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Pediatric Reference Intervals in Thyroid Function Testing

Siemens Healthineers helps you meet the challenges involved in establishing reference intervals for tests performed in the pediatric setting.

Thyroid disease in children is associated with impaired physical and cognitive development. Thyroid-stimulating hormone (TSH) levels are considered to be the most sensitive parameter for diagnosing hyperthyroidism and hypothyroidism, and for monitoring thyroid replacement therapy. Free T4 is indispensible as well, since it directly reflects hormone production by the thyroid gland. Free T3 may provide additional information.

Age-specific reference intervals are extremely important for interpreting thyroid hormone measurements in the pediatric population. Unfortunately, there are very few studies that provide this information.

We conducted extensive studies to establish pediatric thyroid hormone reference intervals on Siemens systems, including the ADVIA Centaur,® Dimension Vista,® Dimension® EXL,™ and IMMULITE® 2000/2000 XPi systems. The data represented in the table on page 2 includes age groups from 30 days of life to 20 years, with relevant subsets from this pediatric population.

Study Design

The pediatric samples were collected prospectively from apparently healthy pediatric subjects, under consent/assent. Eight collection sites located across the U.S. collected the samples and shipped them frozen to a single laboratory for testing.

Three age subgroups were included:

- Infants: subjects aged 1 month to 23 months of age
- Children: subjects aged 2 to 12 years of age
- Adolescents: subjects aged 13 to 20 years of age
- Reference intervals were established across genders
- Approximately equal numbers of males and females were included
- Reference intervals for infants, children, and adolescents for the thyroid hormones were established according to CLSI guideline C28-A3c[1]
- Samples from healthy euthyroid individuals were considered normal if they met the strict inclusion criteria
- All patients were screened for the presence of thyroid autoantibodies and risk factors for thyroid disorders

For each assay tested, the lower and upper reference limits were estimated as the 2.5th and the 97.5th percentiles of the distribution of test results for each of the two older subgroups. For the infant subgroup, a robust measure of location and spread, as developed by Horn and Pesce, was used for obtaining reference intervals.[2] Over 405 pediatric subjects were included in the final analysis of the combined study.

Laboratory Efficiency and Cost-Effectiveness

Siemens Healthineers helps you meet your pediatric thyroid testing needs by establishing age specific reference intervals that are system- and method-specific using robust, statistically sound studies, and well-characterized patient samples.

Fast, accurate results from the laboratory can help physicians diagnose a thyroid condition and determine treatment in a timely manner. Siemens' assays for thyroid function can be run on the fully automated ADVIA Centaur, IMMULITE, Dimension Vista, and Dimension EXL systems.

	Age group	Sample size	3rd Gen TSH	Free T4		Free T3		T4		T3	
			(µIU/mL) (mIU/L)	(ng/dL)	(pmol/L)	(pg/mL)	(pmol/L)	(µg/dL)	(nmol/L)	(ng/mL)	(nmol/L)
ADVIA Centaur Systems	Infants (01–23M)	72	0.87–6.15	0.94–1.44	12.1–18.6	3.3–5.2	5.1–8.0	6.0–13.2	77.8–170.0	1.17–2.39	1.80–3.68
	Children (02–12Y)	190	0.67–4.16	0.86–1.40	11.1–18.1	3.3–4.8	5.1–7.4	5.5–12.1	71.0–156.1	1.05–2.07	1.62–3.19
	Adolescents (13–20Y)	129	0.48–4.17	0.83–1.43	10.7–18.4	3.0–4.7	4.7–7.2	5.5–11.1	71.0–143.2	0.86–1.92	1.32–2.96
IMMULITE 2000/ XPi Systems	Infants (01–23M)	90	0.83–6.5	0.80–1.27	10.3–16.3	3.6–7.5	5.5–11.5	6.2–11.8	80–152	116–241	1.8–3.7
	Children (02–12Y)	197	0.58–4.1	0.74–1.28	9.5–16.5	3.7–6.6	5.7–10.1	5.4–11.1	70–143	109–206	1.7–3.2
	Adolescents (13–20Y)	148	0.39–4.0	0.75–1.27	9.7–16.3	3.1–5.9	4.8–9.1	4.9–10.2	63–131	93–170	1.4–2.6
Dimension Vista Systems	Infants (01–23M)	82	0.816–5.91*	0.88–1.48	11.3–19.1	3.34–5.24	5.1–8.1	7.4–14.3	95–184		
	Children (02–12Y)	191	0.662–3.90	0.81–1.35	10.4–17.4	3.31–4.88	5.1–7.5	6.8–12.5	88–161		
	Adolescents (13–20Y)	148	0.463–3.98	0.78–1.33	10.0–17.1	2.91–4.53	4.5–7.0	6.0–11.6	77–149		
Dimension EXL Systems	Infants (01–23M)	75	0.867–6.43*	0.93–1.45	12.0–18.7	3.47–5.29	5.3–8.2	6.6–13.4	85–173		
	Children (02–12Y)	185	0.704–4.01	0.82–1.40	10.6–18.0	3.35–4.82	5.2–7.4	5.8–11.8	75–152		
	Adolescents (13–20Y)	147	0.516–4.13	0.78–1.34	10.0–17.3	2.91–4.70	4.5–7.2	5.4–10.6	70–136		

On the ADVIA Centaur system, the infant, children, and adolescent group sample size for 3rd Gen TSH was 94, 198 and 150 respectively. On the Dimension EXL system, the infant group sample size for FT4 was 77, while the children's group for FT4 and T4 included 187 and 186 samples, respectively. For the Dimension Vista system, the T4 sample size for the children's and adolescents' age groups was 190 and 147 respectively. On the IMMULITE system, the infant group sample size for FT3 and FT4 was 81, and for T4 was 82. For the children's group the sample size for TSH and FT3 was 195. The Dimension EXL T4 intervals are also applicable to the Dimension RxL® and Xpand® systems.

*Data from these infant populations 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 between 0.816-5.91 uIU/mL for Dimension Vista TSH and 0.867-6.43 uIU/mL for the Dimension EXL TSH. Refer to Instructions for Use for additional information.

A Comprehensive Panel of Thyroid Function Assays

You can rely on Siemens Healthineers to provide the thyroid function assays that today's physicians demand. Siemens Healthineers offers a wide range of assays to aid in the clinical assessment of thyroid status. Our menu includes a pioneering, ultra-sensitive, 3rd Gen TSH assay, thyroid hormones and antibodies, including thyroglobulin.

For additional information on Siemens Healthineers thyroid solutions, visit **siemens.com/thyroid.**

References:

1. CLSI. "Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition." Volume 28, Number 30, Guideline C28-A3c, 2010.
2. Horn PS, Pesce AJ. Reference Intervals: A User's Guide, Washington, DC: AACC Press; 2005.

Local Contact Information

Siemens Healthcare
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Telephone: +1 914-631-8000
siemens.com/healthcare

Siemens Healthcare Headquarters
Siemens Healthcare GmbH
Henkestr.127
91052 Erlangen
Germany
Telephone: +49 9131 84-0
siemens.com/healthcare

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