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

A. 510(k) Number:

k110738

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for multiple immunoassay analytes

D. Type of Test:

Not applicable

E. Applicant:

Microgenics Corporation

F. Proprietary and Established Names:

MAS Omni-Core

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I, reserved	862.1660	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below

2. Indication(s) for use:

   Thermo Scientific MAS Omni-Core is intended for use an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include

Omni-Core with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with their expected ranges as a means of assuring consistent performance of reagent and instrument.

3. Special conditions for use statement(s):

   For in vitro diagnostic use

   For prescription use

4. Special instrument requirements:

   For use with the specific systems listed in the package insert

I. Device Description:

The Omni-Core controls are liquid stable control material prepared from human serum. Analyte levels are adjusted with various animal extracts and non-protein materials including drugs, drug metabolites, and purified chemicals. Amylase, alanine aminotransferase, creatine kinase and lipase are obtained from porcine tissue; alkaline phosphatase and gamma glutamyl transferase are from bovine tissue; lactate dehydrogenase is from avian tissue. Preservatives and stabilizers are added to maintain product integrity. Controls are provided in frozen liquid form

Omni-CORE is prepared from components which are derived from human source material have been tested and found non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C (HCV), HIV-1 and HIV-2.

The control is offered in three levels (1, 2, or 3) or in combination.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   MAS®Chem-TRAK H

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

   k092051

3. Comparison with predicate

	Candidate Device k110738	**Predicate** Mas Chem TRAK H k092051
Indications for Use	Intended for monitoring assay conditions in many clinical laboratory determinations.	Same
Analyte	Multiple analytes	Same
Matrix	Human serum	Same
Format	Frozen Liquid	Frozen liquid
Number of levels	3	Same
Shelf life	3 years -20 degrees C	2.5 years at -20 degrees C

Assigned analytes:	Acetaminophen	Acetaminophen
	Albumin	Albumin
	ALK Phos. (Alkaline Phosphatase)	Alkaline Phosphatase,
	alpha-1-Acid Glycoprotein	
	Alpha-1-Antitrypsin	
	Alpha-2-Macroglobulin	
	Alanine Aminotransferase	Alanine Aminotransferase
	Amikacin	Amikacin
	Amylase	Amylase –
	Antistreptolysin 0 (ASO) -	
	Apolipoprotein A1	Apolipoprotein A (APO A)
	Apolipoprotein B	Apolipoprotein B (APO B)
	Aspartate Aminotransferase	Aspartate Aminotransferase,
	Beta 2 Microglobulin	
	Bile Acids	
	Direct Bilirubin,	Direct Bilirubin,
	Total Bilirubin	Total Bilirubin
	Blood Urea Nitrogen,	Blood Urea Nitrogen
	C3 Complement	C3 Complement
	C4 Complement	C4 Complement

	Caffeine	Caffeine
	Calcium	Calcium
	Carbamazepine	Carbamazepine –
	Ceruloplasmin	
	Chloride	Chloride
	Cholesterol	Cholesterol
	Creatine Kinase	Creatine Kinase
	CO2	CO2
	Copper	
	Cortisol	
	C-Reactive Protein (CRP)	C-Reactive Protein, CRP
	Creatinine	Creatinine
	Digoxin	Digoxin
	Disopyramide	Disopyramide
	Ethanol	Ethanol
	Ethosuximide	Ethosuximide
	Ferritin	Ferritin
	Gentamicin	Gentamicin
	Gamma Glutamyltransferase	Gamma Glutamyltransferase
	Glucose	Glucose
	Haptoglobin	Haptoglobin
	HDL Cholesterol	HDL Cholesterol
	-	Human Chorionic Gonadotrophin
	IgA	IgA
	IgE	-
	IgG	IgG
	IgM	IgM
	-	
	-	
	Iron	Iron
	Lactic Acid	Lactic Acid
	LDH	LDH
	LDL-Cholesterol	LDL-Cholesterol
	Lidocaine	Lidocaine
	Lipase	Lipase
	Lipoprotein (a)	Lipoprotein (LpA)
	Lithium	Lithium
	Magnesium	Magnesium
	Methotrexate	Methotrexate
	N-Acetylprocainamide,	N-Acetylprocainamide
	Osmolality	Osmolality

	Phenobarbital	Phenobarbital
	Phenytoin	Phenytoin
	Phosphorus	Phosphorus
	Potassium	Potassium
	Prealbumin	
	Primidone	
	Procainamide	
	Pseudocholinesterase	Pseudocholinesterase
	Quinidine	Quinidine
	RF	
	Salicylate	Salicylate
	Sodium	Sodium
	T3 uptake	T3 uptake
	Thyroxine Total T4	Thyroxine Total T4
	Theophylline	Theophylline
	Thyroid Stimulating Hormone, TSH	Thyroid Stimulating Hormone, TSH
	Tobramycin	Tobramycin
	Total Iron Binding Capacity	Total Iron Binding Capacity
	Total Protein	Total Protein
	Transferrin	Transferrin
	Triglycerides	Triglycerides
	Tricyclic Antidepressants	Tricyclic Antidepressants
	Uric Acid	Uric Acid
	Valproic Acid	Valproic Acid
	Vancomycin	Vancomycin
	Zinc	

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

None were referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

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

Analyte components:

Target values:	Level 1	Level 2	Level 3	units
Acetaminophen	25	82.5	140	ug/mL
Albumin	2.5	5	7.5	g/dL
Alkaline Phosphatase	45	197.5	350	U/L
alpha-1-Acid Glycoprotein	43	85	127	mg/dL
alpha-1-Antitrypsin	77	153.5	230	mg/dL
alpha-2-Macroglobulin	90	178	280	mg/dL
ALT	40	120	200	U/L
Amikacin	5	17.5	30	ug/mL
Amylase	90	320	550	U/L
Antistreptolysin O	89	194.5	300	IU/mL
Apolipoprotein A1	90	160	230	mg/dL
Apolipoprotein B	46	103	160	mg/dL
AST	40	155	270	U/L
Beta 2 Microglobulin	1.5	6.5	10	mg/L
Bile Acids	4.5	8	10	umol/L
Direct (DBIL) Bilirubin,	0.6	2.38	3.75	mg/dL
Total (BILT)	1	4.1	7.2	mg/dL
BUN	15	40	65	mg/dL
C3 Complement	79	170.5	262	mg/dL
C4 Complement	20	35	50	mg/dL
Caffeine	5	12	20	ug/mL
Calcium	6.5	9.25	12	mg/dL
Carbamazepine	4	9	14	ug/mL
Ceruloplasmin	17	38.5	60	mg/dL
Chloride	85	95	105	mMol/L
Cholesterol	115	167.5	220	mg/dL
CK	90	345	600	U/L
CO2	16	24	32	mMol/L
Cortisol	4	19.5	35	ug/dL

C-Reactive Protein	0.8	3.9	7	mg/dL
Creatinine	1	4	7	mg/dL
Digoxin	1	1.85	2.7	ng/mL
Disopyramide	1.5	3	5	ug/mL
Ethanol	20	100	180	mg/dL
Ethosuximide	35	100	150	ug/mL
Ferritin	25	195	370	ng/mL
Gentamicin	1.7	4.35	7	ug/mL
GGT	40	95	150	mg/dL
Glucose	65	207.5	350	mg/dL
Haptoglobin	64	139	214	mg/dL
HDL Cholesterol	30	50	70	mg/dL
IgA	134	268	402	mg/dL
IgE	152	286	420	IU/mL
IgG	541	1270	2000	mg/dL
IgM	58	109.5	161	mg/dL
Iron	75	152.5	240	ug/dL
Lactic Acid	1.25	3.875	6.5	mMol/L
LDH	100	225	350	U/L
LDL-Cholesterol	45	72.5	100	mg/dL
Lidocaine	1.5	4.75	8	ug/mL
Lipase	225	312.5	400	U/L
Lipoprotein (a)	4	9.5	15	mg/dL
Lithium	0.8	1.5	2.2	mEq/dL
Magnesium	1	2.75	4.5	mg/dL
Methotrexate	0.35	2.5	2.8	uMol/L
NAPA	3	8	13	ug/mL
Phenobarbital	10	30	50	ug/mL
Phenytoin	5	13.5	22	ug/mL
Phosphorus	2.2	4.85	7.5	mg/dL
Potassium	2.5	4.25	6	mEq/L
Prealbumin	12	28.5	45	mg/dL
Primidone	4	11	18	ug/mL
Procainamide	3	7.5	12	ug/mL
Pseudocholinesterase	2.5	6.5	10.5	U/mL
Quinidine	1.5	3.75	6	ug/mL
RF	45	72.5	100	IU/mL
Salicylate	7	11	15	mg/dL
Sodium	115	130	145	mEq/dL
Thyroxine, Total T4	7	12	17	ug/dL
Theophylline	5	15	25	ug/mL
Tobramycin	1.5	4.5	7.5	ug/mL
Total Protein	4.5	8.25	12	g/dL
Transferrin	150	285	420	mg/dL
Triglycerides	90	155	220	mg/dL

Thyroid Stimulating Hormone, TSH	2.5	9	14	uIU/mL
Tricyclic Antidepressants (TCA)	40	100	180	ng/mL
Uric Acid	3.3	7.15	11	mg/dL
Valproic Acid	25	72.5	120	ug/mL
Vancomycin	7.5	21.25	35	ug/mL

In addition, the following analytes are not set to a specific range, but are assigned as found in human serum. These include: copper, total iron binding capacity, osmolality, T3-uptake, and zinc.

Value Assignment:
Value assignment ranges for controls are established at ±20% or ±3SDs around the mean, whichever is broader. Narrower ranges (such as ±2SDs or ±15%) may be used as long as the min and max values in the data set are within the established ranges. Data are collected from two or three different laboratories over two or three separate days.

Stability:
Stability under the following conditions are evaluated.

Stability condition	Stability evaluated by:	Stability claim:
Open Vial Stability between 2-8°C	Recovery difference fresh vs. 30 day open vial.	14 days for bilirubin (30 days for all other analytes)
Closed Vial Stability between 2-8°C	Recovery difference fresh vs. 30 day closed vial.	30 days
Closed vial stability at–20°C	Recovery at zero time versus recovery at test date.	Currently labeled for 3 years.

The package insert states that laboratories should establish internal mean and range criteria based upon local test system evaluation and tolerance limits.

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:

The expected values are provided in the labeling for each specific lot.

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 substantial equivalence decision.