April 7, 2026

Roche Diagnostics
Samantha Logan
Regulatory Affairs Specialist
9115 Hague Road
Indianapolis, Indiana 46256

Re: K260048
Trade/Device Name: Elecsys Anti-HAV IgM
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A virus (HAV) serological assays
Regulatory Class: Class II
Product Code: LOL
Dated: January 7, 2026
Received: January 7, 2026

Dear Samantha Logan:

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)*
K260048

Device Name
Elecsys Anti-HAV IgM

Indications for Use *(Describe)*
Immunoassay for the in vitro qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV 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 signs and symptoms of hepatitis or persons who may be at risk for hepatitis A infection. The assay is intended for use as an aid in the laboratory diagnosis of an acute or recently acquired hepatitis A virus (HAV) infection. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HAV.
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.

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

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Elecsys Anti-HAV 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	Samantha Logan Phone: 317-441-4912 Email: samantha.logan@roche.com
Date Prepared	February 20, 2026
Proprietary Name	Elecsys Anti-HAV IgM
Common Name	Elecsys Anti-HAV IgM
Classification Name	866.3310 Hepatitis A (HAV) serological assays
Product Codes	LOL
Predicate Devices	Access anti-HAV IgM
Establishment Registration	Roche Diagnostics Operations Inc 1823260

1. DEVICE DESCRIPTION

The Elecsys Anti-HAV IgM immunoassay utilizes a μ-capture test concept based on a monoclonal h-IgM directed biotinylated antibody, cell culture derived Hepatitis A Virus and a ruthenylated monoclonal antibody directed to HAV. Capture of formed immune complexes from the reaction mixture is based on biotin binding to streptavidin-coated magnetic microparticles which are collected on a measuring cell electrode. Signal generation is triggered by the application of a voltage to the electrode (electrochemiluminescence technology). Results are determined automatically by comparing the signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration. The Elecsys Anti-HAV IgM test kit includes 2 Anti-HAV IgM calibrators, one consisting of human serum negative for anti-HAV IgM and one positive calibrator consisting of Anti-HAV IgM in human serum. PreciControl Anti-HAV IgM is also available and is packaged and sold separately.

The Elecsys PreciControl Anti-HAV IgM contains control serum based on human serum in the negative and positive concentration ranges. The controls are used for monitoring the accuracy of Elecsys Anti-HAV IgM immunoassays.

2. INDICATIONS FOR USE

Immunoassay for the in vitro qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV 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 signs and symptoms of hepatitis or persons who may be at risk for hepatitis A infection. The assay is intended for use as an aid in the laboratory diagnosis of an acute or recently acquired hepatitis A virus (HAV) infection. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HAV.

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

3. TECHNOLOGICAL CHARACTERISTICS

The primary technological characteristics and intended use of Elecsys Anti-HAV IgM are substantially equivalent to other legally marketed immunoassay tests for the in vitro qualitative detection of IgM antibodies to hepatitis A virus in 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 to use of the of assay in pediatric populations.

The technological characteristics of the Elecsys Anti-HAV IgM are compared to the identified predicate device, Access anti-HAV IgM (K251995) in Table 1.

Table 1: Similarities and Differences between the Elecsys Anti-HAV IgM and the Access anti-HAV IgM (K251995).

Device & Predicate Device(s):	**K260048**	**K251995**
Device Trade Name	Elecsys Anti-HAV IgM	Access anti-HAV IgM
General Device Characteristic Similarities		
Regulation Number	21 CFR 866.3310	Same
Regulation Name	Hepatitis A virus (HAV) serological assays	Same
Regulatory Class	II	Same
Product Code	LOL	Same
Intended Use	Immunoassay for the in vitro qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV 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 signs and symptoms of hepatitis or persons who may be at risk for hepatitis A infection. The assay is intended for use as an aid in the laboratory diagnosis of an acute or recently acquired hepatitis A virus (HAV) infection.	The Access anti-HAV IgM assay is a paramagnetic particle, chemiluminescent immunoassay for the in vitro qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV IgM) in human pediatric (2 through 21 years) and adult serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, dipotassium (K2) EDTA, and tripotassium (K3) EDTA] using the DxI 9000 Access Immunoassay Analyzer. The Access anti-HAV IgM assay results may be used as an aid in the laboratory diagnosis of

	Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HAV. The **e**lectro**c**hemi**l**uminescenc e **i**mmuno**a**ssay "ECLIA" is intended for use on **cobas** e immunoassay analyzers.	acute or recent hepatitis A virus (HAV) infection in individuals with signs and symptoms of hepatitis A virus, when used in conjunction with other serological and clinical information. This assay is not intended for use for screening donors of blood or blood products or human cells, tissues, or cellular or tissue-based products (HCT/Ps).
Test principle	µ Capture test principle	Two-step sandwich immunoassay
Analyte measured	Anti-HAV IgM	Same
General Device Characteristic Differences		
Sample type/matrix	Human serum and plasma (potassium EDTA, lithium heparin, sodium heparin, sodium citrate)	Serum and Plasma [Lithium Heparin, Lithium Heparin separator tube, dipotassium (K2) EDTA, and tripotassium (K3) EDTA]
Instrument platform	**cobas e** immunoassay analyzers	DxI 9000 Access Immunoassay Analyzer
Calibrator	AHAVIGM Cal1 AHAVIGM Cal2	Access anti-HAV IgM Calibrator
Controls	PreciControl Anti-HAV IgM	Access anti-HAV IgM

4. METHOD COMPARISON PERFORMANCE EVALUATION

One hundred and twenty-three (123) pediatric (age 2 through 21 years) serum samples were prospectively collected and tested for IgM antibodies to HAV on both the Elecsys Anti-HAV IgM assay and a comparator assay. The calculated NPA was 100% with a 95% CI of 97.0% - 100%. The PPA was not calculated due to there not being any reactive results.

Due to the low prevalence of HAV 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-HAV IgM human positive serum and compared to samples from a single pool of non-reactive adult serum (≥ 22 years of age) that were spiked with the same volume of positive sample. The percent difference between the index values of pediatric (spiked) and adult (spiked) samples were calculated. The percent difference between the pediatric and adult samples met the acceptance criteria of ≤ 20%.

5. CONCLUSIONS

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