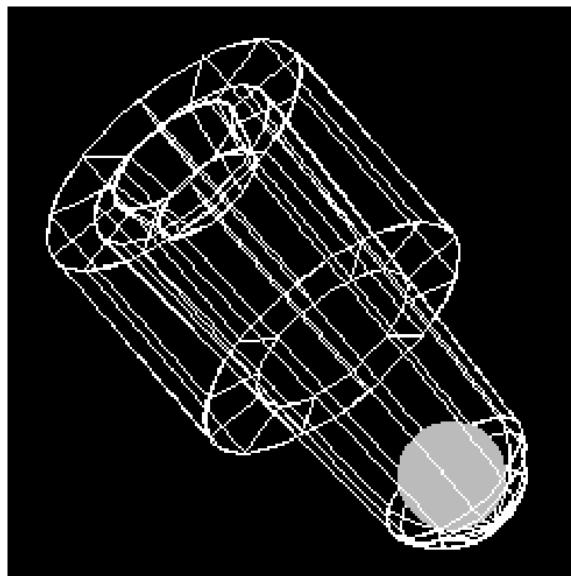


IMMULITE[®] and IMMULITE[®] 2000 Reference Range Compendium

First English Edition

*Werner Kühnel, Ph.D.
Marketing Manager, Scientific Affairs
DPC Biermann, Germany*



Getting Around

This compendium was designed for electronic viewing and navigation. Simply click on the *bookmarks* — the list of document sections and analytes appearing on the left side of your screen — or go to the Index and click on the page numbers framed in red.

Temporarily eliminating the bookmark list improves legibility because the current *page* expands to occupy the full width of your screen. Function key **F5** acts as a toggle in Adobe Acrobat Reader version 4.x, on both PCs and Macintoshes, to remove and restore the bookmarks.

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Note: In earlier versions of the Reader, or on other platforms, different key combinations may be assigned to these tasks. For example, in version 3.x for the PC, **Ctrl+6** (“page only”) and **Ctrl+7** (“page and bookmarks”) serve, respectively, to remove and restore the bookmarks.

Preface

In this booklet, I have tried to assemble all known reference limits for Diagnostic Products Corporation's IMMULITE® and IMMULITE® 2000 immunoassays. I have drawn not only from material in package inserts, technical reports and other DPC publications, but also from IMMULITE and IMMULITE 2000 reference range studies summarized in journal articles and scientific presentations throughout the world.

The correct interpretation of laboratory results often depends critically on the availability of reference values generated with a compatible assay system and appropriate to the patient's sex, age, developmental stage and other characteristics. This is particularly true for infants and children. Accordingly, a notable feature of this booklet is its inclusion of extensive pediatric data, much of which has not yet been published elsewhere.

In particular, it summarizes a recent multivariate pediatric reference range study involving 700 subjects and 14 analytes. This important study — designated [ElmPed] in the tabulations — was conducted by Dr. M. W. Elmlinger (Department of Pediatrics, Eberhard-Karls University, Tübingen, Germany) who has been responsible for a number of other published studies based on the IMMULITE system.

Serum samples were collected from children in apparent good health, with no signs of endocrinological disease. The reference values were obtained using IMMULITE assays, for FSH, LH, estradiol, progesterone, DHEA-SO₄, cortisol, TSH, free and total T₄, free and total T₃, prolactin, growth hormone and ferritin. Results were partitioned by sex and by age or developmental status (Tanner stage) prior to statistical analysis.

As pediatric reference ranges are not yet available for all IMMULITE assays, I have sometimes tabulated published values obtained with other immunoassays. Because these values — carefully flagged as “Pediatric Reference Ranges from the Literature” — were not determined with the IMMULITE or IMMULITE 2000 systems, they should be used for orientation only.

So far as possible, reference range information has been summarized in a uniform manner throughout this booklet, using percentiles and interpercentile ranges (explained in the Appendix). For the reader's convenience, this compendium also includes other types of information used in the interpretation of certain types of assay: therapeutic and toxic ranges, for assays used in therapeutic drug monitoring (TDM); cutoffs, for drugs of abuse (DOA) assays; and Classes, for allergen-specific IgE assays.

The origin of the reference limits, cutoffs, etc. is clearly indicated, line by line, in the rightmost column, by an

alphanumeric key to the bibliography (at the end of this document).

The aim was completeness, but no doubt I have overlooked a number of relevant publications on DPC's automated chemiluminescent immunoassay systems. In hopes of making future editions of this compendium still more useful and comprehensive, I look forward to hearing from readers who know of other significant publications summarizing reference range studies performed with IMMULITE or IMMULITE 2000 assays.

*Werner Kühnel, Ph.D.
Marketing Manager, Scientific Affairs
DPC Biermann, Germany*

Acknowledgements

Many individuals have made important contributions to this compendium. I am especially grateful to my personal friend Dr. Martin Elmlinger for permitting me to publish a preliminary analysis of his extensive, ground-breaking study of IMMULITE pediatric reference values; and to all those who have published and/or brought to my attention other relevant clinical studies. I am also indebted to Serpil Duygulu for layout design and data entry, and to Rebecca Spitz and Sandy Hack for additional desktop publishing and editorial support.

Notes and Disclaimers

The tabulated percentiles and interpercentile ranges represent guidelines only. Because of differences which may exist between laboratories and locales with respect to population, laboratory technique and selection of reference groups, each laboratory should *establish or verify* the appropriateness of adopting the reference limits suggested in this compendium.

The results summarized here are not all from the same centers or the same populations; hence care should be exercised when comparing results.

Reference limits flagged as “from the literature” were *not* generated with IMMULITE or IMMULITE 2000 assays. These values should be used for orientation only. (This is especially true for the more extreme percentiles.)

Appropriate *decision* (or “action”) limits cannot be automatically identified with *reference* limits: the latter have a descriptive rather than a normative character.

For each assay, the most current package insert represents the definitive source for the assay’s parameters and intended use. For a better perspective on the values tabulated in this booklet, consult the references indicated in the rightmost column.

Translator’s Note

This is the first English translation of Dr. Kühnel’s valuable compendium, which has been available in German for some time. We have done our best to check the translation in its entirety; but in an undertaking of this magnitude, it is inevitable that some errors will have escaped detection.

Not all assays are available in the United States. Accordingly, for each analyte, we have indicated which assay formats, if any, have been cleared by the Food and Drug Administration (FDA).

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ACTH

- Assay Formats: IMMULITE (LKAC)
- FDA Cleared: IMMULITE
- Calibration Range: up to 1,250 pg/mL
- Detection Limit: 9 pg/mL

	n	Median pg/mL	95% Range pg/mL		Ref
Healthy adults	59	24	ND – 46		DPC P/I, Vog99
<i>Pediatric Reference Ranges from the Literature</i>					
Cord blood serum			50 – 570		Tie99
Newborns			10 – 185		Tie99

Alpha Fetoprotein (AFP)

- Assay Formats: IMMULITE (LKAP); IMMULITE 2000 (L2KAP)
- FDA Approved: IMMULITE, IMMULITE 2000
- Calibration Range: up to 300 IU/mL (WHO 1st IS 72/225)
- Detection Limit: 0.2 IU/mL
- Conversion: IU/mL (WHO 1st IS 72/225) × 1.21 → ng/mL

	n	Median IU/mL	Central 90% IU/mL	97.5 %ile IU/mL	Ref
Healthy males and females	382	1.21	0.56 – 2.64	2.97	ZB148
	n	Median IU/mL	Abs Range IU/mL	99 %ile IU/mL	Ref
Healthy males	119	1.6	0.5 – 5.5	5	DPC P/I
Pregnancy, 2nd Trimester (week + day)					
<i>There is no FDA-approved "Triple Screening" test in the United States.</i>					
14+3		21.73			Van99
15+3		25.00			Van99
16+3		28.75			Van99
17+3		33.08			Van99
18+3		38.05			Van99
19+3		43.78			Van99
20+3		50.36			Van99
21+3		57.93			Van99

Albumin, Urinary

- Assay Formats: IMMULITE (LKHA)
- FDA Cleared: IMMULITE
- Calibration Range: 25 to 60 µg/mL
- Detection Limit: 0.5 µg/mL

	n	Median µg/min	Central 95% µg/min	95 %ile µg/min	Ref
Healthy adults	55	6	ND – 18	13	DPC P/I

BR-MA (CA 15-3)

- Assay Formats: IMMULITE (LKBR); IMMULITE 2000 (L2KBR)
- Calibration Range: up to 300 U/mL
- Detection Limit: 1.0 U/mL (IMMULITE); 0.2 U/mL (IMMULITE 2000)

	n	Median U/mL	Central 95% U/mL		Ref
Healthy adults	99	26	9 – 51		DPC P/I
	n	Median U/mL	Central 90% U/mL	97.5 %ile U/mL	Ref
Females	477	22	9.2 – 38	42	ZB148

Cannabinoids (THCA)

- Assay Formats: IMMULITE (LKTH)
- FDA Cleared: IMMULITE
- Calibration Range: 10 to 250 ng/mL
- Detection Limit: 1.8 ng/mL

Interpretation			Cutoff ng/mL		Ref
Negative for cannabinoids			50		DPC P/I

Carbamazepine

- Assay Formats: IMMULITE (LKCB)
- Calibration Range: 1.25 to 20 µg/mL
- Detection Limit: 0.2 µg/mL
- Conversion: µg/mL × 4.23 → µmol/L

			Range µg/mL		Ref
Therapeutic range			4 – 12		Tie99
Toxic levels			> 15		Tie99

CEA

- Assay Formats: IMMULITE (LKCE); IMMULITE 2000 (L2KCE)
- FDA Approved: IMMULITE, IMMULITE 2000
- Calibration Range: up to 550 ng/mL
- Detection Limit: 0.2 ng/mL (IMMULITE); 0.15 ng/mL (IMMULITE 2000)

	n	Median ng/mL	Central 90% ng/mL	97.5 %ile ng/mL	Ref
Males					
Smoking	166	1.8	0.52 – 6.3	8.9	ZB148
Nonsmoking	312	1.9	0.37 – 3.3	4.3	ZB148
Females					
Smoking	98	1.3	0.42 – 4.8	5.4	ZB148
Nonsmoking	346	0.73	0.21 – 2.5	3.0	ZB148
	n	Median ng/mL		95 %ile ng/mL	Ref
Nonmalignant Diseases					
Pulmonary diseases	32	2.8		11.2	DPC P/I
Renal diseases	19	1.5		6.3	DPC P/I
Hepatitis	47	1.9		8.5	DPC P/I
Thyroid diseases	65	1.1		4.9	DPC P/I
Other nonmalignant diseases	80	1.9		13.6	DPC P/I
Malignant Diseases					
Bladder cancer	27	1.5		83.1	DPC P/I
Breast cancer	46	4.1		2,230	DPC P/I
Colorectal cancer	944	5.1		849	DPC P/I
Esophageal cancer	44	4.5		323	DPC P/I
Lung cancer	52	4.8		355	DPC P/I
Ovarian cancer	50	1.3		24.6	DPC P/I
Renal cancer	39	1.0		3.5	DPC P/I
Pancreatic cancer	19	19.4		495	DPC P/I
Stomach cancer	25	56.5		277	DPC P/I
Prostate cancer	29	1.2		13.2	DPC P/I
Rectal cancer	21	1.4		23.8	DPC P/I
Other cancers	86	2.0		233	DPC P/I

CK-MB

- Assay Formats: IMMULITE (LKCP); IMMULITE *Turbo* (LSKCP)
- FDA Approved: IMMULITE, IMMULITE *Turbo*
- Calibration Range: up to 500 ng/mL
- Detection Limit: 0.2 ng/mL (IMMULITE); 0.4 ng/mL (IMMULITE *Turbo*)

	n	Median ng/mL	Abs Range ng/mL	95 %ile ng/mL	Ref
Healthy adults	100	1.09	ND – 5.8	3	DPC P/I

Cocaine Metabolite

- Assay Formats: IMMULITE (LKCN)
- FDA Cleared: IMMULITE
- Calibration Range: 100 to 5,000 ng/mL
- Detection Limit: 28 ng/mL

Interpretation			Cutoff ng/mL		Ref
Negative for benzoylecgonine			300		DPC P/I

Cortisol

- Assay Formats: IMMULITE (LKCO); IMMULITE 2000 (L2KCO)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 1 to 50 µg/dL
- Detection Limit: 0.2 µg/dL
- Conversion: µg/dL × 27.59 → nmol/L

SERUM			Range µg/dL		Ref
Healthy adults					
a.m.			5 – 25		DPC P/I
p.m.			2.5 – 12.5		DPC P/I

Cortisol (continued)

IMMULITE Pediatric Reference Ranges

	n	Median µg/dL	Central 90% µg/dL		Ref
Boys					
1 – 7 d	27	18.5	9.0 – 50		ElmPed
8 – 15 d	18	11.2	6.9 – 21		ElmPed
1 – 3 y	13	9.8	4.9 – 16.8		ElmPed
4 – 6 y	26	9.2	3.9 – 24		ElmPed
7 – 8 y	26	14.4	7.0 – 27		ElmPed
9 – 10 y	30	11.5	3.5 – 27		ElmPed
11 y	22	12.4	4.8 – 21		ElmPed
12 y	17	16.2	9.0 – 25		ElmPed
13 y	20	15.8	8.4 – 27		ElmPed
14 y	32	16.0	7.8 – 23		ElmPed
15 y	39	13.5	8.4 – 25		ElmPed
16 y	31	16.1	6.5 – 22		ElmPed
17 y	22	17.3	10.4 – 24		ElmPed
18 – 19 y	8	16.8	11.8 – 28		ElmPed
Tanner stage 1	33	13.6	5.3 – 30		ElmPed
Tanner stage 2–3	73	14.8	4.9 – 23		ElmPed
Tanner stage 4	40	15.4	7.5 – 25		ElmPed
Tanner stage 5	37	16.1	10.3 – 24		ElmPed

Note: Pediatric samples were collected at random times throughout the day.

Cortisol (continued)

IMMULITE Pediatric Reference Ranges

	n	Median µg/dL	Central 90% µg/dL		Ref
Girls					
1 – 7 d	17	22	7.4 – 40		ElmPed
8 – 15 d	20	12.4	8.6 – 22		ElmPed
1 – 3 y	14	7.6	5.5 – 18.9		ElmPed
4 – 6 y	22	7.9	5.0 – 22		ElmPed
7 – 8 y	24	10.6	4.1 – 22		ElmPed
9 – 10 y	40	11.9	4.5 – 26		ElmPed
11 y	21	13.2	6.7 – 22		ElmPed
12 y	18	14.0	5.5 – 26		ElmPed
13 y	25	16.0	7.8 – 22		ElmPed
14 y	29	16.9	8.1 – 27		ElmPed
15 y	48	14.4	6.6 – 27		ElmPed
16 y	40	14.0	8.7 – 25		ElmPed
17 y	30	14.2	8.7 – 24		ElmPed
18 – 19 y	12	16.5	11.3 – 22		ElmPed
Tanner stage 1	28	11.2	3.7 – 21		ElmPed
Tanner stage 2–3	70	14.4	5.7 – 25		ElmPed
Tanner stage 4	31	15.8	8.8 – 24		ElmPed
Tanner stage 5	66	14.6	9.1 – 24		ElmPed

Note: Pediatric samples were collected at random times throughout the day.

URINE (EXTRACTED)	n	Median µg/24h	Central 90% µg/24h		Ref
Healthy adults	50	41	9.5 – 148		Elm97

C-Peptide

- Assay Formats: IMMULITE (LKPE); IMMULITE 2000 (L2KPE)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 0.5 to 14 ng/mL (WHO 1st IRP 84/510)
- Detection Limit: 0.3 ng/mL
- Conversion: ng/mL × 331 → pmol/L

SERUM	n	Median ng/mL	Central 95% ng/mL		Ref
Healthy adults, fasting	35	1.6	0.9 – 4		DPC P/I

URINE		Median µg/24h	Central 95% µg/24h		Ref
24-hour urine		79	2 – 260		DPC P/I

C-Reactive Protein (CRP)

- Assay Formats: IMMULITE (LKCR)
- FDA Cleared: IMMULITE
- Calibration Range: up to 50 mg/dL (WHO 1st IS 85/506)
- Detection Limit: 0.01 mg/dL

	n	Median mg/dL	95% Range mg/dL		Ref
Healthy adults	100	0.14	ND – 1.1		DPC P/I

Cytokeratin 18

- Assay Formats: IMMULITE (LKCK)
- Calibration Range: up to 50 ng/mL
- Detection Limit: 0.03 ng/mL

	n	Median ng/mL	95% Range ng/mL		Ref
Healthy adults	100	0.9	ND – 3.8		DPC P/I

DHEA-SO₄

- Assay Formats: IMMULITE (LKDS); IMMULITE 2000 (L2KDS)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 30 to 1,000 µg/dL
- Detection Limit: 2 µg/dL (IMMULITE); 1.4 µg/dL (IMMULITE 2000)
- Conversion: µg/dL × 0.02714 → µmol/L

	n	Median µg/dL	Central 95% µg/dL		Ref
Males	70	280	80 – 560		DPC P/I
Females	132	170	35 – 430		DPC P/I
Pregnancy					
1st Trimester		230			DPC P/I
2nd Trimester		130			DPC P/I
3rd Trimester		65			DPC P/I

DHEA-SO₄ (continued)

Reference Ranges from the Literature

	n	Median µg/dL	Central 90% µg/dL		Ref
Males					
10 – 19 y	6	215			Kub86
20 – 29 y	17	420	280 – 640		Kub86
30 – 39 y	21	300	120 – 520		Kub86
40 – 49 y	23	250	95 – 530		Kub86
50 – 59 y	29	160	70 – 310		Kub86
60 – 69 y	37	130	42 – 290		Kub86
70 – 79 y	18	80	28 – 175		Kub86
80 – 89 y	4	36			Kub86
Females					
10 – 19 y	2	140			Kub86
20 – 29 y	23	185	65 – 380		Kub86
30 – 39 y	29	150	45 – 270		Kub86
40 – 49 y	29	120	32 – 240		Kub86
50 – 59 y	18	85	26 – 200		Kub86
60 – 69 y	21	50	13 – 130		Kub86
70 – 79 y	8	40	17 – 90		Kub86
80 – 89 y	6	26			Kub86
Postmenopausal	60	55	10 – 190		Kub86

DHEA-SO₄ (continued)

IMMULITE Pediatric Reference Ranges

	n	Median µg/dL	Central 90% µg/dL		Ref
Boys					
1 – 7 d	27	163	91 – 376		ElmPed
8 – 15 d	18	118	37 – 224		ElmPed
1 – 3 y	13	11	6 – 21		ElmPed
4 – 6 y	27	16	5 – 186		ElmPed
7 – 8 y	26	26	10 – 94		ElmPed
9 – 10 y	31	36	16 – 75		ElmPed
11 y	22	42	20 – 152		ElmPed
12 y	17	59	18 – 344		ElmPed
13 y	21	80	21 – 243		ElmPed
14 y	32	104	19 – 286		ElmPed
15 y	40	190	59 – 310		ElmPed
16 y	31	167	47 – 357		ElmPed
17 y	22	180	102 – 341		ElmPed
18 – 19 y	8	193	108 – 441		ElmPed
Tanner stage 1	33	26	8 – 87		ElmPed
Tanner stage 2–3	74	60	20 – 151		ElmPed
Tanner stage 4	41	156	75 – 282		ElmPed
Tanner stage 5	37	234	121 – 368		ElmPed

DHEA-SO₄ (continued)

IMMULITE Pediatric Reference Ranges

	n	Median µg/dL	Central 90% µg/dL		Ref
Girls					
1 – 7 d	14	158	73 – 367		ElmPed
8 – 15 d	20	114	44 – 247		ElmPed
1 – 3 y	14	14	6 – 79		ElmPed
4 – 6 y	23	19	6 – 38		ElmPed
7 – 8 y	22	30	13 – 68		ElmPed
9 – 10 y	40	29	14 – 160		ElmPed
11 y	22	45	12 – 98		ElmPed
12 y	18	70	28 – 177		ElmPed
13 y	25	56	23 – 167		ElmPed
14 y	30	114	32 – 301		ElmPed
15 y	48	115	39 – 288		ElmPed
16 y	40	179	58 – 354		ElmPed
17 y	30	208	97 – 399		ElmPed
18 – 19 y	12	211	145 – 395		ElmPed
Tanner stage 1	26	24	13.2 – 65		ElmPed
Tanner stage 2–3	70	54	22 – 175		ElmPed
Tanner stage 4	31	114	57 – 230		ElmPed
Tanner stage 5	66	208	76 – 378		ElmPed

Digitoxin

- Assay Formats: IMMULITE (LKDG)
- FDA Cleared: IMMULITE
- Calibration Range: 5 to 60 ng/mL
- Detection Limit: 0.65 ng/mL
- Conversion: ng/mL × 1.307 → nmol/L

			Range ng/mL		Ref
Therapeutic range			20 – 35		Tie99
Toxic levels			> 45		Tie99

Digoxin

- Assay Formats: IMMULITE (LKDI)
- FDA Cleared: IMMULITE
- Calibration Range: 0.5 to 8.0 ng/mL
- Detection Limit: 0.1 ng/mL
- Conversion: ng/mL \times 1.281 \rightarrow nmol/L

			Range ng/mL		Ref
Therapeutic range			0.8 – 2.4		Smi69
Toxic levels			2.1 – 8.7		Smi69

ECP

- Assay Formats: IMMULITE (LKEO)
- Calibration Range: up to 200 ng/mL
- Detection Limit: 0.2 ng/mL

	n	Median ng/mL	Lower 95% ng/mL		Ref
Healthy adults	56	10	ND – 24		DPC P/I

EPO (Erythropoietin)

- Assay Formats: IMMULITE (LKEP)
- FDA Cleared: IMMULITE
- Calibration Range: up to 200 mU/mL (WHO 2nd IRP 67/343)
- Detection Limit: 0.24 mU/mL

	n	Median mU/mL	Abs Range mU/mL	95 %ile mU/mL	Ref
Healthy adults	60	11.2	2.6 – 34	29.5	DPC P/I
	n	Median mU/mL	Central 95% mU/mL		Ref
Healthy males	34	8.9	3.5 – 17.6		Elm99b
Healthy females	41	11.6	3.7 – 19.4		Elm99b

IMMULITE Pediatric Reference Ranges

Boys

Prepubertal	12	11.3	3.1 – 22.2		Elm99b
Puberty	9	21.5	5.3 – 31.0		Elm99b
Postpubertal	15	10.9	3.7 – 18.8		Elm99b

Girls

Prepubertal	13	8.1	2.8 – 16.5		Elm99b
Puberty	11	12.9	4.0 – 21.6		Elm99b
Postpubertal	10	6.9	3.3 – 15.8		Elm99b

Estradiol (E2)

- Assay Formats: IMMULITE (LKE2); IMMULITE 2000 (L2KE2)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 20 to 2,000 pg/mL
- Detection Limit: 12 pg/mL (IMMULITE); 10 pg/mL (IMMULITE 2000)
- Conversion: pg/mL \times 3.671 \rightarrow pmol/L

	n	Median pg/mL	Central 95% pg/mL		Ref
Menstrual Cycle (54 subjects)					
Follicular phase	708	42	ND – 160		ZB157
Follicular phase, d 2–3	108	31	ND – 84		ZB157
Periovulatory \pm 3 d	378	133	34 – 400		ZB157
Luteal phase	604	93	27 – 246		ZB157
	n	Median pg/mL	Central 90% pg/mL		Ref
Females					
Untreated postmenopausal	27	ND	ND – 30		DPC P/I
Treated postmenopausal	27	ND	ND – 93		DPC P/I
Oral contraceptives	61	24.5	ND – 102		DPC P/I

Estradiol (continued)

	n	Median pg/mL	Abs Range pg/mL		Ref
Females					
On conjugated estrogens	14	41	16 – 90		Rod98
On estradiol valerate	8	84	60 – 177		Rod98
	n	Median pg/mL	Central 90% pg/mL		Ref
Adult males	50	29.7	ND – 56		DPC P/I
IMMULITE Pediatric Reference Ranges					
	n	Median pg/mL	Central 90% pg/mL		Ref
Boys					
1 – 7 d	27	15	ND – 54		ElmPed
8 – 15 d	19	18	ND – 32		ElmPed
1 – 3 y	13	ND	ND – 14		ElmPed
4 – 6 y	28	13	ND – 21		ElmPed
7 – 8 y	26	12	ND – 21		ElmPed
9 – 10 y	29	13	ND – 20		ElmPed
11 y	22	13	ND – 24		ElmPed
12 y	17	12	ND – 29		ElmPed
13 y	21	12	ND – 49		ElmPed
14 y	32	17	ND – 48		ElmPed
15 y	40	21	ND – 67		ElmPed
16 y	31	23	ND – 36		ElmPed
17 y	22	16	ND – 25		ElmPed
18 – 19 y	8	17	ND – 32		ElmPed
Tanner stage 1	33	11	ND – 21		ElmPed
Tanner stage 2–3	73	13	ND – 23		ElmPed
Tanner stage 4	41	20	ND – 42		ElmPed
Tanner stage 5	37	23	ND – 86		ElmPed

Estradiol (continued)

IMMULITE Pediatric Reference Ranges

	n	Median pg/mL	Central 90% pg/mL	Ref
Girls				
1 – 7 d	13	22	ND – 31	ElmPed
8 – 15 d	19	24	ND – 36	ElmPed
1 – 3 y	14	12	ND – 18	ElmPed
4 – 6 y	22	15	ND – 22	ElmPed
7 – 8 y	24	16	ND – 20	ElmPed
9 – 10 y	40	13	ND – 36	ElmPed
11 y	23	25	ND – 45	ElmPed
12 y	18	15	ND – 44	ElmPed
13 y	25	22	ND – 42	ElmPed
14 y	30	46	16 – 136	ElmPed
15 y	48	46	ND – 196	ElmPed
16 y	40	63	26 – 192	ElmPed
17 y	29	44	14 – 124	ElmPed
18 – 19 y	12	60	17 – 184	ElmPed
Tanner stage 1	28	ND	ND – 18	ElmPed
Tanner stage 2–3	71	22	ND – 62	ElmPed
Tanner stage 4	31	37	13 – 71	ElmPed
Tanner stage 5	65	69	23 – 188	ElmPed

Note: Pediatric results were analyzed without regard to menstrual cycle position

Unconjugated Estriol (uE3)

- Assay Formats: IMMULITE (LKEF)
- FDA Approved: IMMULITE
- Calibration Range: 0.25 to 30 ng/mL
- Detection Limit: 0.2 ng/mL
- Conversion: ng/mL \times 3.467 \rightarrow nmol/L

	n	Median ng/mL	Central 95% ng/mL		Ref
Pregnancy, 3rd Trimester (week)					
27	21	6.5	2.9 – 12.7		DPC P/I
28	21	7.3	3.3 – 14.3		DPC P/I
29	19	8.2	3.7 – 16.0		DPC P/I
30	19	9.2	4.1 – 17.9		DPC P/I
31	22	10.3	4.6 – 19.9		DPC P/I
32	18	11.4	5.1 – 22.1		DPC P/I
33	18	12.7	5.7 – 24.4		DPC P/I
34	20	14.0	6.3 – 27.0		DPC P/I
35	19	15.5	7.0 – 29.7		DPC P/I
36	20	17.0	7.7 – >30		DPC P/I
37	19	18.7	8.5 – >30		DPC P/I
38	20	20.4	9.3 – >30		DPC P/I
39	18	22.3	10.2 – >30		DPC P/I
40	14	24.3	11.1 – >30		DPC P/I
Pregnancy, 2nd Trimester (week + day)					
<i>There is no FDA-approved "Triple Screening" test in the United States.</i>					
14+3		0.99			Van99
15+3		1.27			Van99
16+3		1.64			Van99
17+3		2.11			Van99
18+3		2.71			Van99
19+3		3.50			Van99
20+3		4.51			Van99
21+3		5.81			Van99

Ferritin

- Assay Formats: IMMULITE (LKFE); IMMULITE 2000 (L2KFE)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 1,500 ng/mL (WHO 2nd IS 80/578)
- Detection Limit: 1.5 ng/mL (IMMULITE); 0.4 ng/mL (IMMULITE 2000)
- Conversion: ng/mL \times 1.307 \rightarrow nmol/L

	n		Central 95% ng/mL		Ref
Adult males	225		28 – 397		DPC P/I
Adult females	194		6 – 159		DPC P/I

IMMULITE Pediatric Reference Ranges

	n	Median ng/mL	Central 90% ng/mL		Ref
Boys					
1 – 7 d	26	128	34 – 432		ElmPed
8 – 15 d	19	77	32 – 233		ElmPed
1 – 3 y	13	17.3	4.2 – 62		ElmPed
4 – 6 y	28	30	13.4 – 75		ElmPed
7 – 8 y	26	40	18.2 – 90		ElmPed
9 – 10 y	30	36	17.2 – 73		ElmPed
11 y	22	43	22 – 93		ElmPed
12 y	17	47	25 – 78		ElmPed
13 y	21	30	19.5 – 49		ElmPed
14 y	32	35	15.1 – 70		ElmPed
15 y	40	37	9.9 – 98		ElmPed
16 y	31	37	9.9 – 82		ElmPed
17 y	22	31	14.0 – 92		ElmPed
18 – 19 y	8	25	11.2 – 115		ElmPed
Tanner stage 1	33	36	14.0 – 78		ElmPed
Tanner stage 2–3	74	41	21 – 74		ElmPed
Tanner stage 4	41	38	14.4 – 87		ElmPed
Tanner stage 5	37	24	9.8 – 101		ElmPed

Ferritin (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/mL	Central 90% ng/mL	Ref
Girls				
1 – 7 d	14	247	46 – 620	ElmPed
8 – 15 d	18	112	53 – 237	ElmPed
1 – 3 y	14	22	9.8 – 73	ElmPed
4 – 6 y	23	32	8.6 – 74	ElmPed
7 – 8 y	24	45	23 – 76	ElmPed
9 – 10 y	40	40	11.0 – 73	ElmPed
11 y	23	52	21 – 92	ElmPed
12 y	18	42	12.8 – 81	ElmPed
13 y	25	39	15.5 – 64	ElmPed
14 y	30	33	11.0 – 76	ElmPed
15 y	48	28	4.2 – 75	ElmPed
16 y	39	37	6.8 – 122	ElmPed
17 y	29	25	9.1 – 45	ElmPed
18 – 19 y	12	26	6.6 – 58	ElmPed
Tanner stage 1	28	43	15.8 – 71	ElmPed
Tanner stage 2–3	71	41	10.4 – 92	ElmPed
Tanner stage 4	31	34	9.2 – 93	ElmPed
Tanner stage 5	65	27	6.3 – 60	ElmPed

Folic Acid

- Assay Formats: IMMULITE (LKFO), IMMULITE 2000 (L2KFO)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 0.5 to 24 ng/mL
- Detection Limit: 0.3 ng/mL
- Conversion: ng/mL \times 2.266 \rightarrow nmol/L

SERUM	n		Central 95% ng/mL		Ref
Healthy adults	100		3 – 17		DPC P/I
<i>Pediatric Reference Ranges from the Literature</i>					
Hospitalized boys					
0 – 1 y	111		7.2 – 22.4		Hic93a
2 – 3 y	105		2.5 – 15.0		Hic93a
4 – 6 y	154		0.5 – 13.0		Hic93a
7 – 9 y	103		2.3 – 11.9		Hic93a
10 – 12 y	105		1.5 – 10.8		Hic93a
13 – 18 y	127		1.2 – 8.8		Hic93a
Hospitalized girls					
0 – 1 y	73		6.3 – 22.7		Hic93a
2 – 3 y	135		1.7 – 15.7		Hic93a
4 – 6 y	104		2.7 – 14.1		Hic93a
7 – 9 y	102		2.4 – 13.4		Hic93a
10 – 12 y	90		1.0 – 10.2		Hic93a
13 – 18 y	159		1.2 – 7.2		Hic93a
BLOOD					
	n		Central 95% ng/mL		Ref
Healthy Adults					
Whole blood	88		43 – 295		DPC P/I
Red cell	88		93 – 641		DPC P/I

FSH

- Assay Formats: IMMULITE (LKFS); IMMULITE 2000 (L2KFS)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 170 mIU/mL (WHO 2nd IRP 78/549)
- Detection Limit: 0.1 mIU/mL

	N	Median mIU/mL	Central 95% mIU/mL		Ref
Adult males	135	3.8	0.7 – 11.1		DPC P/I
Menstrual Cycle (54 subjects)					
Follicular phase	762	6.2	2.8 – 11.3		ZB157
Follicular phase, d 2–3	108	6.6	3.0 – 14.4		ZB157
Midcycle	54	13.6	5.8 – 21		ZB157
Luteal phase	604	3.4	1.2 – 9.0		ZB157
Females					
Oral contraceptives	12	1.7	ND – 4.9		DPC P/I
Postmenopausal	76	90.5	21.7 – 153		DPC P/I
Postmenopausal (ERT)	16	27	9.7 – 111		DPC P/I
IMMULITE Pediatric Reference Ranges					
	N	Median mIU/mL	Central 90% mIU/mL		Ref
Boys					
1 – 7 d	28	0.23	ND – 1.16		ElmPed
8 – 15 d	20	0.61	ND – 1.20		ElmPed
1 – 3 y	13	1.50	0.58 – 2.4		ElmPed
4 – 6 y	26	0.48	0.10 – 5.8		ElmPed
7 – 8 y	26	1.04	0.15 – 3.1		ElmPed
9 – 10 y	31	0.87	0.24 – 4.2		ElmPed
11 y	22	2.1	0.46 – 6.4		ElmPed
12 y	17	2.8	0.80 – 10.0		ElmPed
13 y	21	3.4	0.71 – 6.9		ElmPed
14 y	32	2.9	0.76 – 7.2		ElmPed
15 y	39	4.2	1.16 – 13.0		ElmPed
16 y	30	3.8	0.61 – 7.9		ElmPed
17 y	22	4.8	2.5 – 11.4		ElmPed
18 – 19 y	8	7.1	2.0 – 14.5		ElmPed
Tanner stage 1	33	0.87	0.16 – 3.5		ElmPed
Tanner stage 2–3	74	2.4	0.44 – 6.0		ElmPed
Tanner stage 4	39	4.5	1.40 – 11.8		ElmPed
Tanner stage 5	37	4.0	1.28 – 14.9		ElmPed

FSH (continued)

IMMULITE Pediatric Reference Ranges

	n	Median mIU/mL	Central 95% mIU/mL		Ref
Boys					
Cord blood serum	37	0.24	ND – 1.2		ZB157
0.1 – 3 y	72	0.6	ND – 5.5		ZB157
4 – 9 y	31	0.23	ND – 1.9		ZB157
	n	Median mIU/mL	Central 90% mIU/mL		Ref
Girls					
1 – 7 d	17	0.14	ND – 0.65		ElmPed
8 – 15 d	20	0.25	ND – 0.89		ElmPed
1 – 3 y	14	1.44	0.67 – 3.3		ElmPed
4 – 6 y	21	1.00	0.23 – 2.6		ElmPed
7 – 8 y	23	1.15	0.20 – 5.8		ElmPed
9 – 10 y	40	1.54	0.43 – 6.5		ElmPed
11 y	22	5.2	0.74 – 8.4		ElmPed
12 y	18	4.8	0.96 – 12.9		ElmPed
13 y	25	5.4	2.1 – 9.3		ElmPed
14 y	30	4.7	1.52 – 11.3		ElmPed
15 y	48	5.1	1.78 – 11.5		ElmPed
16 y	40	5.8	1.48 – 11.7		ElmPed
17 y	30	4.2	1.34 – 9.4		ElmPed
18 – 19 y	12	3.6	1.06 – 9.5		ElmPed
Tanner stage 1	27	1.15	0.38 – 3.6		ElmPed
Tanner stage 2–3	70	4.3	1.25 – 8.9		ElmPed
Tanner stage 4	31	5.6	1.65 – 9.1		ElmPed
Tanner stage 5	66	5.0	1.20 – 12.3		ElmPed
	n	Median mIU/mL	Central 95% mIU/mL		Ref
Girls					
Cord blood serum	30	ND			ZB157
0.1 – 3 y	57	2.3	0.11 – 13		ZB157
4 – 9 y	28	0.8	0.11 – 1.6		ZB157

Note: Pediatric results were analyzed without regard to menstrual cycle position

GI-MA (CA 19-9)

- Assay Formats: IMMULITE (LKGI)
- Calibration Range: up to 1000 U/mL
- Detection Limit: 2.0 U/mL

	n	Median U/mL	Abs Range U/mL		Ref
Healthy adults	70	5.1	ND – 33		DPC P/I
	n	Median U/mL	Central 90% U/mL	97.5 %ile U/mL	Ref
Males	470	3.1	2.5 – 19	24	ZB148
Females	435	4.1	2.6 – 19	25	ZB148
Males and females combined	905	3.5	2.5 – 19	24	ZB148

Growth Hormone (hGH)

- Assay Formats: IMMULITE (LKGH)
- FDA Cleared: IMMULITE
- Calibration Range: up to 40 ng/mL
- Detection Limit: 0.01 ng/mL
- Conversion: ng/mL \times 2.6 \rightarrow mIU/L (WHO IRP 80/505)

	n		Abs Range ng/mL		Ref
Healthy adults	62		0.06 – 5.0		DPC P/I

IMMULITE Pediatric Reference Ranges

	n	Median ng/mL	Central 90% ng/mL		Ref
Boys					
1 – 7 d	26	11.8	1.18 – 27		ElmPed
8 – 15 d	20	4.8	0.69 – 17.3		ElmPed
1 – 3 y	12	1.23	0.43 – 2.4		ElmPed
4 – 6 y	27	0.38	0.09 – 2.5		ElmPed
7 – 8 y	26	0.68	0.15 – 3.2		ElmPed
9 – 10 y	31	0.56	0.09 – 1.95		ElmPed
11 y	22	0.88	0.08 – 4.7		ElmPed
12 y	17	0.69	0.12 – 8.9		ElmPed
13 y	21	1.10	0.10 – 7.9		ElmPed
14 y	32	0.46	0.09 – 7.1		ElmPed
15 y	39	1.30	0.10 – 7.8		ElmPed
16 y	31	1.00	0.08 – 11.4		ElmPed
17 y	22	2.4	0.22 – 12.2		ElmPed
18 – 19 y	8	1.60	0.97 – 4.7		ElmPed

Growth Hormone (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/mL	Central 90% ng/mL		Ref
Boys					
Tanner stage 1	33	0.65	0.12 – 2.8		ElmPed
Tanner stage 2–3	74	0.66	0.10 – 5.7		ElmPed
Tanner stage 4	40	0.55	0.07 – 7.9		ElmPed
Tanner stage 5	37	2.1	0.10 – 15.1		ElmPed
Girls					
1 – 7 d	14	13.0	2.4 – 24		ElmPed
8 – 15 d	18	5.0	1.07 – 17.6		ElmPed
1 – 3 y	14	1.28	0.50 – 3.5		ElmPed
4 – 6 y	23	0.71	0.10 – 2.2		ElmPed
7 – 8 y	24	1.20	0.16 – 5.4		ElmPed
9 – 10 y	40	0.56	0.08 – 3.1		ElmPed
11 y	23	0.37	0.12 – 6.9		ElmPed
12 y	17	0.65	0.14 – 11.2		ElmPed
13 y	25	2.2	0.21 – 17.8		ElmPed
14 y	30	0.73	0.14 – 9.9		ElmPed
15 y	48	1.25	0.24 – 10.0		ElmPed
16 y	40	2.4	0.26 – 11.7		ElmPed
17 y	30	1.75	0.30 – 10.8		ElmPed
18 – 19 y	12	1.00	0.24 – 4.3		ElmPed
Tanner stage 1	28	1.10	0.24 – 5.4		ElmPed
Tanner stage 2–3	70	0.58	0.13 – 8.5		ElmPed
Tanner stage 4	31	1.50	0.14 – 13.4		ElmPed
Tanner stage 5	66	1.31	0.24 – 9.9		ElmPed

Note: Pediatric samples were collected at random times throughout the day.

HCG

- Assay Formats: IMMULITE (LKCG); IMMULITE *Turbo* (LSKCG); IMMULITE 2000 (L2KCG)
- FDA Cleared: IMMULITE, IMMULITE *Turbo*, IMMULITE 2000
- Calibration Range: up to 5,000 mIU/mL (WHO 3rd IS 75/537)
- Detection Limit: 1.1 mIU/mL (IMMULITE); 3.3 mIU/mL (IMMULITE *Turbo*); 0.4 mIU/mL (IMMULITE 2000)

	n		Abs Range mIU/mL		Ref
Males	428		ND – 2.5		ZB157
Nonpregnant females	369		ND – 5.3		ZB157
	n	Median mIU/mL			Ref
Pregnancy, 2nd Trimester (week + day)					
<i>There is no FDA-approved “Triple Screening” test in the United States.</i>					
14+3		38,254			Van99
15+3		32,608			Van99
16+3		27,795			Van99
17+3		23,693			Van99
18+3		20,196			Van99
19+3		17,215			Van99
20+3		14,674			Van99
21+3		12,508			Van99
	n	Median mIU/mL	Central 95% mIU/mL		Ref
Pregnancy					
1.3-2 (Gest) / 3.3-4 (LMP)	30	71	16 – 156		ZB157
2-3 (Gest) / 4-5 (LMP)	54	607	101 – 4,870		ZB157
3-4 (Gest) / 5-6 (LMP)	34	5,243	1,110 – 31,500		ZB157
4-5 (Gest) / 6-7 (LMP)	34	26,983	2,560 – 82,300		ZB157
5-6 (Gest) / 7-8 (LMP)	36	52,090	23,100 – 151,000		ZB157
6-7 (Gest) / 8-9 (LMP)	33	93,598	27,300 – 233,000		ZB157
7-11 (Gest) / 9-13 (LMP)	116	117,678	20,900 – 291,000		ZB157
11-16 (Gest) / 13-18 (LMP)	72	40,989	6,140 – 103,000		ZB157
16-21 (Gest) / 18-23 (LMP)	80	20,868	4,720 – 80,100		ZB157
21-39 (Gest) / 23-41 (LMP)	104	15,352	2,700 – 78,100		ZB157

Note: Results are summarized by gestational age in weeks (Gest) and weeks since last menstrual period (LMP).

Free Beta HCG

- Assay Formats: IMMULITE (LKFB)
- Calibration Range: up to 80 ng/mL (WHO 1st IRP 75/551)
- Detection Limit: 0.02 ng/mL

			Abs Range ng/mL		Ref
Healthy nonpregnant females			ND – 0.1		DPC P/I
Postmenopausal females			ND – 0.1		DPC P/I
Males			ND – 0.1		DPC P/I

Cat-Specific IgE (E1)

- Assay Formats: IMMULITE (LKE1)
- FDA Cleared: IMMULITE
- Calibration Range: 0.35 to 100 IU/mL
- Detection Limit: 0.1 IU/mL

Interpretation			Range IU/mL	Class	Ref
Negative for E1			< 0.35	0	DPC P/I
Positive for E1			0.35 – 0.69	I	DPC P/I
Strongly positive for E1			0.70 – 3.49	II	DPC P/I
Strongly positive for E1			3.50 – 17.49	III	DPC P/I
Strongly positive for E1			17.50 – 52.49	IV	DPC P/I
Strongly positive for E1			52.50 – 99.9	V	DPC P/I
Strongly positive for E1			100 & over	VI	DPC P/I

Dog-Specific IgE (E5)

- Assay Formats: IMMULITE (LKE5)
- FDA Cleared: IMMULITE
- Calibration Range: 0.35 to 100 IU/mL
- Detection Limit: 0.1 IU/mL

Interpretation			Range IU/mL	Class	Ref
Negative for E5			< 0.35	0	DPC P/I
Positive for E5			0.35 – 0.69	I	DPC P/I
Strongly positive for E5			0.70 – 3.49	II	DPC P/I
Strongly positive for E5			3.50 – 17.49	III	DPC P/I
Strongly positive for E5			17.50 – 52.49	IV	DPC P/I
Strongly positive for E5			52.50 – 99.9	V	DPC P/I
Strongly positive for E5			100 & over	VI	DPC P/I

Latex-Specific IgE

- Assay Formats: IMMULITE (LKLX)
- FDA Cleared: IMMULITE
- Calibration Range: 0.35 to 100 IU/mL
- Detection Limit: 0.2 IU/mL

Interpretation			Range IU/mL	Class	Ref
Negative for latex			< 0.35	0	DPC P/I
Positive for latex			0.35 – 0.69	I	DPC P/I
Strongly positive for latex			0.70 – 3.49	II	DPC P/I
Strongly positive for latex			3.50 – 17.49	III	DPC P/I
Strongly positive for latex			17.50 – 52.49	IV	DPC P/I
Strongly positive for latex			52.50 – 99.9	V	DPC P/I
Strongly positive for latex			100 & over	VI	DPC P/I

Mite-Specific IgE (D1)

- Assay Formats: IMMULITE (LKDP)
- FDA Cleared: IMMULITE
- Calibration Range: 0.35 to 100 IU/mL
- Detection Limit: 0.1 IU/mL

Interpretation			Range IU/mL	Class	Ref
Negative for D1			< 0.35	0	DPC P/I
Positive for D1			0.35 – 0.69	I	DPC P/I
Strongly positive for D1			0.70 – 3.49	II	DPC P/I
Strongly positive for D1			3.50 – 17.49	III	DPC P/I
Strongly positive for D1			17.50 – 52.49	IV	DPC P/I
Strongly positive for D1			52.50 – 99.9	V	DPC P/I
Strongly positive for D1			100 & over	VI	DPC P/I

Total IgE

- Assay Formats: IMMULITE (LKIE); IMMULITE 2000 (L2KIE)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 2,000 IU/mL (WHO 2nd IRP 75/502)
- Detection Limit: 1.0 IU/mL

	n	Median IU/mL		95 %ile IU/mL	Ref
Adults	48	20.4		87	DPC P/I

IMMULITE Pediatric Reference Ranges

	n	Median IU/mL		95 %ile IU/mL	Ref
Healthy Children					
0 – 1 y	15	6.6		29	DPC P/I
1 – 2 y	34	10.1		49	DPC P/I
2 – 3 y	29	12.9		45	DPC P/I
3 – 9 y	106	14.4		52	DPC P/I

IL-1 β

- Assay Formats: IMMULITE (LKL1)
- Calibration Range: up to 1,000 pg/mL (1st IS 86/680)
- Detection Limit: 1.5 pg/mL

	n		Abs Range pg/mL		Ref
Healthy adults	47		ND – 5		DPC P/I

IL2R

- Assay Formats: IMMULITE (LKIP)
- Calibration Range: up to 7,200 U/mL
- Detection Limit: 5 U/mL

	n	Median U/mL	95% Range U/mL		Ref
Healthy adults	87	391	223 – 710		DPC P/I
IMMULITE Pediatric Reference Ranges					
	n	Median U/mL	Central 95% U/mL		Ref
Healthy Children					
3 – 3.5 y	11	605	243 – 888		Sac99
3.5 – 4.5 y	29	435	52 – 908		Sac99
4.5 – 5.5 y	15	416	304 – 731		Sac99
5.5 – 6.5 y	26	382	223 – 603		Sac99
6.5 – 7.5 y	16	410	246 – 661		Sac99
7.5 – 8.5 y	22	379	258 – 661		Sac99
8.5 – 9.5 y	17	323	258 – 597		Sac99
9.5 – 10.5 y	27	343	201 – 661		Sac99
10.5 – 11.5 y	19	355	124 – 597		Sac99
11.5 – 12.5 y	21	312	124 – 623		Sac99
12.5 – 13.5 y	18	298	137 – 628		Sac99
13.5 – 14.5 y	24	390	45 – 507		Sac99
14.5 – 15.5 y	20	325	186 – 655		Sac99
15.5 – 16.5 y	28	373	68 – 532		Sac99
16.5 – 17.0 y	15	243	147 – 381		Sac99

IL-6

- Assay Formats: IMMULITE (LK6P)
- Calibration Range: up to 1000 pg/mL (1st IS 89/548)
- Detection Limit: 5 pg/mL

	n	Median pg/mL	Lower 95% pg/mL		Ref
Healthy adults	86	ND	ND – 9.7		DPC P/I

IMMULITE Pediatric Reference Ranges

	n	Median pg/mL	Central 90% pg/mL		Ref
Newborns	74	23	18 – 26		Kru99

	n	Median pg/mL	Central 95% pg/mL		Ref
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Healthy Children

3 – 3.5 y	11	12.0	ND – 23		Sac99
3.5 – 4.5 y	29	12.0	ND – 27		Sac99
4.5 – 5.5 y	15	12.0	ND – 24		Sac99
5.5 – 6.5 y	26	4.0	ND – 14.0		Sac99
6.5 – 7.5 y	16	ND	ND – 8.0		Sac99
7.5 – 8.5 y	22	ND	ND – 17.0		Sac99
8.5 – 9.5 y	17	ND	ND – 15.0		Sac99
9.5 – 10.5 y	27	0.5	ND – 27		Sac99
10.5 – 11.5 y	19	ND	ND – 15.0		Sac99
11.5 – 12.5 y	21	2.2	ND – 19.1		Sac99
12.5 – 13.5 y	18	ND	ND – 14.0		Sac99
13.5 – 14.5 y	24	ND	ND – 18.8		Sac99
14.5 – 15.5 y	20	8.0	ND – 25		Sac99
15.5 – 16.5 y	28	2.2	ND – 14.8		Sac99
16.5 – 17.0 y	15	ND	ND – 14.0		Sac99

IL-8

- Assay Formats: IMMULITE (LK8P)
- Calibration Range: up to 7,500 pg/mL (NIBSC 89/520)
- Detection Limit: 2 pg/mL

SERUM	n		Abs Range pg/mL		Ref
Healthy adults	50		ND – 62		DPC P/I
	n	Median pg/mL	Central 95% pg/mL		Ref
Adults	97	5	5 – 15		Ste99
IMMULITE Pediatric Reference Ranges					
	n	Mean pg/mL	Mean ± 2SD pg/mL		Ref
Infants, w 2–3	31	25	ND – 63		Moo99
	n	Median pg/mL	Central 95% pg/mL		Ref
Cord blood plasma	135	15	5 – 29		Ste99
	n	Median pg/mL	Central 95% pg/mL		Ref
Healthy Children					
3 – 3.5 y	11	ND	ND – 12		Sac99
3.5 – 4.5 y	29	ND	ND – 7		Sac99
4.5 – 5.5 y	15	ND	ND – 12		Sac99
5.5 – 6.5 y	26	ND	ND – 7		Sac99
6.5 – 7.5 y	16	ND	ND – 5		Sac99
7.5 – 8.5 y	22	ND	ND – 5		Sac99
8.5 – 9.5 y	17	ND	ND – 6		Sac99
9.5 – 10.5 y	27	ND	ND – 6		Sac99
10.5 – 11.5 y	19	ND	ND – 5		Sac99
11.5 – 12.5 y	21	ND	ND – 7		Sac99
12.5 – 13.5 y	18	ND	ND – 6		Sac99
13.5 – 14.5 y	24	ND	ND – 6		Sac99
14.5 – 15.5 y	20	ND	ND – 14		Sac99
15.5 – 16.5 y	28	ND	ND – 9		Sac99
16.5 – 17.0 y	15	ND	ND – 5		Sac99
	n	Median pg/mL	Central 95% pg/mL		Ref
HEMOLYSATE					
Adults	97	48.5	21 – 98		Ste99
Cord blood	135	373	132 – 820		Ste99

Insulin

- Assay Formats: IMMULITE (LKIN), IMMULITE 2000 (L2KIN)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 400 μ IU/mL
- Detection Limit: 2 μ IU/mL

	n	Median μ IU/mL	Central 95% μ IU/mL		Ref
Healthy adults, fasting	52	11.9	6 – 27		DPC P/I

LH

- Assay Formats: IMMULITE (LKLH); IMMULITE 2000 (L2KLH)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 200 mIU/mL (WHO 1st IRP 68/40; 2nd IRP 80/552)
- Detection Limit: 0.7 mIU/mL (IMMULITE); 0.05 mIU/mL (IMMULITE 2000)

	n	Median mIU/mL	Central 95% mIU/mL		Ref
Adult males	135	2.4	0.8 – 7.6		DPC P/I

Menstrual Cycle (54 subjects)

Follicular phase	762	4.6	1.1 – 11.6		ZB157
Midcycle	54	39	17 – 77		ZB157
Luteal phase	658	4.3	ND – 14.7		ZB157
Perimenstrual \pm 9 d	959	3.9	ND – 12.0		ZB157

Females

Oral contraceptives	104	3.1	ND – 8.0		DPC P/I
Postmenopausal	75	24.9	11.3 – 40		DPC P/I

LH (continued)

IMMULITE Pediatric Reference Ranges

	n	Median mIU/mL	Central 90% mIU/mL		Ref
Boys					
1 – 7 d	28	< 0.7	< 0.7		ElmPed
8 – 15 d	20	< 0.7	< 0.7		ElmPed
1 – 3 y	10	1.0	0.8 – 1.3		ElmPed
4 – 6 y	17	0.9	0.7 – 6.5		ElmPed
7 – 8 y	20	0.8	0.7 – 1.3		ElmPed
9 – 10 y	27	0.9	0.7 – 2.1		ElmPed
11 y	15	0.7	0.3 – 1.4		ElmPed
12 y	17	0.9	0.3 – 3.5		ElmPed
13 y	20	1.2	0.4 – 4.6		ElmPed
14 y	32	2.1	0.6 – 5.8		ElmPed
15 y	39	2.0	0.5 – 7.1		ElmPed
16 y	31	1.9	0.5 – 8.0		ElmPed
17 y	22	2.2	0.9 – 4.5		ElmPed
18 – 19 y	8	2.8	1.6 – 4.8		ElmPed
Tanner stage 1	28	0.9	0.7 – 1.2		ElmPed
Tanner stage 2–3	68	0.9	0.3 – 4.4		ElmPed
Tanner stage 4	39	1.6	0.5 – 4.7		ElmPed
Tanner stage 5	37	2.8	0.7 – 10.6		ElmPed
	n	Median mIU/mL	Central 95% mIU/mL		Ref
Boys					
Cord blood serum	36	ND	ND – 3.6		ZB157
0.1 – 1.5 y	54	1.0	ND – 4.1		ZB157
1.6 – 9 y	46	ND	ND – 3.8		ZB157

LH (Continued)

IMMULITE Pediatric Reference Ranges

	n	Median mIU/mL	Central 90% mIU/mL		Ref
Girls					
1 – 7 d	17	< 0.7	< 0.7		ElmPed
8 – 15 d	20	< 0.7	< 0.7		ElmPed
1 – 3 y	7	1.3	0.9 – 1.9		ElmPed
4 – 6 y	14	0.8	0.7 – 0.9		ElmPed
7 – 8 y	18	0.9	0.7 – 2.0		ElmPed
9 – 10 y	29	0.9	0.7 – 2.3		ElmPed
11 y	20	0.7	0.3 – 6.2		ElmPed
12 y	17	1.0	0.5 – 9.8		ElmPed
13 y	25	1.9	0.4 – 4.6		ElmPed
14 y	30	4.2	0.5 – 25		ElmPed
15 y	48	3.9	0.5 – 16		ElmPed
16 y	39	3.3	0.6 – 21		ElmPed
17 y	30	5.9	1.7 – 11		ElmPed
18 – 19 y	12	5.0	2.3 – 11		ElmPed
Tanner stage 1	23	0.8	0.7 – 2.0		ElmPed
Tanner stage 2–3	61	1.0	0.4 – 11		ElmPed
Tanner stage 4	30	4.6	0.9 – 13		ElmPed
Tanner stage 5	66	4.8	1.1 – 19		ElmPed
	n	Median mIU/mL	Central 95% mIU/mL		Ref
Girls					
Cord blood serum	31	ND			ZB157
0.1 – 1.5 y	46	0.7	ND – 2.3		ZB157
1.6 – 9 y	38	ND	ND – 1.3		ZB157

Note: Pediatric results were analyzed without regard to menstrual cycle position.

LH / FSH Ratio (LFR)

$$\text{LFR} = \text{LH (mIU/mL)} / \text{FSH (mIU/mL)}$$

	n	Median	Central 95%		Ref
Menstrual Cycle (54 subjects)					
Follicular phase, d 2–5	221	0.60	0.15 – 1.51		ZB157
Follicular phase, d 2–9	436	0.66	0.18 – 1.64		ZB157
Follicular phase, d 2–11 up to 5 days before LH peak	452	0.66	0.18 – 1.45		ZB157

Beta-2 Microglobulin

- Assay Formats: IMMULITE (LKBM); IMMULITE 2000 (L2KBM)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 500 ng/mL
- Detection Limit: 0.3 ng/mL

SERUM	n	Median ng/mL	Central 95% ng/mL	95 %ile ng/mL	Ref
Adults		1,260	1,010 – 1,730		DPC P/I
Males	424	1,552		2,157	DPC P/I
Females	370	1,473		2,295	DPC P/I
Males and females combined	794	1,509		2,164	DPC P/I
	n	Median ng/mL	Central 90% ng/mL	97.5 %ile ng/mL	Ref
Males and females	878	1,496	670 – 2,143	2,329	ZB148
<i>Pediatric Reference Ranges from the Literature</i>					
	n		Central 95% ng/mL		Ref
Hospitalized boys					
1 – 30 d	68		1,603 – 4,790		Sol97a
31 – 182 d	73		1,423 – 3,324		Sol97a
183 – 365 d	39		897 – 3,095		Sol97a
1 – 3 y	158		827 – 2,228		Sol97a
4 – 6 y	142		567 – 2,260		Sol97a
7 – 9 y	97		772 – 1,712		Sol97a
10 – 12 y	92		699 – 1,836		Sol97a
13 – 15 y	103		681 – 1,954		Sol97a
16 – 18 y	54		724 – 1,874		Sol97a

Beta-2 Microglobulin (continued)

Pediatric Reference Ranges from the Literature

	n		Central 95% ng/mL		Ref
Hospitalized girls					
1 – 30 d	50		1,722 – 4,547		Sol97a
31 – 182 d	68		1,024 – 3,774		Sol97a
183 – 365 d	27		999 – 2,282		Sol97a
1 – 3 y	129		742 – 2,396		Sol97a
4 – 6 y	123		546 – 2,170		Sol97a
7 – 9 y	79		736 – 1,766		Sol97a
10 – 12 y	68		704 – 1,951		Sol97a
13 – 15 y	82		787 – 1,916		Sol97a
16 – 18 y	77		555 – 1,852		Sol97a
URINE					
Healthy adults			ND – 300		DPC P/I

Myoglobin

- Assay Formats: IMMULITE (LKMY); IMMULITE *Turbo* (LSKMY)
- FDA Cleared: IMMULITE, IMMULITE *Turbo*
- Calibration Range: up to 1,000 ng/mL
- Detection Limit: 0.5 ng/mL (IMMULITE); 2.6 ng/mL (IMMULITE *Turbo*)

	n	Median ng/mL	97.5 %ile ng/mL		Ref
Adults	258	25	70		DPC P/I

Nicotine Metabolite

- Assay Formats: IMMULITE (LKNM)
- Calibration Range: 10 to 500 ng/mL
- Detection Limit: 2 ng/mL

			Cutoff ng/mL		Ref
Distinguish smoker status			25		DPC P/I

OM-MA (CA 125)

- Assay Formats: IMMULITE (LKOP); IMMULITE 2000 (L2KOP)
- FDA Approved: IMMULITE, IMMULITE 2000
- Calibration Range: up to 500 U/mL
- Detection Limit: 0.2 U/mL (IMMULITE); 0.3 U/mL (IMMULITE 2000)

	n	Median U/mL	Central 90% U/mL	97.5 %ile U/mL	Ref
Females	474	6.1	2.6 – 18	24	ZB148
	n	Median U/mL	Abs Range U/mL		Ref
Healthy females	64	4.8	1.9 – 16.3		DPC P/I

Opiates Screen

- Assay Formats: IMMULITE (LKOS)
- FDA Cleared: IMMULITE
- Calibration Range: 50 to 1,000 ng/mL
- Detection Limit: 5 ng/mL

Interpretation			Cutoff ng/mL		Ref
Negative for opiates			300		DPC P/I

Osteocalcin

- Assay Formats: IMMULITE (LKOC)
- Calibration Range: up to 100 ng/mL
- Detection Limit: 0.1 ng/mL

	n		Central 95% ng/mL		Ref
Healthy adults	40		3.1 – 13.7		DPC P/I

PAP

- Assay Formats: IMMULITE (LKPA)
- FDA Approved: IMMULITE
- Calibration Range: up to 100 ng/mL
- Detection Limit: 0.02 ng/mL

	n	Median ng/mL		97.5 %ile ng/mL	Ref
Healthy males	51	1.7		3.4	DPC P/I
	n	Median ng/mL	Central 90% ng/mL	97.5 %ile ng/mL	Ref
Healthy males	525	1.4	0.89 – 2.3	2.7	ZB148

Phenytoin

- Assay Formats: IMMULITE (LKPN)
- Calibration Range: 2.5 – 40 µg/mL
- Detection Limit: 0.03 µg/mL
- Conversion: µg/mL × 3.964 → µmol/L

			Range µg/mL		Ref
Therapeutic range			10 – 20		Tie99
Toxic range			> 20		Tie99

Progesterone

- Assay Formats: IMMULITE (LKPG); IMMULITE 2000 (L2KPG)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 0.2 to 40 ng/mL
- Detection Limit: 0.2 ng/mL
- Conversion: ng/mL × 3.18 → nmol/L

	n	Median ng/mL	Central 95% ng/mL		Ref
Menstrual Cycle (27 subjects)					
Follicular phase	382	0.47	ND – 1.13		ZB157
Midfollicular, d 5–11	186	0.43	ND – 0.98		ZB157
Midcycle	27	1.06	0.48 – 1.72		ZB157
Luteal phase	323	8.9	0.95 – 21		ZB157
Midluteal, d 7–8	54	13.1	6.0 – 24		ZB157
	n	Median ng/mL	Abs Range ng/mL		Ref
Females					
Postmenopausal	34	0.36	ND – 1.0		DPC P/I
Oral contraceptives	19	0.70	0.34 – 0.92		DPC P/I
Pregnancy					
1st Trimester	28	22.2	9.3 – 33.2		DPC P/I
2nd Trimester	10	35.4	29.5 – 50.0		DPC P/I
3rd Trimester	8	102	83.1 – 160		DPC P/I
	n	Median ng/mL	Central 95% ng/mL		Ref
Healthy males	70	0.35	ND – 0.75		DPC P/I

Progesterone (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/mL	Central 90% ng/mL		Ref
Boys					
1 – 7 d	27	1.00	0.44 – 3.0		ElmPed
8 – 15 d	19	0.87	0.35 – 2.3		ElmPed
1 – 3 y	12	0.30	ND – 0.61		ElmPed
4 – 6 y	28	0.48	ND – 1.29		ElmPed
7 – 8 y	26	0.57	0.26 – 1.07		ElmPed
9 – 10 y	29	0.62	ND – 1.06		ElmPed
11 y	22	0.54	0.32 – 1.05		ElmPed
12 y	17	0.70	0.32 – 1.53		ElmPed
13 y	21	0.74	0.41 – 1.46		ElmPed
14 y	32	0.88	0.39 – 1.24		ElmPed
15 y	40	0.99	0.64 – 2.5		ElmPed
16 y	31	1.10	0.74 – 3.7		ElmPed
17 y	22	1.40	0.82 – 1.90		ElmPed
18 – 19 y	8	1.58	1.20 – 3.0		ElmPed
Tanner stage 1	33	0.58	0.27 – 1.04		ElmPed
Tanner stage 2–3	73	0.70	0.34 – 1.20		ElmPed
Tanner stage 4	41	1.13	0.68 – 2.50		ElmPed
Tanner stage 5	37	1.40	0.84 – 3.1		ElmPed
	n	Median ng/mL	Central 95% ng/mL		Ref
Boys					
Cord blood serum	27	520	345 – 650		ZB157
0.1 – 0.4 y	33	1.5	0.3 – 14		ZB157
0.5 – 1 y	14	0.8	ND – 2.0		ZB157
1.1 – 9 y	42	0.4	ND – 1.3		ZB157

Progesterone (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/mL	Central 90% ng/mL		Ref
Girls					
1 – 7 d	14	0.68	0.25 – 2.2		ElmPed
8 – 15 d	19	0.89	0.35 – 1.42		ElmPed
1 – 3 y	14	0.24	ND – 0.61		ElmPed
4 – 6 y	22	0.44	ND – 0.99		ElmPed
7 – 8 y	24	0.50	0.25 – 0.99		ElmPed
9 – 10 y	40	0.55	0.13 – 1.00		ElmPed
11 y	22	0.66	0.37 – 0.92		ElmPed
12 y	17	0.78	0.49 – 1.68		ElmPed
13 y	25	0.72	0.40 – 1.46		ElmPed
14 y	30	1.20	0.56 – 12.3		ElmPed
15 y	48	1.40	0.70 – 13.4		ElmPed
16 y	40	5.0	0.65 – 14.5		ElmPed
17 y	30	1.40	0.77 – 11.3		ElmPed
18 – 19 y	12	2.4	1.27 – 13.0		ElmPed
Tanner stage 1	28	0.46	0.23 – 0.77		ElmPed
Tanner stage 2–3	70	0.70	0.36 – 2.2		ElmPed
Tanner stage 4	30	1.25	0.57 – 9.5		ElmPed
Tanner stage 5	66	2.4	0.75 – 14.6		ElmPed
	n	Median ng/mL	Central 95% ng/mL		Ref
Girls					
Cord blood serum	27	570	465 – 755		ZB157
0.1 – 0.4 y	24	1.2	0.25 – 17		ZB157
0.5 – 1 y	19	0.8	0.2 – 1.6		ZB157
1.1 – 9 y	38	0.4	ND – 1.4		ZB157

Note: Pediatric results were analyzed without regard to menstrual cycle positions.

Prolactin

- Assay Formats: IMMULITE (LKPR); IMMULITE 2000 (L2KPR)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 150 ng/mL
- Detection Limit: 0.5 ng/mL (IMMULITE); 0.16 ng/mL (IMMULITE 2000)
- Conversion: ng/mL \times 21.2 \rightarrow mIU/L (WHO 3rd IS 84/500)

	n	Median ng/mL	Abs Range ng/mL		Ref
Adult males	19	6.2	2.5 – 17		DPC P/I
	n	Median ng/mL	Central 95% ng/mL		Ref
Adult females	115	9.4	1.9 – 25		ZB157
Menstrual Cycle (53 subjects)					
Entire cycle	1,555	13.0	4.6 – 37		ZB157
Follicular phase	803	12.1	4.5 – 33		ZB157
Midcycle	53	17	6.3 – 46		ZB157
Luteal phase	699	13.9	4.9 – 40		ZB157
Pregnancy					
1st Trimester	39	16	3.2 – 43		ZB187
2nd Trimester	52	49	13 – 166		ZB187
3rd Trimester	54	113	13 – 318		ZB187

Prolactin (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/mL	Central 90% ng/mL		Ref
Boys					
1 – 7 d	26	162	58 – 392		ElmPed
8 – 15 d	20	125	45 – 254		ElmPed
1 – 3 y	13	15.9	7.7 – 49		ElmPed
4 – 6 y	27	7.7	2.8 – 12.8		ElmPed
7 – 8 y	25	6.7	2.7 – 18.2		ElmPed
9 – 10 y	29	6.7	4.5 – 12.9		ElmPed
11 y	22	7.0	2.6 – 15.0		ElmPed
12 y	17	5.9	3.9 – 13.2		ElmPed
13 y	21	7.4	3.6 – 17.6		ElmPed
14 y	32	8.0	4.4 – 14.2		ElmPed
15 y	40	10.4	4.7 – 17.9		ElmPed
16 y	31	6.5	3.4 – 13.5		ElmPed
17 y	22	6.0	2.5 – 14.8		ElmPed
18 – 19 y	8	10.8	7.2 – 15.5		ElmPed
Tanner stage 1	32	6.7	3.2 – 16.9		ElmPed
Tanner stage 2–3	73	6.5	3.6 – 13.0		ElmPed
Tanner stage 4	41	10.0	4.5 – 15.8		ElmPed
Tanner stage 5	37	7.9	2.6 – 17.0		ElmPed
	n	Median ng/mL	Central 95% ng/mL		Ref
Boys					
Cord blood serum	27	295	150 – 565		ZB157
0.1 – 0.5 y	36	19	4 – 65		ZB157
0.6 – 9 y	55	8	0.6 – 29		ZB157

Prolactin (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/mL	Central 90% ng/mL		Ref
Girls					
1 – 7 d	13	156	31 – 328		ElmPed
8 – 15 d	19	145	54 – 326		ElmPed
1 – 3 y	14	12.2	4.9 – 67		ElmPed
4 – 6 y	23	7.1	3.1 – 11.2		ElmPed
7 – 8 y	24	7.0	3.3 – 14.9		ElmPed
9 – 10 y	40	7.3	3.4 – 22		ElmPed
11 y	22	8.4	3.6 – 27		ElmPed
12 y	17	7.8	3.2 – 15.0		ElmPed
13 y	25	8.7	4.9 – 18.5		ElmPed
14 y	30	11.0	3.6 – 26		ElmPed
15 y	48	10.1	4.9 – 19.1		ElmPed
16 y	40	10.3	3.1 – 17.9		ElmPed
17 y	30	8.6	3.3 – 15.8		ElmPed
18 – 19 y	12	12.6	7.8 – 33		ElmPed
Tanner stage 1	28	7.0	3.3 – 17.0		ElmPed
Tanner stage 2–3	70	7.6	3.5 – 21		ElmPed
Tanner stage 4	30	7.6	3.1 – 14.8		ElmPed
Tanner stage 5	66	10.8	4.6 – 21		ElmPed
	n	Median ng/mL	Central 95% ng/mL		Ref
Girls					
Cord blood serum	28	380	200 – 675		ZB157
0.1 – 0.5 y	28	15	1 – 140		ZB157
0.6 – 9 y	55	11	2 – 43		ZB157

PSA

- Assay Formats: IMMULITE (LKPS); IMMULITE 2000 (L2KPS)
- FDA Approved: IMMULITE, IMMULITE 2000
- Calibration Range: 0.04 to 150 ng/mL
- Detection Limit: 0.03 ng/mL (IMMULITE); 0.04 ng/mL (IMMULITE 2000)

	n			99.4 %ile ng/mL	Ref
Males					
Healthy males	473			4.0	DPC P/I
	n	Median ng/mL	Central 90% ng/mL	97.5 %ile ng/mL	Ref
Combined: 20 – 70 y	1,486	0.75	0.20 – 2.9	3.7	ZB148
20 – 40 y	297	0.57	0.16 – 1.5	1.8	ZB148
40 – 50 y	471	0.70	0.16 – 1.7	2.2	ZB148
50 – 60 y	418	0.86	0.24 – 3.0	3.9	ZB148
60 – 70 y	300	1.2	0.27 – 4.8	6.9	ZB148

Third Generation PSA

- Assay Formats: IMMULITE (LKUP); IMMULITE 2000 (L2KUP)
- FDA Approved: IMMULITE, IMMULITE 2000
- Calibration Range: up to 20 ng/mL
- Detection Limit: 0.003 ng/mL

				95 %ile ng/mL	Ref
Males					
Healthy males, 20 – 85 y				2.8	DPC P/I
	n	Median ng/mL	Central 90% ng/mL	97.5 %ile ng/mL	Ref
Combined: 20 – 70 y	1,075	0.67	0.23 – 2.6	3.7	ZB148
20 – 40 y	253	0.52	0.19 – 1.3	1.5	ZB148
40 – 50 y	328	0.65	0.22 – 1.6	1.9	ZB148
50 – 60 y	306	0.80	0.25 – 2.6	3.6	ZB148
60 – 70 y	188	1.2	0.29 – 5.6	6.9	ZB148

Free PSA

- Assay Formats: IMMULITE (LKPF); IMMULITE 2000 (L2KPF)
- Calibration Range: up to 25 ng/mL
- Detection Limit: 0.02 ng/mL

	n	Median ng/mL		95 %ile ng/mL	Ref
Males					
Healthy males	425	0.14		0.42	DPC P/I
	n	Median ng/mL	Central 90% ng/mL	97.5 %ile ng/mL	Ref
Combined: 20 – 70 y	1,072	0.17	0.038 – 0.50	0.66	ZB148
20 – 40 y	252	0.13	ND – 0.33	0.37	ZB148
40 – 50 y	328	0.16	0.041 – 0.39	0.45	ZB148
50 – 60 y	305	0.19	0.058 – 0.49	0.58	ZB148
60 – 70 y	187	0.25	0.084 – 0.87	1.1	ZB148

Intact PTH

- Assay Format: IMMULITE (LKPH); IMMULITE *Turbo* (LSKPT); IMMULITE 2000 (L2KPH)
- FDA Cleared: IMMULITE, IMMULITE *Turbo*, IMMULITE 2000
- Calibration Range: up to 2,500 pg/mL
- Detection Limit: 1 pg/mL (IMMULITE); 4 pg/mL (IMMULITE *Turbo*); 0.7 pg/mL (IMMULITE 2000)
- Conversion: pg/mL \times 0.1053 \rightarrow pmol/L

	n	Median pg/mL	Central 95% pg/mL		Ref
Healthy adults	105	32	12 – 72		DPC P/I
Healthy adults 23 – 70 y	47		9.5 – 75		Mic97
Healthy adults 71 – 94 y	51		4.7 – 114		Mic97
IMMULITE Pediatric Reference Ranges					
Children 1 – 17 y	36		12 – 95		Mic97
<i>Pediatric Reference Ranges from the Literature</i>					
Cord blood serum	20		ND – 3.0		Sax97

Pyrilinks®-D

- Assay Formats: IMMULITE (LKPD)
- FDA Cleared: IMMULITE
- Calibration Range: 7 to 300 nmol/L
- Detection Limit: 4.4 nmol/L
- Conversion: nmol/L × 0.413 → µg/L (DPD)
- Conversion: mmol/L × 0.1131 → g/L (Creatinine)
- Conversion: nmol DPD/mmol Creatinine × 3.652 → µg DPD/g Creatinine

	n		Central 90% nmol DPD/mmol Cr		Ref
Males	121		2.3 – 5.4		DPC P/I
Females, premenopausal	312		3.0 – 7.4		DPC P/I
	n	Median nmol DPD/mmol Cr	Central 90% nmol DPD/mmol Cr		Ref
Males	31	5.8	1.8 – 11.9		Elm99a
Females, premenopausal	23	4.1	2.1 – 10.7		Elm99a
Females, postmenopausal	14	4.8	2.5 – 14.4		Elm99a
Females, osteoporosis	23	8.7	3.4 – 22.9		Elm99a

IMMULITE Pediatric Reference Ranges

	n	Median nmol DPD/mmol Cr	Central 95% nmol DPD/mmol Cr		Ref
Prepubertal	42	29.8	13.4 – 60.4		Elm99a
Pubertal	23	37.3	11.4 – 85.9		Elm99a
Postpubertal	27	10.5	3.9 – 24.6		Elm99a
	n	Median nmol DPD/mmol Cr	Central 94% nmol DPD/mmol Cr		Ref

Boys

9 y	18	12.9	1.5 – 23		Ham99
10 y	76	13.8	4.5 – 26		Ham99
11 y	110	16.4	5.9 – 31		Ham99
12 y	98	19.5	7.3 – 43		Ham99
13 y	67	19.5	7.4 – 36		Ham99
14 y	59	16.2	3.2 – 43		Ham99
15 y	73	11.7	2.8 – 28		Ham99
16 y	47	6.8	2.2 – 21		Ham99
17 y	32	6.6	1.1 – 26		Ham99
18 y	24	5.3	1.5 – 8.8		Ham99

Pyrilinks®-D (continued)

IMMULITE Pediatric Reference Ranges

	n	Median nmol DPD/mmol Cr	Central 95% nmol DPD/mmol Cr		Ref
Girls					
9 y	21	14.6	6.2 – 21.8		Ham99
10 y	118	18.3	3.8 – 34.4		Ham99
11 y	112	18.7	8.1 – 33.8		Ham99
12 y	113	19.2	6.8 – 40.0		Ham99
13 y	88	13.6	4.2 – 35.7		Ham99
14 y	80	10.6	3.5 – 23.6		Ham99
15 y	84	7.7	3.8 – 15.1		Ham99
16 y	65	6.5	1.7 – 13.7		Ham99
17 y	73	5.4	1.6 – 12.2		Ham99
18 y	28	4.6	1.9 – 7.8		Ham99
<i>Pediatric Reference Ranges from the Literature</i>					
	n	Median nmol DPD/mmol Cr	Abs Range nmol DPD/mmol Cr		Ref
Boys, 4.0 – 10.0 y	27	24	13.7 – 41		Rau96
Girls, 4.0 – 10.0 y	20	24	10.5 – 45		Rau96

SHBG

- Assay Formats: IMMULITE (LKSH); IMMULITE 2000 (L2KSH)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 180 nmol/L
- Detection Limit: 0.2 nmol/L (IMMULITE); 0.02 nmol/L (IMMULITE 2000)

	n	Median nmol/L	Central 95% nmol/L		Ref
Healthy males	122	32	13 – 71		DPC P/I
Healthy males	50	32.3	7.2 – 100		ZB157
Menstrual Cycle (26 subjects)					
Entire cycle	758	54	27 – 109		ZB157
Follicular phase	393	53	26 – 103		ZB157
Midcycle	26	52	11 – 97		ZB157
Luteal phase	339	56	28 – 112		ZB157

SHBG (continued)

	n	Median nmol/L	Central 95% nmol/L		Ref
Females					
Nonpregnant	111	51	18 – 114		DPC P/I
	n	Median nmol/L	Abs Range nmol/L		Ref
Oral contraceptives	18	119	56 – 159		ZB157
Postmenopausal, untreated	29	63	20 – 142		ZB157
Hirsute	24	41	19.9 – 85		ZB157
Pregnancy					
1st Trimester	39	138	26 – 241		ZB187
2nd, 3rd Trimesters	107	266	85 – 491		ZB187
	n		Central 95% nmol/L		Ref
<i>Pediatric Reference Ranges from the Literature</i>					
Hospitalized boys					
1 – 30 d	57		10.8 – 71		Sol97b
31 – 365 d	93		60 – 209		Sol97b
1 – 3 y	109		42 – 156		Sol97b
4 – 6 y	75		39 – 146		Sol97b
7 – 9 y	70		38 – 114		Sol97b
10 – 12 y	113		32 – 93		Sol97b
13 – 15 y	78		13 – 63		Sol97b
16 – 18 y	34		10.6 – 54		Sol97b
Hospitalized girls					
1 – 30 d	49		11.8 – 51		Sol97b
31 – 365 d	68		50 – 181		Sol97b
1 – 3 y	98		51 – 158		Sol97b
4 – 6 y	73		48 – 142		Sol97b
7 – 9 y	29		31 – 103		Sol97b
10 – 12 y	60		20 – 100		Sol97b
13 – 15 y	80		16.6 – 77		Sol97b
16 – 18 y	39		9.3 – 75		Sol97b

Total T3

- Assay Formats: IMMULITE (LKT3); IMMULITE 2000 (L2KT3)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 40 to 600 ng/dL
- Detection Limit: 35 ng/dL (IMMULITE); 19 ng/dL (IMMULITE 2000)
- Conversion: ng/dL \times 0.01536 \rightarrow nmol/L

	n	Median ng/dL	Central 95% ng/dL		Ref
Healthy adults			82 – 179		DPC P/I
Pregnancy					
1st trimester	39	177	121 – 308		ZB187
2nd, 3rd trimesters	104	232	152 – 362		ZB187
IMMULITE Pediatric Reference Ranges					
		Median ng/dL	Central 95% ng/dL		Ref
Children (118 Subjects)					
1.0 y		139	ND – 256		DPC P/I
2.0 y		141	36 – 254		DPC P/I
3.0 y		141	42 – 248		DPC P/I
4.0 y		137	44 – 236		DPC P/I
5.0 y		134	44 – 231		DPC P/I
6.0 y		131	44 – 225		DPC P/I
7.0 y		128	43 – 220		DPC P/I
8.0 y		126	42 – 216		DPC P/I
9.0 y		124	42 – 212		DPC P/I
10.0 y		122	42 – 209		DPC P/I
11.0 y		120	41 – 205		DPC P/I
12.0 y		118	41 – 202		DPC P/I

Total T3 (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/dL	Central 90% ng/dL	Ref
Boys				
1 – 7 d	26	444	210 – 578	ElmPed
8 – 15 d	20	170	98 – 377	ElmPed
1 – 3 y	12	182	126 – 253	ElmPed
4 – 6 y	27	193	112 – 236	ElmPed
7 – 8 y	26	200	125 – 260	ElmPed
9 – 10 y	31	164	114 – 213	ElmPed
11 y	22	179	141 – 220	ElmPed
12 y	17	195	139 – 235	ElmPed
13 y	21	164	134 – 262	ElmPed
14 y	31	169	128 – 220	ElmPed
15 y	40	176	112 – 224	ElmPed
16 y	31	161	115 – 219	ElmPed
17 y	22	126	76 – 164	ElmPed
18 – 19 y	8	122	79 – 152	ElmPed
Tanner stage 1	33	180	114 – 257	ElmPed
Tanner stage 2–3	74	164	124 – 229	ElmPed
Tanner stage 4	41	169	97 – 231	ElmPed
Tanner stage 5	37	147	94 – 212	ElmPed

Total T3 (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/dL	Central 90% ng/dL	Ref
Girls				
1 – 7 d	14	466	238 – 534	ElmPed
8 – 15 d	17	231	83 – 372	ElmPed
1 – 3 y	14	175	138 – 217	ElmPed
4 – 6 y	23	182	148 – 261	ElmPed
7 – 8 y	24	204	143 – 270	ElmPed
9 – 10 y	40	163	109 – 202	ElmPed
11 y	22	184	132 – 255	ElmPed
12 y	18	192	146 – 219	ElmPed
13 y	25	172	132 – 239	ElmPed
14 y	30	148	117 – 213	ElmPed
15 y	48	149	105 – 198	ElmPed
16 y	40	158	107 – 199	ElmPed
17 y	30	126	78 – 188	ElmPed
18 – 19 y	12	100	52 – 139	ElmPed
Tanner stage 1	28	181	122 – 267	ElmPed
Tanner stage 2–3	70	170	113 – 246	ElmPed
Tanner stage 4	31	154	118 – 212	ElmPed
Tanner stage 5	66	144	82 – 202	ElmPed

Free T3

- Assay Formats: IMMULITE (LKF3); IMMULITE 2000 (L2KF3)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 1 to 40 pg/mL
- Detection Limit: 1.0 pg/mL
- Conversion: pg/mL \times 1.536 \rightarrow pmol/L

	n		Central 95% pg/mL		Ref
Euthyroid					
IMMULITE	212		1.5 – 4.1		DPC P/I
IMMULITE 2000	212		1.8 – 4.2		DPC P/I

IMMULITE Pediatric Reference Ranges

	n	Median pg/mL	Central 90% pg/mL		Ref
Boys					
1 – 7 d	27	3.0	1.68 – 9.2		ElmPed
8 – 15 d	17	3.6	2.0 – 9.8		ElmPed
1 – 3 y	13	2.8	1.90 – 4.9		ElmPed
4 – 6 y	27	4.0	1.60 – 6.0		ElmPed
7 – 8 y	26	3.8	2.60 – 6.8		ElmPed
9 – 10 y	31	5.1	2.1 – 14.9		ElmPed
11 y	22	3.8	2.3 – 5.2		ElmPed
12 y	17	3.5	2.5 – 4.6		ElmPed
13 y	21	3.6	2.6 – 4.7		ElmPed
14 y	31	3.9	2.8 – 5.0		ElmPed
15 y	40	3.5	2.3 – 4.6		ElmPed
16 y	31	3.6	2.4 – 5.0		ElmPed
17 y	22	3.4	2.1 – 4.2		ElmPed
18 – 19 y	8	3.0	2.0 – 4.1		ElmPed
Tanner stage 1	33	4.0	2.5 – 11.8		ElmPed
Tanner stage 2–3	74	3.8	2.2 – 5.6		ElmPed
Tanner stage 4	40	3.5	2.3 – 4.9		ElmPed
Tanner stage 5	37	3.3	2.0 – 4.4		ElmPed

Free T3 (continued)

IMMULITE Pediatric Reference Ranges

	n	Median pg/mL	Central 90% pg/mL	Ref
Girls				
1 – 7 d	17	4.4	1.87 – 14.8	ElmPed
8 – 15 d	20	3.4	1.99 – 5.6	ElmPed
1 – 3 y	14	3.8	2.3 – 5.4	ElmPed
4 – 6 y	23	4.3	3.0 – 6.4	ElmPed
7 – 8 y	24	4.6	2.6 – 7.5	ElmPed
9 – 10 y	40	5.5	1.30 – 11.2	ElmPed
11 y	22	3.8	2.2 – 4.7	ElmPed
12 y	18	3.4	2.6 – 4.1	ElmPed
13 y	25	3.5	2.5 – 5.2	ElmPed
14 y	30	3.6	2.8 – 5.2	ElmPed
15 y	47	3.2	2.4 – 4.2	ElmPed
16 y	40	3.2	2.5 – 3.9	ElmPed
17 y	30	3.0	2.0 – 4.4	ElmPed
18 – 19 y	12	3.2	2.5 – 6.2	ElmPed
Tanner stage 1	28	4.6	2.4 – 8.6	ElmPed
Tanner stage 2–3	70	3.6	2.3 – 8.3	ElmPed
Tanner stage 4	30	3.4	2.7 – 4.4	ElmPed
Tanner stage 5	66	3.2	2.2 – 5.0	ElmPed

Total T4

- Assay Formats: IMMULITE (LKT4); IMMULITE 2000 (L2KT4)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 1.0 to 24 µg/dL
- Detection Limit: 0.4 µg/dL (IMMULITE); 0.3 µg/dL (IMMULITE 2000)
- Conversion: µg/dL × 12.87 → nmol/L

	n	Median µg/dL	Central 95% µg/dL		Ref
Healthy adults	314	7.7	5.2 – 12.5		DPC P/I
Pregnancy					
1st Trimester	39	11.5	7.8 – 16.2		ZB187
2nd, 3rd Trimesters	107	12.5	9.1 – 18.3		ZB187
IMMULITE Pediatric Reference Ranges					
	n	Median µg/dL	Central 95% µg/dL		Ref
Children (118 Subjects)					
1.0 y		9.2	3.52 – 17.4		DPC P/I
2.0 y		8.9	3.53 – 16.8		DPC P/I
3.0 y		8.6	3.70 – 15.7		DPC P/I
4.0 y		8.3	3.91 – 14.4		DPC P/I
5.0 y		8.2	3.97 – 13.8		DPC P/I
6.0 y		8.0	4.02 – 13.3		DPC P/I
7.0 y		7.8	4.06 – 12.9		DPC P/I
8.0 y		7.7	4.09 – 12.5		DPC P/I
9.0 y		7.6	4.12 – 12.1		DPC P/I
10.0 y		7.5	4.15 – 11.8		DPC P/I
11.0 y		7.4	4.17 – 11.5		DPC P/I
12.0 y		7.3	4.19 – 11.2		DPC P/I

Total T4 (continued)

IMMULITE Pediatric Reference Ranges

	n	Median µg/dL	Central 90% µg/dL		Ref
Boys					
1 – 7 d	28	15.8	7.7 – 61		ElmPed
8 – 15 d	19	41	21 – 66		ElmPed
1 – 3 y	13	7.5	4.8 – 10.6		ElmPed
4 – 6 y	27	9.2	6.2 – 11.7		ElmPed
7 – 8 y	26	10.0	6.3 – 14.0		ElmPed
9 – 10 y	31	9.7	4.7 – 15.6		ElmPed
11 y	22	9.2	6.3 – 11.1		ElmPed
12 y	17	8.8	7.2 – 10.9		ElmPed
13 y	21	8.0	5.1 – 10.2		ElmPed
14 y	31	7.9	6.2 – 9.6		ElmPed
15 y	39	7.5	5.1 – 9.9		ElmPed
16 y	31	7.4	5.5 – 9.6		ElmPed
17 y	22	6.5	4.6 – 9.8		ElmPed
18 – 19 y	8	7.0	4.7 – 9.2		ElmPed
Tanner stage 1	33	10.5	5.6 – 15.2		ElmPed
Tanner stage 2–3	74	8.5	5.6 – 11.2		ElmPed
Tanner stage 4	39	7.6	5.5 – 9.7		ElmPed
Tanner stage 5	37	7.1	4.6 – 10.0		ElmPed

Total T4 (continued)

IMMULITE Pediatric Reference Ranges

	n	Median µg/dL	Central 90% µg/dL		Ref
Girls					
1 – 7 d	17	18.9	4.8 – 67		ElmPed
8 – 15 d	18	38	13.6 – 83		ElmPed
1 – 3 y	14	9.6	6.5 – 13.3		ElmPed
4 – 6 y	23	9.6	7.8 – 12.6		ElmPed
7 – 8 y	24	10.2	7.6 – 12.4		ElmPed
9 – 10 y	39	8.9	5.8 – 14.3		ElmPed
11 y	23	8.6	6.2 – 12.5		ElmPed
12 y	18	7.6	6.5 – 9.0		ElmPed
13 y	25	7.8	5.2 – 9.5		ElmPed
14 y	30	8.6	6.8 – 11.1		ElmPed
15 y	48	7.3	5.7 – 9.5		ElmPed
16 y	40	7.4	5.9 – 9.0		ElmPed
17 y	30	7.3	6.2 – 8.7		ElmPed
18 – 19 y	12	7.2	4.8 – 9.0		ElmPed
Tanner stage 1	28	10.3	7.4 – 13.5		ElmPed
Tanner stage 2–3	70	8.3	6.1 – 12.5		ElmPed
Tanner stage 4	31	7.8	6.4 – 9.4		ElmPed
Tanner stage 5	66	7.5	5.8 – 9.4		ElmPed

Free T4

- Assay Formats: IMMULITE (LKF4); IMMULITE 2000 (L2KF4)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 0.2 to 6 ng/dL
- Detection Limit: 0.15 ng/dL (IMMULITE); 0.18 ng/dL (IMMULITE 2000)
- Conversion: ng/dL \times 12.87 \rightarrow pmol/L

	n	Median ng/dL	Central 95% ng/dL		Ref
Euthyroid		1.3	0.8 – 1.9		DPC P/I
Hypothyroid		0.3	ND – 1.0		DPC P/I
Hyperthyroid		3.4	1.2 – > 6		DPC P/I
Pregnancy					
1st Trimester	4	1.04			DPC P/I
2nd Trimester	14	1.00			DPC P/I
3rd Trimester	12	0.88			DPC P/I
Pregnancy					
1st Trimester	38	1.25	0.86 – 1.87		ZB187
2nd, 3rd Trimesters	105	1.08	0.64 – 1.92		ZB187
IMMULITE Pediatric Reference Ranges					
	n	Median ng/dL	Central 95% ng/dL		Ref
Children 1.0 – 12 y	118	1.35	0.65 – 2.3		DPC P/I

Free T4 (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/dL	Central 90% ng/dL	Ref
Boys				
1 – 7 d	28	4.9	1.71 – 6.6	ElmPed
8 – 15 d	18	2.2	1.33 – 3.6	ElmPed
1 – 3 y	13	1.50	0.98 – 2.0	ElmPed
4 – 6 y	27	1.50	0.93 – 1.77	ElmPed
7 – 8 y	26	1.30	1.00 – 1.87	ElmPed
9 – 10 y	31	1.90	0.80 – 6.2	ElmPed
11 y	22	1.25	0.97 – 7.1	ElmPed
12 y	17	1.20	0.94 – 1.74	ElmPed
13 y	21	1.10	0.65 – 1.50	ElmPed
14 y	31	1.20	0.95 – 1.55	ElmPed
15 y	39	1.20	0.69 – 1.80	ElmPed
16 y	30	1.33	0.96 – 2.1	ElmPed
17 y	22	1.35	0.92 – 1.80	ElmPed
18 – 19 y	8	1.20	0.77 – 1.59	ElmPed
Tanner stage 1	33	1.50	0.90 – 5.6	ElmPed
Tanner stage 2–3	74	1.20	0.92 – 3.7	ElmPed
Tanner stage 4	39	1.35	0.86 – 1.71	ElmPed
Tanner stage 5	36	1.30	0.80 – 1.72	ElmPed

Free T4 (continued)

IMMULITE Pediatric Reference Ranges

	n	Median ng/dL	Central 90% ng/dL		Ref
Girls					
1 – 7 d	17	5.0	2.30 – 6.9		ElmPed
8 – 15 d	19	3.3	1.69 – 5.2		ElmPed
1 – 3 y	14	1.35	0.86 – 1.90		ElmPed
4 – 6 y	23	1.50	1.11 – 2.1		ElmPed
7 – 8 y	24	1.50	1.10 – 1.98		ElmPed
9 – 10 y	40	1.75	0.90 – 3.6		ElmPed
11 y	22	1.20	0.92 – 6.8		ElmPed
12 y	18	1.00	0.72 – 1.88		ElmPed
13 y	24	1.10	0.71 – 1.38		ElmPed
14 y	30	1.30	1.04 – 2.1		ElmPed
15 y	48	1.25	0.88 – 1.60		ElmPed
16 y	40	1.30	1.10 – 1.70		ElmPed
17 y	30	1.35	0.93 – 1.60		ElmPed
18 – 19 y	12	1.45	0.72 – 1.74		ElmPed
Tanner stage 1	28	1.55	0.80 – 2.3		ElmPed
Tanner stage 2–3	69	1.20	0.90 – 3.6		ElmPed
Tanner stage 4	31	1.20	0.90 – 1.45		ElmPed
Tanner stage 5	66	1.40	1.00 – 1.70		ElmPed

TBG

- Assay Formats: IMMULITE (LKTb); IMMULITE 2000 (L2KTB)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 3.5 to 80 µg/mL (WHO 1st IS 88/638)
- Detection Limit: 1.1 µg/mL (IMMULITE); 1.0 µg/mL (IMMULITE 2000)
- Conversion: µg/mL × 18.5 → nmol/L

	N	Median µg/mL	Abs Range µg/mL	97.5 %ile µg/mL	Ref
Healthy adults	75	19	13 – 39	31	DPC P/I
	N	Median µg/mL	Central 95% µg/mL		Ref
Pregnancy					
1st Trimester	39	31	19 – 49		ZB187
2nd, 3rd Trimesters	105	46	30 – 68		ZB187
<i>Pediatric Reference Ranges from the Literature</i>					
	N		Central 95% µg/mL		Ref
Hospitalized boys					
10 – 12 m	189		16.2 – 32.9		Hic93b
1 – 3 y	167		16.4 – 32.0		Hic93b
4 – 6 y	100		16.6 – 29.8		Hic93b
7 – 12 y	184		16.5 – 28.8		Hic93b
13 – 18 y	158		13.4 – 25.6		Hic93b
Hospitalized girls					
10 – 12 m	138		17.7 – 32.0		Hic93b
1 – 3 y	112		19.3 – 33.8		Hic93b
4 – 6 y	91		18.3 – 30.8		Hic93b
7 – 12 y	133		15.0 – 29.2		Hic93b
13 – 18 y	130		13.7 – 28.7		Hic93b

Total Testosterone

- Assay Formats: IMMULITE (LKTT); IMMULITE 2000 (L2KTT)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 20 to 1,600 ng/dL
- Detection Limit: 10 ng/dL
- Conversion: ng/dL \times 0.03467 \rightarrow nmol/L

	n	Median ng/dL	Central 95% ng/dL		Ref
Males					
Males 20 – 49 y	68	625	286 – 1,511		DPC P/I
Males > 50 y	19	438	212 – 742		DPC P/I
Healthy males	99	410	200 – 810		ZB157
Menstrual Cycle (26 subjects)					
Entire cycle	758	47	ND – 118		ZB157
Follicular phase	393	48	ND – 118		ZB157
Midcycle	26	58	21 – 104		ZB157
Luteal phase	339	44	ND – 119		ZB157
Females					
Ovulating	41	67	65 – 119		DPC P/I
	n	Median ng/dL	Abs Range ng/dL		Ref
Oral contraceptives	13	59	54 – 71		DPC P/I
Oral contraceptives	39	40	ND – 110		ZB157
Postmenopausal	27	63	49 – 113		DPC P/I
	n	Median ng/dL		95 %ile ng/dL	Ref
Postmenopausal	103	30		80	ZB157
	n	Median ng/dL	Abs Range ng/dL		Ref
Postmenopausal, untreated	29	20	ND – 100		ZB157
Postmenopausal, treated	29	30	ND – 100		ZB157
Surgical	30	30	ND – 60		ZB157
Pregnancy					
1st Trimester	20	70	30 – 230		ZB157
2nd Trimester	20	90	30 – 200		ZB157
3rd Trimester	19	110	30 – 190		ZB157

Total Testosterone (continued)

			Range ng/dL		Ref
<i>Pediatric Reference Ranges from the Literature</i>					
Boys					
Cord blood serum			13 – 55		Tie99
Premature			37 – 198		Tie99
Newborns			75 – 400		Tie99
Prepubertal, 1 – 10 y			2 – 30		Tie99
Tanner stage 1			2 – 23		Tie99
Tanner stage 2			5 – 70		Tie99
Tanner stage 3			15 – 280		Tie99
Tanner stage 4			105 – 545		Tie99
Tanner stage 5			265 – 800		Tie99
Girls					
Cord blood serum			5 – 45		Tie99
Premature			5 – 22		Tie99
Newborns			20 – 64		Tie99
Prepubertal, 1 – 10 y			1 – 20		Tie99
Tanner stage 1			2 – 10		Tie99
Tanner stage 2			5 – 30		Tie99
Tanner stage 3			10 – 30		Tie99
Tanner stage 4			15 – 40		Tie99
Tanner stage 5			10 – 40		Tie99

Free Androgen Index (FAI)

$$\text{FAI} = \text{Total Testosterone (nmol/L)} \times 100 / \text{SHBG (nmol/L)}$$

	n	Median	Central 95%		Ref
Healthy males	50	35.0	14.8 – 95		ZB157
Menstrual Cycle (26 subjects)					
Entire cycle	758	2.9	0.8 – 10		ZB157
Follicular phase	393	3.1	0.8 – 9.3		ZB157
Midcycle	26	3.6	1.3 – 17		ZB157
Luteal phase	339	2.8	0.8 – 11		ZB157
	n	Median	Abs Range		Ref
Females					
Oral contraceptives	18	1.2	ND – 3.4		ZB157
Postmenopausal, untreated	29	1.5	ND – 6.6		ZB157
Hirsute	24	5.6	1.7 – 20.6		ZB157

Theophylline

- Assay Formats: IMMULITE (LKTN)
- FDA Cleared: IMMULITE
- Calibration Range: 1 to 60 µg/mL
- Detection Limit: 0.3 µg/mL

			Range µg/mL		Ref
Therapeutic range			10 – 20		Web77
Toxic levels			> 20		Web77

Thyroglobulin

- Assay Formats: IMMULITE (LKTY); IMMULITE 2000 (L2KTY)
- FDA Approved: IMMULITE, IMMULITE 2000
- Calibration Range: up to 300 ng/mL (CRM 457)
- Detection Limit: 0.2 ng/mL

	n	Median ng/mL	Central 95% ng/mL		Ref
Healthy Adults					
IMMULITE	110	10.2	1.7 – 56		DPC P/I
IMMULITE 2000	110	11.0	1.6 – 60		DPC P/I

Anti-TG Ab

- Assay Formats: IMMULITE (LKTG); IMMULITE 2000 (L2KTG)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 3,000 IU/mL (WHO 1st IRP 65/93)
- Detection Limit: 3 IU/mL (IMMULITE); 2.2 IU/mL (IMMULITE 2000)

	n		95 %ile IU/mL		Ref
Healthy Adults	117		40		DPC P/I
	n		97 %ile IU/mL		Ref
Healthy Adults					
1 – 50 y	139		40		Boh00, Boh98
> 50 y	145		80		Boh00, Boh98

Anti-TPO Ab

- Assay Formats: IMMULITE (LKTO); IMMULITE 2000 (L2KTO)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 1000 IU/mL (WHO 1st IRP 66/387)
- Detection Limit: 7 IU/mL (IMMULITE); 5.0 IU/mL (IMMULITE 2000)

	n		79 %ile IU/mL		Ref
Healthy adults	75		35		DPC P/I
	n		92 %ile IU/mL		Ref
Healthy adults	130		35		DPC P/I
Healthy Adults	n		93 %ile IU/mL		Ref
1 – 50 y	139		35		Boh00, Boh98
> 50 y	145		100		Boh00, Boh98

Thyroid Uptake

- Assay Formats: IMMULITE (LKTU); IMMULITE 2000 (L2KTU)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 10 to 70 % TU

	n	Median % TU	Central 95% % TU		Ref
Healthy adults	58		24 – 35		DPC P/I
Pregnancy					
1st Trimester	39	26	18 – 34		ZB187
2nd, 3rd Trimesters	101	19	16 – 25		ZB187

TNF α

- Assay Formats: IMMULITE (LKNF)
- Calibration Range: up to 1,000 pg/mL (NIBSC 87/650)
- Detection Limit: 1.7 pg/mL

	n		Abs Range pg/mL		Ref
Healthy adults	58		ND – 8.1		DPC P/I

IMMULITE Pediatric Reference Ranges

	n	Median pg/mL	Central 95% pg/mL		Ref
Healthy Children					
3 – 3.5 y	11	14	ND – 120		Sac99
3.5 – 4.5 y	29	56	ND – 204		Sac99
4.5 – 5.5 y	15	105	ND – 250		Sac99
5.5 – 6.5 y	26	68	ND – 146		Sac99
6.5 – 7.5 y	16	62	28 – 132		Sac99
7.5 – 8.5 y	22	67	ND – 138		Sac99
8.5 – 9.5 y	17	64	8 – 108		Sac99
9.5 – 10.5 y	27	53	ND – 179		Sac99
10.5 – 11.5 y	19	75	ND – 262		Sac99
11.5 – 12.5 y	21	75	ND – 251		Sac99
12.5 – 13.5 y	18	70	ND – 250		Sac99
13.5 – 14.5 y	24	46	ND – 209		Sac99
14.5 – 15.5 y	20	64	ND – 154		Sac99
15.5 – 16.5 y	28	64	ND – 210		Sac99
16.5 – 17.0 y	15	36	3.5 – 152		Sac99

TPS™

- Assay Formats: IMMULITE (LKTP)
- Calibration Range: up to 2,400 U/L
- Detection Limit: 6 U/L

	n		Cutoff U/L		Ref
Healthy adults	93		83		DPC P/I

Troponin I

- Assay Formats: IMMULITE (LKTI); IMMULITE *Turbo* (LSKTI)
- FDA Cleared: IMMULITE, IMMULITE *Turbo*
- Calibration Range: up to 180 ng/mL
- Detection Limit: 0.1 ng/mL (IMMULITE); 0.15 ng/mL (IMMULITE *Turbo*)

	n	Median ng/mL		97.5 %ile ng/mL	Ref
Healthy adults	255	ND		1.0	DPC P/I

TSH

- Assay Formats: IMMULITE Third Generation TSH (LKTS); IMMULITE 2000 Third Generation TSH (L2KTS); IMMULITE Rapid TSH (LKRT); IMMULITE 2000 Rapid TSH (L2KRT)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: up to 75 μ IU/mL (WHO 2nd IRP 80/558)
- Detection Limit: 0.01 μ IU/mL (Rapid); 0.002 μ IU/mL (Third Generation)

	n	Median μ IU/mL	Central 95% μ IU/mL		Ref
Euthyroid	152	1.3	0.4 – 4		DPC P/I
	n	Median μ IU/mL	Abs Range μ IU/mL		Ref
Hypothyroid	17	69	7.1 – >75		DPC P/I
Pregnancy					
1st, 2nd, and 3rd Trimesters	144	1.1	0.2 – 3.5		ZB187

IMMULITE Pediatric Reference Ranges

		Median μ IU/mL	Central 95% μ IU/mL		Ref
Children (118 Subjects)					
1.0 y		2.09	0.40 – 8.6		DPC P/I
2.0 y		1.85	0.36 – 7.6		DPC P/I
3.0 y		1.65	0.33 – 6.7		DPC P/I
4.0 y		1.62	0.33 – 6.3		DPC P/I
5.0 y		1.59	0.34 – 6.1		DPC P/I
6.0 y		1.58	0.34 – 6.0		DPC P/I
7.0 y		1.57	0.35 – 5.8		DPC P/I
8.0 y		1.56	0.35 – 5.7		DPC P/I
9.0 y		1.55	0.35 – 5.6		DPC P/I
10.0 y		1.54	0.36 – 5.5		DPC P/I
11.0 y		1.53	0.36 – 5.5		DPC P/I
12.0 y		1.53	0.36 – 5.4		DPC P/I

TSH (continued)

IMMULITE Pediatric Reference Ranges

	n	Median μIU/mL	Central 90% μIU/mL		Ref
Boys					
1 – 7 d	28	5.5	1.99 – 28		ElmPed
8 – 15 d	19	3.6	2.3 – 12.2		ElmPed
1 – 3 y	13	1.35	0.47 – 2.1		ElmPed
4 – 6 y	27	1.91	0.84 – 4.2		ElmPed
7 – 8 y	26	2.1	0.89 – 3.5		ElmPed
9 – 10 y	30	2.6	0.88 – 6.2		ElmPed
11 y	22	2.1	0.58 – 3.7		ElmPed
12 y	17	2.3	1.00 – 4.6		ElmPed
13 y	21	1.74	0.97 – 3.7		ElmPed
14 y	32	1.91	1.15 – 3.8		ElmPed
15 y	40	1.55	0.67 – 2.6		ElmPed
16 y	31	1.58	0.81 – 3.4		ElmPed
17 y	22	1.59	0.95 – 3.0		ElmPed
18 – 19 y	8	1.72	0.92 – 3.1		ElmPed
Tanner stage 1	33	2.4	1.13 – 6.2		ElmPed
Tanner stage 2–3	73	1.76	0.66 – 3.7		ElmPed
Tanner stage 4	41	1.85	0.69 – 3.6		ElmPed
Tanner stage 5	37	1.64	0.92 – 2.7		ElmPed

TSH (continued)

IMMULITE Pediatric Reference Ranges

	n	Median μIU/mL	Central 90% μIU/mL	Ref
Girls				
1 – 7 d	17	5.2	1.81 – 12.0	ElmPed
8 – 15 d	20	3.3	1.78 – 12.6	ElmPed
1 – 3 y	14	1.19	0.61 – 2.2	ElmPed
4 – 6 y	23	1.48	0.72 – 3.0	ElmPed
7 – 8 y	23	1.94	0.54 – 6.0	ElmPed
9 – 10 y	40	2.5	1.24 – 5.6	ElmPed
11 y	22	1.71	0.39 – 2.9	ElmPed
12 y	18	1.90	1.06 – 4.2	ElmPed
13 y	25	2.6	1.01 – 4.8	ElmPed
14 y	29	1.97	0.77 – 4.3	ElmPed
15 y	48	1.08	0.52 – 2.9	ElmPed
16 y	40	1.55	0.46 – 3.7	ElmPed
17 y	30	1.48	0.55 – 3.6	ElmPed
18 – 19 y	12	1.66	0.95 – 4.6	ElmPed
Tanner stage 1	27	2.5	1.12 – 6.0	ElmPed
Tanner stage 2–3	70	1.96	0.77 – 5.0	ElmPed
Tanner stage 4	31	1.69	0.66 – 3.5	ElmPed
Tanner stage 5	66	1.54	0.55 – 4.3	ElmPed

Valproic Acid

- Assay Formats: IMMULITE (LKVA)
- Calibration Range: 10 to 200 µg/mL
- Detection Limit: 1.25 µg/mL
- Conversion: µg/mL × 6.93 → µmol/L

			Range µg/mL		Ref
Therapeutic range			50 – 100		Tie99
Toxic levels			> 100		Tie99

Vitamin B12

- Assay Formats: IMMULITE (LKVB); IMMULITE 2000 (L2KVB)
- FDA Cleared: IMMULITE, IMMULITE 2000
- Calibration Range: 100 to 1,200 pg/mL
- Detection Limit: 50 pg/mL
- Conversion: pg/mL × 0.7378 → pmol/L

	n		Central 95% pg/mL		Ref
Healthy adults	245		160 – 800		DPC P/I

Pediatric Reference Ranges from the Literature

Hospitalized boys

0 – 1 y	127		293 – 1,210		Hic93a
2 – 3 y	142		264 – 1,220		Hic93a
4 – 6 y	156		245 – 1,080		Hic93a
7 – 9 y	103		271 – 1,170		Hic93a
10 – 12 y	105		183 – 1,090		Hic93a
13 – 18 y	159		214 – 865		Hic93a

Hospitalized girls

0 – 1 y	94		228 – 1,510		Hic93a
2 – 3 y	133		416 – 1,210		Hic93a
4 – 6 y	111		313 – 1,410		Hic93a
7 – 9 y	103		247 – 1,170		Hic93a
10 – 12 y	94		197 – 1,020		Hic93a
13 – 18 y	159		182 – 820		Hic93a

Appendix: Data Presentation

Reference value distributions are fundamentally characterized in terms of percentiles.[IFC87] A reference range study is typically summarized via percentiles (*reference limits*) encompassing — by convention — the estimated central 95% of the underlying distribution or (if clinically more appropriate) the lower 95%; narrower intervals (such as the central 90%), or the lowest and highest values observed, are sometimes quoted for studies of limited size. Additional percentiles, like the median, help to characterize the distribution more fully.

Distributions of reference values are rarely summarized parametrically, though parametric methods are often used to estimate percentiles. (Thus, for a Gaussian distribution, the central 95% interval can be estimated as the mean \pm 1.96 standard deviations; but it would be unusual, and not particularly helpful, to supply just the parameters — mean and standard deviation — in a summary.) Accordingly, in this document, we have opted to present reference range data as uniformly as possible in terms of percentiles and interpercentile intervals.

Percentile (%ile) Concentration level dividing a distribution in such way that a specific percentage of the values is less than or equal to that concentration level. (The shorter term *centile* is a synonym.)

	Percent of the values below	Percent of the values above
2.5 %ile	2.5	97.5
5 %ile	5	95
50 %ile (median)	50	50
95 %ile	95	5
97.5 %ile	97.5	2.5

Median The 50th percentile (50 %ile). For a symmetric distribution, this can be estimated by the mean. The term *median* is used here, as in most DPC package inserts and technical reports, as a synonym for *50th percentile* and carries no implication as to the method used for estimating this value.

Central 95% Range Concentration interval bounded by the estimated 2.5th and 97.5th percentiles: 2.5% of the values are cut off from each end of the distribution. For a Gaussian distribution, the central 95% interval can be estimated as the mean \pm 2 standard deviations: more precisely as the mean \pm 1.96 standard deviations. (Specifying the reference interval for an assay in terms of the central 95% is a common, but arbitrary, convention which is not always appropriate.[IFC87])

Central 90% Range Concentration interval bounded by the estimated 5th and 95th percentiles: 5% of the values are cut off from each end of the distribution.

Lower 95% Range Concentration interval bounded from above by the estimated 95th percentile: 5% of the values are cut off from the top end of the distribution. (Asymmetric reference intervals may be appropriate when only one end of the reference interval is of clinical interest.)

Absolute Range Concentration interval bounded by the lowest and highest values observed for subjects in the reference sample group.

Cutoff A clinical decision limit dividing (for example) healthy from sick, therapeutic from toxic, etc.

ND *Not detectable*: a concentration level lower than the assay's stated detection limit. (A nondetectable value in this sense does *not* correspond to a concentration level of zero.)

Detection Limit An assay's detection limit, or *analytical sensitivity*, is the lowest concentration which can be distinguished from zero with a 95% probability. (This is typically estimated as the concentration two standard deviations from the response at zero dose.)

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Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597
Tel: 800.372.1782
Tel: 310.645.8200
Fax: 310.645.9999
E-mail: info@dpconline.com
Web site: www.dpcweb.com