



TBG variation. A decrease in total thyroxine values is found with protein-wasting diseases, certain liver diseases and administration of testosterone, diphenylhydantoin or salicylates. A table of interfering drugs and conditions, which affect total thyroxine values, has been compiled by the Journal of the American Association of Clinical Chemists.

**"NOT INTENDED FOR NEWBORN SCREENING"**

**13.0 EXPECTED RANGES OF VALUES**

A study of euthyroid adult population was undertaken to determine expected values. The mean (R) values, standard deviations (σ) and expected ranges (±2σ) are presented in Table 1 for FT4 and Table 2 for FT3. A nonparametric method (95% Percentile Estimate) was used for TSH in Table 3.

**TABLE 1 - Expected Values – (FT4) (in ng/dl)**

	Adult	Pregnancy
Mean (X)	1.40	1.50
Std. Dev (σ)	0.3	0.37
Expected Ranges (±2σ)	0.8-2.0	0.76-2.24

**TABLE 2 - Expected Values – (FT3) (in pg/ml)**

	Adult	Pregnancy
Mean (X)	2.80	3.0
Std. Dev (σ)	0.375	0.6
Expected Ranges (±2σ)	1.4-4.2	1.8-4.2

**TABLE 3 - Expected Values – (TSH) (in μIU/ml)**

Low Normal Range	0.39
High Normal Range	6.16
70% Confidence Intervals for 2.5 Percentile	
Low Range	0.28-0.53
High Range	5.60-6.82

It is important to keep in mind that establishment of a range of values which can be expected to be found by a given method for a population of "normal"-persons is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons each laboratory should depend upon the range of expected values established by the Manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located.

**14.0 PERFORMANCE CHARACTERISTICS**

**14.1 Precision**

The within and between assay precision of the Free Thyroid Panel were determined by analyses on three different levels of pool control sera. The number, mean values, standard deviation and coefficient of variation for each of these control sera are presented in Table 4 and Table 5 (FT4), Table 6 and Table 7 (FT3) and Table 8 and Table 9 (TSH).

**TABLE 4**

Within Assay Precision – FT4 Values in ng/dl				
Sample	N	X	σ	C.V.
Low	24	0.925	0.057	6.2%
Normal	24	2.00	0.059	2.9%
High	24	2.93	0.071	2.4%

**TABLE 5**

Between Assay Precision				
Sample	N	X	σ	C.V.
Low	10	0.97	0.13	13.4%
Normal	10	2.06	0.09	4.4%
High	10	2.90	0.14	4.5%

\*As measured in ten experiments in duplicate over ten days.

**TABLE 6**

Within Assay Precision – FT3 Values in pg/ml				
Sample	N	X	σ	C.V.
Low	24	2.090	0.152	7.2%
Normal	24	5.308	0.222	4.2%
High	24	9.536	0.473	5.0%

**TABLE 7**

Between Assay Precision				
Sample	N	X	σ	C.V.
Low	10	1.89	0.19	10.0%
Normal	10	5.4	0.50	9.3%
High	10	9.3	0.37	4.0%

\*As measured in ten experiments in duplicate over ten days.

**TABLE 8**

Within Assay Precision – TSH values in μIU/ml				
Sample	N	X	σ	C.V.
Pool 1	24	0.463	0.028	5.95%
Pool 2	24	5.536	0.121	2.19%
Pool 3	24	33.109	2.061	6.23%

**TABLE 9**

Between Assay Precision				
Sample	N	X	σ	C.V.
Pool 1	24	0.445	0.042	9.4%
Pool 2	24	5.811	0.141	2.43%
Pool 3	24	35.19	3.11	4.99%

\*As measured in ten experiments in duplicate over seven days.

**14.2 Sensitivity**

The FT4 procedure has a sensitivity of 0.04 ng/dl. The sensitivity was ascertained by determining the variability of the 0 ng/dl serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose.

The FT3 procedure has a sensitivity of 0.04 pg/ml. The sensitivity was ascertained by determining the variability of the 0 pg/ml serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose.

The TSH sensitivity (detection limit) was ascertained by determining the variability of the 0 μIU/ml serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose: For 1 hr incubation = 0.065 μIU/ml

**14.3 Accuracy**

The Free Thyroid Panel AccuBind® ELISA Test System was compared with reference immunometric methods. The least square regression equation and the correlation coefficient were computed for the ELISAs in comparison with the reference methods. The data obtained are displayed in Table 10-12.

**TABLE 10 (FT4)**

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
Monobind	1.38	y=0.073+0.964(x)	0.920
Reference	1.40		
Range of Values:		0.15-9.5	N=65

**TABLE 11 (FT3)**

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
Monobind	3.11	y=-0.11+0.97(x)	0.985
Reference	3.20		
Range of Values:		0.80-12.5	N=65

**TABLE 12 (TSH)**

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
Monobind	4.54	y=0.47+0.968(x)	0.995
Reference	4.21		
Range of Values:		0.01-61	N=65

Only slight amounts of bias between this method and the reference method are indicated by the closeness of the mean values. The least square regression equation and correlation coefficient indicates excellent method agreement.

**14.4 Specificity**

The cross-reactivity of the antibodies used to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between dose of interfering substance to dose of thyroid hormone needed to displace the same amount of tracer.

**TABLE 13 - FT4**

Substance	Cross Reactivity	Concentration
l-Thyroxine	1.0000	-
d-Thyroxine	0.9800	10 μg/dl
d-Triiodothyronine	0.0150	100 μg/dl
l-Triiodothyronine	0.0300	100 μg/dl
Iodothyrosine	0.0001	100 μg/ml
Diiodothyrosine	0.0001	100 μg/ml
Diiodothyronine	0.0001	100 μg/ml

**TABLE 14 - FT3**

Substance	Cross Reactivity	Concentration
l-Triiodothyronine	1.0000	-
l-Thyroxine	< 0.0002	10 μg/ml
Iodothyrosine	< 0.0001	10 μg/ml
Diiodothyrosine	< 0.0001	10 μg/ml
Diiodothyronine	< 0.0001	10 μg/ml
Phenylbutazone	< 0.0001	10 μg/ml
Sodium Salicylate	< 0.0001	10 μg/ml

**TABLE 15 - TSH**

Substance	Cross Reactivity	Concentration
Thyrotropin (hTSH)	1.0000	-
Folliotropin (hFSH)	< 0.0001	1000 ng/ml

Lutropin Hormone (hLH)	< 0.0001	1000 ng/ml
Chorionic Gonadotropin (hCG)	< 0.0001	1000 ng/ml

**15.0 REFERENCES**

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Size	192(A)
A)	1ml set
B)	1 (7ml)
C)	1 (7ml)
D)	1 (10ml)
E)	1 (7ml)
F)	1 (7ml)
G)	2 plates
H)	1 (20ml)
I)	2 (12ml)
J)	2(8ml)

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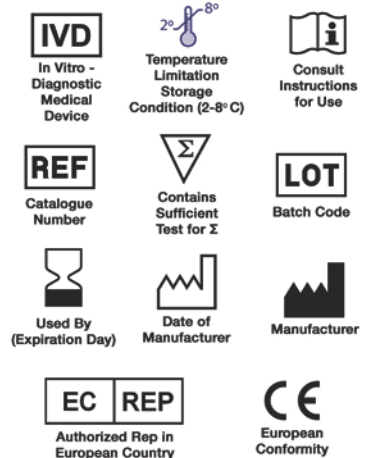


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Size	96(A)	192(B)	
Reagent (fill)	A)	1ml set	1ml set
	B)	1 (1ml)	2 (1ml)
	C)	1 (7ml)	2 (7ml)
	D)	1 (6ml)	2 (6ml)
	E)	1 plate	2 plates
	F)	1 (20ml)	1 (20ml)
	G)	1 (12ml)	2 (12ml)
	H)	1 (8ml)	2 (8ml)
Size	96(A)	192(B)	
Reagent (fill)	A)	1ml set	1ml set
	B)	1 (1ml)	2 (1ml)
	C)	1 (7ml)	2 (7ml)
	D)	1 (6ml)	2 (6ml)
	E)	1 plate	2 plates
	F)	1 (20ml)	1 (20ml)
	G)	1 (12ml)	2 (12ml)
	H)	1 (8ml)	2 (8ml)
Size	96(A)	192(B)	
Reagent (fill)	A)	1ml set	1ml set
	B)	1 (1ml)	2 (1ml)
	C)	1 (7ml)	2 (7ml)
	D)	1 (6ml)	2 (6ml)
	E)	1 plate	2 plates
	F)	1 (20ml)	1 (20ml)
	G)	1 (12ml)	2 (12ml)
	H)	1 (8ml)	2 (8ml)
	96(A)	192(B)	
Reagent (fill)	A)	1ml set	1ml set
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