Elecsys Chagas

cobas®

Materials provided

REF			IVD	Rx only	SYSTEM
09015582162	09015582502	9 x 300			**cobas pro** serology solution

For reagents, refer to the "Reagents" section.

Materials required (but not provided)

REF	Description
07092571162	PreciControl Chagas, 16 x 1.0 mL
09367098190	PreciControl Release Chagas, 16 x 1.0 mL
	General laboratory equipment
	The **cobas pro** serology solution is a combination of the **cobas pro** serology controller, **cobas pro** integrated solutions (**cobas** e 801 analytical units only), and applicable licensed or cleared donor screening assays.

Additional materials for **cobas** e 801 analytical unit:

REF	Description
06908799190	ProCell II M, 2 x 2 L system solution
04880293190	CleanCell M, 2 x 2 L measuring cell cleaning solution
07485409001	Reservoir Cup, 8 cups to supply ProCell II M and CleanCell M
06908853190	PreClean II M, 2 x 2 L wash solution
05694302001	Assay Tip / Assay Cup tray, 6 magazines x 6 magazine stacks x 105 assay tips and 105 assay cups, 3 wasteliners
07485425001	Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution / Elecsys SysClean for Liquid Flow Cleaning Detection Unit
07485433001	PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution / Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
11298500160	ISE Cleaning Solution / Elecsys SysClean, 5 x 100 mL system cleaning solution

For use in the USA only

System information

Short name	ACN (application code number)
CHAGB	10506
CHAGBE (embedded application)	11506
CHAGBR (for use with **cobas** e flow)	12506

Intended use

Elecsys Chagas is an in vitro immunoassay for the qualitative detection of antibodies to *Trypanosoma cruzi* (*T. cruzi*, the causative agent of the Chagas disease) in human serum and plasma. Elecsys Chagas is intended to screen individual human donors, including volunteer donors of whole blood and blood components. The assay is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating and in testing serum specimens to screen cadaveric donors when specimens are obtained after the donor's heart has stopped beating.

It is not intended for use on cord blood specimens.

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use with the **cobas pro** serology solution equipped with a **cobas** e 801 analytical unit.

Summary

Chagas disease (also known as American trypanosomiasis) is caused by the flagellated protozoan parasite *Trypanosoma cruzi*.[1] The parasite is usually transmitted by hematophagous triatomine insects (family of Reduviidae) in endemic areas but also through infected blood components, organ transplantations, congenitally from mother to infant, ingestion of contaminated food and in laboratory accidents.[1, 2]

T. cruzi is found in the Americas, except for isolated cases in which infected persons have carried the parasites to non-endemic regions (e.g. Far East, Australia, Europe).[3, 4, 5] It is estimated that 6-7 million people are infected worldwide, predominantly in Latin America and 20-30 % of these develop symptomatic, potentially life-threatening Chagas disease.[5, 6]

The natural history of the infection is characterized by an acute and a chronic phase. The acute phase lasts 8 to 12 weeks, during which most patients remain asymptomatic or develop nonspecific symptoms.[4] Patients develop a strong immune response to a variety of *T. cruzi* antigens, and a decrease of parasite levels can be observed. The chronic phase begins once parasitemia falls below detectable levels by microscopy (in the absence of anti-

trypanosomal therapy), and infection mostly appears asymptomatic but lifelong. Diagnosis of Chagas disease is usually made by serology, biopsy or PCR. A positive serology is considered as a sign of active *T. cruzi* infection or past exposure. Serologically positive asymptomatic patients are capable of transmitting the parasite to the vector insect and directly to other individuals via blood components, organ donation, or to the fetus transplacentally.[7]

The Elecsys Chagas assay uses recombinant antigens representing FCaBP, FRA and Cruzipain for the determination of antibodies to *T. cruzi*.

Test principle

Double antigen sandwich principle. Total duration of assay: 18 minutes.

- First incubation: 18 µL of sample, biotinylated *T. cruzi*-specific recombinant antigens (FCaBP, FRA and Cruzipain) and *T. cruzi*-specific recombinant antigens (FCaBP, FRA and Cruzipain) labeled with a ruthenium complex[a)] react to form a sandwich complex.
- Second incubation: After streptavidin-coated microparticles have been added, 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 II M. Application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photomultiplier.
- Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the sample with the cutoff value obtained by the Chagas embedded calibration. The Elecsys Chagas result is calculated automatically based on signal to cutoff ratio (cutoff index, COI).

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex ($Ru(bpy)_3^{2+}$)

Reagents

The **cobas** e pack (M, R1, R2) is labeled as CHAGB.

M	Streptavidin-coated microparticles, 1 bottle, 14.1 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.
R1	*T. cruzi*-specific recombinant antigens (*E. coli*)~biotin, 1 bottle, 16.7 mL: Biotinylated *T. cruzi*-specific recombinant antigens (*E. coli*) > 100 µg/L; MES[A)] buffer 50 mmol/L, pH 6.5; preservative.
R2	*T. cruzi*-specific recombinant antigens (*E. coli*)~$Ru(bpy)_3^{2+}$, 1 bottle, 16.7 mL: *T. cruzi*-specific recombinant antigens (*E. coli*) labeled with ruthenium complex > 100 µg/L; MES buffer 50 mmol/L, pH 6.5; preservative.

A) MES = 2-morpholino-ethane sulfonic acid

CHAGB Cal1	Non-reactive calibrator 1, 2 vials each for 1.0 mL: Human serum, non-reactive for anti-*T. cruzi* antibodies; buffer; preservative.
CHAGB Cal2	Reactive calibrator 2, 2 vials each for 1.0 mL: Human serum, reactive for anti-*T. cruzi* antibodies; buffer; preservative.

Warnings and precautions

For in vitro diagnostic use.

This test is not intended for use as an aid in diagnosis of *T. cruzi* infection.

Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards

Apply all relevant local disposal regulations to determine safe disposal.

The Safety Data Sheet is available for professional users on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317	May cause an allergic skin reaction.

Prevention:

P261	Avoid breathing mist or vapours.

P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.

Disposal:

P501	Dispose of contents/container to an approved waste disposal plant.

Hazardous components:

- 2-methyl-2H-isothiazol-3-one
- 2-methyl-2H-isothiazol-3-one hydrochloride

Product safety labeling follows EU GHS guidance.

Contact phone: +1-866-744-6397

All human material should be considered potentially infectious.

The calibrators (CHAGB Cal1, CHAGB Cal2) have been prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.

The testing methods use assays that have been approved or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 98/79/EC, Annex II, List A).

The serum containing anti-*T. cruzi* IgG (CHAGB Cal2) was 0.2 micron filtrated.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a donor specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[8, 9]

Avoid foam formation in all reagents and sample types (specimens, calibrators, and controls).

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the **cobas** e pack **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the cobas e pack

unopened at 2-8 °C	up to the stated expiration date
on the **cobas** e 801 analytical unit	16 weeks

Stability of the calibrators

unopened at 2-8 °C	up to the stated expiration date
on the **cobas** e 801 analytical unit at 20-25 °C	use only once, stable onboard for up to 5 hours

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the lid of the vials.

Calibration

Calibration frequency: Calibration must be performed once per reagent lot using CHAGB Cal1, CHAGB Cal2, and fresh reagent (i.e., not more than 24 hours after the **cobas** e pack was registered on the analytical unit).

Recalibration is required as follows:

- every 12 weeks when using the same reagent lot
- every 28 days when using the same **cobas** e pack on the analytical unit
- as required, such as when quality control findings are outside the defined limits

Quality control

For quality control, use PreciControl Chagas.

Controls for the various concentration ranges must be run individually at least once every 24 hours when the test is in use, once per **cobas** e pack, and following each calibration.

PreciControl Chagas values must be within the ranges specified in the control value sheet.

When the assay control values are within range, sample results are generated, and a valid release control result is required to release test results. If an assay control value is not within range, sample results are not generated for in-process or scheduled samples. For troubleshooting information, refer to User Assistance **cobas pro** serology solution or contact US Customer Technical Support.

Release control

For release control, use PreciControl Release Chagas.

Result validation is based on test result batches that are concluded by release control measurements. A release control result within defined limits is required to validate a batch of previously measured test results utilizing the **cobas pro** serology controller software. Initial reactive results will not be invalidated by a failed release control and must be retested in duplicate. Repeatedly reactive results will not be invalidated by a failed release control and stay reactive. Other results rendered invalid due to a failed release control result must be retested after resolving the cause for the failed control measurement.

For a valid batch of sample results, the release control is tested at user-defined intervals with a maximum span of every 300 samples or 350 determinations within 24 hours from the PreciControl and must be tested in order to release the test results. Reactive results will not be invalidated.

The release control must meet specifications defined in the PreciControl Release Chagas value sheet in order to validate the system functionality and release test results.

For troubleshooting information, refer to User Assistance **cobas pro** serology solution or contact US Customer Technical Support.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum and Li-heparin, K2 EDTA, K3 EDTA, CPD and Na-citrate plasma collected using standard sampling tubes.

Serum and Li-heparin and K2 EDTA plasma collected in tubes containing separating gel.

Samples on-the-clot are stable for 7 days at 15-30 °C and 14 days at 2-8 °C. Do not freeze samples on-the-clot.

Samples off-the-clot are stable for 7 days at 20-25 °C, 14 days at 2-8 °C, and 12 months at -20 °C (± 5 °C). Samples off-the-clot may be frozen up to 4 times.

Cadaveric samples off-the-clot are stable for 3 days at 15-30 °C, 14 days at 2-8 °C, and 12 months at -20 °C (± 5 °C). Samples off-the-clot may be frozen up to 5 times.

All whole-blood samples and samples containing precipitates need to be centrifuged before performing the assay for 10 to 15 minutes at 2000 to 4000 RCF (relative centrifugal force = x g).

The sample types listed were tested with a selection of sample collection tubes or systems that were commercially available at the time of testing. Not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials that could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube / collection system manufacturer.

Do not use pools of samples.

Do not use heat-inactivated samples.

Do not use samples and controls stabilized with azide.

The performance of the Elecsys Chagas assay has not been established with body fluids other than serum and plasma or with cadaveric plasma specimens.

Sample stability claims were established by experimental data by the manufacturer only for the temperatures/time frames as stated in the method sheet.

Test procedure

The reagents (M, R1, R2) in the kit are ready for use and are supplied in **cobas** e packs.

For optimum performance of the assay follow the directions given in this document for the analytical unit concerned. Refer to the appropriate user guide for analytical unit-specific assay instructions.

Resuspension of the microparticles takes place automatically prior to use.

Place the cooled (stored at 2-8 °C) **cobas** e pack on the reagent manager.

Avoid foam formation.

The system automatically regulates the temperature of the reagents and the opening/closing of the **cobas** e pack.

Calibrators

The calibrators are supplied ready-for-use in vials compatible with the system.

Place the calibrators in the sample zone.

Read in all the information necessary for calibrating the assay.

Perform **only 1** calibration procedure per vial.

All information required for correct operation is available via **cobas** link.

Calculation

The analytical unit automatically calculates the cutoff based on the measurement of CHAGB Cal1 and CHAGB Cal2.

The result of a sample is given either as reactive or non-reactive as well as in the form of a cutoff index (signal sample/cutoff).

Interpretation of results

Initial result

Numeric result	Result	Interpretation/further steps
COI < 1.00	Non-reactive	Non-reactive for *T. cruzi*-specific antibodies. No further testing needed.
COI ≥ 1.00	Reactive	Reactive in the Elecsys Chagas assay. All initially reactive samples should be retested in duplicate with the Elecsys Chagas assay. Redetermination of samples with an initial COI ≥ 1.00 can be performed automatically (see section **cobas** e flow).

Final result

Numeric result	Final Result	Interpretation/further steps
One or both of the duplicate retests have a COI ≥ 1.00	Repeatedly reactive	Repeatedly reactive samples must be confirmed according to supplementary algorithms.
Both of the duplicate retests have a COI < 1.00	Non-reactive	Non-reactive for *T. cruzi*-specific antibodies. No further testing needed.

cobas e flow

A **cobas** e flow is a procedure programmed into the system to enable a fully automated sequence of measurements and the calculation of assay combinations to perform decision algorithms.

A **cobas** e flow is available to perform a repetition of measurements in duplicate automatically for samples with an initial cutoff index ≥ 1.00 (CHAGBR).

Limitations of the test

A non-reactive test result does not completely rule out the possibility of an infection with *T. cruzi*. Serum or plasma samples from the very early (pre-seroconversion) phase or the late phase of *T. cruzi* infection can occasionally yield non-reactive findings. New *T. cruzi* variants may also lead to non-reactive Chagas results.

The detection of *T. cruzi* antibodies is not a diagnosis of Chagas.

It is recommended that repeatedly reactive specimens are confirmed by supplemental testing. Individuals who are repeatedly reactive should be referred for medical evaluation which may include additional testing.

The performance of the Elecsys Chagas assay has not been established with body fluids other than serum and plasma or with cadaveric plasma specimens.

Testing of cadaveric serum specimens from patients with plasma dilution due to transfusions of > 2000 mL of blood or colloids within 48 hours, or > 2000 mL of crystalloids within 1 hour (or any combination thereof) prior to collection of the specimens has not been verified.

Specific performance data

Representative performance data is given below. Results obtained in individual laboratories may differ.

Precision

A study was performed based on guidance from CLSI EP05-A3 (n = 84). Testing was conducted at 1 site using 1 lot of the Elecsys Chagas assay and 1 lot of PreciControl Chagas. Panel members and controls were tested in 4 replicates, 1 run per day for 21 days, for a total of 84 data points. The following results were obtained:

Overall precision for Elecsys Chagas

Sample	Mean (COI)	Repeatability SD (COI)	Repeatability % CV	Within-laboratory SD (COI)	Within-laboratory % CV
Human specimen 01	0.093	0.001	1.4	0.001	1.5
Human specimen 02	1.15	0.023	2.0	0.039	3.4
Human specimen 03	2.67	0.052	1.9	0.096	3.6
Human specimen 04	7.90	0.130	1.6	0.261	3.3

Sample	Mean (COI)	Repeatability SD (COI)	Repeatability % CV	Within-laboratory SD (COI)	Within-laboratory % CV
Human specimen 05	0.768	0.010	1.3	0.023	3.1
PreciControl CHAG1 B	0.102	0.001	1.2	0.002	1.7
PreciControl CHAG2 B	4.03	0.037	0.9	0.121	3.0

Reproducibility

A study was performed based on guidance from CLSI EP05-A3 (n = 270). Testing was conducted at 3 external sites using 3 lots of the Elecsys Chagas reagent kit and 3 lots each of PreciControl Chagas and PreciControl Release Chagas. Panel members and controls were tested in 2 runs per day for 5 days with 3 sample replicates per run. The results for Elecsys Chagas are presented in the following tables.

Overall repeatability and reproducibility for Elecsys Chagas

Sample	Mean (COI)	Repeatability SD (COI)	Repeatability % CV	Between run SD (COI)	Between run % CV	Between day SD (COI)	Between day % CV
High *T. cruzi* antibody	10.1	0.179	1.77	0.116	1.15	0.089	0.885
Low *T. cruzi* antibody	1.86	0.027	1.42	0.017	0.896	0.016	0.841
PC[A)] CHAG1 B	0.111	0.002	1.59	0.001	1.19	0.003	2.34
PC CHAG2 B	3.84	0.069	1.80	0.088	2.30	0.037	0.952

A) PC = PreciControl

Overall repeatability and reproducibility for Elecsys Chagas

Sample	Mean (COI)	Intermediate precision SD (COI)	Intermediate precision % CV	Between site SD (COI)	Between site % CV	Between lot SD (COI)	Between lot % CV	Reproducibility SD (COI)	Reproducibility % CV
High *T. cruzi* antibody	10.1	0.231	2.29	0.035	0.345	0.348	3.45	0.419	4.15
Low *T. cruzi* antibody	1.86	0.035	1.88	0.012	0.639	0.028	1.51	0.047	2.50
PC[A)] CHAG1 B	0.111	0.003	3.07	0.001	1.31	0.006	5.10	0.007	6.09
PC CHAG2 B	3.84	0.118	3.07	0.000	0.000	0.090	2.36	0.149	3.87

A) PC = PreciControl

Results: The precision and reproducibility of the Elecsys Chagas assay demonstrated minor variability from run to run, day to day, and between reagent lots.

Analytical specificity

The effect of the following endogenous substances on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

Endogenous substances

Compound	Concentration tested
Bilirubin	≤ 753 µmol/L or ≤ 44 mg/dL
Hemoglobin	≤ 0.311 mmol/L or ≤ 500 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 4912 nmol/L or ≤ 1200 ng/mL
Albumin	≤ 7.0 g/dL

Additionally, naturally elevated samples for bilirubin, rheumatoid factor, triglycerides (lipemic), hemoglobin and albumin were tested; no false reactive results were found.

No false non-reactive result due to high-dose hook effect was found with the Elecsys Chagas assay.

In rare cases, interference due to extremely high titers of antibodies to immunological components, streptavidin or ruthenium can occur and these effects are minimized by assay formulation and design.

Clinical specificity

A total of 3754 fresh serum specimens and 3824 fresh plasma specimens from volunteer whole blood donors were collected at 3 blood centers. The specimens were collected from donors that had not been screened on a previous donation using an FDA-licensed test for antibodies to *T. cruzi* (i.e., first time donors).

The initial and repeat reactive rates for the serum specimens were 0.05 % (2/3754). The initial and repeat reactive rates for the plasma specimens were 0.00 % (0/3824).

Specificity based on assumed zero prevalence of antibody to *T. cruzi* in whole blood donors was estimated in this study to be 99.97 % (7576/7578) with a 95 % confidence interval of 99.90 % to 99.99 %.

Specificity of Elecsys Chagas

Specimen category	Number tested	Number initially reactive (% of tested)	Number repeatedly reactive (% of tested)	Number positive by supplemental testing (% of repeatedly reactive)	Specificity (%) (95 % CI)
Volunteer blood donors - serum	3754	2 (0.05)	2 (0.05)	0 (0.00)	99.95 3752/3754 (99.81, 99.99)
Volunteer blood donors - plasma	3824	0 (0.00)	0 (0.00)	0 (0.00)	100.00 3824/3824 (99.90, 100)
Total donors	7578	2 (0.03)	2 (0.03)	0 (0.00)	99.97 7576/7578 (99.90, 99.99)

Clinical sensitivity

A total of 371 confirmed positive specimens from the categories shown in the table below were tested using the Elecsys Chagas assay at 3 clinical sites.

Sensitivity was estimated to be 100 % (371/371) with a 95 % confidence interval of 98.98 % to 100 % for preselected positive specimens.

Reactivity of the Elecsys Chagas assay in individuals known to be positive for anti-*T. cruzi* antibodies

Specimen category	Number tested	Number positive	Number repeatedly reactive (% of tested)	Number repeatedly reactive that were positive (% of repeatedly reactive)	Sensitivity (%) (95 % CI)
T. cruzi PCR Positive	102	102	102 (100)	102 (100)	100 102/102 (96.37, 100)
T. cruzi Serology Positive	269	269	269 (100)	269 (100)	100 269/269 (98.59, 100)
Total	371	371	371 (100)	371 (100)	100 371/371 (98.98, 100)

An additional 912 specimens from Chagas endemic areas were tested using the Elecsys Chagas assay at 3 clinical sites.

Reactivity of the Elecsys Chagas assay in individuals from Chagas endemic areas

Sample group	Number tested initial draw	Initially reactive (% of tested)	Repeatedly reactive (% of tested)	Confirmed positive (n) (% of repeatedly reactive)
Individuals from endemic areas - multiple countries[A)]	802	268 (33.42)	268 (33.42)	267[B)] (99.63)
Individuals from endemic areas - Mexico	110	0 (0.00)	0 (0.00)	0 (0.00)
Total	912	268 (29.39)	268 (29.39)	267 (99.63)

A) Individuals from Chagas endemic areas included specimens from the following areas: El Salvador (200), Argentina (72), Uruguay (158), Paraguay (125), Bolivia (96), and Chile (151).

B) 2 specimens were repeat reactive on the comparator test and non-reactive on Elecsys Chagas assay, 1 sample was confirmed reactive, and 1 sample had an inconclusive status.

Other specimen conditions or disease states

230 samples containing potentially interfering substances were tested with the Elecsys Chagas assay comprising specimens:

- containing antibodies against HIV, HBV, HCV, HTLV-I/II, CMV, HSV IgG / IgM, and Dengue
- containing autoantibodies (ANA) and elevated titers of rheumatoid factor
- containing antibodies against *Candida*, *Escherichia coli*, *Chlamydia*, *Treponema pallidum* (syphilis), *Plasmodium*, *Toxoplasma gondii*, and *Leishmania*
- after vaccination against influenza
- containing heterophilic (EBV) or human anti-mouse antibodies (HAMA)
- for hyper-IgG / IgM interference
- from pregnant women and multiparous pregnancies

Results showed no interference from the above agents.

Performance characteristics of cadaveric specimen testing

Storage

Performance has been established for the use of cadaveric serum specimens (including specimens collected post-mortem, non-heart-beating) that have been collected up to 24 hours after death.[10] Follow general standards and/or regulations for collection, storage, and handling.

If specimens are not processed directly after initial centrifugation, it is recommended to remove the supernatant from the clot, red blood cells, or separator gel until further processing.

Cadaveric samples off-the-clot are stable for 3 days at 15-30 °C, 14 days at 2-8 °C and 12 months at -20 °C (± 5 °C). Samples off-the-clot may be frozen up to 5 times.

Specimen category	Storage at 15-30 °C 3 days Recovery vs. t=0	Storage at 2-8 °C 14 days Recovery vs. t=0	Storage at -20 °C (± 5 °C) 12 months Recovery vs. t=0	Freeze/Thaw 5 cycles Recovery vs. t=0
Cadaveric non-reactive [mean Δ COI]	0.0071	0.0004	0.0124	0.0011
Cadaveric reactive [mean % recovery]	99.1	99.6	97.0	94.2

Reproducibility

20 cadaveric donor serum specimens and 20 living donor serum specimens were spiked with human plasma reactive for antibodies to *T. cruzi* to create low-level reactive specimens. Each specimen was tested once per day for 6 days using 3 lots of the Elecsys Chagas assay. Reproducibility in % CV of each specimen category was determined.

Overall reproducibility for Elecsys Chagas

Specimen category[A)]	Number tested	Mean (COI)	Reproducibility SD (COI)	Reproducibility % CV
Cadaveric donor	360	2.06	0.158	7.64
Living donor	360	2.09	0.0845	4.05

A) Cadaveric serum specimens were collected up to 1 hour after death

Clinical specificity

Specificity was determined by testing 55 cadaveric serum specimens and 55 living donor serum specimens. Each specimen was tested once using 3 lots of the Elecsys Chagas assay.

Specificity of Elecsys Chagas

Specimen category[A)]	Number tested	Number non-reactive (% of tested)	Number repeatedly reactive (% of tested)	Specificity (%) (95 % CI)
Cadaveric donor - Lot 1	55	55 (100)	0 (0.00)	100 (93.47, 100)
Cadaveric donor - Lot 2	55	55 (100)	0 (0.00)	100 (93.47, 100)
Cadaveric donor - Lot 3	55	55 (100)	0 (0.00)	100 (93.47, 100)

Specimen category[A)]	Number tested	Number non-reactive (% of tested)	Number repeatedly reactive (% of tested)	Specificity (%) (95 % CI)
Living donor - Lot 1	55	55 (100)	0 (0.00)	100 (93.47, 100)
Living donor - Lot 2	55	55 (100)	0 (0.00)	100 (93.47, 100)
Living donor - Lot 3	55	55 (100)	0 (0.00)	100 (93.47, 100)

A) Cadaveric serum specimens were collected up to 24 hours after death

Analytical sensitivity

Cadaveric serum specimens and living donor serum specimens were spiked with human plasma reactive for antibodies to *T. cruzi* to create low-level reactive specimens. Each specimen was tested once using each of 3 lots of the Elecsys Chagas assay. All specimens were reactive on all 3 reagent lots.

Sensitivity of Elecsys Chagas

Specimen category[A)]	Number tested	Mean (COI)	Number positive (% of tested)	Sensitivity (%) (95 % CI)
Cadaveric donor - Lot 1	55	2.08	55 (100)	100 (93.47, 100)
Cadaveric donor - Lot 2	55	2.12	55 (100)	100 (93.47, 100)
Cadaveric donor - Lot 3	55	2.16	55 (100)	100 (93.47, 100)
Living donor - Lot 1	55	2.13	55 (100)	100 (93.47, 100)
Living donor - Lot 2	55	2.15	55 (100)	100 (93.47, 100)
Living donor - Lot 3	55	2.20	55 (100)	100 (93.47, 100)

A) Cadaveric serum specimens were collected up to 24 hours after death

Additional information

For further information, refer to the User Guide for the corresponding analytical unit and to the Method Sheets of all necessary components (if available in your country).

Report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

Symbols

For definition of symbols used, refer to navifyportal.roche.com.

In addition to the ISO 15223-1 standard, Roche Diagnostics uses the following symbols and signs:

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Elecsys Chagas

cobas®

References

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Change log

Due to technical reasons, changes that have been made since the last version of this document are listed in the following table instead of indicated by change bars in the margin.

Document Revision Information

Doc. Rev. 4.0 (Method sheet available on FDA website only)	Cadaveric claims were added to the following new and existing sections: Intended use, Specimen collection and preparation, Limitations of the test, Performance characteristics of cadaveric specimen testing, and References Rounding corrections were made to the following entries in the Mean (COI) column of the Precision table: HSP 02, HSP 03, HSP 04, and PC CHAG B Missing entry for "percent of repeatedly reactive" was added to “Volunteer blood donors – plasma” in the Specificity of Elecsys Chagas table
Doc. Rev. 5.0 (Current version of method sheet)	Several editorial and layout updates were made