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**SUMMARY OF SAFETY AND EFFECTIVENESS**

**Free T3 Method for Bayer Technicon Immuno 1® System**

Listed below is a comparison of the performance between the Immuno 1 Free T3 method and a similar device that was granted clearance of substantial equivalence (INCSTAR Clinical Assays™ GammaCoat™ Free T3 RIA kit). The information used in the Summary of Safety and Effectiveness was extracted from the Immuno 1 Free T3 method sheet and the Clinical Assays Free T3 Instruction Manual.

**INTENDED USED**

This *in vitro* method is intended to quantitatively measure Free T3 in human serum on a *Technicon Immuno-1* system. Measurements of Free T3 are used in the diagnosis and treatment of thyroid diseases.

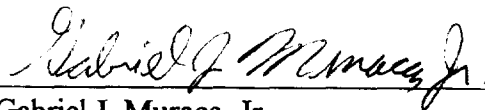
<b>METHOD</b>	<b>Immuno 1 Free T3</b>	<b>Clinical Assays (predicate Device)</b>
<b>Part No.</b>	Reagents T01-3662-51 Calibrators T03-3663-01	CA-1751
<b>Minimum Detectable Conc.</b>	0.2 pg/mL	0.02 pg/mL
<b>Precision (Between-Run)</b>	1.7 pg/mL 8.2% 5.4 pg/mL 4.1% 12.8 pg/mL 2.7%	2.2 pg/mL 6.9% 8.3 pg/mL 7.1% 15.8 pg/mL 8.4%
<b>Correlation</b>	y = 0.95x - 0.08 where y = Immuno 1 Free T3 method x = Clinical Assays Free T3 method n = 103 r = 0.94 S <sub>yx</sub> = 0.71 pg/mL	

## SPECIFICITY

% Crossreactivity of :

	<b>Immuno 1 Free T3</b>	<b>Clinical Assays Free T3</b>
Diiodo-L-tyrosine	<0.1	<0.02
3-Iodo-L-tyrosine	<0.1	<0.02
Methimazole	0.0	N/R
Phenylbutazone	<0.1	<0.02
6-n-Propyl-2-thyouracil	<0.1	N/R
Tetraiodothyro-acetic acid	<0.1	N/R
L-Thyroxine (T4)	<0.1	<0.02
D-Thyroxine	<0.1	<0.02
Ibuprofen	0	N/R
Phenobarbital	0	N/R
Phenytoin	0	N/R
Acetaminophen	0	N/R
3,5 Diiodo-L-Thyronine	<0.1	<0.02
Acetyl Salicylic Acid	<0.1	N/R
Heparinic Acid	<0.1	N/R
L-3,3'5'Triiodo-Thyronine	0.34	N/R
Triiodothyroacetic acid	0.37	N/R
Fenoprofen	<0.1	N/R

N/R = Not Reported



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