

JAN 21 1997

K964748

**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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Contact Person: Mary Koning

Date Prepared: November 21, 1996

**2. Device name**  
Proprietary name: Elecsys® Prolactin Assay  
Common name: Electrochemiluminescence assay for the determination of prolactin.

Classification name: System, Test, Prolactin

**3. Predicate device**  
We claim substantial equivalence to the Enzymun® Prolactin Assay (K900695).

**4. Device Description**  
Sandwich principle. Total duration of assay: 18 minutes (37 °C).  
•1st incubation (9 min.): 10µL of sample, a biotinylated monoclonal prolactin-specific antibody (75 µL), and a monoclonal prolactin-specific antibody labeled with a ruthenium complex (75 µL)\*\* react to form a sandwich complex.  
•2nd incubation (9 min.): after addition of streptavidin-coated microparticles (40 µL), the complex becomes bound to the solid phase via interaction of biotin and streptavidin.  
\*\*Tris(2,2'-bipyridyl)ruthenium(II) complex (Ru(bpy)<sup>2+</sup><sub>3</sub>)

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## 510(k) Summary, Continued

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**4.  
Device  
Description**

•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.

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**5.  
Intended use**

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

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**6.  
Comparison  
to predicate  
device**

The Boehringer Mannheim Elecsys® Prolactin 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® Prolactin Assay (K900695).

The following table compares the Elecsys® Prolactin Assay with the predicate device, Enzymun® Prolactin 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 prolactin
  - Sample type: Serum and plasma
  - Antibody: Same pair of mouse monoclonal prolactin antibodies
  - Solid phase binding principle: Streptavidin/Biotin
  - Assay standardization: World Health Organization Standard (WHO) #84/500
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## 510(k) Summary, Continued

**6. Comparison to predicate device cont.**

**Differences:**

Feature	Elecsys® Prolactin	Enzymun-Test® Prolactin
Detection method	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.

**Performance Characteristics:**

Feature	Elecsys® Prolactin			Enzymun-Test® Prolactin		
	Modified NCCLS (µIU/mL):			Modified NCCLS (µIU/mL):		
Level	<u>Low</u>	<u>Mid</u>	<u>High</u>	<u>Low</u>	<u>Mid</u>	<u>High</u>
N	60	60	60	119	119	120
Within-Run: Mean	229.8	1843.5	4662.1	10.1	28.3	63.0
% CV	2.4	1.9	2.4	2.1	2.4	1.9
Total: Mean	229.8	1843.5	4662.1	10.1	28.3	63.0
% CV	3.1	3.4	3.3	4.5	2.7	2.2
Lower Detection Limit	10 µIU/mL			27.56 µIU/mL		

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## 510(k) Summary, Continued

### 6. Comparison to predicate device, (cont.)

#### Performance Characteristics:

Feature	Elecsys® Prolactin	Enzymun-Test® Prolactin																																								
Linearity	10-10,000 µIU/mL (with a deviation from a linear line of ±10%)	27.56-6,360 mIU/mL (with a deviation from a linear line of ±10%)																																								
Method Comparison	Vs Enzymun-Test® Prolactin <u>Least Squares</u> $y = 1.14x - 33.36$ $r = 0.9986$ SEE = 40.088 N = 99  <u>Passing/Bablok</u> $y = 1.101x - 19.40$ $r = 0.9986$ SEE = 9.001 N = 99	Vs Enzymun-Test® Prolactin <u>Least Squares</u> $y = 0.79x + 2.63$ $r = 0.996$ SEE = 3.764 N = 76																																								
Interfering substances	No interference at:	No interference at:																																								
Bilirubin	25 mg/dL	64.5 mg/dL																																								
Hemoglobin	1 g/dL	1 mg/dL																																								
Lipemia	1500 mg/dL	1250 mg/dL																																								
Biotin	30 ng/mL	100 ng/mL																																								
Rheumatoid Factor	1700 µIU/mL	no interference																																								
Specificity	<table border="1"> <thead> <tr> <th>Level tested</th> <th>% Cross-reactivity</th> </tr> </thead> <tbody> <tr> <td>HGH</td> <td>200 mU/mL</td> <td>0.00</td> </tr> <tr> <td>HPL</td> <td>100 ng/mL</td> <td>0.00</td> </tr> <tr> <td>HCG</td> <td>1000 IU/mL</td> <td>0.00</td> </tr> <tr> <td>TSH</td> <td>500 µIU/mL</td> <td>0.00</td> </tr> <tr> <td>FSH</td> <td>2 IU/mL</td> <td>0.00</td> </tr> <tr> <td>LH</td> <td>1 IU/mL</td> <td>0.00</td> </tr> </tbody> </table>	Level tested	% Cross-reactivity	HGH	200 mU/mL	0.00	HPL	100 ng/mL	0.00	HCG	1000 IU/mL	0.00	TSH	500 µIU/mL	0.00	FSH	2 IU/mL	0.00	LH	1 IU/mL	0.00	<table border="1"> <thead> <tr> <th>Level tested</th> <th>% Cross-reactivity</th> </tr> </thead> <tbody> <tr> <td>HGH</td> <td>2 mU/mL</td> <td>0.00</td> </tr> <tr> <td>HPL</td> <td>100 ng/mL</td> <td>0.00</td> </tr> <tr> <td>HCG</td> <td>625 IU/mL</td> <td>0.00</td> </tr> <tr> <td>TSH</td> <td>50 µIU/mL</td> <td>0.00</td> </tr> <tr> <td>FSH</td> <td>38 IU/mL</td> <td>0.00</td> </tr> <tr> <td>LH</td> <td>12.5 IU/mL</td> <td>0.00</td> </tr> </tbody> </table>	Level tested	% Cross-reactivity	HGH	2 mU/mL	0.00	HPL	100 ng/mL	0.00	HCG	625 IU/mL	0.00	TSH	50 µIU/mL	0.00	FSH	38 IU/mL	0.00	LH	12.5 IU/mL	0.00
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