

SUMMARY OF SAFETY AND EFFECTIVENESS

K-963080

Testosterone Method for the Bayer Immuno 1[®] System

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Listed below is a comparison of the performance between the Immuno 1 Testosterone method and a similar device that was granted clearance of substantial equivalence (DPC Coat-a-Count[®] Total Testosterone RIA kit). The information used in the Summary of Safety and Effectiveness was extracted from the Immuno 1 Testosterone method sheet and the DPC Total Testosterone method sheet.

INTENDED USE

This *in vitro* method is intended to quantitatively measure testosterone in human serum on a Technicon Immuno 1 system. Measurements of Testosterone are used in the diagnosis and treatment of various hormonal sexual disorders.

METHOD	Immuno 1 Testosterone	DPC (predicate Device)
Part No.	Reagents T01-3694-51 Calibrators T03-3695-01	TKTT1 (100 tubes)
Minimum Det. Conc.	0.04 ng/mL	0.04 ng/mL
Precision (Between-Run)	0.86 ng/mL 6.3% 3.13 ng/mL 3.5% 8.58 ng/mL 2.2%	0.93 ng/mL 12% 2.64 ng/mL 6.4% 6.72 ng/mL 6.0%
Correlation	$y=0.98x + 0.01$ where y =Immuno 1 Total Testosterone method x =DPC Total Testosterone method $n=335$ $r=0.990$ $S_{yx}=0.41$ ng/mL	

Specificity

Crossreactant	Immuno 1 % Crossreactivity	DPC Coat-a-Count % Crossreactivity
Aldosterone	ND	0
5 β -Androstan-3 α ,17 β -diol	0.3	0.4
Androstenedione	0.4	0.5
5 α -Androstan-3 β ,17 β -diol	1.2	0.04
5-Androsten-3 β ,17 β -diol	0.8	0.2
5 α -Androstan-3,17-dione	ND	0.05
Androsterone	ND	0
Corticosterone	ND	0
Cortisol	ND	0
Cortisone	ND	0
Danazol	ND	0.09
11-Deoxycortisol	ND	0
Dexamethasone	ND	0
DHEA	ND	0
DHEA-Sulfate	ND	0.01
5 α -Dihydrotestosterone	4.7	3.3
Estradiol	0.1	0.02
5(10)-Estren-17 α -ethynyl-17 β -ol-3-one	ND	0.2
4-Estren-7 α -methyl-17 β -ol-one	ND	1.1
19-Nortestosterone	7.6	20
Estrone	ND	0.01
Ethisterone	0.5	0.7
Fluoxymesterone	ND	0.01
19-Hydroxyandrostenedione	ND	2
11-Ketotestosterone	-1.2	16
11 β -Hydroxytestosterone	14.2	0.8
Methyltestosterone	2.2	1.7
Norethindrone	0.1	0.1
Prednisone	ND	0
Progesterone	ND	0
Spirolactone	ND	0
Triamcinolone	-0.1	0.2
5 α -Androstan-3 α ,17 β -diol	0.2	NR
Desoxycortisone	ND	NR
Estriol	ND	NR
11 β -Hydroxyandrostanedione	ND	NR
11 β -Hydroxyandrostenedione	ND	NR
17-Hydroxyprogesterone	ND	NR

NR= None reported

ND=None detected

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