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Every child deserves accurate results

Pediatric reference intervals for diagnosis and treatment you can count on

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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interpreted using reference intervals derived from adult populations, hospitalized pediatric populations, or outdated methodologies.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[1]
- 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.

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- Thyroid

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:

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

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.

Vitamin D Status	Range	
	(ng/mL)	(nmol/L)
Deficiency	<15	37.5
Insufficiency	15 to <20	37.5 to <50
Sufficiency	20–100	50–250

A review of the available literature suggests pediatric recommendations for 25(0H) vitamin D levels shown in the following table.

Specimen Type		Observed Values (12 months up to 21 years)	
		(ng/mL)	nmol/L)
Median 25(0H) vitamin D	Serum	23.8	59.5
	Plasma	12.7	31.8
Range	Serum	11.4–45.8	28.5–114.5
	Plasma	5.2–35.2	13.0–88.0

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.[1] 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.

Group	Specimen Type	Reference Interval	
		(µg/mL)	(µmol/L)
Neonates	Serum	8–20	41.6–104

Chemistry

A reference interval for healthy populations was established in accordance with CLSI document EP28 A3c. As with all in vitro diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.

Atellica® CH Glucose Hexokinase (GluH_3) Assay

Group	Specimen Type	Reference Interval	
		(mg/dL)	(mmol/L)
Newborn	Serum/plasma	40–60	2.2–3.3
Newborn >1 day	Serum/plasma	50–80	2.8–4.4
Child	Serum/plasma	60–100	3.3–5.6
Infant/child	Cerebrospinal fluid	60–80	3.3–4.4

Atellica CH Glucose Oxidase (GluO) Assay

Group	Specimen Type	Reference Interval	
		(mg/dL)	(mmol/L)
Infants and children	Cerebrospinal fluid	60–80	3.3–4.4

Atellica CH Total Bilirubin (TBil_2) Assay

Age	Expected Values	
	(mg/dL)	(µmol/L)
0–1 day	<8.0	137
1–2 days	<12.0	205
3–5 days	<16.0	274
>5 days–60 years	0.3–1.2	5–21

>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.

ADVIA Centaur HBcT2 Assay	Comparative Anti-HBc Total Assay		
	Reactive	Nonreactive	Total
Reactive	3	1	**4**
Nonreactive	0	232	**232**
Total	**3**	**233**	**236**

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%).

Reproductive Endocrinology

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

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

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

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

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Atellica IM and ADVIA Centaur Enhanced Estradiol (EE2) Assay

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

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

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

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Atellica IM and ADVIA Centaur Follicle-stimulating Hormone (FSH) Assay

Age (years)	Number of Samples	Median mIU/mL (IU/L)	Interval mIU/mL (IU/L)
Male			
2–3	12	0.7	<0.3[a]–1.3[b]
4–9	57	1.0	0.4–2.0
10–11	55	2.0	0.4–4.6
12–21	181	3.0	1.4–7.5
Female			
2–3	18	3.0	1.3[a]–5.0[b]
4–9	46	1.8	0.5–5.0
10–11	55	4.7	1.4–9.3
12–21	162	5.7	2.2–10.1

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.

FSH Pediatric Reference Value Characterized by Tanner Stage

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

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Atellica IM and ADVIA Centaur Luteinizing Hormone (LH) Assay

Age (years)	Number of Samples	Median mIU/mL (IU/L)	Interval mIU/mL (IU/L)
Male			
2–3	12	<0.07	<0.07[a]–0.07[b]
4–9	57	<0.07	<0.07–0.4
10–12	89	0.8	<0.07–2.9
13–21	151	2.8	1.0–7.1
Female			
2–3	18	<0.07	<0.07[a]–0.07[b]
4–9	47	<0.07	<0.07–0.2
10–12	93	2.7	<0.07–11.8
13–21	127	4.6	1.0–52.2

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

Tanner Stage	Number of Samples	Median mIU/mL (IU/L)	Interval mIU/mL (IU/L)
Male			
1	74	<0.07	<0.07–0.9
2	65	0.7	<0.07–2.4
3	63	2.1	0.4–5.0
4	59	2.8	1.1–6.6
5	48	4.2	1.1–8.4
Female			
1	74	<0.07	<0.07–4.9
2	47	1.7	<0.07–9.6
3	65	3.9	0.6–15.9
4	47	5.2	0.9–32.8
5	52	5.0	0.6–69.9

Atellica IM and ADVIA Centaur Progesterone (PRG) Assay

Age (years)	Number of Samples	Median (ng/mL)	Interval (ng/mL)	Median (nmol/L)	Interval (nmol/L)
Female					
12	38	0.29	<0.21–1.74	0.92	<0.67–5.53
13–21	127	0.65	<0.21–12.40	2.07	<0.67–39.43

Progesterone Pediatric Reference Intervals Characterized by Tanner Stage

Tanner Stage	Number of Samples	Median (ng/mL)	Interval (ng/mL)	Median (nmol/L)	Interval (nmol/L)
Female					
1	N/A	N/A	–	N/A	–
2	18	0.31	<0.21[a]–10.37[b]	0.97	<0.67[a]–32.98[b]
3	49	0.34	<0.21–10.35	1.08	<0.67–32.90
4	45	0.52	<0.21–8.66	1.65	<0.67–27.55
5	52	0.89	<0.21–15.51	2.81	<0.67–49.32

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.

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Atellica IM and ADVIA Centaur Prolactin (PRL) Assay

Age (years)	Number of Samples	Median (ng/mL)	Interval (ng/mL)	Median (µIU/mL)	Interval (µIU/mL)
Male					
2–3	12	8.6	3.6[a]–28 .6[b]	183.4	76.3[a]–606.3[b]
4–9	57	7.3	4.5–18.0	154.8	95.4–382.2
10–16	203	6.3	3.2–13.5	133.6	67.8–284.9
17–21	37	7.9	5.4–15.4	167.5	115.1–326.7
Female					
2–3	18	7.4	3.l[a]–15. 7[b]	15 6.9	65.7[a]–332.8[b]
4–9	47	7.1	3.1–15.8	150.5	66.6–334.1
10–12	93	7.2	3.5–18.2	152.6	75.0–386.7
13–21	127	9.2	4.3–23.11	195.0	89.9–489.7

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.

Prolactin Pediatric Reference Values Characterized by Tanner Stage

Tanner Stage	Number of Samples	Median (ng/mL)	Interval (ng/mL)	Median (µIU/mL)	Interval (µIU/mL)
Male					
1	74	7.2	3.7–18.5	153.7	78.4–391.1
2	65	5.9	2.4–13.7	125.1	49.4–289.4
3	63	5.7	3.5–11.9	120.8	74.2–252.7
4	59	7.4	3.2–15.5	156.9	67.8–328.6
5	48	7.7	4.9–14.5	162.2	105.6–306.9
Female					
1	74	7.2	3.1–18.7	152.6	65.7–395.9
2	47	6.9	3.7–21.8	146.3	78.9–461.7
3	65	8.5	4.0–18.2	180.2	84.0–386.5
4	47	9.2	4.0–20.8	195.0	84.8–439.3
5	52	8.8	4.3–24.9	185.5	90.4–526.4

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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

Age (years)	Number of Samples	Median		Interval	
		(ng/dL)	(nmol/L)	(ng/dL)	(nmol/L)
Male					
2–10	147	<7.00	<0.24	<7.00–10.50	<0.24–0.36
11	34	10.73	0.37	<7.00–478.50	<0.24–16.60
12	35	132.47	4.60	<7.00–487.97	<0.24–16.93
13	34	199.02	6.91	8.28–549.79	0.29–19.08
14	34	228.39	7.93	8.91–535.34	0.31–18.58
15	27	327.89	11.38	65.96–756.50	2.29–26.25
16–21	149	453.86	15.75	228.16–710.74	7.92–24.66
Female					
2–10	159	<7.00	<0.24	<7.00–11.86	<0.24–0.41
11–15	174	12.95	0.45	<7.00–27.57	<0.24–0.96
16–21	145	19.81	0.69	11.78–43.34	0.41–1.50

Sex Hormone-binding Globulin Pediatric Reference Intervals

Age (years)	Number of Samples	Median		Interval	
		(µg/mL)	(nmol/L)	(µg/mL)	(nmol/L)
Male					
2–10	147	8.90	93.68	3.29–15.42	34.64–162.29
11	34	5.62	59.18	1.68–10.90	17.66–114.73
12	35	4.81	50.60	1.45–11.06	15.24–116.39
13	34	3.02	31.83	1.39–10.37	14.67–109.13
14	34	3.00	31.57	1.24–7.66	13.07–80.64
15	27	2.51	26.45	1.12–3.84	11.84–40.47
16–21	149	2.38	25.05	1.05–4.73	11.08–49.80
Female					
2–10	160	7.18	75.55	2.76–15.05	29.07–158.46
11–15	175	4.53	47.72	1.48–9.67	15.62–101.74
16–21	145	4.45	46.81	1.84–15.37	19.36–161.78

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FAI (%): Pediatric Males and Females by Age

Age (years)	Number of Samples	Median (%)	Interval (%)
Male			
2–10	147	0.07	<0.07–1.09
11	34	0.59	0.07–56.77
12	35	7.90	0.20–60.95
13	34	23.33	0.30–71.07
14	34	28.36	0.53–71.17
15	27	46.41	8.63–80.53
16–21	149	62.30	33.19–109.15
Female			
2–10	159	0.14	<0.07–0.91
11–15	174	0.98	0.26–3.86
16–21	145	1.50	0.42–5.29

Testosterone Pediatric Reference Values Characterized by Tanner Stage

Tanner Stage	Number of Samples	Median		Interval	
		(ng/dL)	(nmol/L)	(ng/dL)	(nmol/L)
Male					
1	101	<7.00	<0.24	<7.00–13.06	<0.24–0.45
2	78	<7.00	<0.24	<7.00–79.13	<0.24–2.75
3	64	59.67	2.07	<7.00–499.18	<0.24–17.32
4	88	376.84	13.08	79.10–747.17	2.74–25.93
5	129	451.17	15.66	224.83–669.65	7.80–23.24
Female					
1	138	<7.00	<0.24	<7.00–10.06	<0.24–0.35
2	60	8.17	0.28	<7.00–30.11	<0.24–1.04
3	49	12.98	0.45	<7.00–30.49	<0.24–1.06
4	98	17.37	0.60	<7.00–35.19	<0.24–1.22
5	133	19.76	0.69	11.80–39.30	0.41–1.36

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

Tanner Stage	Number of Samples	Median		Interval	
		(µg/mL)	(nmol/L)	(µg/mL)	(nmol/L)
Male					
1	101	9.26	97.44	4.03–15.35	42.43–161.54
2	78	7.16	75.38	2.53–13.91	26.61–146.40
3	64	4.39	46.23	1.32–10.29	13.91–108.35
4	88	2.73	28.78	1.16–6.12	12.18–64.42
5	129	2.38	25.05	1.21–4.65	12.77–48.93
Female					
1	139	7.90	83.20	2.81–15.28	29.56–160.80
2	61	5.14	54.12	1.55–10.35	16.29–108.98
3	49	4.71	49.59	1.50–12.91	15.83–135.89
4	98	4.33	45.58	1.67–9.47	17.53–99.70
5	133	4.39	46.21	1.88–13.40	19.75–141.10

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

Tanner Stage	Number of Samples	Median (%)	Interval (%)
Male			
1	101	0.07	<0.07–0.72
2	78	0.19	<0.07–6.78
3	64	7.98	<0.07–56.18
4	88	47.74	8.13–99.66
5	129	61.22	30.87–98.86
Female			
1	138	0.10	<0.07–0.81
2	60	0.57	0.09–3.47
3	49	1.01	0.26–3.75
4	98	1.17	0.40–5.00
5	133	1.43	0.44–5.29

Specific Proteins

Atellica CH Anti-Streptolysin-O_2 (ASO_2) Assay

Group	Specimen Type	Reference Interval (IU/mL)
Children (preschool)	Serum/plasma	≤100
Children (school age)	Serum/plasma	≤250

Atellica CH Complement (C3) Assay

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

Thyroid

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

Pediatric Age Group	Number of Samples	Reference Intervals	
		(pg/mL)	(pmol/L)
Infants (1–23 months)	72	3.3–5.2	5.1–8.0
Children (2–12 years)	190	3.3–4.8	5.1–7.4
Adolescents (13–20 years)	129	3.0–4.7	4.7–7.2

Atellica IM and ADVIA Centaur Triiodothyronine (T3) Assay

Pediatric Age Group	Number of Samples	Reference Intervals	
		(ng/mL)	(nmol/L)
Infants (1–23 months)	72	1.17–2.39	1.80–3.68
Children (2–12 years)	190	1.05–2.07	1.62–3.19
Adolescents (13–20 years)	129	0.86–1.92	1.32–2.96

Atellica IM and ADVIA Centaur Free Thyroxine (FT4) Assay

Pediatric Age Group	Number of Samples	Reference Intervals	
		(ng/dL)	(pmol/L)
Infants (1–23 months)	72	0.94–1.44	12.1–18.6
Children (2–12 years)	190	0.86–1.40	11.1–18.1
Adolescents (13–20 years)	129	0.83–1.43	10.7–18.4

Atellica IM and ADVIA Centaur Thyroxine (T4) Assay

Pediatric Age Group	Number of Samples	Reference Intervals	
		(µg/dL)	(nmol/L)
Infants (1–23 months)	72	6.0–13.2	77.8–170.0
Children (2–12 years)	190	5.5–12.1	71.0–156.1
Adolescents (13–20 years)	129	5.5–11.1	71.0–143.2

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

Pediatric Age Group	Number of Samples	Reference Interval µIU/mL (mIU/L)
Infants[a] (1–23 months)	94	0.87–6.15
Children (2–12 years)	198	0.67–4.16
Adolescents (13–20 years)	150	0.48–4.17

a. The upper limit (97.5th percentile) of the infant reference interval was determined to be 6.15 µIU/mL(mIU/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 (mIU/L).

TORCH

Atellica IM and ADVIA Centaur Cytomegalovirus (CMV) IgG Assay

A population of 229 pediatric subjects was tested.

Population	Number of Samples	Reactive	Nonreactive
Pediatric subjects (2–21 years)	229	82 (35.8%)	147 (64.2%)

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

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

Dimension EXL LOCI Free Thyroxine (FT4L) Assay

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

Dimension EXL LOCI Thyroxine (T4) Assay

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

Dimension EXL LOCI Thyroid-stimulating Hormone (TSHL) Assay

Pediatric Age Group	Number of Samples	Reference Intervals	
		(µIU/mL)	(mIU/L)
Infants (1–23 months)	75	0.867–6.43	0.867–6.43
Children (2–12 years)	185	0.704–4.01	0.704–4.01
Adolescents (13–20 years)	147	0.516–4.13	0.516–4.13

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.

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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:
1. CLSI. EP28-A3c: Defining, establishing, and verifying reference intervals in the clinical laboratory; approved guideline-third edition.
2. Boutroy MJ, et al. Caffeine, a metabolite of theophylline during the treatment of apnea in the premature infant. J Pediatr. 1979; 94:996-998.

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Published by
Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
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Published by Siemens Healthcare Diagnostics Inc. · Order No. 30-21-DX-552-76 · 03-2021 · ©Siemens Healthcare Diagnostics Inc., 2021