12/17/2025

Roche Diagnostics
Kelly Brennan
Regulatory Affairs Manager
9115 Hague Rd.
Indianapolis, Indiana 46256

Re: K253839
Trade/Device Name: Elecsys Anti-SARS-CoV-2
Regulation Number: 21 CFR 866.3983
Regulation Name: SARS-Cov-2 Serology Test
Regulatory Class: Class II
Product Code: QVP
Dated: December 1, 2025
Received: December 1, 2025

Dear Kelly Brennan:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 2025.12.17 09:59:27 -04'00'

Jorge L. Munoz, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253839

Device Name
Elecsys Anti-SARS-CoV-2

Indications for Use *(Describe)*
Elecsys Anti-SARS-CoV-2 is an immunoassay intended for the in vitro qualitative detection of total antibodies to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum and Li-heparin, K2-EDTA and K3-EDTA plasma collected on or after 15 days post-symptom onset. The test is intended 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 601 immunoassay analyzer.

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
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"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."

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

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	Kelly Brennan Phone: (317) 361-9101 Email: kelly.brennan@roche.com
Date Prepared	Dec 01, 2025
Proprietary Name	Elecsys Anti-SARS-CoV-2
Common Name	SARS-CoV-2 serology test
Classification Name	SARS-CoV-2 serology test
Regulation Number	866.3983
Product Codes	QVP
Predicate Device	Elecsys Anti-SARS-CoV-2

1. DEVICE DESCRIPTION

Elecsys Anti-SARS-CoV-2 is a qualitative, serological, double-antigen sandwich principle immunoassay to be used on the **cobas e** 601 analyzer with an 18-minute test time. Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration. The Elecsys Anti-SARS-CoV-2 assay uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARS-CoV-2.

The reagent working solutions include: rackpack (kit placed on the analyzer)

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R1 SARS-CoV-2-Ag~biotin, (gray cap), 1 bottle, 16 mL: Biotinylated SARS-CoV-2-specific recombinant antigen (E. coli) < 0.5 mg/L; HEPES[a]) buffer 50 mmol/L, pH 7.7; preservative.
- R2 SARS-CoV-2 Ag~Ru(bpy) (black cap), 1 bottle, 16 mL: SARS-CoV-2-specific recombinant antigen labeled with ruthenium complex < 0.5 mg/L; HEPES(b) buffer 50 mmol/L, pH 7.7; preservative.

(a) HEPES = [4-(2-hydroxyethyl)-piperazine]-ethane sulfonic acid

The Elecsys Anti-SARS-CoV-2 assay includes two liquid calibrators, which are packed with the test kit:

- ACOV2 Cal1 Negative calibrator 1 (white cap), 2 bottles of 0.67 mL: Human serum, non-reactive for anti-SARS-CoV-2 antibodies; buffer; preservative.
- ACOV2 Cal2 Positive calibrator 2 (black cap), 2 bottles of 0.67 mL: Human serum, reactive for anti-SARS-CoV-2 antibodies; buffer; preservative.

2. INDICATIONS FOR USE

Elecsys Anti-SARS-CoV-2 is an immunoassay intended for the in vitro qualitative detection of total antibodies to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum and Li-heparin, K_2-EDTA and K_3-EDTA plasma collected on or after 15 days post-

symptom onset. The test is intended 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** 601 immunoassay analyzer.

3. TECHNOLOGICAL CHARACTERISTICS

Technical characteristics comparison table between Elecsys Anti-SARS-CoV-2 (K250768) and Elecsys Anti-SARS-CoV-2 (K253839)

Item	Predicate, K250768 (Elecsys Anti-SARS-CoV-2)	Candidate Device, K253839 (Elecsys Anti-SARS-CoV-2)
Proprietary name	Elecsys Anti-SARS-CoV-2	Same
Regulation Number	21 CFR 866.3983	Same
Regulation Name	SARS-CoV-2 serology test	Same
Regulatory Class	II	Same
Product Code	QVP	Same
Intended use	Elecsys Anti-SARS-CoV-2 is an immunoassay intended for the in vitro qualitative detection of total antibodies to Severe Acute Respiratory Coronavirus (SARS-CoV-2) in human serum and Li-heparin, K_2-EDTA and K_3-EDTA plasma collected on or after 15 days post-symptom onset. The test is intended 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 the **cobas e** 601 immunoassay analyzer.	Same
Test Principle	Sandwich principle. Total duration of assay: 18 minutes. • 1st incubation: 20 µL of sample, biotinylated	Same

Item	Predicate, K250768 (Elecsys Anti-SARS-CoV-2)	Candidate Device, K253839 (Elecsys Anti-SARS-CoV-2)
	SARS-CoV-2-specific recombinant antigen and SARS-CoV-2-specific recombinant antigen labeled with a ruthenium complex[a)] 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. 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 reaction product of the sample with the signal of the cutoff value previously obtained by calibration. [a)] Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy))	
Instrument	**cobas e** immunoassay analyzers	Same
Reagent Composition	The reagent rackpack (M, R1, R2) is labeled as ACOV2. • M Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative. • R1 SARS-CoV-2-Ag~biotin, (gray cap), 1 bottle, 16 mL: Biotinylated SARS-CoV-2-specific recombinant antigen (E. coli) <	Same

Item	Predicate, K250768 (Elecsys Anti-SARS-CoV-2)	Candidate Device, K253839 (Elecsys Anti-SARS-CoV-2)
	0.5 mg/L; HEPES[b)] buffer 50 mmol/L, pH 7.7; preservative. • R2 SARS-CoV-2 Ag~Ru(bpy) (black cap), 1 bottle, 16 mL: SARS-CoV-2-specific recombinant antigen labeled with ruthenium complex < 0.5 mg/L; HEPESb) buffer 50 mmol/L, pH 7.7; preservative. [b)] HEPES = [4-(2-hydroxyethyl)-piperazine]-ethane sulfonic acid	
Sample Type/Matrix	Serum, Li-Heparin, K2-EDTA and K3-EDTA	Same
Calibrator	• ACOV2 Cal1 Negative calibrator 1 (white cap), 2 bottles of 0.67 mL: Human serum, non-reactive for anti-SARS-CoV-2 antibodies; buffer; preservative. • ACOV2 Cal2 Positive calibrator 2 (black cap), 2 bottles of 0.67 mL: Human serum, reactive for anti-SARS-CoV-2 antibodies; buffer; preservative.	Same
Calibration Interval	Calibration frequency: Calibration must be performed once per reagent lot using ACOV2 Cal1, ACOV2 Cal2 and fresh reagent (i.e., not more than 24 hours since the reagent kit was registered on the analyzer). Calibration interval may be extended based on acceptable verification of calibration by the laboratory. Renewed calibration is recommended as follows: • every 25 days when using the same reagent lot • every 7 days when using the same reagent pack • as required: e.g. quality control findings outside the defined limits	Same
Controls	PreciControl Anti-SARS-CoV-2 or other suitable control material	Same

<table>
<tr><th>Item</th><th>Predicate, K250768
(Elecsys Anti-SARS-CoV-2)</th><th>Candidate Device, K253839
(Elecsys Anti-SARS-CoV-2)</th></tr>
<tr><td>Interpretation of Results</td><td>Results obtained with the Elecsys Anti-SARS-CoV-2 Assay can be interpreted as follows:<table><tr><th>Numeric Result</th><th>Result Message</th><th>Interpretation</th></tr><tr><td>COI < 1.0</td><td>Non-reactive</td><td>Negative for anti-SARS-CoV-2 antibodies</td></tr><tr><td>COI ≥ 1.0</td><td>Reactive</td><td>Positive for anti-SARS-CoV-2 antibodies</td></tr></table>Note: A numeric COI is provided as part of the result output. Do not report COI outside of the laboratory. Only the Result message with or without Interpretation should be reported outside the lab.</td><td>Same</td></tr>
<tr><td>Analytical Cutoff Sensitivity</td><td>1.137 BAU/mL</td><td>4.776 BAU/mL</td></tr>
</table>

4. CONCLUSIONS

The information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence to Elecsys Anti-SARS-CoV-2.