510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k162530

B. Purpose for Submission:

Addition of the following 13 assayed analytes to a previously cleared quality control material (k132091): Acetaminophen, ACTH, Amikacin, Calcitonin, Human Growth Hormone, Lithium, Salicylate, Thyroglobulin, Tobramycin, Free Estriol, EPO, NT Pro-BNP and Troponin T.

C. Measurand:

Quality control materials for Acetaminophen, ACTH, Amikacin, Calcitonin, Human Growth Hormone, Lithium, Salicylate, Thyroglobulin, Tobramycin, Estriol Free, EPO, NT Pro BNP, Troponin T, Alpha Fetoprotein (AFP), Anti-thyroglobulin, Anti-thyroperoxidase, Human Chorionic Gonadotropin (BhCG), BNP (1-32), CA 125, CA 15-3, CA 19-9, Carbamazepine, Carcinogenic Embryonic Antigen (CEA), CK-MB, Cortisol, C-Peptide, DHEA-Sulfate, Digoxin, Estradiol, Ferritin, Folate, Prostate Specific Antigen Free, Follicle Stimulating Hormone (FSH), Triiodothyronine Free (FT3), Thyroxine Free (FT4), Gentamicin, Homocysteine, Immunoglobulin E, Insulin, Luteinizing Hormone, Myoglobin, Parathyroid Hormone (PTH) (1-84), Phenobarbital, Phenytoin, Progesterone, Prolactin, Prostate Specific Antigen Total, Sex Hormone Binding Globulin, T-Uptake, Testosterone, Theophylline, Troponin I, Thyroid Stimulating Hormone (TSH), Triiodothyronine Total (TT3), Thyroxine Total (TT4), Valproic Acid, Vancomycin, Vitamin B12, 25-OH Vitamin D.

D. Type of Test:

Not applicable.

E. Applicant:

Techno-Path Manufacturing Ltd.

F. Proprietary and Established Names:

Multichem IA Plus

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1660

2. Classification:

   Class I, reserved

3. Product code:

   JJY

4. Panel:

   Clinical chemistry (75)

H. Intended Use:

1. Intended use(s):

   See "Indication(s) for use" below

2. Indication(s) for use:

   For In Vitro Diagnostic use only. Multichem IA Plus is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   The package insert lists the following instruments for which the quality control material is intended: Abbott Architect platforms, Beckman Access II platforms, Roche Cobas platforms and Beckman DXI platforms.

I. Device Description:

The Multichem IA Plus controls are prepared from human serum with added constituents of human and animal origin, chemicals, therapeutic drugs, stabilizers and preservatives. The control is available in liquid form.

Three levels of control are available to allow performance monitoring within the clinical range.

Each donor unit used in the preparation of the control material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and non-reactive for HBsAg.

The following kit configurations are available:

Multichem IA Plus

Model IA310A (Trilevel) with Level 1, 2 & 3 control; 12 vials with 5 mL contents

Model 05P56-10 (Trilevel) with Level 1, 2 & 3 control; 12 vials with 5 mL contents

Model IA311A with Level 1 control; 12 vials with 5 mL contents

Model IA312A with Level 2 control; 12 vials with 5 mL contents

Model IA313A with Level 3 control; 12 vials with 5 mL contents

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Multichem IA Plus

2. Predicate 510(k) number(s):

   k132091

3. Comparison with predicate:

Similarities		
Characteristics	Multichem IA Plus Assayed Control (k162530, Candidate Device)	Multichem IA Plus Assayed Control (k132091, Predicate Device)
Intended Use	Multichem IA Plus is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Same
Form	Liquid, Frozen	Same
Matrix	Processed Human Serum	Same

Differences		
Characteristics	Multichem IA Plus Assayed Control (k162530, Candidate Device)	Multichem IA Plus Assayed Control (k132091, Predicate Device)
Assayed Analytes	Same plus 13 analytes: Acetaminophen, ACTH, Amikacin, Calcitonin, Human Growth Hormone, Lithium, Salicylate, Thyroglobulin, Tobramycin, Free Estriol, EPO, NT Pro-BNP and Troponin T	Alpha Fetoprotein (AFP), Anti-thyroglobulin, Anti-thyroperoxidase, Human Chorionic Gonadotropin (hCG), BNP (1-32), CA 125, CA 15-3, CA 19-9, Carbamazepine, Carcinogenic Embryonic Antigen (CEA), CK-MB, Cortisol, C-Peptide, DHEA-Sulfate, Digoxin, Estradiol, Ferritin, Folate, Prostate Specific Antigen Free, Follicle Stimulating Hormone (FSH), Triiodothyronine Free (FT3), Thyroxine Free (FT4), Gentamicin, Homocysteine, Immunoglobulin E, Insulin, Luteinizing Hormone, Myoglobin, Parathyroid Hormone (PTH) (1-84), Phenobarbital, Phenytoin, Progesterone, Prolactin, Prostate Specific Antigen Total, Sex Hormone Binding Globulin, T-Uptake, Testosterone, Theophylline, Troponin I, Thyroid Stimulating Hormone (TSH), Triiodothyronine Total (TT3), Thyroxine Total (TT4), Valproic Acid, Vancomycin, Vitamin B12, 25-OH Vitamin D.
Storage Shelf Life (Unopened)	36 Months @ -20°C to -80°C	30 Months @ -20°C to -80°C
Storage Open Vial	10 days at 2 to 8°C, with the following exceptions: BNP = 1 hour, C-Peptide = 7 days, Folate = 2 days, Homocysteine = 7 days, PTH Intact = 4 days, Troponin I = 4 days, 25OH Vitamin D = 4 days, ACTH = 8 hours, Calcitonin and Troponin T = 7 days at 2 to 8°C.	10 days at 2 to 8°C, with the following exceptions: BNP = 1 hour, C-Peptide = 7 days, Folate = 2 days, Homocysteine = 7 days, PTH Intact = 4 days, Troponin I = 4 days, and 25OH Vitamin D = 4 days at 2 to 8°C.

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents, 2009.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Not applicable.

   b. Linearity/assay reportable range:

   Not applicable.

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   Traceability -

   The base matrix of the three control levels is processed human serum. The traceability / source of materials used to prepare the three control levels for the 13 new assayed analytes are as listed in the table below:

Assigned Analytes	Source of Material
Acetaminophen	Chemical - Therapeutic Drug
ACTH	Endogenous and spiked with purified human ACTH
Amikacin	Chemical - Therapeutic Drug
Calcitonin	Endogenous and spiked with purified human Calcitonin
EPO	Endogenous and spiked with purified human EPO
hGH	Endogenous and spiked with purified human or recombinant Growth Hormone
Free Estriol	Endogenous and spiked with chemical
Lithium	Chemical - Therapeutic Drug
NT Pro-BNP	Endogenous and spiked with purified recombinant NT Pro-BNP
Salicylate	Chemical - Therapeutic Drug
Thyroglobulin	Endogenous and spiked with purified human Thyroglobulin
Tobramycin	Chemical - Therapeutic Drug
Troponin T	Endogenous and spiked with purified human Troponin T

Stability -

Shelf-Life (closed vial) and in-use (open vial) stability testing protocols and acceptance criteria were described and found to be adequate.

Real-time stability testing supports a shelf-life stability claim of 36 months when stored frozen at -20 ºC to -80ºC for the Multichem IA Plus three level controls.

Real-Time stability testing supports open vial stability claims as listed below:

- Acetaminophen, Amikacin, EPO, hGH, Free Estriol, Lithium, NT Pro-BNP, Salicylate, Thyroglobulin and Tobramycin of 10 days at 2 to 8°C
- ACTH of 8 hours at 2 to 8°C
- Calcitonin and Troponin T of 7 days at 2 to 8°C

Value Assignment -

The value assignment for all analytes was performed on analyte specific assay/analyzer systems using the proposed new value assignment protocol. Fifteen replicates of each analyte were tested over a minimum of three runs with a minimum of three replicates per run using and run over multiple days. The mean from the 15 data points was used as the target concentration. The assignment of value assignment ranges was established based on the 3SD value for each level of the analyte control. The target mean and range for each analyte level along with their respective acceptance criteria were provided for review and found acceptable. Representative values for target mean and range for each analyte for a lot are provided in tabular form in the value assignment sheets.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected values are provided in the value assignment sheets provided with the package insert.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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