VI. SPECIMEN COLLECTION AND PREPARATION

 warns of the measurement of androstenedione (4-Androstenedione-3,17-dione) in serum or plasma. This assay is intended for in vitro diagnostic use.

 VII. PROCEDURAL NOTES

 A.

 B.

 C.

 D.

 IX. RESULTS

 The results in this package insert were calculated using log-linear curve fit. Other data reduction methods may give slightly different results.

 A. Calculate the mean counts per minute (cpm) for each Standard, Control and unknown. Calculate the % B/T or % B/Bo for each Standard, Control and unknown as follows:

 B.

 C.

 D.

 X. LIMITATIONS

 The reagents supplied in this kit are optimized to measure androstenedione levels in serum or plasma.

 Avoid repeated freezing and thawing of reagents or specimens.

 Hematologic and genomic specimens may give false androstenedione values and should not be used.

 XI. QUALITY CONTROL

 Maximum binding (B %) or counts bound in the absence of unlabelled antigen, is approximately 35% when freshly iodinated tracer is used and may fall to 20% as it nears the expiration date.

 Maximum binding (B %) = 50.9. Sodium azide may react with lead and copper plumbing to form explosive metal azides. Dispose of all nonradioactive reagents by flushing with large amounts of water through the plumbing system.

 V. PRECAUTIONS

 In vitro diagnostic use.

 Radiolabeled Material – Not for Internal or External Use in Humans or Animals.

 The following precautions should be observed in handling radiolabeled material:

 Warning: POTENTIAL BIOHAZARDOUS MATERIAL

 This kit contains certain reagents made with human serum or plasma. The serum or plasma used has been tested by and FDA-approved method and found to be non-reactive for HIV-1 Antibody, Hepatitis A and B.

 As stated in Section IV, some of the reagents in this kit contain sodium azide as a preservative. For all such reagents, the concentration of sodium azide is 5.09%. Sodium azide may react with lead and copper plumbing to form explosive metal azides. Dispose of all nonradioactive reagents by flushing with large amounts of water through the plumbing system.

 VI. SPECIMEN COLLECTION AND PREPARATION

 Serum or plasma should be used and the usual precautions for venipuncture should be observed. The serum or plasma may be stored at 2–8°C for up to 24 hours and should be frozen at 0°C or lower for longer periods. Repeated freezing and thawing of the samples may decrease androstenedione levels. Do not use grossly hemolyzed or grossly lipemic specimens.

 Assay values for plasma samples (heparin or EDTA) may be lower than for serum.

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 Assay values for plasma samples (heparin or EDTA) may be lower than for serum.

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In another study, results were as follows:

It is recommended that each laboratory establish its own expected ranges for androstenedione. Results of normal range studies conducted with the ICN Pharmaceuticals, Inc. Androstenedione Coated-TubeRIA Assay by an independent laboratory are reported below:

<table>
<thead>
<tr>
<th>POPULATION</th>
<th>N</th>
<th>MEAN (ng/mL)</th>
<th>2SD RANGE (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>39</td>
<td>1.46</td>
<td>0.30 - 2.63</td>
</tr>
<tr>
<td>Females</td>
<td>49</td>
<td>1.54</td>
<td>0.10 - 2.99</td>
</tr>
<tr>
<td>All Subjects</td>
<td>88</td>
<td>1.53</td>
<td>0.14 - 2.92</td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Males (20-40 years)</td>
<td>20</td>
<td>1.70</td>
<td>0.30 - 3.10</td>
</tr>
<tr>
<td>Females (20-40 years)</td>
<td>38</td>
<td>1.65</td>
<td>0.21 - 3.08</td>
</tr>
</tbody>
</table>

EDL = 0.99 ng/mL

CAUTION: The above data must not be employed in lieu of data obtained by the user in the laboratory.

XII. EXPECTED VALUES

It is recommended that each laboratory establish its own expected ranges for androstenedione. Results of normal range studies conducted with the ICN Pharmaceuticals, Inc. Androstenedione Coated-TubeRIA Assay by an independent laboratory are reported below:

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</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>13</td>
<td>1.57</td>
<td>0.53 - 2.61</td>
</tr>
<tr>
<td>Females</td>
<td>19</td>
<td>1.41</td>
<td>0.37 - 2.44</td>
</tr>
</tbody>
</table>

XIII. PERFORMANCE CHARACTERISTICS

All performance characteristics are expressed in ng/mL. To convert to nmol/L: ng/mL x 3.45 = nmol/L

A. Sensitivity: The theoretical sensitivity, or minimum detection limit, calculated by the interpolation of the mean minus two standard deviations of 10 replicates of the 0 ng/mL Androstenedione Standard, is 0.03 ng/mL.

B. Precision: The intra-assay precision was determined from the mean of average duplicates for 13 separate runs. The inter-assay precision was determined from the mean of 12 replicates each.

C. Recovery: Three serum samples containing different levels of endogenous androstenedione were spiked with known amounts of androstenedione and assayed.

D. Linearity of Dilution: Three serum samples were diluted with 0 ng/mL Androstenedione Standard and assayed.

E. Specificity: The cross-reactivity of the Androstenedione antiserum has been measured against various compounds. The percent cross-reactivity is expressed as the ratio of the androstenedione concentration to the concentration of the reacting compound at 50% binding of the 0 ng/mL Standard A.

XIV. REFERENCES


