December 30, 2025

Techno-Path Manufacturing , Ltd.
Alan Mcdonagh
RA Specialist
Fort Henry Business Park,
Ballina
Co. Tipperary, V94 FF1P
Ireland

Re: K242492
Trade/Device Name: Multichem ID-G (09339892190); Multichem ID-G (SR102G); Multichem ID-G (SR102MG); Multichem ID-GNeg (09339906190); Multichem ID-GNeg (SR102N); Multichem ID-GNeg (SR102MN)
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed Quality Control Material For Clinical Microbiology Assays
Regulatory Class: Class II
Product Code: QCH
Dated: December 30, 2025
Received: December 4, 2025

Dear Alan McDonagh:

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,

Uwe Scherf -S

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)*
K242492

Device Name
Multichem ID-G, Multichem ID-GNeg

Indications for Use *(Describe)*
Multichem ID-G: Multichem ID-G is intended for use as a qualitative positive quality control serum to monitor the precision of laboratory testing procedures for Anti-HBc IgG, Anti-HCV IgG, HBsAg, Anti-Treponema pallidum IgG and Anti-HIV 1 IgG detected by Roche cobas heterogeneous immunoassay systems. These products are not intended to replace manufacturer's recommended controls provided in their package insert. Quality Control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

Multichem ID-GNeg: Multichem ID-GNeg is intended for use as a qualitative negative quality control serum to monitor the precision of laboratory testing procedures for Anti-HBc IgG, Anti-HCV IgG, HBsAg, Anti-Treponema pallidum IgG and Anti-HIV 1 IgG detected by Roche cobas heterogeneous immunoassay systems. These products are not intended to replace manufacturer's recommended controls provided in their package insert. Quality Control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

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.

510(k) SUMMARY

Date of Summary: December 30, 2025

Product Name: Multichem ID-G (09339892190); Multichem ID-G (SR102G); Multichem ID-G (SR102MG); Multichem ID-GNeg (09339906190); Multichem ID-GNeg (SR102N); Multichem ID-GNeg (SR102MN)

Sponsor: Techno-path Manufacturing, Ltd.

Correspondent:
Alan McDonagh
RA Specialist
Fort Henry Business Park,
Ballina, Tipperary,
Ireland
Telephone: +353 (0) 61 525700
Email: technopath.regulatoryaffairs@lgcgroup.com

Common Name: Assayed quality control material for clinical microbiology assays.

Regulation Number: 21 CFR 866.3920

Classification: Class II

Product Code(s): QCH

Predicate Device: PreciControl Anti-HAV II [K190428]

Substantial Equivalency:

Device & Predicate Device(s):	K190428	K242492
Device Trade Name	PreciControl Anti-HAV II	Multichem ID-G/Multichem ID-GNeg
General Device Characteristic Similarities		
Intended Use/Indications For Use	PreciControl Anti-HAV II is used for quality control of the Elecsys Anti-HAV II immunoassay on cobas e immunoassay analyzers.	Multichem ID-G is intended for use as a qualitative positive quality control serum to monitor the precision of laboratory testing procedures for Anti-HBc IgG, Anti-HCV IgG, HBsAg, Anti-Treponema pallidum IgG, and Anti-HIV 1 IgG detected by the Roche cobas heterogeneous immunoassay systems. These products are not intended to replace manufacturer's recommended controls provided in their package insert. Quality Control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

		Multichem ID-GNeg is intended for use as a qualitative negative quality control serum to monitor the precision of laboratory testing procedures for Anti-HBc IgG, Anti-HCV IgG, HBsAg, Anti-Treponema pallidum IgG, and Anti-HIV 1 IgG detected by the Roche cobas heterogeneous immunoassay systems. These products are not intended to replace manufacturer's recommended controls provided in their package insert. Quality Control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.
Summary	PreciControl Anti-HAV II is a ready-for-use control serum based on human serum both in the negative and positive concentration range. The controls are used for monitoring the performance of the Elecsys Anti-HAV II immunoassay.	Multichem ID-GNeg/Multichem ID-G is designed for and intended to be used solely with the procedures and immunoassays indicated in the Instructions for Use. These products are not intended to replace manufacturer's recommended controls provided in their package insert.
General Device Characteristic Differences		
Form:	Liquid	Liquid
Matrix:	Human blood	Human blood
Storage:	2–8°C	2–8°C
Open Vial Stability:	8 weeks at 2–8°C	30 days at 2–8°C
Shelf Life:	15 months at 2–8°C	Multichem ID-G: 11 months at 2–8°C Multichem ID-GNeg: 11 months at 2–8 °C
Analyte(s):	Antibodies against hepatitis A virus (HAV)	anti-HIV-1 IgG, anti-HBc IgG, anti-HCV, IgG HBsAg, anti-Treponema pallidum IgG

Intended Use

Multichem ID-G is intended for use as a qualitative positive quality control serum to monitor the precision of laboratory testing procedures for Anti-HBc IgG, Anti-HCV IgG, HBsAg, Anti-Treponema pallidum IgG, and Anti-HIV 1 IgG detected by the Roche cobas heterogeneous immunoassay systems. These products are not intended to replace manufacturer's recommended controls provided in their package insert. Quality Control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

Multichem ID-GNeg is intended for use as a qualitative negative quality control serum to monitor

the precision of laboratory testing procedures for Anti-HBc IgG, Anti-HCV IgG, HBsAg, Anti-Treponema pallidum IgG, and Anti-HIV 1 IgG detected by the Roche cobas heterogeneous immunoassay systems. These products are not intended to replace manufacturer's recommended controls provided in their package insert. Quality Control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

Test Principle

Not applicable; this is control material to monitor performance of a test.

Device Description

Multichem ID-G and Multichem ID-GNeg are each supplied as single level controls. These products are prepared from human plasma. Multichem ID-G contains Hepatitis B Surface Antigen (HBsAg), and lgG antibodies to HIV-1 (Human Immunodeficiency Virus Type 1), HCV (Hepatitis C Virus), HBc (Hepatitis B Core Antigen) and Treponema pallidum. Multichem ID-GNeg does not contain analytes for HBsAg, anti-HIV-1 lgG, anti-HCV lgG, anti-HBc lgG, and anti-Treponema pallidum lgG. These controls are provided in liquid form for convenience. Each control is available as either 1 or 4 vials x 4 ml/vial.
Multichem ID-G is manufactured by adding the required analytes to the negative delipidated human serum base matrix, described above. Human disease state plasma that has tested positive for the required analyte using an FDA-cleared/approved assay is used to spike the base matrix to each target specification and within the ranges set for the Roche Immunoassay systems (Tables 1 and 2).

Table 1: Design Input Specifications for Multichem ID-G on the Roche Immunoassays.

ANALYTES	Product Specification UNITS	Positive When:	TARGET	LOW	HIGH
Anti-HIV-1 IgG	COI	>1	4.0	2.5	6.0
Anti-HCV IgG	COI	>1	10.0	3.0	12.0
Anti-*Treponema pallidum* IgG	COI	>1	2.0	1.5	4.0
Anti-HBc IgG	COI	<1	0.5	0.2	0.8
HBsAg	COI	>1	2.5	1.5	5.0

Table 2: Specifications for Raw Material Analyte Volume in the final product.

Analytes	Raw Material I.D. Number	Origin	Raw Material Analyte Volume (mL)
HBsAg	RMR-32108	Australia	6.0 mL
anti-HIV 1 IgG	RMR-32103	Australia	1.5 mL
anti-HCV IgG	RMR-32105	Australia	0.4 mL
anti-Treponema palladium IgG	RMR-32106	Australia	28.6 mL
anti-HBc IgG	RMR-32107	Australia	12.5 mL

Performance Data

1. Precision/Reproducibility:

   A. Precision.

Within-laboratory precision was evaluated using Roche assays Elecsys HIV Duo, Elecsys anti-HCV II, Elecsys Syphilis, Elecsys anti-HBc II and Elecsys HBsAg II. Testing was performed on Roche cobas e 801, using 3 lots of QC material, which were tested in 2 replicates per run, 2 runs per day, for 20 days. The results are summarized in the following table.

Table 3. Within-laboratory precision of Multichem ID-G and Multichem ID-GNeg.

Immunoassay System	QC (POS/NEG)	COI	Repeatability		Within-Laboratory Precision	
			SD (COI)	%CV	SD (COI)	%CV
anti-HIV	POS	2.01	0.040	1.9	2.023	1.9
	NEG	0.18	0.010	4.0	0.180	0.0
anti-HCV	POS	11.74	0.080	0.7	0.240	2.0
	NEG	0.06	0.003	3.1	0.004	6.7
anti-HBc	POS	0.53	0.006	0.0	0.014	0.0
	NEG	2.29	0.030	1.3	0.030	1.3
HBsAg	POS	2.96	0.075	0.0	0.108	0.0
	NEG	0.37	0.023	6.2	0.025	6.9
anti-T. pallidum	POS	2.17	0.060	2.9	0.060	2.9
	NEG	0.14	0.000	2.0	0.140	0.00

B. Reproducibility

Reproducibility was evaluated using Roche assays Elecsys HIV Duo, Elecsys anti-HCV II, Elecsys Syphilis, Elecsys anti-HBc II and Elecsys HBsAg II. Testing was performed at 2 sites on analyzers Roche cobas e 801 using 3 QC lots, which were tested in 5 replicates per run, 1 run per day, over 5 days with a total of 150 replicates for each control. The results are summarized in the following table.

Table 4. Reproducibility of Multichem ID-G and Multichem ID-GNeg.

Immunoassay system	Component	Positive			Negative		
		COI	Standard Deviation (COI)	% CV	COI	Standard Deviation (COI)	% CV
HIV Ab	Repeatability (Within-Run)	2.00	0.03	1.51	0.20	0.01	2.98
	Between-Day/Run		0.01	0.57		0.00	0.00
	Between-Lot		0.02	1.05		0.00	1.41
	Between-Site		0.20	9.23		0.00	0.96
	Total Reproducibility		0.20	9.42		0.01	4.67
anti-HCV	Repeatability (Within-Run)	11.89	0.13	1.12	0.10	0.00	3.44
	Between-Day/Run		0.07	0.55		0.00	1.90
	Between-Lot		0.15	1.31		0.00	0.00
	Between-Site		0.09	0.76		0.00	3.93
	Total Reproducibility		0.23	1.96		0.00	5.56
Anti-HBc	Repeatability (Within-Run)	0.53	0.01	1.56	2.10	0.02	1.08
	Between-Day/Run		0.00	0.55		0.00	0.00
	Between-Lot		0.01	2.33		0.00	0.14
	Between-Site		0.02	4.50		0.06	2.76
	Total Reproducibility		0.03	5.34		0.07	2.96
Syphilis	Repeatability (Within-Run)	2.11	0.04	1.82	0.10	0.01	8.28

	Between-Day/Run		0.03	1.64		0.00	3.38
	Between-Lot		0.06	2.96		0.00	0.00
	Between-Site		0.20	10.25		0.02	13.17
	Total Reproducibility		0.22	10.95		0.02	15.92
HBsAg	Repeatability (Within-Run)	3.10	0.0928	3.0	0.42	0.0300	7.1
	Between-Day/Run		0.0396	1.3		0.0166	3.9
	Between-Lot		0.0531	1.7		0.0000	0.0
	Between-Site		0.2367	7.6		0.0644	15.3
	Total Reproducibility		0.2627	8.5		0.0730	17.3

2. Stability

Shelf-life and open vial stability were evaluated using Roche assays Elecsys HIV Duo, Elecsys anti-HCV II, Elecsys Syphilis, Elecsys anti-HBc II and Elecsys HBsAg II. Testing was performed using 3 QC lots stored at 2-8°C and at -80°C. Stability studies supported a shelf-life stability claim of 11 months at the recommended storage conditions (2-8°C) and an open-vial stability claim of 90 days when stored at 2-8°C, for both positive and negative controls.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.