2 μg/dL to 961.1 μg/dL with the commercially available diagnostic kit.

* Representative performance data are shown. Variables such as differences in sampling size and sample population may impact the correlation of the assay, therefore, results obtained at individual laboratories may vary from these data.

**BIBLIOGRAPHY**


