

# Pediatric Reference Intervals in Thyroid Function Testing

## Siemens 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 indispensable 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.

Siemens conducted extensive studies to establish pediatric thyroid hormone reference intervals on Siemens systems including ADVIA Centaur®, Dimension Vista®, and Dimension EXL®. 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 USA collected the samples and shipped them frozen to a single laboratory for testing.

Three age subgroups were included:

- Infants: subjects aged  $\geq 1$  month to  $< 2$  years of age
- Children: subjects aged  $\geq 2$  to  $< 13$  years of age
- Adolescents: subjects aged  $\geq 13$  to  $< 20$  years of age

Reference intervals were established across genders, and approximately equal numbers of males and females were included.

Reference intervals for infants (1 month–23 months), children (2–12 years), and adolescents (13–20 years) for the thyroid hormones were established according to CLSI guideline C28-A3c.<sup>1</sup>

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.<sup>2</sup> Over 405 pediatric subjects were included in the final analysis of the combined study.

### Laboratory Efficiency and Cost-Effectiveness

Siemens is helping 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 systems.

	Age group	Sample size	3rd Gen TSH*	Free T4		Free T3		T4		T3	
			( $\mu$ IU/mL) (mIU/L)	(ng/dL)	(pmol/L)	(pg/mL)	(pmol/L)	( $\mu$ g/dL)	(nmol/L)	(ng/dL)	(nmol/L)
ADVIA Centaur	Infants (01–23M)	72	TBD	0.94–1.44	12–19	3.28–5.19	5.1–8.0	6.03–13.18	78–170	1.17–2.39	1.8–3.7
	Children (02–12Y)	190	0.64–6.27	0.86–1.40	11–18	3.34–4.80	5.1–7.4	5.50–12.10	71–156	1.05–2.07	1.6–3.2
	Adolescents (13–20Y)	129	0.55–4.78	0.83–1.43	11–18	3.04–4.65	4.7–7.2	5.50–11.10	71–143	0.86–1.92	1.3–3.0
Dimension Vista	Infants (01–23M)	82	0.741–5.24	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	0.628–3.90	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	0.438–3.98	0.78–1.33	10.0–17.1	2.91–4.53	4.5–7.0	6.0–11.6	77–149		
Dimension EXL	Infants (01–23M)	75	0.781–5.72	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 Dimension EXL, the infant group sample size for FT4 was 77, while the childrens' group for FT4 and T4 included 187 and 186 samples, respectively. For Dimension Vista, the T4 sample size for the childrens' and adolescents' age groups was 190 and 147 respectively. The Dimension EXL T4 intervals are also applicable to the Dimension RxL and Xpand systems. The Dimension EXL and Vista TSH, FT4 and FT3 assays are available with LOCI® technology.

The Dimension Vista and Dimension EXL pediatric reference interval claims are not applicable in the U.S.

## A Comprehensive Panel of Thyroid Function Assays

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

For additional information on Siemens' thyroid solutions, visit [www.siemens.com/thyroid](http://www.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.

\*The ADVIA Centaur TSH3-UL assay was tested in a previous study. Refer to the ADVIA Centaur TSH3-UL Instructions for Use for the specific age ranges studied

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