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K964889

**BOEHRINGER
MANNHEIM
CORPORATION**

510(k) Summary



Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Submitter name, address, contact
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Date Prepared: December 5, 1996

2. Device name
Proprietary name: Elecsys® Testosterone Assay
Common name: Electrochemiluminescence assay for the determination of testosterone .

Classification name: System, Test, Testosterone

3. Predicate device
We claim substantial equivalence to the Coat-A-Count® Total Testosterone Assay (K81340).
(K844423)

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510(k) Summary, Continued

**4.
Device
Description**

Competition principle. Total duration of assay: 18 minutes.

•1st incubation (9 min.): 50 μL of sample is incubated with a testosterone-specific biotinylated antibody (55 μL) and a testosterone derivative labeled with a ruthenium complex (55 μL).** The binding sites of the labeled antibody become occupied partly by the sample analyte (depending on its concentration) and partly by the ruthenium-labeled hapten to form the respective immunocomplexes.

•2nd incubation (9 min.): After addition of streptavidin-coated microparticles (40 μL), the entire complex is bound to the solid phase via interaction of biotin and streptavidin.

•The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier (0.4 second read frame).

•Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.

**Tris(2,2'-bipyridyl)ruthenium(II) complex ($\text{Ru}(\text{bpy})_3^{2+}$)

**5.
Intended use**

Immunoassay for the in vitro quantitative determination of testosterone in serum and plasma.

**6.
Comparison
to predicate
device**

The Boehringer Mannheim Elecsys® Testosterone Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Coat-A-Count® Total Testosterone Assay (K81340).

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6. Comparison to predicate device, cont.

The following table compares the Elecsys® Testosterone Assay with the predicate device, Coat-A-Count® Total Testosterone Assay. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

Similarities:

- Intended Use: Immunoassay for the in vitro quantitative determination of testosterone
- Sample type: Serum and plasma

Differences:

Feature	Elecsys® Testosterone	Coat-A-Count® Total Testosterone
Solid-Phase Binding Principal	Streptavidin/Biotin	Antibody-coated tubes
Reaction test principle	Electrochemiluminescence	Radioimmunoassay (RIA)
Instrument required	Elecsys® 2010	Gamma counter
Calibration Stability	A calibration is recommended every 7 days if kit is not consumed; 4 weeks with same reagent lot if reagent is consumed within 7 days.	Calibration required every run

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510(k) Summary, Continued

6.
Comparison
to predicate
device, cont.

Performance Characteristics:

Feature	Elecsys® Testosterone	Coat-A-Count® Total Testosterone
Precision Level Within-Run: N Mean %CV Total: N Mean %CV	Modified NCCLS (ng/mL):	Modified NCCLS (ng/mL):
	<u>Low</u> <u>Mid</u> <u>High</u>	<u>Low</u> <u>Mid</u> <u>High</u>
	60 60 60	-- -- --
	0.24 2.75 7.01	-- -- --
	4.62 1.39 1.09	-- -- --
	60 60 60	20 20 20
	0.24 2.75 7.01 7.41 2.21 1.68	0.76 2.64 6.72 11.0 6.4 6.0
Lower Detection Limit	0.02 ng/mL	0.04 ng/mL
Linearity	0.02-15.00 ng/mL (with a deviation from a linear line of ±10%)	0.04-16.00 ng/mL (with a deviation from a linear line of ±10%)
Method Comparison	Vs RIA for Testosterone <u>Least Squares</u> $y = 0.956x + 0.049$ $r = 0.963$ SEE = 0.459 N = 71 <u>Passing/Bablok</u> $y = 1.02 x - 0.108$ $r = 0.963$ SEE = 0.349 N = 71	Vs RIA for Testosterone <u>Least Squares</u> $y = 1.23x + 0.16$ $r = 0.987$ SEE = --- N = 83

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Premarket Notification, 510(k) for Elecsys® Testosterone, Continued

F.
Substantial
equivalence,
cont.

Performance Characteristics, cont:

Feature	Elecsys® Testosterone	Coat-A-Count® Total Testosterone
Interfering substances	No interference at:	No interference at:
Bilirubin	25 mg/dL	Not listed
Hemoglobin	1.0 g/dL	Not listed
Lipemia	1500 mg/dL	Not listed
Biotin	30 ng/mL	Not listed
Specificity	Level tested (ng/mL) %Cross-reactivity	Level tested (ng/mL) %Cross-reactivity
5- α -Dihydrotestosterone	40 1.89	50 3.3
11-Ketotestosterone	40 10.4	1.3 16
11- β -Hydroxytestosterone	40 8.34	2000 0.8
Ethisterone	40 0.02	50 0.7
5-Androstene-3 β ,17 β -diol	40 0.30	250 0.2
Androstenedione	40 0.91	--- ---
5- α -Androstan-3 β ,17 β -diol	40 0.51	1000 0.04
Danazol	40 0.00	200 0.09
Norgestrel	40 0.00	--- ---
Estradiol	40 0.00	1000 0.02