April 7, 2026

Roche Diagnostics
Ailsa Grieve
Quality & Regulatory FLEX Engineer
9115 Hague Road
Indianapolis, Indiana 46256

Re: K260049
Trade/Device Name: Elecsys Anti-HBc IgM
Regulation Number: 21 CFR 866.3173
Regulation Name: Hepatitis B virus antibody assays
Regulatory Class: Class II
Product Code: SEI
Dated: January 7, 2026
Received: January 7, 2026

Dear Ailsa Grieve:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Noel J. Gerald -S for

Uwe Scherf, M.Sc., Ph.D.
Director
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)*
K260049

Device Name
Elecsys Anti-HBc IgM

Indications for Use *(Describe)*
Immunoassay for the in vitro qualitative determination of IgM antibodies to hepatitis B core antigen (anti-HBc IgM) in human serum and plasma (potassium EDTA, lithium heparin, sodium heparin, sodium citrate) from adult and pediatric (2 through 21 years of age) patients with symptoms of hepatitis or who may be at risk for hepatitis B (HBV) infection. The presence of anti-HBc IgM, in conjunction with other laboratory results and clinical information, is indicative of acute or recent hepatitis B virus (HBV) infection. The immunoassay's performance has not been established for the monitoring of HBV disease or therapy.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on the 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.

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.

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Elecsys Anti-HBc IgM
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 Road Indianapolis, IN 46250
Contact	Ailsa Grieve Phone: (463) 280-0782 Email: ailsa.grieve@roche.com
Date Prepared	February 20, 2026
Proprietary Name	Elecsys Anti-HBc IgM
Common Name	Elecsys Anti-HBc IgM
Classification Name	Hepatitis B virus antibody assays
Product Codes	SEI, 866.3173
Predicate Devices	Abbott ARCHITECT CORE-M (P060035)
Establishment Registration	Roche Diagnostics Operations Inc. 1823260

1. DEVICE DESCRIPTION

The Elecsys Anti-HBc IgM immunoassay is a qualitative, serologic, μ-capture assay with a total test time of 18 minutes. The sample is first automatically prediluted before being incubated with anti-Fdy reagent to block the specific IgG. In the second incubation, biotinylated monoclonal h-IgM-specific antibodies, HBcAg labeled with ruthenium complex, and streptavidin-coated microparticles are added to the sample. The biotinylated antibodies and ruthenium-labeled antigen form a sandwich complex with the anti-HBc IgM antibodies present in the sample. The complex is bound to the solid phase via the interaction of biotin and streptavidin. The microparticles are magnetically captured on the surface of an electrode and the bound complex is washed. Application of a voltage to the electrode induces chemiluminescence, which is measured by a photomultiplier. Results are determined automatically by the Elecsys software by comparing the electrochemiluminescence signal obtained from the sample with the signal of the cut-off value previously obtained by anti-HBc IgM calibration.

2. INDICATIONS FOR USE

Immunoassay for the in vitro qualitative determination of IgM antibodies to hepatitis B core antigen (anti-HBc IgM) in human serum and plasma (potassium EDTA, lithium heparin, sodium heparin, sodium citrate) from adult and pediatric (2 through 21 years of age) patients with symptoms of hepatitis or who may be at risk for hepatitis B (HBV) infection. The presence of anti-HBc IgM, in conjunction with other laboratory results and clinical information, is indicative of acute or recent hepatitis B virus (HBV) infection. The immunoassay's performance has not been established for the monitoring of HBV disease or therapy.

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

3. TECHNOLOGICAL CHARACTERISTICS

The primary technological characteristics and intended use of Elecsys Anti-HBc IgM are substantially equivalent to other legally marketed immunoassay tests for the in vitro qualitative detection of IgM antibodies to hepatitis B core antigen in human serum and plasma. There are no changes to the assay reagents due to the addition of the pediatric claim. Updated labeling has been included in this submission that contains revisions related to the use of the assay in pediatric populations.

The technological characteristics of Elecsys Anti-HBc IgM are compared to the identified predicate device, Abbot ARCHITECT CORE-M (P060035) in Table 1. There is no change to the technological characteristics of the assay due to the addition of the pediatric claim.

Table 1: Similarities and Differences between the Elecsys Anti-HBc IgM and the Abbot ARCHITECT CORE-M (P060035)

Device & Predicate Device(s):	**K260049**	**P060035**
Device Trade Name	Elecsys Anti-HBc IgM	Abbott ARCHITECT CORE-M
General Device Characteristic Similarities		
Regulation Number	21 CFR 866.3173	Same
Regulation Name	Hepatitis B virus antibody assays	Same
Regulatory Class	II	Same
Product Code	SEI	Same
Intended Use	Immunoassay for the in vitro qualitative determination of IgM antibodies to hepatitis B core antigen (anti HBc IgM) in human serum and plasma (potassium EDTA, lithium heparin, sodium heparin, sodium citrate) from adult and pediatric (2 through 21 years of age) patients with symptoms of hepatitis or who may be at risk for hepatitis B (HBV) infection. The presence of anti HBc IgM, in conjunction with other laboratory results and clinical information, is indicative of acute or recent hepatitis B virus (HBV) infection. The immunoassay's performance has not been established for the monitoring of HBV disease or therapy. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.	The ARCHITECT CORE-M assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgM antibody to hepatitis B core antigen (IgM anti-HBc) in human adult and pediatric serum or plasma (dipotassium EDTA, lithium heparin, and sodium heparin) and neonatal serum on the ARCHITECT i System. The ARCHITECT CORE-M assay is to be used as an aid in the diagnosis of acute or recent hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information.

Analyte Measured	Anti-HBc IgM	Same
Test Principle	μ Capture test principle	Two-step immunoassay
General Device Characteristic Differences		
Sample Type/Matrix	Serum and plasma (potassium EDTA, lithium heparin, sodium heparin, sodium citrate)	Serum or plasma (dipotassium EDTA, lithium heparin, and sodium heparin)
Calibrator	AHBCIGM Cal1 AHBCIGM Cal2	ARCHITECT CORE-M Calibrators
Controls	PreciControl Anti-HBc IgM	ARCHITECT CORE-M Controls
Instrument Platform	Cobas e immunoassay analyzers	ARCHITECT i System

4. METHOD COMPARISON PERFORMANCE EVALUATION

One hundred and nineteen (119) pediatric (age 2-21 years) serum samples were prospectively collected and tested for IgM antibodies to hepatitis B core in individuals at risk with and without signs and symptoms. Samples were tested using both the Elecsys Anti-HBc IgM assay and a comparator assay. The calculated NPA was 100% with a 95% CI of 96.9 - 100%. The PPA was not calculated due to no reactive results. Due to the low prevalence of HBV in the pediatric population, a spiking study was conducted to demonstrate equivalent performance of the assay in adult and pediatric samples. Thirty negative pediatric samples, with ages ranging from 2 through 21 years, were spiked with anti-HBc IgM human positive serum and compared to samples of non-reactive adult serum (≥22 years of age) that were spiked with the same volume of positive sample. Percent difference between the index values of pediatric (spiked) and adult (spiked) samples were calculated. The percent difference between the pediatric and adult samples was ±12%.

5. CONCLUSIONS

The submitted information in this premarket notification for Elecsys Anti-HBc IgM supports a substantial equivalence decision.