04/13/2026

Roche Diagnostics
Alyssa Agana
Regulatory Affairs Manager
9115 Hague Rd
Indianapolis, Indiana 46256

Re: K252280
Trade/Device Name: Elecsys Anti-SARS-CoV-2 S
Regulation Number: 21 CFR 866.3983
Regulation Name: SARS-Cov-2 Serology Test
Regulatory Class: Class II
Product Code: QVP
Dated: July 22, 2025
Received: July 22, 2025

Dear Alyssa Agana:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JORGE L. MUNOZ -S

Digitally signed by JORGE L. MUNOZ -S
Date: 2026.04.13 08:11:38 -04'00'

Jorge Munoz
Deputy Branch Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252280

Device Name
Elecsys Anti-SARS-CoV-2 S

Indications for Use *(Describe)*
Elecsys Anti-SARS-CoV-2 S is an electrochemiluminescence immunoassay intended for quantitative detection of total antibodies to SARS-CoV-2 in human serum and plasma (lithium heparin, K2-EDTA, K3-EDTA, and sodium citrate) samples collected on or after 15 days post-symptom onset. The Elecsys Anti-SARS-CoV-2 S assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay 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.

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Elecsys Anti-SARS-CoV-2 S
510(k) Summary (k252280)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Name	Roche Diagnostics
Address	9115 Hague Rd Indianapolis, IN 46256
Contact	Alyssa Agana Phone: (760) 978-2351 Email: alyssa.agana@roche.com
Date Prepared	August 15, 2025
Proprietary Name	Elecsys Anti-SARS-CoV-2 S
Common Name	SARS-CoV-2 serology test
Classification Name	SARS-CoV-2 serology test
Regulation Number	866.3983
Product Codes	QVP JJX (for optional CalCheck Anti-SARS-CoV-2 S)
Predicate Device	DEN210040: VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack, VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator

1. DEVICE DESCRIPTION

Elecsys Anti-SARS-CoV-2 S test system includes Elecsys Anti-SARS-CoV-2 S assay, calibrators known as CalSet Anti-SARS-CoV-2 S, and the quality control material, PreciControl Anti-SARS-CoV-2 S.

Elecsys Anti-SARS-CoV-2 S is a quantitative, serological, double-antigen sandwich principle immunoassay to be used on the **cobas e** immunoassay family of analyzers with an 18-minute test time.

Test Principle:

- 1st incubation: 12 µL of sample are incubated with biotinylated SARS-CoV-2 specific recombinant antigen and SARS-CoV-2 specific recombinant antigen labeled with a ruthenium complex to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, 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/ProCell M/ProCell II M. 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 barcode or e barcode.

CalSet Anti-SARS-CoV-2 S: Two levels of calibrator used for calibrating the Elecsys Anti SARS CoV 2 S assay on **cobas e** immunoassay analyzers.

PreciControl Anti-SARS-CoV-2: Used for quality control of the Elecsys Anti-SARS-CoV-2 S immunoassay on the **cobas e** immunoassay analyzers. There are two levels of controls, reactive and non-reactive, based on human serum.

CalCheck Anti-SARS-CoV-2 S: Optional assayed control material (5 lyophilized levels) for use in calibration verification. Customer convenience material available in instances where calibration verification is required by certification agencies, or where the user wishes to document calibration verification.

2. INTENDED USE

Elecsys Anti-SARS-CoV-2 S is an electrochemiluminescence immunoassay intended for quantitative detection of total antibodies to SARS-CoV-2 in human serum and plasma (lithium heparin, K_2-EDTA, K_3-EDTA, and sodium citrate) samples collected on or after 15 days post-symptom onset. The Elecsys Anti-SARS-CoV-2 S assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

3. INDICATIONS FOR USE COMPARISON

The electrochemiluminescent immunoassay, Elecsys Anti-SARS-CoV-2 S, is substantially equivalent to the chemiluminescent immunoassay, VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack / VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Calibrator. Both test systems are for the detection of antibodies to SARS-CoV-2 in human serum and plasma samples collected on or after 15 days post-symptom onset. This VITROS predicate was used as part of a composite comparator method used in the clinical study. The data for Elecys Anti-SARS-CoV-2 S immunoassay shows equal to or better than the claimed performance for VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack / VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Calibrator.

4. TECHNOLOGICAL COMPARISON

The immunoassays have similar technological characteristics (chemiluminescent and electrochemiluminescence). Both devices involve binding and washing steps and measurement of light or chemiluminescent signals. Both devices require calibrators.

5. NON-CLINICAL PERFORMANCE EVALUATION

All studies were conducted on the **cobas e** 801 analyzer with the Elecsys Anti-SARS-CoV-2 S immunoassay.

Within-Laboratory Precision: A within-laboratory precision study was performed using 2 lots of the Elecsys Anti-SARS-CoV-2 S reagent packs, 2 lots of the CalSet Anti-SARS-CoV-2 S

calibrators, and one **cobas e** 801 analyzer. One PreciControl PC ACOV2S2 (Positive Control, PC) and 6 human serum pools were tested in 3 replicates 2 separate times per day on 5 days using 4 reagent pack lot/calibrator lot combinations. The within-laboratory precision data are summarized below.

Elecsys Anti-SARS-CoV-2 S assay Within-Laboratory Precision

Sample	Mean (BAU/mL)	N	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Calibrator Lot		Between-Reagent Lot		Overall, Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	% CV	SD	%CV	SD	%CV
1	0.708	120	0.0141	1.99	0.00752	1.06	0.0018	0.255	0.00274	0.387	0.0214	3.02	0.0269	3.8
2	0.904	120	0.012	1.33	0.0147	1.62	0	0	0.00207	0.229	0.00421	0.466	0.0195	2.16
3	13.2	120	0.106	0.805	0.0832	0.63	0.0877	0.663	0	0	0.199	1.51	0.256	1.94
4	122	120	1.17	0.958	0	0	0.765	0.628	0	0	0.357	0.293	1.44	1.18
5	206	120	1.50	0.731	0.558	0.272	1.31	0.64	0	0	0	0	2.07	1.01
6	231	120	2.29	0.988	1.41	0.611	0.372	0.161	0	0	2.60	1.13	3.76	1.63
PC	9.16	120	0.078	0.852	0.0959	1.05	0.0463	0.506	0	0	0.0347	0.347	0.136	1.48

Reproducibility: Reproducibility was assessed according to CLSI EP05-A3 with 1 lot of Elecsys Anti-SARS-CoV-2 and PreciControl Anti-SARS-CoV-2 S tested at 3 test sites, in 2 runs per day, 3 replicates per run, for 5 days for a minimum of 90 measurements per sample. The CV% ranges are as follows:

Elecsys Anti-SARS-CoV-2 S assay Reproducibility

Sample	Mean (BAU/mL)	N	Repeatability		Between-Run		Between-Day		Between-Site		Reproducibility	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
1	0.727	90	0.0441	6.06	0	0	0	0	0	0	0.0441	6.06
2	0.913	90	0.0152	1.67	0.00333	0.364	0.00844	0.924	0.0102	1.12	0.0205	2.24
3	13.1	90	0.14	1.06	0.0578	0.441	0.0696	0.531	0.101	0.769	0.194	1.48
4	123	90	1.43	1.16	0.741	0.6	0.678	0.549	1.01	0.82	2.02	1.63
5	207	90	2.06	0.992	1.13	0.544	1.23	0.591	1.9	0.918	3.26	1.57
6	235	90	2.43	1.03	1.35	0.574	1.2	0.511	1.75	0.743	3.5	1.49
PC	9.23	90	0.11	1.19	0.0643	0.696	0.072	0.78	0.0165	0.179	0.147	1.59

Linearity: Linearity was assessed according CLSI EP06, 2nd Ed. 3 serum and 3 plasma (sodium citrate) samples containing high levels of SARS-CoV-2 antibodies were diluted with negative

sample to prepare a dilution series comprised of 15 levels. Each level had 4 replicates. For serum samples, linearity was demonstrated for the interval of 0.22 BAU/mL to 287 BAU/mL with deviations from linearity within 15 %. For plasma samples, linearity was demonstrated for the interval of 0.22 BAU/mL to 303 BAU/mL with deviations from linearity within 15 %. Taking into consideration the estimates of Limit of Blank, Limit of Detection, Limit of Quantitation, precision, and linearity, the analytical measuring interval is 0.40 BAU/mL to 250 BAU/mL.

Detection Limits: The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI EP17-A2 requirements.

The Limit of Blank corresponds to the highest measurement result that is likely to be observed for analyte-free samples with a probability of 95 %. The Limit of Blank was estimated as the 95th percentile value from $n \geq 60$ measurements of analyte-free samples over several independent series. The Limit of Blank is 0.30 BAU/mL.

The Limit of Detection is the lowest concentration of antibodies to SARS-CoV-2 in a sample that can be detected with a probability of 95 %. The Limit of Detection was calculated based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection is 0.35 BAU/mL.

The Limit of Quantitation is defined as the lowest amount of analyte in a sample that can be accurately quantified with a $CV \leq 20$ %. It has been determined using low concentration of anti-SARS-CoV-2-S samples. The Limit of Quantitation is 0.40 BAU/mL.

INTERFERENCES:

Hook Effect: Four plasma samples with a high titer for anti-SARS-CoV-2 spike antibodies were each serially diluted with an anti-SARS-COV-2 antibody negative plasma sample to a 12 member dilution series. Dilution steps were tested in duplicate with one lot of the Elecsys Anti-SARS-COV-2 S assay on analyzer. The mean count results for each dilution were calculated. No false negative results due to a high-dose hook effect were found with the Elecsys Anti-SARS-CoV-2 S assay but occurrence of high-dose hook effect cannot be completely excluded.

Endogenous Substances: The recovery of analyte values in the presence of potentially interfering substances using the Elecsys Anti-SARS-CoV-2 S assay was determined on the analyzer, with

one lot of reagent. A dilution series was prepared starting by diluting samples spiked with the potentially interfering substance, with the exception of Anti-Nuclear Antibodies (ANA), where the high ANA concentrations were tested without titration. The recovery for each sample was calculated by comparison to the reference (unspiked) sample. Each substance was tested up to the listed concentrations and no interference was observed:

- Bilirubin: 1129 µmol/L or 66 mg/dL
- Hemoglobin: 1000 mg/dL or 10 g/L
- Intralipid: 2000 mg/dL
- Cholesterol: 400 mg/dL
- Triglycerides: 2000 mg/dL
- Biotin: 4912 nmol/L or 1200 ng/mL
- Rheumatoid factors: 1200 IU/mL
- IgG: 7.0 g/dL or 70 g/L
- IgA: 1.6 g/dL or 16 mg/mL
- IgM: 1.0 g/dL or 10 mg/mL
- Anti-Nuclear Antibodies (ANA): 1:1280

Exogenous Interference (special drugs): Drug interferences are measured based on recommendations given in CLSI guidelines EP07 and EP37 and other published literature. 17 common drugs were tested at 3x the daily dose and no interference with the assay was found, except for Itraconazole. Itraconazole was then tested at 1.5x the daily dose and within acceptance criteria. 17 special drugs were tested and no interference with the assay was found.

Analytical Specificity – Potential Cross-reactivity: A study was conducted to assess the influence of potentially cross-reacting antibodies to pathogens other than SARS-CoV-2 or autoimmune disorders on the performance of the assay.

1582 human samples, negative for anti-SARS-CoV-2 (collected before October 2019) but containing potentially cross-reacting antibodies to pathogens other than SARS-CoV-2 and autoimmune disorders were tested in single determination. All results were non-reactive except for one sample out of 15 containing Metapneumovirus that had a false positive result.

Reagent, Calibrator, and Control Stability: The assay can be stored on the analyzer for up to 16 weeks. To establish stability, a freshly opened **cobas e** pack was placed on the analyzer and calibrated with CalSet Anti-SARS-CoV-2 S. Human samples were tested in duplicate with one lot of reagent. Multiple timepoints were tested and were within specification to support a 16 week onboard the analyzer.

Lot calibration stability was tested by placing a fresh **cobas e** pack. The pack was calibrated on the analyzer. Samples were tested in duplicate determinations. Aliquots of the samples were then tested at multiple timepoints using the initial calibration to demonstrate the stability of the calibration. Recovery or deviation of the mean of each sample was calculated based on the mean of the samples after initial calibration. Data was within specifications to support calibration stability of 42 days when using the same reagent lot on the **cobas e** 801 analyzer.

On-board calibration stability was tested using one lot of the assay. The **cobas e** pack was freshly opened and calibrated with CalSet Anti-SARS-CoV-2 S on the analyzer. Samples were measured in duplicate. At multiple timepoints, aliquots of the same samples were tested with the same **cobas e** pack that was kept under on-board storage conditions. Samples were measured in duplicate using the initial calibration. Recovery and deviation of each sample was calculated on the mean of the samples after initial calibration. Data was within the specifications and support a 14 day calibration stability when the same **cobas e** pack is stored on the analyzer.

CalSet Anti-SARS-CoV-2 S stability was tested at 2-8 °C and at -20 °C once reconstituted. The calibrators were allowed to stand closed for 15 minutes per the method sheet instructions, stored as indicated and then tested (n=4 determinations each) at various time points. Results were compared to a reference signal of an unstressed calibrator measured in the same run. Median of signal was calculated and calibrator stability was determined by calculation of the recovery of the calibrator signals of stressed calibrators compared to the unstressed calibrator. The data met specifications for a claim of 14 days at 2-8 °C and 3 months at -20 °C.

PreciControl on-board stability of one lot was assessed by storing control level 1 and 2 vials at 20-25 °C for several hours (stressed). The stressed material was measured on the analyzer in the same run with unstressed (stored at 2-8°C) in four replicates. Recovery was calculated based on the result for the unstressed PreciControls. Data was within specification and support a 4 hour storage at 20-25°C.

PreciControl Anti-SARS-CoV-2 S was assessed for stability after first opening and supports a claim of 8 weeks at 2-8 °C. The study was conducted by testing the controls after initial opening,

then storing at 2-8 °C and testing the same control vial at later timepoints. The results of the opened control vials were compared to an unstressed (newly opened) control vial; the results were within specifications.

PreciControl Anti-SARS-CoV-2 S stability after first opening with a -20 °C storage condition was also tested and supports the claim of 3 months. One lot was assessed by storing control vials at -25° to -15°C for several months (stressed). The stressed material was measured on the **cobas e** 801 immunoassay analyzer in the same run with unstressed control levels 1 and 2 in four replicates. Recovery was calculated based on the result for the unstressed PreciControls and met specifications.

Specimen Stability: Sample stability was assessed at 15 -25 °C. Samples for each serum and plasma (Li-heparin, K2-EDTA, and Na-citrate) were initially tested, then stored at 15 -25 °C, followed by testing at multiple timepoints. Each sample had 5 determinations at each timepoint. Recovery or deviation of the mean of each sample was calculated based on the mean of the sample results at the initial timepoint. The data was within specifications and supports a claim of 14 days at 15 – 25 °C. In addition, the same experiment was conducted with samples at 2 - 8 °C and supports a claim of 14 days at 2 - 8 °C.

Frozen sample stability was assessed by conducting initial testing of the samples followed by freezing at -20°C (± 5°C), then retesting. Each serum and plasma (Li-heparin, K2-EDTA, and Na-citrate) sample was measured in five determinations. Recovery or deviation of the mean of each sample was calculated based on the mean of the samples at the initial timepoint. Results are within specification and support storage of samples for 3 months at - 20°C (± 5 °C).

The number of times a samples can be frozen was studied by testing serum samples at the initial timepoint, then freezing and thawing multiple times. The serum and plasma (Li-heparin, K2-EDTA, and Na-citrate) samples were tested in triplicate at each timepoint and the recovery or deviation of the mean of each sample was calculated based on the mean of the samples at the initial timepoint. Data supports that samples can be frozen 3 times.

A fresh/frozen study was conducted to show that the results of samples for Elecsys Anti-SARS-COV-2 S are comparable if they had been frozen or measured directly after blood draw (fresh). In total, 100 serum and plasma samples were measured on one analyzer. All results were within specification.

Dilution: Studies were conducted on the first WHO International Standard Anti-SARS-CoV-2 immunoglobulin (human) 20/136, to support manual dilution. Samples were run in triplicate on one analyzer, across 3 runs. Specifications were fulfilled with recovery rates of 90-112% demonstrated across a range of 0.616-8.84 BAU/mL.

Studies to assess diluting 1:30 and 1: 400 were also conducted to support diluting samples above the assay measuring range with Diluent Universal. 4 samples (two serum and two sodium citrate plasma) were diluted manually, as well as automatically on the analyzer, then tested in a four fold determination with one reagent lot and by two operators. The manual and automated dilution studies passed specification.

Correct recovery of target values of reference material was observed with 1:30 and 1:400 dilution. Linear Concentration recovery was confirmed for the extended measuring range.

Matrix Comparison: The effect on detection of the analyte in the presence of anticoagulants for the Elecsys Anti-SARS-CoV-2 S assay was determined on the analyzer by comparing values obtained from samples drawn into serum and plasma collection tubes (Li-heparin, K_2-EDTA, K_3-EDTA, Na-citrate). Serum/plasma pairs were tested for each kind of anticoagulant in single determination with one lot of the Elecsys Anti-SARS-CoV-2 S assay. The results were within specification and support the use of serum and plasma (Li-heparin, K_2-EDTA, K_3-EDTA, Na-citrate) with the assay.

Additionally, sample pairs from at least six donors drawn in serum or plasma tubes and in serum or plasma separation tubes (containing separation gel) from three different manufacturers were compared. Measurements were performed on the analyzer in duplicate with one reagent lot and evaluated on the basis of deviation/recovery relative to the reference tube without separating gel. The data support the usage of Elecsys Anti-SARS-CoV-2 S with serum tubes containing separating gel and Li-Heparin and EDTA plasma tubes containing separating gel.

6. CLINICAL PERFORMANCE EVALUATION

Negative Percent Agreement: 3612 samples obtained before October 2019 were tested internally with the Elecsys Anti-SARS-CoV-2 S assay. One false positive sample was detected resulting in a Negative Percent Agreement (NPA) of 99.97 % with a lower 95 % confidence limit of 99.84%.

Positive Percent Agreement: The positive percent agreement of Elecsys Anti-SARS-CoV-2 S was evaluated in a clinical performance evaluation study in which results were obtained under routine laboratory conditions and compared to the results of a composite comparator method comprised of 3 anti-SARS-CoV-2 serology assays. Blood samples were collected in the United States between April and August of 2020. SARS-CoV-2 seropositivity was determined by majority rule (≥ 2 out of 3) of FDA de novo and Emergency Use Authorized (EUA) anti-SARS-CoV-2 serology assays. Sensitivity of Elecsys Anti-SARS-CoV-2 relative to the composite comparator was established using specimens collected from individuals with a history of SARS-CoV-2 infection and calculated and reported as positive percent agreement (PPA). Serum and plasma samples were tested at 2 clinical laboratories on the **cobas e** 801 analyzer. Due to clinical relevance, the performance of the Elecsys Anti-SARS-CoV-2 S immunoassay was determined by the results from samples collected ≥ 15 days post symptom onset (DPSO) (excluding data from immunocompromised subjects). Of 118 tested specimens collected ≥ 15 DPSO, 116 were reactive with the Elecsys Anti-SARS-CoV-2 S assay and the comparator, demonstrating a PPA of 100 % (95% CI 96.79 – 100 %).

NPA was evaluated in 2 separate studies:

(1) With samples presumed negative for SARS-CoV-2 antibodies: 3612 specimens collected prior to October 2019 and presumed SARS-CoV-2 antibody negative. One out of 3612 had a false positive with the candidate test. The resulting negative percent agreement (NPA) in this study was 99.97 %. The lower 95 % confidence limit was 99.84 %.

(2) With samples evaluated with the composite comparator method: 490 serum and plasma samples collected inside the US prior to the COVID-19 pandemic with candidate test results compared to the composite comparator method. Out of the 490 samples, one sample was reactive based on the composite comparator method; 489 samples were non-reactive. The NPA for specimens from subjects with no prior infection was 100% with a 95% CI of 99.22-100%.

7. CONCLUSIONS

The analytical and clinical performance observed demonstrate that the Elecsys Anti-SARS-CoV-2 S assay is substantially equivalent to the predicate.