

K964841

MAR 24 1997

**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

Boehringer Mannheim Corporation
2400 Bisso Lane
P.O. Box 4117
Concord, CA 94524-4117
(510) 674 - 0690 extension 8415
FAX 510 687 - 1850

Contact Person: ~~Mary Koning~~ Patricia M. Klimley 25 Feb 2/24/97

Date Prepared: December 2, 1996

2. Device name

Proprietary name: Elecsys® Progesterone Assay

Common name: Electrochemiluminescence assay for the determination of progesterone.

Classification name: System, Test, Progesterone

3. Predicate device

We claim substantial equivalence to the Enzymun® Progesterone Assay (K931117).

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**4.
Device
Description**

Competition principle. Total duration of assay: 18 minutes (37 °C).

•1st incubation (9 min.): 50 µL sample - in the presence of a progesterone-derivative labeled with a ruthenium complex(65 µL)** are incubated with Danazol to release progesterone.

•2nd incubation (9 min.): After addition of biotinylated polyclonal progesterone-specific antibodies (50 µL) and streptavidin-coated microparticles (50 µL), progesterone from the sample competes with the labeled progesterone derivative for the antibody binding sites. At the same time the entire complex becomes bound to the solid phase via interaction of biotin and streptavidin. The proportion of labeled progesterone derivative bound to the solid phase is inversely proportional to the progesterone content of the sample.

•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 (Ru(bpy)²⁺)₃

**5.
Intended use**

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

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6. Comparison to predicate device

The Boehringer Mannheim Elecsys® Progesterone Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test® Progesterone Assay (K931117).

The following table compares the Elecsys® Progesterone Assay with the predicate device, Enzymun-Test® Progesterone 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 progesterone
- Sample type: Serum and plasma
- Antibody: Same polyclonal progesterone antibody
- Solid phase binding principle: Streptavidin/Biotin

Differences:

Feature	Elecsys® Progesterone	Enzymun® Progesterone
Assay Standardization	Enzymun® Progesterone	ID-GC/MS
Reaction test principle	Electrochemiluminescence	ELISA/1-step sandwich assay.
Instrument required	Elecsys® 2010	ES 300
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.	Full calibration required every 2 weeks. One-point calibration required every run.

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6. Comparison to predicate device, cont

Performance Characteristics:

Feature	Elecsys® Progesterone	Enzymun® Progesterone
Precision	Modified NCCLS (ng/mL):	Modified NCCLS (ng/mL):
Level	<u>Low</u> <u>Mid</u> <u>High</u>	<u>Low</u> <u>Mid</u> <u>High</u>
N	60 60 60	60 60 60
Within-Run: Mean	3.1 7.8 88.2	0.7 2.6 24.3
%CV	3.7 1.9 0.7	13.3 3.6 2.3
Total: Mean	3.1 7.8 88.2	0.7 2.6 24.3
%CV	6.8 3.1 0.8	22.4 5.9 2.6
Lower Detection Limit	0.05 ng/mL	0.4 ng/mL
Linearity	0.05-100 ng/mL (with a deviation from a linear line of $\pm 10\%$)	0.4-30 ng/mL (with a deviation from a linear line of $\pm 10\%$)
Method Comparison	Vs Enzymun-Test® Progesterone <u>Least Squares</u> $y = 1.04x + 0.165$ $r = 0.9914$ SEE = 0.620 N = 53 <u>Passing/Bablok</u> $y = 1.07x - 0.059$ $r = 0.9914$ SEE = 0.349 N = 53	Vs Enzymun-Test® Progesterone <u>Least Squares</u> $y = 1.01x + 0.27$ $r = 0.997$ SEE = 0.717 N = 48
Interfering substances	No interference at: Bilirubin 25 mg/dL Hemoglobin 0.6 g/dL Lipemia 400 mg/dL Biotin 30 ng/mL	No interference at: 64.5 mg/dL 1 g/dL 250 mg/dL 50 ng/mL

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6. Comparison to predicate device, cont

Performance Characteristics:

Feature	Elecsys® Progesterone		Enzyman® Progesterone	
	Level tested (nMol/L)	% Cross-reactivity	Level tested	% Cross-reactivity
Testosterone	4.7	< 0.1	---	0.03
Danazol	2,000	< 0.1	---	<0.001
5-Pregnen-3β-ol-20-one	15	< 0.1	---	0.13
17α-Hydroxyprogesterone	14	< 0.1	---	0.25
5β-Dihydroxyprogesterone	20	< 0.1	---	3.0
4-Pregnene-20α-ol-3-one	20	< 0.1	---	0.02
4-Androstene-3,17-dione	13	< 0.1	---	0.02
5β-Pregnene-3α-ol-20-one	20	< 0.1	---	1.7
Corticosterone	48	< 0.1	---	0.6
5α-Dihydrotestosterone	0.93	< 0.1	---	1.4