

May 1, 2010

**Endocrinology Service Update: Reference Range Update**

**Test Title:** 17-alpha-hydroxy Progesterone by HPLC-MS/MS

**Test Code:** 500270

**CPT Code:** 83498 (no change)

**Effective Date:** June 21, 2010

**Explanation of change:** The reference range for 17-alpha-hydroxyProgesterone (17-OHP) by HPLC-MS/MS will be updated to reflect the lower limit of quantitation.

In an effort to make 17-OHP reference ranges consistent with the lower limit of quantitation, Esoterix will be updating reference ranges for Infants, Prepubertal Children, Tanner 1 and 2 for Pubertal Males, and Tanner 1 for Pubertal Females. These ranges will be updated to incorporate "less than" signs instead of the previous numerical range. There is no change in the assay performance, methodology, specimen requirements, or pricing.

Please refer to the attached chart for updated reference ranges. For additional information, please call us at 800 444-9111. We value you as a customer and thank you for choosing Esoterix.

Description	Predicate Reference Range	New Reference Range																																																																																																
<p>Reference Range 17-OHP, HPLC-MS/MS</p> <p>Reporting units of ng/dL</p>	<p><b>Gender Range (ng/dL)</b></p> <p><b>Newborns (&lt;8 days):</b> Premature (26 - 28w) Day 4: 124 - 841 Premature (31 - 35w) Day 4: 26 - 568</p> <p>Full Term Day 3: 7 – 77</p> <p><b>Male (1-11mo):</b> Levels increase after the first week to peak values ranging from 40 - 200 between 30 and 60 days. Values then decline to the prepubertal range of 3 - 90 before one year.</p> <p><b>Female (1-11mo):</b> 13 - 106</p> <p><b>Prepubertal Children:</b></p> <p><b>Male (&lt;10 yrs):</b> Prepubertal: 3 – 90 <b>Female (&lt;9 yrs):</b> Prepubertal: 3 – 90</p> <p><b>Pubertal Males</b></p> <table border="1"> <thead> <tr> <th>Tanner Stage</th> <th>Age (Years)</th> <th>Range (ng/dL)</th> <th>Mean (ng/dL)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>&lt;9.8</td> <td>3 – 90</td> <td>38</td> </tr> <tr> <td>2</td> <td>9.8 – 14.5</td> <td>5 – 115</td> <td>51</td> </tr> <tr> <td>3</td> <td>10.7 – 15.4</td> <td>10 – 138</td> <td>57</td> </tr> <tr> <td>4</td> <td>11.8 – 16.2</td> <td>29 – 180</td> <td>80</td> </tr> <tr> <td>5</td> <td>12.8 – 17.3</td> <td>24 – 175</td> <td>97</td> </tr> </tbody> </table> <p><b>Pubertal Females</b></p> <table border="1"> <thead> <tr> <th>Tanner Stage</th> <th>Age (Years)</th> <th>Range (ng/dL)</th> <th>Mean (ng/dL)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>&lt;9.2</td> <td>3 – 82</td> <td>31</td> </tr> <tr> <td>2</td> <td>9.2 – 13.7</td> <td>11 – 98</td> <td>49</td> </tr> <tr> <td>3</td> <td>10.0 – 14.4</td> <td>11 – 155</td> <td>70</td> </tr> <tr> <td>4</td> <td>10.7 – 15.6</td> <td>18 – 230</td> <td>91</td> </tr> <tr> <td>5</td> <td>11.8 – 18.6</td> <td>20 – 265</td> <td>108</td> </tr> </tbody> </table> <p><b>Gender Range (ng/dL)</b></p> <p><b>Adult Males:</b> 27 - 199 <b>Adult Females</b></p> <p><b>Follicular:</b> 15 - 70 <b>Luteal:</b> 35 - 290</p>	Tanner Stage	Age (Years)	Range (ng/dL)	Mean (ng/dL)	1	<9.8	3 – 90	38	2	9.8 – 14.5	5 – 115	51	3	10.7 – 15.4	10 – 138	57	4	11.8 – 16.2	29 – 180	80	5	12.8 – 17.3	24 – 175	97	Tanner Stage	Age (Years)	Range (ng/dL)	Mean (ng/dL)	1	<9.2	3 – 82	31	2	9.2 – 13.7	11 – 98	49	3	10.0 – 14.4	11 – 155	70	4	10.7 – 15.6	18 – 230	91	5	11.8 – 18.6	20 – 265	108	<p><b>Gender Range (ng/dL)</b></p> <p><b>Newborns (&lt;8 days):</b> Premature (26 - 28w) Day 4: 124 - 841 Premature (31 - 35w) Day 4: 26 - 568</p> <p>Full Term Day 3: &lt;78</p> <p><b>Male (1-11mo):</b> Levels increase after the first week to peak values ranging from 40 - 200 between 30 and 60 days. Values then decline to a prepubertal value of &lt;91 before one year.</p> <p><b>Female (1-11mo):</b> 13 - 106</p> <p><b>Prepubertal Children:</b></p> <p><b>Male (&lt;10 yrs):</b> Prepubertal: &lt;91 <b>Female (&lt;9 yrs):</b> Prepubertal: &lt;91</p> <p><b>Pubertal Males</b></p> <table border="1"> <thead> <tr> <th>Tanner Stage</th> <th>Age (Years)</th> <th>Range (ng/dL)</th> <th>Mean (ng/dL)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>&lt;9.8</td> <td>&lt;91</td> <td>38</td> </tr> <tr> <td>2</td> <td>9.8 – 14.5</td> <td>&lt;116</td> <td>51</td> </tr> <tr> <td>3</td> <td>10.7 – 15.4</td> <td>10 – 138</td> <td>57</td> </tr> <tr> <td>4</td> <td>11.8 – 16.2</td> <td>29 – 180</td> <td>80</td> </tr> <tr> <td>5</td> <td>12.8 – 17.3</td> <td>24 – 175</td> <td>97</td> </tr> </tbody> </table> <p><b>Pubertal Females</b></p> <table border="1"> <thead> <tr> <th>Tanner Stage</th> <th>Age (Years)</th> <th>Range (ng/dL)</th> <th>Mean (ng/dL)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>&lt;9.2</td> <td>&lt;83</td> <td>31</td> </tr> <tr> <td>2</td> <td>9.2 – 13.7</td> <td>11 – 98</td> <td>49</td> </tr> <tr> <td>3</td> <td>10.0 – 14.4</td> <td>11 – 155</td> <td>70</td> </tr> <tr> <td>4</td> <td>10.7 – 15.6</td> <td>18 – 230</td> <td>91</td> </tr> <tr> <td>5</td> <td>11.8 – 18.6</td> <td>20 – 265</td> <td>108</td> </tr> </tbody> </table> <p><b>Gender Range (ng/dL)</b></p> <p><b>Adult Males:</b> 27 - 199 <b>Adult Females</b></p> <p><b>Follicular:</b> 15 - 70 <b>Luteal:</b> 35 - 290</p>	Tanner Stage	Age (Years)	Range (ng/dL)	Mean (ng/dL)	1	<9.8	<91	38	2	9.8 – 14.5	<116	51	3	10.7 – 15.4	10 – 138	57	4	11.8 – 16.2	29 – 180	80	5	12.8 – 17.3	24 – 175	97	Tanner Stage	Age (Years)	Range (ng/dL)	Mean (ng/dL)	1	<9.2	<83	31	2	9.2 – 13.7	11 – 98	49	3	10.0 – 14.4	11 – 155	70	4	10.7 – 15.6	18 – 230	91	5	11.8 – 18.6	20 – 265	108
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