Exceptional diagnostics for reproductive disease state management.

Access Unconjugated Estriol

Estriol (E3) is one of the three major naturally occurring estrogens, the others being estradiol (E2) and estrone (E1). In non-pregnant females, the major estrogen is estradiol produced by the ovaries. During pregnancy, estriol is secreted by the placenta and fetus and becomes the dominant estrogen form.¹ Estriol production is very low in men and non-pregnant women in comparison to levels produced during pregnancy.

The primary form of estriol measured during pregnancy is unconjugated estriol (also referred to as “free” estriol or uE3). Maternal serum uE3 levels have been used as a functional marker of the fetal-placental unit and in the evaluation of pregnancy complications.² Generally, a healthy fetal-placental unit will generate increasing amounts of estriol throughout pregnancy, resulting in a corresponding increase in maternal serum uE3.

Access Unconjugated Estriol offers:
• 30-minute time to first result provides efficiency
• Fully automated method aids in improving lot-to-lot consistency
• Excellent precision and low end sensitivity for high confidence in results
• Clinically relevant reportable range of 0.017 - 6.9 ng/mL reduces the need for manual sample dilution
• Standardized to GC-MS

¹ Tietz textbook of clinical chemistry and molecular diagnostics. 4th ed; P. 2185
² Adapted from Tietz textbook of clinical chemistry and molecular diagnostics. 4th ed; P. 2185

Concentration of unconjugated estriol (uE3) in maternal serum as a function of gestational age.
Access Unconjugated Estriol

Expected Values

Each laboratory should establish its own reference ranges to ensure proper representation of specific populations.

Imprecision

One study, using commercially available human serum-based control material generating a total of 20 assays, 3 replicates per assay, over 10 days provided the data below. Data was analyzed using an analysis of variance (ANOVA).

<table>
<thead>
<tr>
<th>Sample</th>
<th>Grand Mean (n=60) (ng/mL)</th>
<th>Within Run SD (ng/mL)</th>
<th>Within Run (% CV)</th>
<th>Total SD (ng/mL)</th>
<th>Total Imprecision (% CV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>0.267</td>
<td>0.016</td>
<td>6.15</td>
<td>0.029</td>
<td>10.75</td>
</tr>
<tr>
<td>Medium</td>
<td>2.594</td>
<td>0.085</td>
<td>2.51</td>
<td>0.123</td>
<td>4.73</td>
</tr>
<tr>
<td>High</td>
<td>4.832</td>
<td>0.085</td>
<td>1.76</td>
<td>0.165</td>
<td>3.42</td>
</tr>
</tbody>
</table>

Characteristics

- Sample Type / Size: Serum / 25 μL
- Time to First Result: 30 min
- Analytical Sensitivity: 0.017 ng/mL
- Approximate Calibrator Levels: 0, 0.07, 0.34, 0.86, 3.4 & 6.9 ng/mL
- Reportable Range: 0.017 – 6.9 ng/mL
- Open Pack Stability: 28 days
- Calibration Stability: 28 days

Ordering Information

- Reagent Kit (2 x 50 tests): 33570
- Calibrators (2 sets: S0 x 4.0 mL, S1-S6 x 2.5 mL): 33575

References


Access Reproductive – A Menu that Matters

Access reproductive solutions are part of a comprehensive assay menu featured on Access and UniCel Immunoassay Systems. To learn more, visit www.beckmancoulter.com/reproductive.