510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K242492

B Applicant

Techno-Path Manufacturing, Ltd.

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QCH	Class II	21 CFR 866.3920 - Assayed Quality Control Material For Clinical Microbiology Assays	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of the Quality Control (QC) material for Roche cobas assays detecting analytes anti-HIV-1 (Human Immunodeficiency Virus Type 1) IgG, anti-HBc (Hepatitis B Core Antigen) IgG, anti-HCV (Hepatitis C Virus) IgG, Hepatitis B Surface Antigen (HBsAg), and anti-*Treponema pallidum* IgG.

B Measurand:

- Anti-HIV-1 IgG,
- Anti-HBc IgG,

• Anti-HCV IgG,
• HBsAg,
• Anti-*Treponema pallidum* IgG.

C Type of Test:

QC materials to monitor the performance of *in-vitro* testing for the qualitative detection of human HBsAg, anti-HIV-1 IgG, anti-HCV IgG, anti-HBc IgG, and anti-*Treponema pallidum* IgG assays performed with the Roche immunoassays on the Roche cobas systems.

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for 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.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

The performance of Multichem ID-G and Multichem ID-GNeg was evaluated on the Roche cobas systems e 402 (K220134 cleared on 09/16/2022), and e 801 (K162606 cleared on 01/23/2017).

IV Device/System Characteristics:

A 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, HCV, HBc 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 Assays.

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

B Principle of Operation:

Used as QC in accordance with the assay's Instructions for Use.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Elecsys Anti-HAV II

B Predicate 510(k) Number(s):
K190428

C Comparison with Predicate(s):

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/ID-GNeg is intended for use as a qualitative positive/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

VI Standards/Guidance Documents Referenced:

Special Controls under 21 CFR 866.3920

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

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 that were tested in 2 replicates per run, 2 runs per day, for 20 days. A total of 240 replicates for each control were tested. The results are summarized in table 3.

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 that were tested in 5 replicates per run, 1 run per day, over 5 days. A total of 150 replicates for each control were tested. The results are summarized in table 4.

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. Linearity:

   N/A

3. Analytical Specificity/Interference:

   N/A

4. Assay Reportable Range:

   N/A

5. Stability:

   Stability 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 1 site using 3 QC lots that were tested in 3 replicates at month 0, 11, 24, and 35 for shelf-life at 2-8ºC or at days 0, 90, and 91 for open vial stability at 2-8ºC.
   Stability studies supported a shelf-life claim of 11 months at the intended storage conditions (2-8ºC) and open-vial claim of 90 days when stored at 2-8ºC. Technopath requested a 30-day open vial claim for Multichem ID-GNeg and Multichem ID-G.

6. Detection Limit:

   N/A

7. Assay Cut-Off:

   N/A

B Comparison Studies:

1. Method Comparison with Predicate Device:

   N/A

2. Matrix Comparison:

   N/A

C Clinical Studies:

1. Clinical Sensitivity:

   N/A

2. Clinical Specificity:

   N/A

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   N/A

D Clinical Cut-Off:

N/A

E Expected Values/Reference Range:

Multichem ID-G and Multichem ID-GNeg are qualitative controls. The expected results are listed in Table 1.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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