510(k) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21CFR 807.92.

Applicant Name	Techno-path Manufacturing Ltd.
Applicant Address	Fort Henry Business Park, Ballina Co. Tipperary V94 FF1P Ireland

Device Identification

Trade Name	Multichem ID-HIVp24
Common Name	N/A
Classification Name	Assayed quality control material for clinical microbiology assays
Regulation Number	21 CFR 866.3920
Product code	QCH

Device Substantial Equivalence

Predicate Device	
Predicate Trade Name	BioRad VIROTROL® HIV-1 Ag
Predicate Common Name	N/A
Predicate Classification Name	Kit, quality control for blood banking reagents
Regulation Number	21 CFR 864.9650
Product code	KSF
Predicate 510(k) Number	BK930033

1. Device Description

Multichem ID-HIV p24 is supplied as a single level, liquid control that is ready-to-use with barcodes that are designed for application on to the targeted platform. It consists of disease state human serum diluted with negative human serum.
Multichem ID-HIV p24 is a liquid stable, third-party quality control used to monitor the precision of laboratory testing procedures and is an integral part of good laboratory practices. A control is provided to allow performance monitoring of the test system. The Multichem ID-HIV p24 Quality Control has been prepared from human plasma to which preservatives and stabilizers have been added. Multichem ID-HIV p24 is intended for use as a qualitative quality control serum to monitor the precision of laboratory testing procedures for the HIV-1 p24 antigen detected by the heterogeneous immunoassay systems listed in the package insert. These products are not intended to replace manufacturer's recommended controls provided in their package insert.

Intended Use/Indications for Use

Multichem ID-HIVp24 is intended for use as a qualitative quality control serum to monitor the precision of laboratory testing procedures for the HIV-1 p24 antigen detected by the heterogeneous immunoassay systems listed in the Instructions for Use. 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.

2. Comparison with Predicate Device

Table 2. General Device Characteristic Similarities

	Subject Device: Multichem ID-HIVp24	**Predicate Device: BK930033** VIROTROL HIV-1 Ag
Intended Use	Multichem ID-HIVp24 is intended for use as a qualitative quality control to monitor the precision of laboratory testing procedures for the HIV-1 p24 antigen detected by 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.	VIROTROL HIV-1 Ag is intended for use as an unassayed reactive quality control with in vitro assay procedures for determination of antigens to Human Immunodeficiency Virus Type 1 (HIV-1). This product is intended to provide a means of estimating precision and has the potential for detecting systematic deviations from specific laboratory testing procedures.
Form	Liquid	Same
Storage	2 - 8°C Single use only; discard after use.	Same
Matrix	Serum	Same
Assay Target Analyte	HIV-1 p24 Antigen	HIV-1 p24 antigen

Table 3. General Device Characteristic Differences

	Subject Device: Multichem ID-HIVp24	**Predicate Device: BK930033** VIROTROL HIV-1 Ag
Open Vial Stability	30 days at 2 – 8°C	60 days at 2 – 8°C
Shelf Life	13 months at 2 – 8°C	18 months at 2 – 8°C

3. Non-Clinical Performance Evaluation

A summary of nonclinical performance testing associated with the Multichem ID-HIVp24 Quality Control is as follows:

4.1 Precision

A 20-day precision study with two runs per day and two replicates per run using three lots of the Multichem ID-HIVp24 quality control was performed on the cobas e801 instrument by a single operator which resulted in 240 replicates (80 replicates per each QC lot). The data obtained were analyzed for the components of Cut-off Index (COI) variation within-run (repeatability), and between-runs. As demonstrated in Table 4a the variability between-run, and within-run was low.

Table 4a. Precision of Multichem ID-HIVp24 on the cobas e801 instrument

Sample	N	Mean COI	Within-Run (Repeatability)		Between-Run	
			SD	% CV	SD	% CV
HIV p24	240	5.65	0.09	1.74	0.11	1.99

N= number of replicates tested, COI = Cut-off Index, SD = Standard Deviation, %CV = percent Coefficient of Variation.

4.2 Reproducibility

A five-day reproducibility study was performed using three lots of the Multichem ID-HIVp24 quality control, with five replicates per lot on the cobas e801 instrument at three different sites, which resulted in a total of 225 replicates (75 replicates per each QC lot). The data obtained were analyzed for the components of Cut-off Index (COI) variation within-run, between-days, between-sites, and between the three QC lots. As demonstrated in Table 4b the percent coefficient of variation (%CV) was low between the various sources of variability.

Table 4b. Reproducibility of Multichem ID-HIV p24 on the cobas e801 instrument

Sample	N	Mean COI	Within-Run		Between-Day		Between-Site		Between-QC Lots	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV
HIV p24	225	6.08	0.87	1.41	0.87	1.51	0.58	9.68	0.58	9.55

N= number of replicates tested, COI = Cut-off Index, SD = Standard Deviation, %CV = percent Coefficient of Variation.

4. Conclusions

The Multichem ID-HIVp24 is a serum-based quality control reagent used for monitoring the performance of immunoassay procedures for the qualitative detection of HIV-1 p24 antigen. It is comprised of ready-to-use, barcoded vials that have an expiration of 13 months when stored at 2 – 8°C. The Multichem ID-HIVp24 has the same technology, similar intended use and the data presented demonstrate that the device is as safe, as effective, and performs as well as the predicate device.