K961491

mannheim boehringer Diagnostics

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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: April 4, 1996

2. Device name

Proprietary name: Elecsys® TSH Assay

Common name: Electrochemiluminescence assay for the thyroid stimulating hormone.

Classification name: Radioimmunoassay-thyroid stimulating hormone

3. Predicate device

We claim substantial equivalence to the Enzymun-Test® TSH (K915195).

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4. Device Description

Sandwich principle: Total duration of assay: 18 minutes (37°C).
•1st Incubation (9 minutes): Sample (50µL), a biotinylated monoclonal TSH-specific antibody (60 µL), and a monoclonal TSH-specific antibody labeled with a ruthenium complex (50 µL) react to form a sandwich complex.
•2nd Incubation (9 minutes): After addition of streptavidin-coated microparticles (40 µL) the complex becomes 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 a 2-point calibration curve and a master curve provided via the reagent bar code.

5. Intended use

Immunoassay for the in vitro quantitative determination of Thyroid Stimulating Hormone in human serum and plasma.

6. Comparison to predicate device

The Boehringer Mannheim Elecsys® TSH 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® TSH.

The following table compares the Elecsys® TSH with the predicate device, Enzymun-Test® TSH.

Similarities:
•Intended Use: Immunoassay for the in vitro quantitative determination of Thyroid Stimulating Hormone

•Sample type: Serum and plasma

•Antibody: Mouse Monoclonal anti-TSH

•Solid phase binding principle: Streptavidin/Biotin

•Assay standardization: World Health Organization (WHO)

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6. Substantial equivalence, cont.

Differences:

Feature	Elecsys® TSH	Enzymun-Test® TSH
Reaction test principle	Electrochemiluminescence	ELISA/1-step sandwich assay using streptavidin technology
Instrument required	Elecsys® 2010	ES 300
Assay Range	Reportable Range: 0.01 µU/ml - 100 µU/ml	Reportable Range: 0.03 µU/ml - 40.00 µU/ml
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 is required every 2 weeks

Performance Characteristics:

Feature	Elecsys® TSH			Enzymun-Test® TSH		
Precision	Modified NCCLS (µU/ml):			Modified NCCLS (µU/ml):		
Level	Sample	Control 1	Control 2	Low	Mid	High
N	60	60	60	120	120	120
Within-Run	0.914	2.451	10.670	0.09	1.23	23.13
%CV	2.08	1.88	1.47	20.0	2.7	2.6
Total	0.914	2.451	10.670	0.09	1.23	23.13
%CV	3.28	2.20	1.76	48.9	5.2	4.6
Sensitivity	Functional Sensitivity: 0.01 µU/ml Lower Detection Limit: 0.005 µU/mL			Lower Detection Limit: 0.03 µU/ml		

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6. Substantial equivalence, cont.

Performance Characteristics:

Feature	Elecsys® TSH	Enzymun-Test® TSH
Linearity	0.01 µU/mL - 100 µU/mL (within ±10% deviation from the linear line)	0.03 µU/mL - 40.00 µU/mL (within ±10% deviation from the linear line)
Method Comparison	Vs Enzymun-Test® TSH Least Squares: y = 1.09x + 0.14 r = 0.991 SEE = 0.798 N = 132 Passing/Bablok: y =1.12X - 0.05 r=0.991 SEE =0.798 N=132	Vs Nichols 3rd Generation Least Squares: y = 1.02x - 0.24 r= 0.985 SEE = 1.12 N= 142
Interfering substances	No interference at:	No interference at:
Bilirubin	25 mg/dL	64.5 mg/dL
Hemoglobin	1 g/dL	1 g/dL
Lipemia	1500 mg/dL	1250 mg/dL
Biotin	30 ng/mL	30 ng/mL
RF	339 IU/mL	No concentration reported
Specificity	Conc / % Cross-Reactivity	No Cross-Reactivity detected at:
HCG	200 / 0	200 U/mL
LH	400 / 0.038	200 mU/mL
FSH	400 / 0.008	200 mU/mL
HGH	400 / 0.00004	Not reported