Every child deserves accurate results

Pediatric reference intervals for diagnosis and treatment you can count on

siemens-healthineers.com
Currently, many pediatric laboratory tests are inappropriately interpreted using reference intervals derived from adult populations, hospitalized pediatric populations, or outdated methodologies. In addition, challenges with limited sample volume and integrating pediatric testing can adversely affect workflow. Age-specific reference intervals are extremely important for interpreting measurements in the pediatric population, but unfortunately, there are very few studies that provide this information.

Siemens Healthineers helps you meet the challenges involved in establishing reference intervals for tests performed in the pediatric setting. We have conducted extensive studies to establish clinically relevant pediatric reference intervals for many disease states on Siemens Healthineers systems, including Atellica® Solution, ADVIA Centaur®, and Dimension® EXL™ systems. Benefits of using these reference intervals include:

• Accurately determined reference intervals using robust statistically sound studies and well-characterized healthy populations for proper clinical interpretation of pediatric lab results
• Increased lab efficiency and cost-effectiveness by use of established pediatric reference intervals
• Improved workflow through optimized processing of pediatric samples with minimal sample volume requirements

Developing accurate reference intervals is often impeded by limited availability of samples from healthy pediatric populations. Fast, accurate results with appropriate age-specific reference intervals from the laboratory can help physicians diagnose and determine treatment in a timely manner. Siemens Healthineers is committed to providing these reference intervals and supporting initiatives to protect the lives of our most vulnerable patients.
Pediatric Reference Intervals for Select Atellica CH, Atellica IM, and ADVIA Centaur Assays

**Allergy**

**Atellica® IM Total IgE (tIgE) and ADVIA Centaur Total IgE (ItgE) Assay**

Data was obtained on serum samples from 103 clinically normal adults. The observed range of these samples was 0 to 378 IU/mL, with a geometric mean of 17 IU/mL. Refer to the following table for the distribution. Samples from 109 healthy children were assayed with the following results:

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of Samples</th>
<th>Geometric Mean (IU/mL)</th>
<th>Geometric Mean ±2SD (IU/mL)</th>
<th>Range (IU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>7</td>
<td>8.5</td>
<td>0.61–117.4</td>
<td>1.4–52.3</td>
</tr>
<tr>
<td>1–4</td>
<td>45</td>
<td>9.3</td>
<td>0.28–313.5</td>
<td>0.4–351.6</td>
</tr>
<tr>
<td>5–10</td>
<td>30</td>
<td>18.5</td>
<td>0.61–555.1</td>
<td>0.5–393.0</td>
</tr>
<tr>
<td>11–15</td>
<td>27</td>
<td>25.7</td>
<td>1.40–481.1</td>
<td>1.9–170.0</td>
</tr>
</tbody>
</table>

**Bone**

**Atellica IM and ADVIA Centaur Vitamin D (VitD) Assay**

Pediatric samples with normal values for PTH and TSH were included in this study. Based on the 95% confidence interval, the following values were established following CLSI guideline EP28-A3c.

A review of the available literature suggests pediatric recommendations for 25(OH) vitamin D levels shown in the following table.

<table>
<thead>
<tr>
<th>Vitamin D Status</th>
<th>Range (ng/mL)</th>
<th>Range (nmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deficiency</td>
<td>&lt;15</td>
<td>37.5</td>
</tr>
<tr>
<td>Insufficiency</td>
<td>15 to &lt;20</td>
<td>37.5 to &lt;50</td>
</tr>
<tr>
<td>Sufficiency</td>
<td>20–100</td>
<td>50–250</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Observed Values (12 months up to 21 years) (ng/mL)</th>
<th>nmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median 25(OH) vitamin D</td>
<td>Serum: 23.8</td>
<td>59.5</td>
</tr>
<tr>
<td></td>
<td>Plasma: 12.7</td>
<td>31.8</td>
</tr>
<tr>
<td>Range</td>
<td>Serum: 11.4–45.8</td>
<td>28.5–114.5</td>
</tr>
<tr>
<td></td>
<td>Plasma: 5.2–35.2</td>
<td>13.0–88.0</td>
</tr>
</tbody>
</table>

**Caffeine**

**Emit® Caffeine Assay**

Caffeine is a pharmacologically active metabolite of theophylline. Premature infants receiving theophylline have significant levels of caffeine in their blood because they metabolize theophylline to caffeine. Observed therapeutic range for caffeine in neonates is shown in the following table. Values obtained from the Emit Caffeine Assay should be interpreted in light of serum theophylline levels for those patients receiving theophylline therapy and other clinical signs and symptoms.

<table>
<thead>
<tr>
<th>Group</th>
<th>Specimen Type</th>
<th>Reference Interval (μg/mL)</th>
<th>Reference Interval (μmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonates</td>
<td>Serum</td>
<td>8–20</td>
<td>41.6–104</td>
</tr>
</tbody>
</table>
Chemistry

Atellica® CH Glucose Hexokinase (GluH_3) Assay

<table>
<thead>
<tr>
<th>Group</th>
<th>Specimen Type</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborn</td>
<td>Serum/plasma</td>
<td>40–60 (mg/dL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.2–3.3 (mmol/L)</td>
</tr>
<tr>
<td>Newborn &gt;1 day</td>
<td>Serum/plasma</td>
<td>50–80 (mg/dL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.8–4.4 (mmol/L)</td>
</tr>
<tr>
<td>Child</td>
<td>Serum/plasma</td>
<td>60–100 (mg/dL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.3–5.6 (mmol/L)</td>
</tr>
<tr>
<td>Infant/child</td>
<td>Cerebrospinal fluid</td>
<td>60–80 (mg/dL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.3–4.4 (mmol/L)</td>
</tr>
</tbody>
</table>

Atellica CH Glucose Oxidase (GluO) Assay

<table>
<thead>
<tr>
<th>Group</th>
<th>Specimen Type</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants and children</td>
<td>Cerebrospinal fluid</td>
<td>60–80 (mg/dL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.3–4.4 (mmol/L)</td>
</tr>
</tbody>
</table>

Atellica CH Total Bilirubin (TBil_2) Assay

<table>
<thead>
<tr>
<th>Age</th>
<th>Expected Values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(mg/dL)</td>
</tr>
<tr>
<td>0–1 day</td>
<td>&lt;8.0</td>
</tr>
<tr>
<td>1–2 days</td>
<td>&lt;12.0</td>
</tr>
<tr>
<td>3–5 days</td>
<td>&lt;16.0</td>
</tr>
<tr>
<td>&gt;5 days–60 years</td>
<td>0.3–1.2</td>
</tr>
</tbody>
</table>

>5 days to >29 days are neonates; >29 days to 60 years are children and adults.

Hepatitis

Atellica IM and ADVIA Centaur HBc Total 2 (HBcT2) Assay

A total of 236 specimens were tested, including 54 neonatal (cord blood) specimens and 182 pediatric specimens.

<table>
<thead>
<tr>
<th>ADVIA Centaur HBcT2 Assay</th>
<th>Comparative Anti-HBc Total Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reactive</td>
</tr>
<tr>
<td>Reactive</td>
<td>3</td>
</tr>
<tr>
<td>Nonreactive</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
</tr>
</tbody>
</table>

The relative sensitivity of the ADVIA Centaur HBcT2 Assay was 100% (3/3) (95% CI: 29.2–100%).

The resolved relative specificity of the ADVIA Centaur HBcT2 Assay was 99.6% (232/233)(95% CI: 97.6–100.0%).
Reference intervals for the pediatric population (children and adolescents) were established for the ADVIA Centaur DHEAS, E2, FSH, LH, Progesterone, and Prolactin Assays in accordance with CLSI guideline EP28-A3c. Samples were collected prospectively from apparently healthy pediatric subjects using predefined inclusion criteria. Reference values were generated for subpopulations based on age and Tanner stage subgroups based on physiological development. The study was designed to establish reference values across genders and to include approximately equal numbers of males and females within each age or Tanner stage subgroup. The subject’s Tanner stage was assessed based on pubic hair and genitalia/breast development. The reference intervals and Tanner values are based on the central 90% (5th and 95th percentiles).

### Atellica IM and ADVIA Centaur Dehydroepiandrosterone Sulfate (DHEAS) Assay

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of Samples</th>
<th>Median (µg/dL)</th>
<th>Interval (µg/dL)</th>
<th>Median (µmol/L)</th>
<th>Interval (µmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>11</td>
<td>&lt;3.0</td>
<td>&lt;3.0—21.7&lt;sup&gt;a&lt;/sup&gt;</td>
<td>&lt;0.08</td>
<td>&lt;0.08—0.6&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>4–9</td>
<td>57</td>
<td>19.9</td>
<td>&lt;3.0—88.6</td>
<td>0.5</td>
<td>&lt;0.08—2.4</td>
</tr>
<tr>
<td>10–14</td>
<td>158</td>
<td>123.3</td>
<td>37.3—270.2</td>
<td>3.3</td>
<td>1.0—7.3</td>
</tr>
<tr>
<td>15–21</td>
<td>82</td>
<td>260.4</td>
<td>101.6—522.6</td>
<td>7.1</td>
<td>2.8—14.2</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>15</td>
<td>7.9</td>
<td>3.0—23.7&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.2</td>
<td>&lt;0.08—0.6&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>4–9</td>
<td>45</td>
<td>27.4</td>
<td>&lt;3.0—108.3</td>
<td>0.7</td>
<td>&lt;0.08—2.9</td>
</tr>
<tr>
<td>10–15</td>
<td>174</td>
<td>100</td>
<td>33.4—245.0</td>
<td>2.7</td>
<td>0.9—6.7</td>
</tr>
<tr>
<td>16–21</td>
<td>44</td>
<td>192</td>
<td>98.3—413.4</td>
<td>5.2</td>
<td>2.7—11.2</td>
</tr>
</tbody>
</table>

<sup>a</sup>. Value presented is the minimum reportable value observed; insufficient sample size to calculate a 5th percentile limit.

<sup>b</sup>. Value presented is the maximum value observed; insufficient sample size to calculate a 95th percentile limit.

### Pediatric Reference Intervals Characterized by Tanner Stage

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median (µg/dL)</th>
<th>Interval (µg/dL)</th>
<th>Median (µmol/L)</th>
<th>Interval (µmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>113</td>
<td>40.3</td>
<td>&lt;3.0—152.0</td>
<td>1.1</td>
<td>&lt;0.8—4.1</td>
</tr>
<tr>
<td>2</td>
<td>45</td>
<td>103.2</td>
<td>23.8—267.7</td>
<td>2.8</td>
<td>0.6—7.3</td>
</tr>
<tr>
<td>3</td>
<td>52</td>
<td>175.9</td>
<td>84.7—327.7</td>
<td>4.8</td>
<td>2.3—8.9</td>
</tr>
<tr>
<td>4</td>
<td>53</td>
<td>218.9</td>
<td>85.3—471.1</td>
<td>5.9</td>
<td>2.3—12.8</td>
</tr>
<tr>
<td>5</td>
<td>45</td>
<td>267.4</td>
<td>92.0—520.7</td>
<td>7.3</td>
<td>2.5—14.1</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>79</td>
<td>27.4</td>
<td>&lt;3.0—134.5</td>
<td>0.7</td>
<td>&lt;0.08—3.7</td>
</tr>
<tr>
<td>2</td>
<td>45</td>
<td>86.1</td>
<td>23.1—182.5</td>
<td>2.3</td>
<td>0.6—5.0</td>
</tr>
<tr>
<td>3</td>
<td>55</td>
<td>96.3</td>
<td>32.3—181.1</td>
<td>2.6</td>
<td>0.9—4.9</td>
</tr>
<tr>
<td>4</td>
<td>50</td>
<td>129.4</td>
<td>52.4—278.5</td>
<td>3.5</td>
<td>1.4—7.6</td>
</tr>
<tr>
<td>5</td>
<td>49</td>
<td>176.8</td>
<td>81.1—403.3</td>
<td>4.8</td>
<td>2.2—10.9</td>
</tr>
</tbody>
</table>

Continued on next page
### Atellica IM and ADVIA Centaur Enhanced Estradiol (EE2) Assay

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of Samples</th>
<th>Median (pg/mL)</th>
<th>Interval (pg/mL)</th>
<th>Median (pmol/L)</th>
<th>Interval (pmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>12</td>
<td>&lt;11.8</td>
<td>11.8–51.4</td>
<td>43.3</td>
<td>43.3–188.6</td>
</tr>
<tr>
<td>4–9</td>
<td>57</td>
<td>&lt;11.8</td>
<td>11.8–26.5</td>
<td>43.3</td>
<td>43.3–97.1</td>
</tr>
<tr>
<td>10–13</td>
<td>121</td>
<td>&lt;11.8</td>
<td>11.8–36.6</td>
<td>43.3</td>
<td>43.3–134.4</td>
</tr>
<tr>
<td>14–21</td>
<td>119</td>
<td>22.7</td>
<td>11.8–48.9</td>
<td>83.3</td>
<td>43.3–179.5</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>18</td>
<td>&lt;11.8</td>
<td>11.8–29.1</td>
<td>43.3</td>
<td>43.3–106.8</td>
</tr>
<tr>
<td>4–9</td>
<td>47</td>
<td>&lt;11.8</td>
<td>11.8–43.7</td>
<td>43.3</td>
<td>43.3–160.3</td>
</tr>
<tr>
<td>10–13</td>
<td>55</td>
<td>27.4</td>
<td>11.8–175.6</td>
<td>100.6</td>
<td>43.3–644.5</td>
</tr>
<tr>
<td>14–21</td>
<td>165</td>
<td>66.8</td>
<td>16.1–238.3</td>
<td>245.2</td>
<td>59.1–874.6</td>
</tr>
</tbody>
</table>

*a. Value presented is the minimum reportable value observed; insufficient sample size to calculate a 5th percentile limit.

*b. Value presented is the maximum value observed; insufficient sample size to calculate a 95th percentile limit.

### Pediatric Reference Intervals Characterized by Tanner Stage

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median (pg/mL)</th>
<th>Interval (pg/mL)</th>
<th>Median (pmol/L)</th>
<th>Interval (pmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>74</td>
<td>&lt;11.8</td>
<td>11.8–29.2</td>
<td>43.3</td>
<td>43.3–107.3</td>
</tr>
<tr>
<td>2</td>
<td>65</td>
<td>&lt;11.8</td>
<td>11.8–27.9</td>
<td>43.3</td>
<td>43.3–102.5</td>
</tr>
<tr>
<td>3</td>
<td>63</td>
<td>16.3</td>
<td>11.8–51.3</td>
<td>59.8</td>
<td>43.3–188.3</td>
</tr>
<tr>
<td>4</td>
<td>59</td>
<td>19.0</td>
<td>11.8–43.9</td>
<td>69.7</td>
<td>43.3–161.1</td>
</tr>
<tr>
<td>5</td>
<td>48</td>
<td>28.9</td>
<td>11.8–66.5</td>
<td>106.1</td>
<td>43.3–243.9</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>74</td>
<td>&lt;11.8</td>
<td>11.8–62.7</td>
<td>43.3</td>
<td>43.3–229.9</td>
</tr>
<tr>
<td>2</td>
<td>47</td>
<td>27.9</td>
<td>11.8–195.6</td>
<td>102.4</td>
<td>43.3–717.8</td>
</tr>
<tr>
<td>3</td>
<td>65</td>
<td>54.1</td>
<td>14.0–219.4</td>
<td>198.5</td>
<td>51.3–805.4</td>
</tr>
<tr>
<td>4</td>
<td>47</td>
<td>64.2</td>
<td>15.6–212.2</td>
<td>235.6</td>
<td>57.3–778.9</td>
</tr>
<tr>
<td>5</td>
<td>52</td>
<td>93.0</td>
<td>21.9–297.2</td>
<td>341.5</td>
<td>80.4–1091.0</td>
</tr>
</tbody>
</table>

*Continued on next page*
### Atellica IM and ADVIA Centaur Follicle-stimulating Hormone (FSH) Assay

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of Samples</th>
<th>Median mlU/mL (IU/L)</th>
<th>Interval mlU/mL (IU/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>12</td>
<td>0.7</td>
<td>&lt;0.3&lt;sup&gt;a&lt;/sup&gt;–1.3&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>4–9</td>
<td>57</td>
<td>1.0</td>
<td>0.4–2.0</td>
</tr>
<tr>
<td>10–11</td>
<td>55</td>
<td>2.0</td>
<td>0.4–4.6</td>
</tr>
<tr>
<td>12–21</td>
<td>181</td>
<td>3.0</td>
<td>1.4–7.5</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>18</td>
<td>3.0</td>
<td>1.3&lt;sup&gt;a&lt;/sup&gt;–5.0&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>4–9</td>
<td>46</td>
<td>1.8</td>
<td>0.5–5.0</td>
</tr>
<tr>
<td>10–11</td>
<td>55</td>
<td>4.7</td>
<td>1.4–9.3</td>
</tr>
<tr>
<td>12–21</td>
<td>162</td>
<td>5.7</td>
<td>2.2–10.1</td>
</tr>
</tbody>
</table>

<sup>a</sup> Value presented is the minimum reportable value observed; insufficient sample size to calculate a 5th percentile value.

<sup>b</sup> Value presented is the maximum value observed; insufficient sample size to calculate a 95th percentile limit.

### FSH Pediatric Reference Value Characterized by Tanner Stage

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median mlU/mL (IU/L)</th>
<th>Interval mlU/mL (IU/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>74</td>
<td>1.2</td>
<td>0.4–3.0</td>
</tr>
<tr>
<td>2</td>
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<td>1.7</td>
<td>0.4–4.7</td>
</tr>
<tr>
<td>3</td>
<td>63</td>
<td>2.7</td>
<td>1.1–7.0</td>
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<tr>
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<td>58</td>
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<td>1.2–10.7</td>
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<tr>
<td>5</td>
<td>46</td>
<td>3.7</td>
<td>1.7–7.4</td>
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<tr>
<td><strong>Female</strong></td>
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<td></td>
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</tr>
<tr>
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<td>74</td>
<td>2.3</td>
<td>0.8–6.5</td>
</tr>
<tr>
<td>2</td>
<td>47</td>
<td>4.9</td>
<td>1.2–10.5</td>
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<tr>
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<td>64</td>
<td>5.9</td>
<td>2.4–9.0</td>
</tr>
<tr>
<td>4</td>
<td>46</td>
<td>5.6</td>
<td>1.3–10.0</td>
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| 5           | 50                | 5.2                  | 1.7–18.5               

Continued on next page
### Atellica IM and ADVIA Centaur Luteinizing Hormone (LH) Assay

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of Samples</th>
<th>Median mlU/mL (IU/L)</th>
<th>Interval mlU/mL (IU/L)</th>
</tr>
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<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>12</td>
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<td>&lt;0.07–0.07(^a)</td>
</tr>
<tr>
<td>4–9</td>
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<td>&lt;0.07</td>
<td>&lt;0.07–0.4</td>
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<tr>
<td>10–12</td>
<td>89</td>
<td>0.8</td>
<td>&lt;0.07–2.9</td>
</tr>
<tr>
<td>13–21</td>
<td>151</td>
<td>2.8</td>
<td>1.0–7.1</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>18</td>
<td>&lt;0.07</td>
<td>&lt;0.07–0.07(^a)</td>
</tr>
<tr>
<td>4–9</td>
<td>47</td>
<td>&lt;0.07</td>
<td>&lt;0.07–0.2</td>
</tr>
<tr>
<td>10–12</td>
<td>93</td>
<td>2.7</td>
<td>&lt;0.07–11.8</td>
</tr>
<tr>
<td>13–21</td>
<td>127</td>
<td>4.6</td>
<td>1.0–52.2</td>
</tr>
</tbody>
</table>

\(^a\) Value presented is the minimum reportable value observed; insufficient sample size to calculate a 5th percentile value.

\(^b\) Value presented is the maximum value observed; insufficient sample size to calculate a 95th percentile limit.

### LH Pediatric Reference Value Characterized by Tanner Stage

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median mlU/mL (IU/L)</th>
<th>Interval mlU/mL (IU/L)</th>
</tr>
</thead>
<tbody>
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<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>&lt;0.07–0.9</td>
</tr>
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<td>65</td>
<td>0.7</td>
<td>&lt;0.07–2.4</td>
</tr>
<tr>
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<td>63</td>
<td>2.1</td>
<td>0.8–5.0</td>
</tr>
<tr>
<td>4</td>
<td>59</td>
<td>2.8</td>
<td>1.1–6.6</td>
</tr>
<tr>
<td>5</td>
<td>48</td>
<td>4.2</td>
<td>1.1–8.4</td>
</tr>
<tr>
<td>Female</td>
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<td></td>
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</tr>
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<td>74</td>
<td>&lt;0.07</td>
<td>&lt;0.07–4.9</td>
</tr>
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<td>47</td>
<td>1.7</td>
<td>&lt;0.07–9.6</td>
</tr>
<tr>
<td>3</td>
<td>65</td>
<td>3.9</td>
<td>0.6–15.9</td>
</tr>
<tr>
<td>4</td>
<td>47</td>
<td>5.2</td>
<td>0.9–32.8</td>
</tr>
<tr>
<td>5</td>
<td>52</td>
<td>5.0</td>
<td>0.6–69.9</td>
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</tbody>
</table>

### Atellica IM and ADVIA Centaur Progesterone (PRG) Assay

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<th>Age (years)</th>
<th>Number of Samples</th>
<th>Median (ng/mL)</th>
<th>Interval (ng/mL)</th>
<th>Median (nmol/L)</th>
<th>Interval (nmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>38</td>
<td>0.29</td>
<td>&lt;0.21–1.74</td>
<td>0.92</td>
<td>&lt;0.67–5.53</td>
</tr>
<tr>
<td>13–21</td>
<td>127</td>
<td>0.65</td>
<td>&lt;0.21–12.40</td>
<td>2.07</td>
<td>&lt;0.67–39.43</td>
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### Progesterone Pediatric Reference Intervals Characterized by Tanner Stage

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<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median (ng/mL)</th>
<th>Interval (ng/mL)</th>
<th>Median (nmol/L)</th>
<th>Interval (nmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>–</td>
</tr>
<tr>
<td>2</td>
<td>18</td>
<td>0.31</td>
<td>&lt;0.21–10.37(^a)</td>
<td>0.97</td>
<td>&lt;0.67–32.98(^b)</td>
</tr>
<tr>
<td>3</td>
<td>49</td>
<td>0.34</td>
<td>&lt;0.21–10.35</td>
<td>1.08</td>
<td>&lt;0.67–32.90</td>
</tr>
<tr>
<td>4</td>
<td>45</td>
<td>0.52</td>
<td>&lt;0.21–8.66</td>
<td>1.65</td>
<td>&lt;0.67–27.55</td>
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<tr>
<td>5</td>
<td>52</td>
<td>0.89</td>
<td>&lt;0.21–15.51</td>
<td>2.81</td>
<td>&lt;0.67–49.32</td>
</tr>
</tbody>
</table>

\(^a\) Value presented is the minimum reportable value observed; insufficient sample size to calculate a 5th percentile limit.

\(^b\) Value presented is the maximum value observed; insufficient sample size to calculate a 95th percentile limit.

*Continued on next page*
## Atellica IM and ADVIA Centaur Prolactin (PRL) Assay

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of Samples</th>
<th>Median (ng/mL)</th>
<th>Interval (ng/mL)</th>
<th>Median (µIU/mL)</th>
<th>Interval (µIU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>12</td>
<td>8.6</td>
<td>3.6–28.6&lt;sup&gt;a&lt;/sup&gt;</td>
<td>183.4</td>
<td>76.3–606.3&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>4–9</td>
<td>57</td>
<td>7.3</td>
<td>4.5–18.0</td>
<td>154.8</td>
<td>95.4–382.2</td>
</tr>
<tr>
<td>10–16</td>
<td>203</td>
<td>6.3</td>
<td>3.2–13.5</td>
<td>133.6</td>
<td>67.8–284.9</td>
</tr>
<tr>
<td>17–21</td>
<td>37</td>
<td>7.9</td>
<td>5.4–15.4</td>
<td>167.5</td>
<td>115.1–326.7</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3</td>
<td>18</td>
<td>7.4</td>
<td>3.1–15.7&lt;sup&gt;a&lt;/sup&gt;</td>
<td>15.6&lt;sup&gt;b&lt;/sup&gt;</td>
<td>65.7–332.8&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
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<td>7.1</td>
<td>3.1–15.8</td>
<td>150.5</td>
<td>66.6–334.1</td>
</tr>
<tr>
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<td>93</td>
<td>7.2</td>
<td>3.5–18.2</td>
<td>152.6</td>
<td>75.0–386.7</td>
</tr>
<tr>
<td>13–21</td>
<td>127</td>
<td>9.2</td>
<td>4.3–23.11</td>
<td>195.0</td>
<td>89.9–489.7</td>
</tr>
</tbody>
</table>

<sup>a</sup> Value presented is the minimum reportable value observed; insufficient sample size to calculate a 5th percentile limit.

<sup>b</sup> Value presented is the maximum value observed; insufficient sample size to calculate a 95th percentile limit.

### Prolactin Pediatric Reference Values Characterized by Tanner Stage

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median (ng/mL)</th>
<th>Interval (ng/mL)</th>
<th>Median (µIU/mL)</th>
<th>Interval (µIU/mL)</th>
</tr>
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<tbody>
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<td>Male</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>74</td>
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<td>3.7–18.5</td>
<td>153.7</td>
<td>78.4–391.1</td>
</tr>
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<td>5.9</td>
<td>2.4–13.7</td>
<td>125.1</td>
<td>49.4–289.4</td>
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<td>63</td>
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<td>3.5–11.9</td>
<td>120.8</td>
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<td>156.9</td>
<td>67.8–328.6</td>
</tr>
<tr>
<td>5</td>
<td>48</td>
<td>7.7</td>
<td>4.9–14.5</td>
<td>162.2</td>
<td>105.6–306.9</td>
</tr>
<tr>
<td>Female</td>
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<td></td>
</tr>
<tr>
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<td>74</td>
<td>7.2</td>
<td>3.1–18.7</td>
<td>152.6</td>
<td>65.7–395.9</td>
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<tr>
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<td>6.9</td>
<td>3.7–21.8</td>
<td>146.3</td>
<td>78.9–461.7</td>
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<td>4.0–18.2</td>
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<td>84.0–386.5</td>
</tr>
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<td>47</td>
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<td>4.0–20.8</td>
<td>195.0</td>
<td>84.8–439.3</td>
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<tr>
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<td>52</td>
<td>8.8</td>
<td>4.3–24.9</td>
<td>185.5</td>
<td>90.4–526.4</td>
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</table>
Atellica IM and ADVIA Centaur Testosterone II (TSTII) and Sex Hormone-binding Globulin (SHBG) Assays

Central 90% reference intervals characterized by age and Tanner stage were established for a pediatric population (children and adolescents) in accordance with the CLSI guideline EP28-A3c using a non-parametric approach for sample sizes of at least 120. For populations with a sample size of 40–119, the central 90% reference interval was calculated using an approach to accommodate the smaller sample size. For sample sizes of <40, the reference interval is defined by the 5th and 95th percentiles. Samples were collected prospectively from apparently healthy pediatric subjects (good endocrinological health) using predefined inclusion criteria.

### Testosterone Pediatric Reference Intervals

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of Samples</th>
<th>Median (ng/dL)</th>
<th>Median (nmol/L)</th>
<th>Interval (ng/dL)</th>
<th>Interval (nmol/L)</th>
</tr>
</thead>
<tbody>
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<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–10</td>
<td>147</td>
<td>&lt;7.00</td>
<td>&lt;0.24</td>
<td>&lt;7.00–10.50</td>
<td>&lt;0.24–0.36</td>
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<tr>
<td>11</td>
<td>34</td>
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<td>0.37</td>
<td>&lt;7.00–478.50</td>
<td>&lt;0.24–16.60</td>
</tr>
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<td>12</td>
<td>35</td>
<td>132.47</td>
<td>4.60</td>
<td>&lt;7.00–487.97</td>
<td>&lt;0.24–16.93</td>
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<td>34</td>
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<td>6.91</td>
<td>8.28–549.79</td>
<td>0.29–19.08</td>
</tr>
<tr>
<td>14</td>
<td>34</td>
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<td>7.93</td>
<td>8.91–535.34</td>
<td>0.31–18.58</td>
</tr>
<tr>
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<td>27</td>
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<td>11.38</td>
<td>65.96–756.50</td>
<td>2.29–26.25</td>
</tr>
<tr>
<td>16–21</td>
<td>149</td>
<td>453.86</td>
<td>15.75</td>
<td>228.16–710.74</td>
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<tr>
<td>2–10</td>
<td>159</td>
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<td>&lt;0.24</td>
<td>&lt;7.00–11.86</td>
<td>&lt;0.24–0.41</td>
</tr>
<tr>
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<td>&lt;0.24–0.96</td>
</tr>
<tr>
<td>16–21</td>
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<td>19.81</td>
<td>0.69</td>
<td>11.78–43.34</td>
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### Sex Hormone-binding Globulin Pediatric Reference Intervals

<table>
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<th>Age (years)</th>
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<th>Median (µg/mL)</th>
<th>Median (nmol/L)</th>
<th>Interval (µg/mL)</th>
<th>Interval (nmol/L)</th>
</tr>
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<tbody>
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<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–10</td>
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<td>93.68</td>
<td>3.29–15.42</td>
<td>34.64–162.29</td>
</tr>
<tr>
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<td>34</td>
<td>5.62</td>
<td>59.18</td>
<td>1.68–10.90</td>
<td>17.66–114.73</td>
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<td>35</td>
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<td>50.60</td>
<td>1.45–11.06</td>
<td>15.24–116.39</td>
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<td>1.24–7.66</td>
<td>13.07–80.64</td>
</tr>
<tr>
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<td>11.84–40.47</td>
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<td>25.05</td>
<td>1.05–4.73</td>
<td>11.08–49.80</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2–10</td>
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<td>75.55</td>
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<td>29.07–158.46</td>
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<tr>
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<td>47.72</td>
<td>1.48–9.67</td>
<td>15.62–101.74</td>
</tr>
<tr>
<td>16–21</td>
<td>145</td>
<td>4.45</td>
<td>46.81</td>
<td>1.84–15.37</td>
<td>19.36–161.78</td>
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</table>
### FAI (%): Pediatric Males and Females by Age

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of Samples</th>
<th>Median (%)</th>
<th>Interval (%)</th>
</tr>
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<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–10</td>
<td>147</td>
<td>0.07</td>
<td>&lt;0.07–1.09</td>
</tr>
<tr>
<td>11</td>
<td>34</td>
<td>0.59</td>
<td>0.07–56.77</td>
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<tr>
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<td>35</td>
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<td>0.20–60.95</td>
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<td>34</td>
<td>23.33</td>
<td>0.30–71.07</td>
</tr>
<tr>
<td>14</td>
<td>34</td>
<td>28.36</td>
<td>0.53–71.17</td>
</tr>
<tr>
<td>15</td>
<td>27</td>
<td>46.41</td>
<td>8.63–80.53</td>
</tr>
<tr>
<td>16–21</td>
<td>149</td>
<td>62.30</td>
<td>33.19–109.15</td>
</tr>
<tr>
<td>Female</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2–10</td>
<td>159</td>
<td>0.14</td>
<td>&lt;0.07–0.91</td>
</tr>
<tr>
<td>11–15</td>
<td>174</td>
<td>0.98</td>
<td>0.26–3.86</td>
</tr>
<tr>
<td>16–21</td>
<td>145</td>
<td>1.50</td>
<td>0.42–5.29</td>
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### Testosterone Pediatric Reference Values Characterized by Tanner Stage

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(µg/mL) (nmol/L)</td>
<td>(µg/mL) (nmol/L)</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>101</td>
<td>9.26</td>
<td>97.44</td>
</tr>
<tr>
<td>2</td>
<td>78</td>
<td>7.16</td>
<td>75.38</td>
</tr>
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<td>64</td>
<td>4.39</td>
<td>46.23</td>
</tr>
<tr>
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<td>88</td>
<td>2.73</td>
<td>28.78</td>
</tr>
<tr>
<td>5</td>
<td>129</td>
<td>2.38</td>
<td>25.05</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>138</td>
<td>7.90</td>
<td>83.20</td>
</tr>
<tr>
<td>2</td>
<td>60</td>
<td>5.14</td>
<td>54.12</td>
</tr>
<tr>
<td>3</td>
<td>49</td>
<td>4.71</td>
<td>49.59</td>
</tr>
<tr>
<td>4</td>
<td>98</td>
<td>4.33</td>
<td>45.58</td>
</tr>
<tr>
<td>5</td>
<td>133</td>
<td>4.39</td>
<td>46.21</td>
</tr>
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</table>

### Sex Hormone-binding Globulin Pediatric Reference Values Characterized by Tanner Stage

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(µg/mL) (nmol/L)</td>
<td>(µg/mL) (nmol/L)</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>101</td>
<td>9.26</td>
<td>97.44</td>
</tr>
<tr>
<td>2</td>
<td>78</td>
<td>7.16</td>
<td>75.38</td>
</tr>
<tr>
<td>3</td>
<td>64</td>
<td>4.39</td>
<td>46.23</td>
</tr>
<tr>
<td>4</td>
<td>88</td>
<td>2.73</td>
<td>28.78</td>
</tr>
<tr>
<td>5</td>
<td>129</td>
<td>2.38</td>
<td>25.05</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>139</td>
<td>7.90</td>
<td>83.20</td>
</tr>
<tr>
<td>2</td>
<td>61</td>
<td>5.14</td>
<td>54.12</td>
</tr>
<tr>
<td>3</td>
<td>49</td>
<td>4.71</td>
<td>49.59</td>
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<tr>
<td>4</td>
<td>98</td>
<td>4.33</td>
<td>45.58</td>
</tr>
<tr>
<td>5</td>
<td>133</td>
<td>4.39</td>
<td>46.21</td>
</tr>
</tbody>
</table>

Continued on next page
Specific Proteins

**Atellica CH Anti-Streptolysin-O_2 (ASO_2) Assay**

<table>
<thead>
<tr>
<th>Group</th>
<th>Specimen Type</th>
<th>Reference Interval (IU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children (preschool)</td>
<td>Serum/plasma</td>
<td>≤100</td>
</tr>
<tr>
<td>Children (school age)</td>
<td>Serum/plasma</td>
<td>≤250</td>
</tr>
</tbody>
</table>

**Atellica CH Complement (C3) Assay**

<table>
<thead>
<tr>
<th>Group</th>
<th>Specimen Type</th>
<th>Reference Interval (mg/dL)</th>
<th>(g/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborns</td>
<td>Serum</td>
<td>58.0–108.0</td>
<td>0.60–1.10</td>
</tr>
<tr>
<td>3 months</td>
<td>Serum</td>
<td>67.0–124.0</td>
<td>0.70–1.20</td>
</tr>
<tr>
<td>6 months</td>
<td>Serum</td>
<td>74.0–138.0</td>
<td>0.70–1.40</td>
</tr>
<tr>
<td>9 months</td>
<td>Serum</td>
<td>78.0–144.0</td>
<td>0.80–1.40</td>
</tr>
<tr>
<td>12 months</td>
<td>Serum</td>
<td>80.0–150.0</td>
<td>0.80–1.50</td>
</tr>
<tr>
<td>2–10 years</td>
<td>Serum</td>
<td>80.0–150.0</td>
<td>0.80–1.50</td>
</tr>
<tr>
<td>12–18 years</td>
<td>Serum</td>
<td>85.0–150.0</td>
<td>0.90–1.60</td>
</tr>
</tbody>
</table>

**FAI (%): Pediatric Males and Females by Tanner Stage**

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Number of Samples</th>
<th>Median (%)</th>
<th>Interval (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>101</td>
<td>0.07</td>
<td>&lt;0.07–0.72</td>
</tr>
<tr>
<td>2</td>
<td>78</td>
<td>0.19</td>
<td>&lt;0.07–6.78</td>
</tr>
<tr>
<td>3</td>
<td>64</td>
<td>7.98</td>
<td>&lt;0.07–56.18</td>
</tr>
<tr>
<td>4</td>
<td>88</td>
<td>47.74</td>
<td>8.13–99.66</td>
</tr>
<tr>
<td>5</td>
<td>129</td>
<td>61.22</td>
<td>30.87–98.86</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>138</td>
<td>0.10</td>
<td>&lt;0.07–0.81</td>
</tr>
<tr>
<td>2</td>
<td>60</td>
<td>0.57</td>
<td>0.09–3.47</td>
</tr>
<tr>
<td>3</td>
<td>49</td>
<td>1.01</td>
<td>0.26–3.75</td>
</tr>
<tr>
<td>4</td>
<td>98</td>
<td>1.17</td>
<td>0.40–5.00</td>
</tr>
<tr>
<td>5</td>
<td>133</td>
<td>1.43</td>
<td>0.44–5.29</td>
</tr>
</tbody>
</table>
Based on a pediatric population (infants, children, and adolescents), reference intervals were established using the ADVIA Centaur system in accordance with CLSI guideline C28-A3c. Samples were collected prospectively from apparently healthy (euthyroid) pediatric subjects using predefined inclusion criteria. The ADVIA Centaur FT3, T3, FT4, and T4 reference interval for infants were calculated by a robust measure of location and spread as developed by Horn and Pesce. A non-parametric approach based on the CLSI guideline was used to establish the reference intervals for children and adolescents. The 2.5th and 97.5th percentiles of the distribution of values were calculated for each age group. Based on this population, the following reference intervals were established:

Atellica IM and ADVIA Centaur Free Triiodothyronine (FT3) Assay

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(pg/mL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(pmol/L)</td>
</tr>
<tr>
<td>Infants (1–23 months)</td>
<td>72</td>
<td>3.3–5.2</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>190</td>
<td>3.3–4.8</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>129</td>
<td>3.0–4.7</td>
</tr>
</tbody>
</table>

Atellica IM and ADVIA Centaur Triiodothyronine (T3) Assay

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(ng/mL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(nmol/L)</td>
</tr>
<tr>
<td>Infants (1–23 months)</td>
<td>72</td>
<td>1.17–2.39</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>190</td>
<td>1.05–2.07</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>129</td>
<td>0.86–1.92</td>
</tr>
</tbody>
</table>

Atellica IM and ADVIA Centaur Free Thyroxine (FT4) Assay

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(ng/dL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(pmol/L)</td>
</tr>
<tr>
<td>Infants (1–23 months)</td>
<td>72</td>
<td>0.94–1.44</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>190</td>
<td>0.86–1.40</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>129</td>
<td>0.83–1.43</td>
</tr>
</tbody>
</table>

Atellica IM and ADVIA Centaur Thyroxine (T4) Assay

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(µg/dL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(nmol/L)</td>
</tr>
<tr>
<td>Infants (1–23 months)</td>
<td>72</td>
<td>6.0–13.2</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>190</td>
<td>5.5–12.1</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>129</td>
<td>5.5–11.1</td>
</tr>
</tbody>
</table>

Continued on next page
Reference intervals for the pediatric population (infants, children, and adolescents) were established for the ADVIA Centaur TSH3-Ultra™ Assay in accordance with CLSI guideline EP28-A3c. Samples were collected prospectively from apparently healthy (euthyroid) pediatric subjects using predefined inclusion criteria. A non-parametric approach was used to establish the reference intervals for children and adolescents where the 2.5th and 97.5th percentiles of the distribution of values were calculated. For the infant population, the reference interval was calculated using an approach to accommodate the smaller sample size.

**Atellica IM and ADVIA Centaur Thyroid-stimulating Hormone (TSH3-UL) Assay**

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Interval µIU/mL (mlU/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants a (1–23 months)</td>
<td>94</td>
<td>0.87–6.15</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>198</td>
<td>0.67–4.16</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>150</td>
<td>0.48–4.17</td>
</tr>
</tbody>
</table>

*a. The upper limit (97.5th percentile) of the infant reference interval was determined to be 6.15 µIU/mL (mlU/L). Data from this infant population (n = 94) have demonstrated a highly skewed distribution to the right. Therefore, the estimate of the upper limit of the reference interval has some uncertainty, with a 90% probability that the upper limit of the reference interval can be 5.32–6.98 µIU/mL (mlU/L).*

**TORCH**

**Atellica IM and ADVIA Centaur Cytomegalovirus (CMV) IgG Assay**

A population of 229 pediatric subjects was tested.

<table>
<thead>
<tr>
<th>Population</th>
<th>Number of Samples</th>
<th>Reactive</th>
<th>Nonreactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric subjects</td>
<td>229</td>
<td>82 (35.8%)</td>
<td>147 (64.2%)</td>
</tr>
</tbody>
</table>
Pediatric Reference Intervals for Dimension EXL Thyroid Assays

**Thyroid**

Reference intervals for the pediatric population (infants, children, and adolescents) were established for the Dimension EXL assays in accordance with CLSI guideline EP28-A3c. Samples were collected prospectively from apparently healthy (euthyroid) pediatric subjects using predefined inclusion criteria. The reference interval for infants was calculated by a robust measure of location and spread as developed by Horn and Pesce. A non-parametric approach based on the CLSI guideline was used to establish the reference intervals for children and adolescents. The 2.5th and 97.5th percentiles of the distribution of values were calculated for each age group. Each laboratory should establish its own expected values as performed on the Dimension EXL with LM System.

### Dimension EXL LOCI® Free Triiodothyronine (FT3) Assay

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Intervals (pg/mL)</th>
<th>(pmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants (1–23 months)</td>
<td>75</td>
<td>3.47–5.29</td>
<td>5.3–8.2</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>185</td>
<td>3.35–4.82</td>
<td>5.2–7.4</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>147</td>
<td>2.91–4.70</td>
<td>4.5–7.2</td>
</tr>
</tbody>
</table>

### Dimension EXL LOCI Free Thyroxine (FT4L) Assay

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Intervals (ng/dL)</th>
<th>(pmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants (1–23 months)</td>
<td>77</td>
<td>0.93–1.45</td>
<td>12.0–18.7</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>187</td>
<td>0.82–1.40</td>
<td>10.6–18.0</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>147</td>
<td>0.78–1.34</td>
<td>10.0–17.3</td>
</tr>
</tbody>
</table>

### Dimension EXL LOCI Thyroxine (T4) Assay

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Intervals (µg/dL)</th>
<th>(nmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants (1–23 months)</td>
<td>75</td>
<td>6.6–13.4</td>
<td>85–173</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>186</td>
<td>5.8–11.8</td>
<td>75–152</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>147</td>
<td>5.4–10.6</td>
<td>70–136</td>
</tr>
</tbody>
</table>

### Dimension EXL LOCI Thyroid-stimulating Hormone (TSHL) Assay

<table>
<thead>
<tr>
<th>Pediatric Age Group</th>
<th>Number of Samples</th>
<th>Reference Intervals (µIU/mL)</th>
<th>(mIU/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants (1–23 months)</td>
<td>75</td>
<td>0.867–6.43</td>
<td>0.867–6.43</td>
</tr>
<tr>
<td>Children (2–12 years)</td>
<td>185</td>
<td>0.704–4.01</td>
<td>0.704–4.01</td>
</tr>
<tr>
<td>Adolescents (13–20 years)</td>
<td>147</td>
<td>0.516–4.13</td>
<td>0.516–4.13</td>
</tr>
</tbody>
</table>
At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

The information contained in this document does not supersede that presented in the most recent Instructions for Use.

The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur system. Some performance characteristics for the Atellica IM assay were established using the ADVIA Centaur system.

References: