DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 18, 2017

ROCHE DIAGNOSTICS
JANE E. PHILLIPS, Ph.D.
SENIOR REGULATORY PROGRAM MANAGER
9115 HAGUE ROAD
INDIANAPOLIS, IN 46250

Re: K162895
Trade/Device Name: Elecsys Troponin T Gen 5 STAT Assay, Elecsys Troponin T Gen 5 STAT CalSet, Elecsys PreciControl Troponin, Elecsys Troponin T Gen 5 CalCheck 5
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI, JIT, JJX, JJY
Dated: October 20, 2016
Received: October 21, 2016

Dear Dr. Jane Phillips:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162895

Device Name
Elecsys Troponin T Gen 5 STAT

Indications for Use *(Describe)*

Immunoassay for the in vitro quantitative determination of cardiac troponin T (cTnT) in lithium heparin plasma. The immunoassay is intended to aid in the diagnosis of myocardial infarction.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas system analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162895

Device Name
Elecsys CalSet Troponin T Gen 5 STAT

Indications for Use *(Describe)*

CalSet Troponin T Gen 5 STAT is used for calibrating the quantitative Elecsys Troponin T Gen 5 STAT immunoassay on the cobas system analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162895

Device Name
Elecsys PreciControl Troponin

Indications for Use *(Describe)*

PreciControl Troponin is used for quality control of the Elecsys Troponin I and Elecsys Troponin I STAT immunoassays on the Elecsys and cobas e immunoassay analyzers.

PreciControl Troponin is also used for quality control of the Elecsys Troponin T Gen 5 STAT immunoassay on the cobas system analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162895

Device Name
Elecsys CalCheck Troponin T Gen 5

Indications for Use *(Describe)*

The Elecsys Troponin T Gen 5 CalCheck 5 is an assayed control for use in the calibration verification and for use in the verification of the assay range established by the Elecsys Troponin T Gen 5 reagent on the cobas system analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Device Name

Proprietary name:
(1) Elecsys Troponin T Gen 5 STAT Assay
(2) Elecsys Troponin T Gen 5 STAT CalSet
(3) Elecsys PreciControl Troponin
(4) Elecsys Troponin Gen 5 CalCheck 5

Common name:
(1) Troponin T Gen 5 STAT
(2) CalSet Troponin T Gen 5 STAT
(3) PreciControl Troponin
(4) CalCheck Troponin T Gen 5

Owner

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
Phone: 317-521-2000
Fax: 317-521-2423

Contact

Jane Ellen Phillips, PhD

Date

January 13th, 2017

Classification

The FDA has classified the Elecsys Troponin T Gen 5 STAT (Immunoassay method, troponin subunit) and the Troponin T Gen 5 CalSet (Calibrator, Secondary) as Class II devices.

The FDA has classified the multi-analyte and single-analyte controls, all kinds (assayed and unassayed) as Class I devices (PreciControl Troponin and Troponin T Gen 5 CalCheck 5). As part of the test system, they are considered as Class II devices and included in this submission.

Panel	Product Code	Classification Name	Regulation Citation
Clinical Chemistry	MMI	Immunoassay method, troponin subunit	862.1215
Clinical Chemistry	JIT	Calibrator, Secondary	862.1150
Clinical Chemistry	JJY	Quality control material (assayed and unassayed)	862.1660
Clinical Chemistry	JJX	Single (specified) analyte controls (assayed and unassayed)	862.1660

Substantial Equivalence	The Elecsys Troponin T Gen 5 STAT Test System is substantially equivalent to other devices legally marketed in the United States. (1) Elecsys Troponin T Gen 5 STAT Immunoassay is equivalent to Elecsys Troponin T, 4th generation STAT Immunoassay, Roche Diagnostics (K051752). (2) Elecsys Troponin T Gen 5 STAT CalSet is equivalent to the Elecsys Troponin T CalSet (K961500). (3) Elecsys PreciControl Troponin is equivalent to the Elecsys PreciControl Troponin T (K082699). (4) Elecsys Troponin T Gen 5 CalCheck 5 is equivalent to the Elecsys CA 15-3 II CalCheck 5 (K122242).
Intended Use/Indications for Use	• Immunoassay for the in vitro quantitative determination of cardiac troponin T (cTnT) in lithium heparin plasma. The immunoassay is intended to aid in the diagnosis of myocardial infarction. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas system analyzers. • CalSet Troponin T Gen 5 STAT is used for calibrating the quantitative Elecsys Troponin T Gen 5 STAT immunoassay on the cobas system analyzers. • PreciControl Troponin is used for quality control of the Elecsys Troponin I and Elecsys Troponin I STAT immunoassays on the Elecsys and **cobas e** immunoassay analyzers. PreciControl Troponin is also used for quality control of the Elecsys Troponin T Gen 5 STAT immunoassay on the cobas system analyzers. • The Elecsys Troponin T Gen 5 CalCheck 5 is an assayed control for use in the calibration verification and for use in the verification of the assay range established by the Elecsys Troponin T Gen 5 reagent on the cobas system analyzers.
Device	(1) The Elecsys Troponin T Gen 5 STAT Immunoassay is a two-step sandwich immunoassay on the **cobas e** 411analyzer and a one-step process on the **cobas e** 601 analyzer. The assay uses streptavidin-coated

Substantial Equivalence – Comparison

The following tables compare the Elecsys Troponin T Gen 5 STAT Immunoassay, Elecsys Troponin T Gen 5 STAT CalSet, PreciControl Troponin and Elecsys Troponin T Gen 5 CalCheck5 with their predicate devices.

Comparison of Immunoassays—Elecsys Troponin T STAT Gen 5 and Gen 4 Immunoassays

Immunoassay Comparison		
Feature	**Elecsys Troponin T Gen 5 STAT Immunoassay**	**Predicate Device: Elecsys 4th Generation Troponin T STAT Immunoassay (K051752)**
General Immunoassay Features		
Intended Use/ Indications for Use	Immunoassay for the in vitro quantitative determination of cardiac troponin T (cTnT) in lithium heparin plasma. The immunoassay is intended to aid in the diagnosis of myocardial infarction. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas system analyzers.	Immunoassay for the *in vitro* quantitative determination of cTnT in human serum and plasma. The Elecsys cTnT immunoassay 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 cTnT. The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.
Immunoassay Protocol	Sandwich immunoassay	Same
Detection Protocol	Electrochemiluminescent Immunoassay	Same

Analytical Performance

Precision

Precision of the TnT Gen 5 STAT assay was evaluated on the **cobas e** 411 and **cobas e** 601 analyzer.

Methods:
Within-run precision (repeatability) and total imprecision (intermediate precision) were determined according to the CLSI Guideline EP5-A2.

The protocol consisted of testing different sets of plasma samples and controls in single determinations in four separate aliquots (divided in two runs per day) for 21 operating days (n=84). The measurements were performed on the **cobas e** 411 and **cobas e** 601 with three reagent lots, performing rackpack calibration according to instruction for use.

Results:
Precision goals were met on both instruments and are summarized below.

cobas e 411 analyzer					
		Repeatability		**Intermediate precision**	
Sample (Li heparin plasma)	Mean ng/L	SD ng/L	CV %	SD ng/L	CV %
Human plasma 1	7.27	0.408	5.6	0.746	10.3
Human plasma 2	12.2	0.373	3.1	0.717	5.9
Human plasma 3	152	1.43	0.9	2.20	1.4
Human plasma 4	4673	38.2	0.8	117	2.5
Human plasma 5	9341	64.5	0.7	262	2.8
PreciControl TN1	20.0	0.452	2.3	0.740	3.7
PreciControl TN2	1739	15.5	0.9	36.3	2.1

cobas e 601 analyzer					
		Repeatability		**Intermediate precision**	
Sample (Li heparin plasma)	Mean ng/L	SD ng/L	CV %	SD ng/L	CV %
Human plasma 1	7.42	0.224	3.0	0.473	6.4
Human plasma 2	13.5	0.252	1.9	0.558	4.1
Human plasma 3	154	1.23	0.8	2.24	1.5
Human plasma 4	4831	38.0	0.8	124	2.6

cobas e 601 analyzer					
		Repeatability		**Intermediate precision**	
Sample (Li heparin plasma)	Mean ng/L	SD ng/L	CV %	SD ng/L	CV %
Human plasma 5	9455	62.7	0.7	256	2.7
PreciControl TN1	24.2	0.270	1.1	0.774	3.2
PreciControl TN2	1971	13.3	0.7	45.0	2.3

Troponin T value at intermediate precision of CV = 10%

In addition, we report the value where a CV of ± 10% can be achieved in our product insert. This was determined according to CLSI EP17-A2.

The accuracy goal was defined as intermediate precision equal to a CV of 10 % , using the CLSI EP5-A2 20 day protocol to estimate intermediate precision. Ten Li-Heparin plasma pools were prepared across the low-end of the measuring range of the assay. Data were collected with two lots over 21 days, two runs per day with two replicates per run. Estimates of mean and intermediate precision were calculated for each sample.

The functional relationship between CV and concentration is modeled according to the suggestion in EP17 as:

$\%CV = A * concentration^{B}$

To simplify the fit of the data, the CV and the mean are log-transformed. “Log” here refers to the natural logarithm. After log-transformation a linear regression using least squares can be performed and the model looks like this:

$$log(\%CV) = \tilde{A} + B * log(concentration)$$

With $\tilde{A} = log(A)$

Results are visually assessed and the goodness of fit of the data is evaluated.

The concentration where 10% CV is achieved is calculated by:

$$concentration = \exp\left(\frac{\log(10) - \tilde{A}}{B}\right)$$

Results:

Determination of Troponin T concentration at CV = 10% on cobas e 411 and cobas e 601

Analyzer	Lot	A	B	Troponin T [ng/L]	intermediate precision CV [%]
cobas e 411	170511	4.861	-1.091	10.4	10
cobas e 411	173678	4.407	-1.106	6.70	10
cobas e 601	170511	3.944	-1.052	4.76	10
cobas e 601	173678	3.780	-1.097	3.85	10

LoQ

LoQ/Functional Sensitivity

Methods:
LoQ of the Troponin T Gen 5 STAT assay was determined according to CLSI EP17-A2.

LoQ is defined as the lowest amount of analyte that can be quantitatively established with stated accuracy and stated experimental conditions. The LoQ was set as the lowest concentration of analyte which can be quantified with a CV (intermediate precision) of no more than 20%.

Limit of Quantitation as Functional Sensitivity:
Functional sensitivity has been used as a detection capability performance attribute for the TnTGen5 Assay. It represents the measurand concentration associated with a desired within-lab (intermediate) precision, based upon a precision profile experiment in the low-end region of the measuring interval. This performance attribute however, simply represents a limiting form of the limit of quantitation (LoQ) in which the acceptable accuracy goal is based solely upon a precision requirement. This is suggested by CLSI EP5-A2 for troponin.

The accuracy goal was defined as intermediate precision equal to 20 % CV, using the CLSI EP5-A2 20 day protocol to estimate intermediate precision.

Ten Li-Heparin plasma pools were prepared across the low-end region of the measuring interval and in addition two controls were included. Data were collected with two lots over 21 days, two runs per day with two replicates per run. Estimates of the mean and intermediate precision were calculated for each sample for each reagent lot.

Total CV is based on the total variance, calculated as the sum of the variance components from day, run and within run (21*2*2 = 84 measurements). The square root from the total variance divided by the grand mean times 100 is the results for the total CV [%]. The calculation of the variance components is based on a strict hierarchical model with random factors according CLSI EP5-A2.

The functional relationship between CV and concentration is modeled according to the suggestion in EP17 as:

%CV = A*concentration ^{B}

To simplify the fit of the data, the CV and the mean are log-transformed. “Log” here refers to the natural logarithm. After log-transformation a linear regression using least squares can be performed and the model looks like this:

$$log(\%CV) = \tilde{A} + B * log(concentration)$$

With $\tilde{A} = log(A)$

Results are visually assessed and the goodness of fit of the data is evaluated.

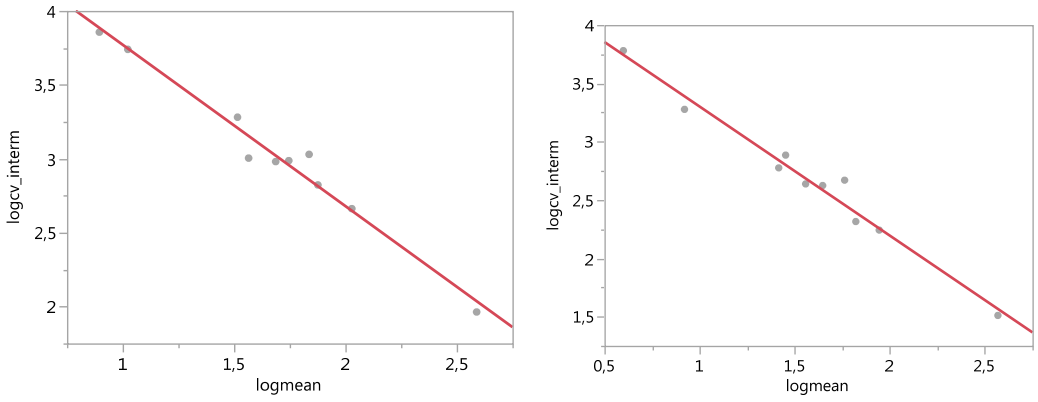
The concentration where 20% CV is achieved is calculated by:

$$concentration = \exp\left(\frac{\log(20) - \tilde{A}}{B}\right)$$

Specification: 20% CV (intermediate precision) at ≤ 6 ng/L

Results:
For visual illustration the graphs below show the relationship between the total CV (log transformed) and concentration (log transformed).

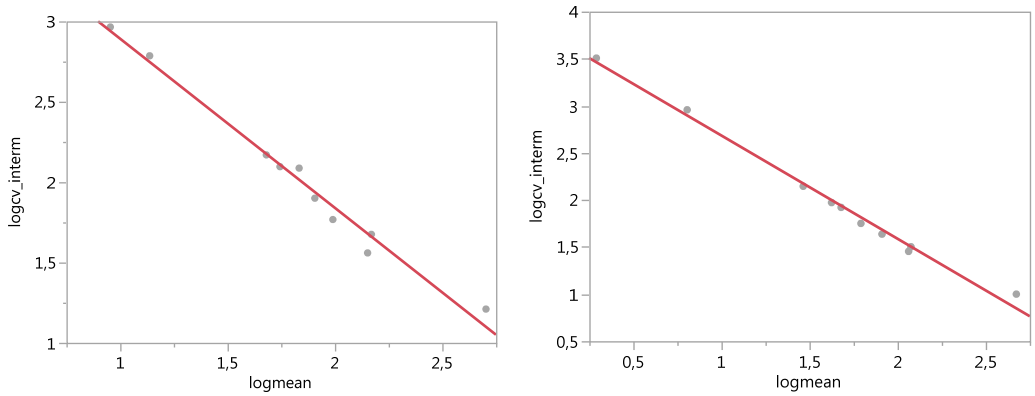
Relationship between the Total CV and Concentration on cobas e 411-Lot 170511 (left) and Lot 173678 (right)



LoQ Results for cobas e 411

Analyzer	Lot	$\hat{A}$	B	Limit of Quantitation [ng/L]	CV [%]
cobas e 411	170511	4.861	-1.091	5.5	20
cobas e 411	173678	4.407	-1.106	3.6	20

Relationship between the Total CV and Concentration on the cobas e 601-Lot 170511 (left) and Lot 173678 (right)



LoQ Results for cobas e 601

Analyzer	Lot	$\hat{A}$	B	Limit of Quantitation [ng/L]	CV [%]
cobas e 601	170511	3.944	-1.052	2.5	20
cobas e 601	173678	3.780	-1.097	2.0	20

LoQ was determined to be 5.5 ng/L on **cobas e** 411 and 2.5 ng/L on the **cobas e** 601 analyzer and meets the specification. LoQ for the assay will be labeled as 6 ng/L.

Linearity

Methods:
The linearity of the Troponin T Gen 5 STAT assay was assessed on the **cobas e** 411 and **cobas e** 601 immunoassay analyzer by diluting one high analyte plasma sample (spiked with recombinant TnT) with native low analyte plasma. 21 concentrations (19

dilutions) throughout the measuring range were prepared. The dilutions were measured in three-fold determination within a single run using one lot.

In the first step, a linearity check was performed with a first order (linear) regression analysis and then with higher order models (quadratic and cubic). Data were analyzed using linear, quadratic and cubic order least square regression analysis according to CLSI protocol EP6-A:

$y = a + b1 * x$ (first order polynomial or linear fit)
$y = a + b1 * x + b2 * x^2$ (second order polynomial fit [quadratic])
$y = a + b1 * x + b2 * x^2 + b3 * x^3$ (third order polynomial fit[cubic])

Results:
The nonlinear coefficient b2 in the second order model (polynomial fit [quadratic]) is significant at the 5% level. Therefore it is used for the calculation of deviation from linearity. For cobas e 411, the test results did not deviate from linearity by more than 6.3%. For cobas e 601, the test results did not deviate from linearity by more than 12.4%.

Linearity was confirmed in the overall range from 3.19 ng/L to 10,439 ng/L. The labeled measuring range is 6 – 10000 ng/L.

High Dose Hook Effect

Methods:
The high dose hook effect of the Troponin T Gen 5 STAT assay was assessed on the **cobas e** 411 and **cobas e** 601 immunoassay analyzer.

Two samples were spiked with analyte to high TnT concentrations. For each sample a dilution series was performed using a low TnT concentration Li-Hep plasma.

The hook concentration reported corresponds to the analyte concentration with a signal corresponding to at least 10% above the highest master calibrator.

Results:
No hook effect was seen up to 100,000 ng/L

Endogenous Interferences

Methods:
The effect on quantitation of analyte in the presence of endogenous interfering substances using the Troponin T Gen 5 STAT was determined on the **cobas e** 411 and **cobas e** 601 immunoassay analyzers for the following 7 interfering substances, Intralipid, biotin, bilirubin, hemoglobin, rheumatoid factors, cholesterol and human serum albumin using three native or spiked (for Bilirubin and Lipemia interference) plasma samples (one low, one medium, and one high concentration of Troponin T) to prepare dilution series that were tested with one reagent lot.

Results:
Recoveries of samples containing interferents were within ± 10% of the values measured in samples not containing interferents.

Labeling states the following:

Interfering Substance	No interference seen up to:
Bilirubin	25 mg/dL
Biotin	20 ng/mL
Lipemia (Intralipid®)	1500 mg/dL
Rheumatoid Factors	900 IU/mL
Hemoglobin	0.1 g/dL
Human Serum Albumin	7 g/dL
Cholesterol	310 mg/dL
HAMA (see below)	322 µg/mL

HAMA Interference

The effect of the presence of human anti-mouse-antibodies on the TnT Gen 5 STAT assay was assessed on the **cobas e** 411 and **cobas e** 601 analyzers. Samples with three different levels of TnT were spiked with potential interfering HAMA and tested in duplicate. The HAMA serum used for the interference testing has been tested in an external laboratory with a commercial assay yielding a HAMA concentration of 805 µg/L.

Results:
Interference of approximately 10% was seen with HAMA concentrations ≥ 322 µg/L.

Analytical Specificity/Cross Reactivity

Methods:
The analytical specificity of the Troponin T Gen 5 STAT assay was assessed on the **cobas e** 411 and **cobas e** 601 analyzers using three concentrations of troponin in plasma samples spiked with the potential cross-reacting compounds listed below. The spiked and non-spiked samples were tested in singlicate on **cobas e** 411 and **cobas e** 601 analyzer.

Note: Human cardiac and skeletal TNC are identical proteins.

Results:
Recoveries of samples containing the potential cross-reactants were within ± 10% of the values measured in samples not containing cross-reactants.

Summary of Cross-Reactivity Study

Interfering Substance	No interference seen up to	Method Sheet claim
Skeletal muscle TnT	60000 ng/L	10000 ng/L
Skeletal muscle TnI	100000 ng/L	100000 ng/L
Cardiac TnI	100000 ng/L	10000 ng/L
Human TnC	80000 ng/L	80000 ng/L

Exogenous Interference Drugs

Methods:
16 common pharmaceutical compounds were spiked into plasma samples. The analyte concentrations were approximately 15 to 9800 ng/mL. The drug concentrations tested are according to the recommendation (if available) given in the CLSI guideline EP7-A. When concentrations are not given in the guideline, we used at least 3-times the maximum recommended dosage.

In addition 18 cardiac drugs were assessed by spiking into human plasma samples. The analyte concentrations were approximately 15 and 1900 ng/L.

Plasma samples were divided into aliquots and spiked with the potential interferents. The reference sample without interferent was spiked with the respective amount of solvent only.

Testing was performed in 3-fold determination with one reagent lot in one run on one **cobas e** 411 and **cobas e** 601 analyzer.

Concentrations of Common Drugs Tested

Active agent	Concentration [mg/L]
Acetylcysteine	1660
Ampicillin-Na	1000
Ascorbic acid	300
Cyclosporine	5
Cefoxitin	2500
Heparin	5000 U
Levodopa	20
Methyldopa +1.5	20
Metronidazole	200
Phenylbutazone	400
Doxycycline	50
Acetylsalicylic Acid	1000
Rifampicin	60
Acetaminophen	200
Ibuprofen	500
Theophylline	100

Concentrations of Cardiac Drugs Tested

Active agent	Concentration [mg/L]
Carvedilol	37.5
Clopidogrel	75
Digoxin	0.25
Epinephrine	0.5
Insulin	1.6
Lidocaine	80
Lisinopril	10
Methylprednisolone	7.5
Metoprolol	150
Nifedipine	30
Phenprocoumon	3
Propafenone	300
Reteplase	33.3
Simvastatin	30
Spironolactone	75
Tolbutamide	1500
Torasemide	15
Verapamil	240

Results:
Recoveries of samples containing the drugs were within ± 10% of the values measured in samples not containing the drugs.

Sample Stability

Methods:
The sample stability was performed in two different studies:
Study 1. Sample stability at 2-8°C
Study 2. Sample stability at -20°C (±5°C)

Study 1 - Sample stability at 2-8°C
Nine samples of Li-Heparin Plasma were aliquoted and measured fresh and after storage at 2-8°C for 9 and 25 hours. Measurements were performed with threefold determination on the **cobas e** 601 analyzer and recovery was calculated.

Study 2 - Sample stability at -20°C (±5°C):
Ten samples of Li-Heparin Plasma were aliquoted and measured fresh and after storage at - 20°C (±5°C) for 13 months. Measurements were performed with threefold determination on the **cobas e** 601 analyzer and recovery was calculated.

Results:
All stressed samples recovered within ± 10% of fresh samples.

The following information will be provided in the method sheet: Stable for 24 hours at 2-8 °C, 12 months at -20 °C (±5°C). Freeze only once.

Calibration Stability

Methods:
The calibration stability on the **cobas e** 411 and **cobas e** 601 immunoassay analyzer for the Troponin T Gen 5 STAT assay was determined by reading the recovery of controls and plasma samples of a day 1 calibration curve.

Onboard Calibration Frequency- Study 1:
Calibration is recommended every 7 days if kit is not consumed.
Three plasma samples and two control levels were tested with reagents opened on day 1 and kept at 22 °C (on board) between test points. Each sample was tested with two-fold determination.

Lot calibration - Study 2:
Calibration is recommended every 12 weeks with the same reagent lot if the reagent pack is consumed within 7 days. Three human plasma samples and two control levels were tested with fresh reagents kits of the same lot after up to 13 weeks. Each sample was tested with two-fold determination.

Results:

	Specification	**Results**
Onboard Calibration Frequency Study 1	7 days	8 days
Lot calibration Study 2	12 weeks	13 weeks

Calibration frequency will be reported as:

- After 12 weeks when using the same reagent lot
- After 7 days when using the same reagent kit

Reagent Stability

Methods:
Reagent stability for the Elecsys Troponin T Gen 5 STAT assay was determined on a **cobas e** 411 and **cobas e** 601 analyzers.

The reagent stability was performed in four different studies:

Study 1 - Reagent stability after first opening
Study 2 - On-board reagent stability
Study 3 - Stress stability
Study 4 - Shelf life stability

Results:

	Specification	**Result**
Reagent stability after first opening	12 weeks	13 weeks
On-board reagent stability	4 weeks	5 weeks
Stress stability	3 weeks	3 weeks
Shelf life stability	n/a	19 months

Reagent stability will be reported as:

- Unopened at 2-8°C: Up to the stated expiration date
- After opening at 2-8°C: 12 weeks
- On the analyzers: 4 weeks

Troponin T Gen 5 STAT Clinical Performance

Expected Values: Healthy Reference Cohort

A total of 1301 healthy subjects (656 females, 645 males), were enrolled and included in the testing for determining the 99th percentile upper reference limit of a normal US population (age range 21 to 89 years) using the Elecsys Troponin T Gen 5 STAT assay, in lithium heparin samples on both the **cobas e** 411 and the **cobas e** 601 analyzers. The 99th percentile upper reference limits were determined to be:

- 19 ng/L for both genders (n = 1301)
- 14 ng/L for females (n = 656)
- 22 ng/L for males (n = 645)

The Universal Definition of AMI takes into consideration the ESC/ACC/AHA/WHF definition. These guidelines recommend the detection of at least one value above the 99th percentile and a rise and/or fall of cardiac troponin in the clinical setting of acute myocardial ischemia. [1]

Diagnostic Sensitivity and Specificity

APACE Population

The Advantageous Predictors of Acute Coronary Syndromes Evaluation (APACE) study is an international, multicentric prospective trial of acute chest pain patients that is currently continuing enrollment (ClinicalTrials.gov number NCT00470587.6). The study sites enrolled all patients who presented to the emergency department with symptoms of chest pain and angina pectoris. Peak of symptoms had to have occurred within the last 12 hours (onset of symptoms reported ranged from 0 to 72 hours). The only exclusion criterion was kidney failure that required dialysis. Diagnosis of MI was done through an independent adjudication committee which included cardiologists. This included 60 day follow-up information on each subject. In the case of a disagreement, a third independent cardiologist was used as the tie breaker. The subjects were diagnosed with acute MI by using the diagnostic criteria described in the ACC/ESC/AHA guidelines reference including ECG changes, symptoms characteristic for ischemia and elevations of cardiac troponin. All 718 subjects had a baseline test result. Five hundred fifteen (515) of the 718 subjects had a second test result at the 3 hour time point and 310 (of the 718) subjects had a test result at the 6 hour time point.

Results:

The clinical performance (clinical sensitivity, clinical specificity, positive predictive value and negative predictive value) of the Elecsys Troponin T Gen 5 STAT assay in the diagnosis of MI in this trial is shown below using a single 99th percentile cutoff 19 ng/L for all patients:

All subjects using 19ng/L cut-off

	Sensitivity		Specificity		PPV		NPV	
Time point	%	95%CI	%	95%CI	%	95%CI	%	95%CI
Baseline	93.5(115/123)	87.6-97.2	86.4(514/595)	83.4-89.0	58.7(115/196)	51.4-65.6	98.5(514/522)	97.0-99.3
3 hour	98.3(59/60)	91.1-100	85.1(387/455)	81.4-88.2	46.5(59/127)	37.6-55.5	99.7(387/388)	98.6-100
6hours	100(37/37)	90.5-100	82.4(225/273)	77.4-86.7	43.5 (37 / 85)	32.8-54.7	100(225/225)	98.4-100

The clinical performance using sex specific cutoffs 14 ng/L for women and 22 ng/L for males is provided below:

Females using 14ng/L cut-off

	Sensitivity		Specificity		PPV		NPV	
Time point	%	95%CI	%	95%CI	%	95%CI	%	95%CI
Baseline	97.1(34/35)	85.1-99.9	77.4(164/212)	71.1-82.8	41.5(34/82)	30.7-52.9	99.4(164/165)	96.7-100
3 hour	100(17/17)	80.5-100	75.2(124/165)	67.8-81.5	29.3(17/58)	18.1-42.7	100(124/124)	97.1-100
6hours	100(15/15)	78.2-100	72.3(68/94)	62.2-81.1	36.6(15/41)	22.1-53.1	100(68/68)	94.7-100

The positive predictive value for females using the lower sex-specific cutoff (14 ng/L) is lower when compared to the higher cutoff of 19 ng/L. When looking at the lower bound of the 95 % CI, up to 69 %, 82 % and 78 % of positive test results for females are non-MI. Troponin results should always be used in conjunction with clinical signs and symptoms.

These observations underline the Universal AMI guideline requirements to use troponin results always in conjunction with at least one of the following criteria: symptoms of ischemia, ECG changes (ST and/or Q wave), left bundle branch block, imaging evidence of viable myocardium loss, wall motion abnormality or intracoronary thrombus to clarify the origin of myocardial injury.

Males using 22 ng/L cut-off

	Sensitivity		Specificity		PPV		NPV	
Time point	%	95%CI	%	95%CI	%	95%CI	%	95%CI
Baseline	90.9(80/88)	82.9-96.0	89.3(342/383)	85.8-92.2	66.1(80/121)	57.0-74.5	97.7(342/350)	95.5-99.0
3 hour	97.7(42/43)	87.7-99.9	86.9(252/290)	82.5-90.6	52.5(42/80)	41.0-63.8	99.6(252/253)	97.8-100
6hours	100(22/22)	84.6-100	86.0(154/179)	80.1-90.8	46.8(22/47)	32.1-61.9	100(154/154)	97.6-100

In a second multicenter study, a total of 1679 subjects presenting emergently with chest pain were enrolled. The trial excluded chest pain subjects with an MI within the last 3 months, subjects with surgery or hospitalization within the last 3 months, subjects with revascularization or percutaneous coronary intervention (PCI) within the last 3 months, subjects with an established acute non-cardiac primary illness and subjects transferred from another hospital or facility. **These excluded subjects could be expected to have elevated troponin concentrations that would likely reflect cardiac comorbidities besides MI, and yield positive results; therefore, the specificity and positive predictive value may be overestimated.** Within this population, there were 173 adjudicated MIs. 1679 of these subjects were evaluated on the **cobas e** 411 analyzer and 1675 subjects were evaluated on the **cobas e** 601 analyzer. Final diagnoses were determined by an independent adjudication committee which included cardiologists and emergency medicine physicians using the universal guidelines.

The clinical performance of the Elecsys Troponin T Gen 5 STAT assay in the diagnosis of MI in this trial is shown below using a single 99th percentile cutoff (i.e., 19 ng/L) for all patients:

Number of myocardial infarctions based on adjudicated diagnosis								
cobas e 411 analyzer					**cobas e** 601 analyzer			
	MI	non-MI	Total			MI	non-MI	Total
N	173	1506	1679		N	173	1502	1675
%	10.3	89.7	100		%	10.3	89.7	100

Clinical performance of single 99th percentile cutoff (19 ng/L) for aid in diagnosis of AMI in both genders						
Instrument	**Time point**	**n**	**Sens[b] % 95 % CI[c]**	**Spec[d] % 95 % CI**	**PPV[e] % 95 % CI**	**NPV[f] % 95 % CI**
cobas e 411 analyzer	Base- line	1628	86.7 % (80.5 - 91.5)	87.8 % (86.0 - 89.5)	44.5 % (39.0 - 50.2)	98.3 % (97.5 - 98.9)
	3 hours	1429	94.4 % (89.2 - 97.5)	87.4 % (85.5 - 89.2)	45.3 % (39.5 - 51.1)	99.3 % (98.6 - 99.7)
	6-9 hours	1178	94.2 % (88.9 - 97.5)	85.3 % (83.0 - 87.4)	45.9 % (40.0 - 51.9)	99.1 % (98.2 - 99.6)
	12-24 hours	887	92.9 % (86.4 - 96.9)	81.7 % (78.8 - 84.3)	42.3 % (36.0 - 48.7)	98.8 % (97.6 - 99.5)
cobas e 601 analyzer	Base- line	1600	86.0 % (79.7 - 90.9)	88.0 % (86.2 - 89.6)	44.9 % (39.3 - 50.6)	98.2 % (97.3 - 98.9)
	3 hours	1415	94.3 % (89.1 - 97.5)	86.6 % (84.6 - 88.4)	43.6 % (37.9 - 49.4)	99.3 % (98.6 - 99.7)
	6-9 hours	1158	94.9 % (89.8 -	85.3 % (83.0 -	46.6 % (40.7 -	99.2 % (98.4 -

Clinical performance of single 99th percentile cutoff (19 ng/L) for aid in diagnosis of AMI in both genders						
Instrument	**Time point**	**n**	**Sens[b] % 95 % CI[c]**	**Spec[d] % 95 % CI**	**PPV[e] % 95 % CI**	**NPV[f] % 95 % CI**
			97.9)	87.4)	52.6)	99.7)
	12-24 hours	872	91.9 % (85.2 - 96.2)	80.6 % (77.6 - 83.3)	40.8 % (34.6 - 47.2)	98.6 % (97.3 - 99.3)

b) Sensitivity = 100xA/A+C

c) CI = confidence interval

d) Specificity = 100xD/B+D

e) Positive predictive value = 100xA/A+B

f) Negative predictive value = 100xD/D+C

	Diagnosis	
	MI	Non-MI
cTnT positive	A	B
cTnT negative	C	D

Clinical performance of gender-specific 99th percentile cutoff (14 ng/L) for aid in diagnosis of AMI in females						
Instrument	**Time point**	**n**	**Sens % 95 % CI**	**Spec % 95 % CI**	**PPV % 95 % CI**	**NPV % 95 % CI**
cobas e 411 analyzer	Base- line	787	87.3 (76.5-94.4)	87.6 (84.9-89.9)	37.9 (30.0-46.4)	98.8 (97.6-99.5)
	3 hours	687	92.0 (80.0-97.8)	86.2 (83.3-88.8)	34.3 (26.3-43.0)	99.3 (98.2-99.8)
	6-9 hours	553	91.7 (80.0-97.7)	85.1 (81.7-88.1)	37.0 (28.3-46.3)	99.1 (97.7-99.7)
	12-24 hours	410	92.3 (79.1-98.4)	79.8 (75.3-83.8)	32.4 (23.9-42.0)	99.0 (97.1-99.8)
cobas e 601 analyzer	Base- line	771	85.7 (74.6-93.3)	88.1 (85.5-90.4)	39.1 (30.9-47.8)	98.6 (97.3-99.3)
	3 hours	682	91.8 (80.4-97.7)	86.9 (84.0-89.4)	35.2 (26.9-44.1)	99.3 (98.2-99.8)
	6-9 hours	536	91.3 (79.2-97.6)	86.5 (83.2-89.4)	38.9 (29.7-48.7)	99.1 (97.6-99.7)
	12-24 hours	399	92.3 (79.1-98.4)	81.4 (77.0-85.3)	35.0 (25.8-45.0)	99.0 (97.1-99.8)

The positive predictive value for females using the lower sex-specific cutoff (14 ng/L) is lower when compared to the higher cutoff of 19 ng/L. When looking at the lower bound of the 95 % CI, up to 69 %, 82 % and 78 % of positive test results for females are non-MI. Troponin results should always be used in conjunction with clinical signs and symptoms.

These observations underline the Universal AMI guideline requirements to use troponin results always in conjunction with at least one of the following criteria: symptoms of ischemia, ECG changes (ST and/or Q wave), left bundle branch block, imaging evidence of viable myocardium loss, wall motion abnormality or intracoronary thrombus to clarify the origin of myocardial injury.

Clinical performance of gender-specific 99th percentile cutoff (22 ng/L) for aid in diagnosis of AMI in males						
Instrument	**Time point**	**n**	**Sens % 95 % CI**	**Spec % 95 % CI**	**PPV % 95 % CI**	**NPV % 95 % CI**
cobas e 411 analyzer	Base- line	841	86.3 (78.0-92.3)	87.3 (84.7-89.6)	48.4 (40.9-55.9)	97.9 (96.5-98.8)
	3 hours	742	95.7 (89.2-98.8)	85.7 (82.8-88.3)	48.6 (41.1-56.1)	99.3 (98.2-99.8)
	6-9 hours	625	93.3 (86.1-97.5)	82.1 (78.5-85.2)	46.7 (39.2-54.2)	98.7 (97.1-99.5)
	12-24 hours	477	94.5 (86.6-98.5)	80.2 (76.0-84.0)	46.3 (38.1-54.7)	98.8 (96.9-99.7)
cobas e 601 analyzer	Base- line	829	85.1 (76.7-91.4)	87.2 (84.6-89.6)	48.0 (40.5-55.6)	97.7 (96.2-98.7)
	3 hours	733	95.6 (89.1-98.8)	86.3 (83.4-88.9)	49.7 (42.1-57.4)	99.3 (98.2-99.8)
	6-9 hours	622	93.5 (86.3-97.6)	82.3 (78.7-85.4)	47.8 (40.3-55.3)	98.6 (97.1-99.5)
	12-24 hours	473	94.4 (86.4-98.5)	80.0 (75.8-83.9)	45.9 (37.7-54.3)	98.8 (96.9-99.7)

Troponin T Gen 5 CalSet

CalSet Comparison		
Feature	**Elecsys Troponin T Gen 5 STAT CalSet**	**Predicate Device: CalSet for the Elecsys 4th Generation Troponin T STAT Immunoassay (K961500)**
General Features		
Intended Use/ Indications for Use	CalSet Troponin T Gen 5 STAT is used for calibrating the quantitative Elecsys Troponin T Gen 5 STAT immunoassay on the cobas system analyzers.	Used for calibrating the quantitative Elecsys Troponin T STAT immunoassay on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Same
Matrix	Human serum	Same
Format	Lyophilized	Same

CalSet Stability

Methods:
The stability for the Elecsys Troponin T CalSet was determined by calculating the recovery of stressed calibrators compared to unstressed/freshly reconstituted calibrators.

Study 1: Combined On Board Stability/ Stability after reconstitution:
Stability of reconstituted Elecsys Troponin T Gen 5 STAT CalSet onboard is claimed to be up to 5 hours at 20 – 25°C within two weeks after reconstitution when stored at 2 – 8°C.

CalSets were reconstituted and kept at 2 – 8°C for three weeks. During this time period the opened calibrators were incubated at 25°C (±2°C) for a total of 6 hours.

Study 2: Stability at - 20°C (±5°C)
Stability of Elecsys Troponin T Gen 5 STAT CalSet at -20°C (±5°C) is claimed to be 3 months. Calibrators should be frozen for one time only and also be used only once after thawing.

CalSets were reconstituted and stored at -20°C (±5°C) for four months.

The TnT concentration of six human plasma samples and two controls was determined using the calibration curve generated by the stressed calibrators and compared to the TnT concentration determined by using the calibration curve generated by the freshly reconstituted calibrators (reference).

Acceptance criteria:
Concentrations of < 14 ng/L: Recovery ± 1.4 ng/L
Concentrations of ≥ 14 ng/L: Recovery 100 ± 10%

Results:
On board stability for the CalSet on the cobas e 411 analyzer (25°C (±2°C) was determined to be up to 5 hours. For the CalSet on the cobas e 601 analyzers, the labeling states to use only once. CalSets stored at -20°C (±5°C) are stable for three months.

CalSet Real-Time Stability

Methods:
Real-time stability of Troponin T Gen 5 STAT CalSet was evaluated as follows:

In the real-time stability study, the Troponin T Gen 5 STAT CalSet material was stored at 2 - 8°C. The stored assay reagents were tested at time point t = 0 and at specified intervals over the shelf life of the device up to the planned shelf life plus one month. Testing was performed using PreciControl Troponin 1 and PreciControl Troponin 2 as well as of internal manufactured control samples.

Data for the time-points tested are available in duplicate. The average on-test recovery value was calculated as the percent recovery compared to the reference value (assigned value of PreciControl Troponin 1 and PreciControl Troponin 2 and assigned value of internal manufactured control samples).

Acceptance Criteria of CalSet Real-Time Stability Testing:

Sample Type	**Recovery of the Reference Value**
PreciControl Troponin 1	90-110%
PreciControl Troponin 2	90-110%
Internal Control samples (concentrations ≤ 100 ng/L)	90-110%
Internal Control samples (concentrations > 100 ng/L)	90-110%

Results:
The Troponin T Gen 5 STAT CalSet is stable for at least 19 months. A shelf-life claim of 18 months has been established.

PreciControl Troponin

PreciControl Comparison		
Feature	**Elecsys PreciControl Troponin**	**Predicate Device: Elecsys PreciControl Troponin T (K082699)**
General Features		
Intended Use/ Indications for Use	PreciControl Troponin is used for quality control of the Elecsys Troponin I and Elecsys Troponin I STAT immunoassays on the Elecsys and **cobas e** immunoassay analyzers. PreciControl Troponin is also used for quality control of the Elecsys Troponin T Gen 5 STAT immunoassay on the cobas system analyzers.	Elecsys PreciControl cTnT is used for quality control of the Elecsys Troponin T (CARDIAC T) immunoassay on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Same
Format	Lyophilized	Same
Matrix	Human serum	Same

PreciControl In-Use Stability

Methods:
The stability for the PreciControl Troponin was determined by calculating the recovery based on the use of stressed PreciControl Troponin 1 and 2 compared to unstressed freshly reconstituted PreciControl Troponin 1 and 2.

Study 1 - Combined in-use stability: On board stability and stability of reconstituted PreciControl Troponin at 2-8°C

Stability of reconstituted PC Troponin onboard is claimed to be up to 5 hours at 20 – 25°C and is claimed to be 4 days when stored at 2 – 8°C.

PreciControl 1 and 2 were reconstituted and kept at 2 – 8°C for 97 h. During this time period the opened controls were incubated at 25°C (±2°C) for a total of 6 hours (6 x 1hour).

Study 2 - Stability of reconstituted PreciControls stored at - 20°C (±5°C):

PC Troponin 1 and 2 were reconstituted and stored at -20°C (±5°C) for 94 days.

Acceptance criteria:
Concentrations of < 14 ng/L: Recovery ± 1.4 ng/L
Concentrations of ≥ 14 ng/L: Recovery 100 ± 10%

Results:
Stability of PreciControl Troponin at -20°C is claimed to be 3 months. Controls should be frozen for one time only and also be used only once after thawing.

PreciControl Real-Time Stability

Methods:
In the real-time stability study, the PreciControl Troponin test material is stored at 2-8°C. The PreciControls were tested in duplicate at specified intervals over the shelf life of the device up to the planned shelf life plus one month (19 months). The average on-test recovery value was calculated as the percent recovery compared to the reference value (Assigned value of PreciControl Troponin 1 and PreciControl Troponin 2

Acceptance Criteria of PreciControl real-time stability testing:

Sample Type	**Recovery of the Reference Value**
PreciControl Troponin 1	90 - 110%
PreciControl Troponin 2	90 - 110%

Results:
The shelf life claim is 18 months.

PreciControl Reconstitution Study

PreciControl Troponin was reconstituted for 60 minutes (reference) and 120 minutes. Samples were evaluated in duplicate on the **cobas e** 411 analyzer. The average recovery after 120 minutes of reconstitution was calculated as percent recovery compared to the value obtained at 60 minutes of reconstitution (the reference value).

The acceptance criterion is recovery of 74-126% for PreciControl Troponin 1 and 81-119% for PreciControl Troponin 2 of the value obtained for the 60 minute reconstituted material.

The data support the package insert claim that the PreciControl Troponin is completely reconstituted after 60 minutes.

Troponin T Gen 5 CalCheck5

CalCheck Comparison		
	Elecsys Troponin T Gen 5 CalCheck 5	**Predicate Device: Elecsys CA 15-3 II CalCheck 5 (K122242)**
General Immunoassay Features		
Intended Use/ Indications for Use	The Elecsys Troponin T Gen 5 CalCheck 5 is an assayed control for use in the calibration verification and for use in the verification of the assay range established by the Elecsys Troponin T Gen 5 reagent on the cobas system analyzers.	The Elecsys CA 15-3 II CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys CA 15-3 II reagent on the indicated Elecsys and cobas e immunoassay analyzers. For *in vitro* diagnostic use only.
Levels	Five	Same
Format	Lyophilized	Same
Matrix	Human serum	Equine serum

Troponin T Gen 5 CalCheck 5 Stability

Methods:
Open vial stability was performed on the **cobas e** 411 and **cobas e** 601 in order to verify the claims for the Troponin T Gen 5 CalCheck 5.

Study 1 - Open-Vial Stability
The on-test and reference materials were tested in duplicate. The on-test material was reconstituted and stored for 5 hours at 25ºC (in an open vial). The reference material was a freshly reconstituted set of CalChecks. The on-test recovery was calculated as a percent of the reference value.

One Troponin T Gen 5 CalCheck 5 lot was evaluated in duplicate.

Acceptance criteria:
CalCheck Level 1: ≤ 6 ng/L
CalCheck Level 2-5: recovery of 90-110% of the reference value.

Results:
The data support the package insert claim that reconstituted Troponin T Gen 5 CalCheck 5 is stable up to 4 hours at 20-25°C.

The CalCheck products are not stored on-board the analyzers, therefore no on-board stability claims are made.

Study 2 - Real-time stability

In the real-time stability study, the Troponin T Gen 5 CalCheck 5 test material is stored at 2-8°C. The CalChecks are tested at T=0 and at intervals over the shelf life of the device up to the planned shelf life plus at least one month. The target shelf life claim for the Troponin T Gen 5 CalCheck 5 is 18 months.

For the lot on stability, data for the time-points 0, 13, 19, 25 and 37 months tested in duplicate will be available. The average on-test recovery value will be calculated as percent recovery compared to the T=0 reference value.

Acceptance criteria:
CalCheck Level 1: < 6 ng/L
CalCheck Level 2-5: recovery of 80-120% of the reference value.

The data will support the package insert claim that unopened Troponin T Gen 5 CalCheck 5 is stable up to the expiration date when stored at 2-8°C.

Results:
The labeled shelf life claim is 18 months.

Troponin T Gen 5 STAT Test System -- Conclusion

The Elecsys Troponin T Gen 5 STAT Assay, Elecsys Troponin T Gen 5 STAT CalSet, Elecsys PreciControl Troponin and Elecsys Troponin T Gen 5 CalCheck 5 substantially equivalent to the Elecsys Gen 4 STAT assay, Elecsys Gen 4 STAT CalSet, Elecsys PreciControl Troponin and Elecsys CalCheck 5 products currently on the market. The clinical and nonclinical data provided in this submission demonstrate that the safety and efficacy of these devices are equivalent to their predicates.