K963137

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510(k) Summary

DEC 16 1996

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.

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1) Submitter name, address, contact

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Date Prepared: August 9, 1996

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2) Device name

Proprietary name: Elecsys® FT3

Common name: free triiodothyronine test system

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3) Predicate device

We claim substantial equivalence to the Enzymun-Test® FT3.

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4) Device Description

The Elecsys FT3 employs a competitive test principle with polyclonal antibodies directed against T3 and with streptavidin microparticles and electrochemiluminescence detection.

- 1st Incubation: Sample (30 µl) and a specific anti-T3 antibody labeled with a ruthenium complex.
- 2nd Incubation: After addition of biotinylated T3 and streptavidin-coated microparticles, the still-free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex is bound to the solid phase via interaction of biotin and streptavidin.

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4) Device Description, cont.

- 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.
- 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.

5) Intended use

For the *in vitro* quantitative determination of free triiodothyronine (FT3) in human serum and plasma.

5) Indications for use

Triiodothyronine is one of the thyroid hormones present in serum which regulate metabolism. Determination of this hormone concentration is important for the diagnostic differentiation of euthyroid, hyperthyroid and hypothyroid states. The major fraction of total triiodothyronine is bound to the transport proteins (TBG, prealbumin, albumin). The free triiodothyronine (fT3) is the physiologically active form of the thyroid hormone triiodothyronine.

The determination of free T3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins; additional determination of a binding parameter of thyroxine-binding globulin (T-uptake, TBG) is therefore unnecessary.[1,2,3]

The sequential testing procedure and the use of a labeled antibody reduces the possibility of interference due to altered binding properties of the serum, as can occur with assays employing labeled antigen (analog method).[4,5]

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5) Indications for use, (cont.)

A variety of methods are available for estimating the free thyroid hormone levels. The direct measurement of fT4 and fT3 via equilibrium dialysis or ultrafiltration is mainly used as a reference method for standardizing the immunological procedures generally used for routine diagnostic purposes.[4]

References

1 Wheeler MH, Lazarus JH. Diseases of the Thyroid. Chapman and Hall Medical. London Glasgow Weinheim New York Tokyo Melbourne Madras 1994;107-115.

2 Pfannenstiel P, Saller B. Schilddrüsenkrankheiten Diagnose und Therapie. Berliner Medizinische Verlagsanstalt GmbH 1995; 2:30-32,60-62.

3 Fisher DA. Physiological variations in thyroid hormones physiological and pathophysiological considerations. Clinical Chemistry 1996;42:135-139.

4 Klee GG. Clinical usage recommendations and analytic performance goals for total and free triiodothyronine measurements. Clinical Chemistry 1996;42:155-159.

5 Wild D. The Immunoassay Handbook. Stockton Press 1994; 338

6) Comparison to predicate device

The Boehringer Mannheim Elecsys FT3 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® FT3.

Similarities:

- Intended use: immunoassay for the *in vitro* quantitative determination of free triiodothyronine (FT3)
- Competitive test principle
- Sample type: serum and plasma
- Antibody: sheep anti-T3 polyclonal
- Capture principle: streptavidin / biotin

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F. Substantial equivalence, cont.

Differences:

Feature	Elecsys FT3	Enzymun-Test FT3
Reaction test principle	streptavidin microparticles and electrochemiluminescence technology	streptavidin-coated tubes and enzyme immunoassay technology
Sample volume	30 µl	100 µl
Instrument required	Elecsys 2010	ES 300
Calibration	a two point calibration renewal is recommended every 7 days or 1 month if the same reagent lot is used and the reagent pack is consumed within 7 days	a full calibration curve run is recommended every 2 weeks

Performance Characteristics:

Feature	Elecsys FT3					Enzymun-Test FT3		
Precision	NCCLS (Modified) (EP5-T2)					NCCLS "Midi" (EP5-T)		
Sample	PC U1*	PC U2*	HS1	HS2	HS3	1	2	3
N	60	60	60	60	60	120	120	120
Mean	7.64	20.8	5.11	10.5	14.4	2.71	7.86	28.97
wi/in run %CV	2.0	2.5	2.3	2.1	2.3	3.8	2.3	2.7
total run %CV	3.6	3.3	4.7	3.1	2.7	4.5	2.4	3.1
Sensitivity	Lower Detection Limit: 0.40 pmol/l 0.26 pg/ml					Lower Detection Limit: 0.47 pmol/l 0.5 pg/ml		
Assay range (LDL to highest standard)	0.40 - 50 pmol/l 0.26 - 32 pg/ml					0.47 - 46 pmol/l 0.5 - 30 pg/ml		

* PC U1 and PC U2 = PreciControl Universal 1 and 2

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F. Substantial equivalence, cont.

Performance Characteristics, continued:

Method Comparison	vs. Enzymun-Test FT3 Least Squares N = 298 y = - 0.22 + 0.90x r = 0.94 Passing/Bablok N = 298 y = - 1.45 + 1.06x r = 0.94	vs. Elkins Equilibrium Dialysis Least Squares N = 22 y = 0.99x +0.203 r = 0.998
Interfering substance: Hemoglobin Lipemia Bilirubin Biotin	No interference up to: 1 g/dl 1500 mg/dl 25 mg/dl 30 ng/ml	No interference up to: 1 g/dl 1250 mg/dl 17 mg/dl 30 ng/ml
Specificity D-T3 L-T4 D-T4 L-rT3 3,3',5-tri-iodothyroacetic acid 3,3',5,5'-tetra-iodothyroacetic acid	% cross reaction 98.86 0.115 0.115 0.007 106.4 0.007	% cross reaction 140 0.16 0.07 0.04 7.5 0.01