

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K040733

B. Purpose for Submission:

To add additional claims to the device's intended use

C. Analyte:

Troponin T

D. Type of Test:

Electrochemiluminescent sandwich-type immunoassay

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys® Troponin T STAT

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1215, Creatine phosphokinase/creatin kinase or isoenzymes test system
2. Classification:
Class II
3. Product Code:
MMI, Immunoassay method, troponin subunit
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

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

2. Indication(s) for use:

Elecsys Troponin T can be used as an aid in the differential diagnosis of acute coronary syndrome to identify necrosis, e.g., acute myocardial infarction. The test is further indicated for the risk stratification of patients presenting with acute coronary syndrome and for cardiac risk in patients with chronic renal failure. The test may also be useful for the selection of more intensive therapy and intervention in patients with elevated levels of cardiac Troponin T.

3. Special condition for use statement(s):
For professional use only
4. Special instrument Requirements:
Roche Elecsys family of immunoassay analyzers

I. Device Description:

The Elecsys Troponin T STAT assay is presented in an assay format with calibrators available as separate components. The assay consists of two wet reagents containing monoclonal anti-Troponin T antibodies, labels, buffer, and preservatives. The assay also contains magnetic beads which constitute the substrate for sample detection. The Elecsys Troponin T STAT assay is dedicated for use with the Elecsys analyzers and utilizes electrochemiluminescence immunoassay technology.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Elecsys® Troponin T STAT
2. Predicate K number(s):
K984105
3. Comparison with predicate:

The device itself is identical to the predicate. The only difference is the intended use (below):

Differences		
Item	Device	Predicate
Intended Use	<p>The electrochemiluminescence immunoassay “ECLIA” is intended for use on the Roche Elecsys family of immunoassay analyzers.</p> <p>Elecsys Troponin T can be used as an aid in the differential diagnosis of acute coronary syndrome to identify necrosis, e.g., acute myocardial infarction. The test is further indicated for the risk stratification of patients presenting with acute coronary syndrome and for cardiac risk in patients with chronic renal failure. The test may also be useful for the selection of more intensive therapy and intervention in patients with elevated levels of</p>	<p>Immunoassay for the in vitro quantitative determination of Troponin T in human serum and plasma.</p> <p>The electrochemiluminescence immunoassay “ECLIA” is intended for use on the Roche Elecsys 1010 and 2010 immunoassay analyzers.</p>

	cardiac Troponin T.	
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K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The assay methodology is based on a sandwich principle where the patient sample reacts with a biotinylated monoclonal anti-Troponin T antibody and a monoclonal anti-Troponin T antibody labeled with a ruthenium complex [Tris (2,2'-bipyridyl) ruthenium (II)-complex] to form a sandwich. Magnetic streptavidin-coated micro particles are added as the solid phase via a chemical interaction between biotin and streptavidin. The reaction mixture is then transferred to a measuring cell where the micro particles are magnetically captured onto an electrode surface. Any unbound substances are removed with the addition of a buffer. In the final reaction step, a voltage is applied to the sample which induces a chemiluminescent reaction. A peak of light is emitted, detected via a photomultiplier, and the area under the curve is measured around the intensity maximum. In this manner the amount of analyte in a patient sample can be directly calculated based upon the area under the curve (directly proportional to the concentration of Troponin T in the patient sample).

The Elecsys line of immunoassays are based on an immunoassay methodology that uses electrochemiluminescence (or ECL) techniques and employ a highly reactive ruthenium chelate complex for the generation of a light signal. In this immunoassay system, the chemiluminescent reactions that lead to the emission of light are initiated electrically rather than chemically. Specifically, the Elecsys assays use a ruthenium (II)-tris (bipyridyl) [Ru (bPY) 3²⁺] - complex and tripropylamine (TPA). Both of these substances are stable in their steady state, but become electrochemically active when a voltage is applied. ECL signal generation occurs when voltage is applied to the detection cell electrode.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not applicable
 - b. *Linearity/assay reportable range:*
Not applicable
 - c. *Traceability (controls, calibrators, or method):*
Not applicable
 - d. *Detection limit:*
Not applicable
 - e. *Analytical specificity:*
Not applicable
 - f. *Assay cut-off:*
Not applicable
2. Comparison studies:
 - a. *Method comparison with predicate device:*
Not applicable

- b. Matrix comparison:*
Not applicable
- 3. Clinical studies:
 - a. Clinical sensitivity:*
Not applicable
 - b. Clinical specificity:*
Not applicable
 - c. Other clinical supportive data (when a and b are not applicable):*

The following literature references were provided in support of clearance of the extended claims:

- Lindahl B, et al. Mechanisms behind the prognostic value of troponin T in unstable coronary artery disease: a FRISC II substudy. *J Am Coll Cardiol.* 2001 Oct;38(4):979-86.
- Aviles RJ, et al. Troponin T levels in patients with acute coronary syndromes, with or without renal dysfunction. *N Engl J Med.* 2002 Jun 27;346(26):2047-52.
- Apple FS, et al. Predictive value of cardiac troponin I and T for subsequent death in end-stage renal disease. *Circulation.* 2002 Dec 3;106(23):2941-5.
- deFilippi C, et al. Cardiac troponin T and C-reactive protein for predicting prognosis, coronary atherosclerosis, and cardiomyopathy in patients undergoing long-term hemodialysis. *JAMA.* 2003 Jul 16;290(3):353-9.
- Hamm CW, et al. Benefit of abciximab in patients with refractory unstable angina in relation to serum troponin T levels. c7E3 Fab Antiplatelet Therapy in Unstable Refractory Angina (CAPTURE) Study Investigators. *N Engl J Med.* 1999 May 27;340(21):1623-9.
- Lindahl B, et al. Troponin T identifies patients with unstable coronary artery disease who benefit from long-term antithrombotic protection. Fragmin in Unstable Coronary Artery Disease (FRISC) Study Group. *J Am Coll Cardiol.* 1997 Jan;29(1):43-8.
- Heidenreich PA, et al. The prognostic value of troponin in patients with non-ST elevation acute coronary syndromes: a meta-analysis. *J Am Coll Cardiol.* 2001 Aug;38(2):478-85.
- Boersma E, et al. Platelet glycoprotein IIb/IIIa inhibitors in acute coronary syndromes: a meta-analysis of all major randomised clinical trials. *Lancet.* 2002 Jan 19;359(9302):189-98. Erratum in: *Lancet* 2002 Jun 15;359(9323):2120.
- Bavry AA, et al. Invasive therapy along with glycoprotein IIb/IIIa inhibitors and intracoronary stents improves survival in non-ST-segment elevation acute coronary

syndromes: a meta-analysis and review of the literature. Am J Cardiol. 2004 Apr 1;93(7):830-5. Review.

Fleming SM and KM Daly. Cardiac troponins in suspected acute coronary syndrome: a meta-analysis of published trials. Cardiology. 2001;95(2):66-73.

The references contained adequate support for the new claims.

4. Clinical cut-off:
Not applicable
5. Expected values/Reference range:
Not applicable

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.