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

A. 510(k) Number:

k110616

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-IMMUNE

MAS Omni-IMMUNE PRO

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-IMMUNE is intended for use an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni-IMMUNE 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 expected ranges as a means of assuring consistent performance of reagent and instrument.

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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:

All Omni-IMMUNE controls are liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or body fluids.

The following analytes are contained in Omni-IMMUNE controls: 17-alpha-OH-progesterone, 25-Hydroxy Vitamin D, acetaminophen, adrenocorticotropic hormone (ACTH), alpha-fetoprotein (AFP), aldosterone, amikacin, benzodiazepine, beta-human chorionic gonadotropin (ß-hCG), beta-2-microglobulin, cancer antigen (CA) 125, CA 15-3, CA 19-9, carbamazepine, carcinoembryonic antigen (CEA), creatinine kinase-MB fraction (CK-MB), cortisol, C-peptide, DHEA-sulfate, digoxin, disopyramide, estradiol, estriol-free, ethosuximide, ferritin, folate, free PSA, free T3, free T4, fructosamine, FSH, gastrin, gentamicin, growth hormone, hCG, homocysteine, IgE, IGF-1, inhibin A, insulin, luteinizing hormone, lidocaine, lithium, N-acetylprocainamide (NAPA), PAP, phenobarbital, phenytoin, phenytoin-free, primidone, procainamide, procalcitonin, progesterone, prolactin, prostate specific antigen (PSA), parathyroid hormone-intact (PTH-intact), quinidine, salicylate, T3, T4, thyroid binding globulin (TBG), testosterone, theophylline, thyroglobulin, tobramycin, tricyclic antidepressants, TSH, Thyroid (T)-uptake, valproic acid, valproic acid-free, vancomycin, and vitamin B12.

The professional (PRO) version of Omni-IMMUNE contains the same constituents as Omni-IMMUNE, plus three additional analytes: Anti-Thyroglobulin (Anti-TG), Anti-Thyroid Peroxidase (Anti-TPO), and Sex Hormone Binding Globulin (SHBG).

Three levels are available for each Omni-Immune control material. Components of the control which are derived from human source material have been tested using FDA accepted methods and found non-reactive for Hepatitis B Surface antigen (HBsAg), Hepatitis C (HCV), HIV-1, and HIV-2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Lyphochek Immunoassay Plus Control

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

k981532

3. Comparison with predicate

	Candidate Device	**Predicate** Bio-Rad Lyphochek Immunoassay Plus Control (k981532)
Indications for Use	Thermo Scientific Omni-IMMUNE Controls are intended for use as assayed controls for monitoring assay conditions in many clinical laboratory determinations.	Same
Analyte	Multiple analytes	Same
Matrix	Human serum	Same
Format	Frozen Liquid	Lyophilized
Number of levels	3	Same
Stability	**Unopened:** Store at -25 to -15ºC until expiration date. **Opened:** 30 days at 2-8ºC	**Unopened:** 2-8°C **Opened**: 7 days at 2 to 8ºC except for certain analytes

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

None were referenced

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 sponsor claims traceability of all analytes contained in the Omni-IMMUNE control materials to commercially available standards.

   Value Assignment

   Value assignment was determined for each analyte contained in the Omni-IMMUNE control solutions using multiple analyzer platforms and replicate assays of samples by two to three clinical laboratories. Participating laboratories conducted these studies in accordance with established protocols. The target value ranges for each analyte were determined through replicate analysis of each analyte on multiple analyzer platforms. Ranges were then assigned to be either ± 20% or ± 3 SDs (whichever is greater). The assigned target values are the average of the observed values. The table below shows typical target values for each analyte, given the stated analyzer platform, along with analyte target value ranges. The labeling states that obtained values should fall within the specified range provided on lot-specific value sheets and that laboratories should establish appropriate acceptance criteria when using this product for its intended use. Analyte target values for additional analyzer platforms are also provided in the labeling.

			Typical Value (Value Range)		
Analyte	**Method**	**Units**	**Level 1**	**Level 2**	**Level 3**
17-alpha-OH-progesterone	LC/MS	ng/mL	101 (80-110)	134 (115-145)	176 (150-200)
25-Hydroxy Vitamin D	Diasorin Liaison	ng/mL	6.5 (4.5-7.5)	8.5 (8.0-9.5)	11.3 (10-15)
Acetaminophen	Abbott Axsym	µg/mL	14 (10-20)	74 (70-95)	132 (130-170)
ACTH	Siemens Immulite	pg/mL	10 (10-40)	30 (30-100)	53 (50-160)
AFP	Beckman Access	ng/mL	11 (8-15)	67 (50-90)	121 (100-160)
Aldosterone	LC/MS	ng/dL	6 (4-7)	25 (20-30)	42 (35-55)
Amikacin	Abbott TDx	µg/mL	5 (5-7)	15 (12-21)	23 (20-30)
Benzodiazepine	Hitachi	ng/mL	42 (30-60)	285 (200-350)	498 (400-600)
Beta-hCG	Abbott Axsym	mIU/mL	7 (0-25)	31 (20-80)	559 (400-700)
Beta-2-Microglobulin	Siemens Immulite	mg/L	1.0 (0.3-1.1)	2.6 (0.9-2.8)	4.2 (2.4-4.5)
CA 125	Siemens Immulite	U/mL	5 (3-6)	23 (20-30)	60 (56-92)
CA 15-3	Siemens Immulite	U/mL	18 (13-22)	51 (30-58)	88 (65-105)
CA 19-9	Beckman Access	U/mL	16 (9-20)	34 (28-42)	159 (130-190)
Carbamazepine	Siemens Dimension RxL	µg/mL	2.7 (2.2-4.2)	8.6 (7.5-10.6)	13.8 (13-17)
CEA	Abbott Axsym	ng/mL	1.8 (1.0-2.5)	14 (10-19)	29.7 (20-35)
CK-MB	Siemens Dimension RxL	ng/mL	1.8 (1.6-3.6)	13.7 (12-32)	29.3 (28-60)
Cortisol	Beckman Access	µg/mL	3.9 (3-5.8)	29.9 (16.5-35)	55.9 (30-65)
C-Peptide	Roche Elecsys	ng/mL	1.0 (0.8-2.0)	2 (1.8-4)	10.6 (10-20)
DHEA-Sulfate	Roche Elecsys	µg/mL	104 (90-110)	306 (270-380)	518 (440-660)
Digoxin	Siemens Dimension RxL	ng/mL	0.7 (0.5-0.9)	1.9 (1.5-2.2)	2.8 (2.5-3.5)
Disopyramide	Mira-Syva	µg/mL	1.8 (0.7-2.0)	5.2 (2.8-5.8)	8.4 (5.0-9.5)
Estradiol	Beckman Access	pg/mL	83 (25-175)	285 (225-525)	480 (450-800)
Estriol, Free	Beckman Access	µg/L	0.5 (0.3-0.7)	0.6 (0.5-0.9)	0.8 (0.7-1.3)
Ethosuximide	Mira-Syva	µg/mL	25 (16-32)	70 (55-84)	108 (96-130)
Ferritin	Siemens Dimension RxL	ng/mL	15 (10-30)	195 (165-215)	362 (325-395)
Folate	Beckman Access	ng/mL	1.5 (1.3 -3.0)	4.4 (4-7)	7.5 (7-12)
Free PSA	Beckman Access	ng/mL	0.22 (0.05-0.35)	2.79 (1.25-3.25)	5.6 (3.5-6.0)
Free T3	Beckman Access	pg/mL	2.7 (2.0-3.5)	3.8 (3.5-5.0)	5.5 (5.0-6.5)
Free T4	Siemens Dimension RxL	ng/dL	0.5 (0.3-0.7)	1.8 (1.5-2.5)	4 (3-5)
Fructosamine	Hitachi	umol/L	335 (250-400)	321 (250-400)	309 (250-400)
FSH	Abbott Axsym	mIU/mL	11.3 (3.5-16)	49.3 (30-54)	83.2 (62-92)
Gastrin	Siemens Immulite	pg/mL	14 (10-20)	246 (175-275)	412 (300-500)
Gentamicin	Siemens Dimension RxL	µg/mL	1.8 (0.8-2.0)	5.1 (3.8-5.8)	8 (7-9)
Growth Hormone	Beckman Access	ng/mL	2 (1-3)	10 (8-14)	17 (15-25)
hCG	Siemens Dimension RxL	mIU/mL	11 (3-15)	51 (30-150)	892 (500-1300)
Homocysteine	Abbott Axsym	µmol/L	5 (4.5 - 7.2)	13 (12-18)	19.8 (19.2-28.8)
IgE	Beckman Access	IU/mL	37 (30-50)	166 (135-213)	278 (240-380)
IGF-1	Siemens Immulite	ng/mL	50 (35-100)	186 (150-350)	320 (280-600)
Inhibin A	Beckman Access	pg/mL	28 (20-30)	34 (28-40)	40 (35-50)
Insulin	Beckman Access	uIU/mL	6 (4-10)	43 (37-85)	77 (70-150)
LH	Abbott Axsym	mIU/mL	8 (3.5-8)	46 (30-56)	82 (57-103)
Lidocaine	Siemens Dimension RxL	µg/mL	1.5 (1.2-1.8)	6 (3.6-6.3)	8 (6-9)
Lithium	Siemens Dimension RxL	mEq/L	0.8 (0.5-1.0)	1.2 (0.9-1.5)	1.6 (1.3-2.0)
NAPA	Abbott Axsym	µg/mL	4.1 (3.2-4.8)	8.2 (6-10)	11.2 (9-15)
PAP	Siemens Immulite	ng/mL	2 (1-3)	20 (10-25)	38 (30-50)
Phenobarbital	Siemens Dimension RxL	µg/mL	15 (12-18)	32 (26-39)	46 (40-60)
Phenytoin	Siemens Dimension RxL	µg/mL	7 (6-9)	16 (13-20)	24 (21-31)
Phenytoin, Free	Abbott TDx	µg/mL	1.8 (1-2)	4.4 (3.5-5.5)	7 (6-8)
Primidone	Mira-Syva	µg/mL	6 (3-6.5)	14 (7.5-15)	20 (12-22)
Procainamide	Abbott Axsym	mIU/mL	1.6 (1.2-2.8)	7.1 (5.5-9.5)	11.8 (10-16)
Procalcitonin	Kryptor	ng/mL	0.3 (0.2-0.6)	1.3 (0.8-2.0)	18 (10-30)
Progesterone	Beckman Access	ng/mL	1.4 (0.4-1.5)	9.6 (7.5-16)	16 (15-30)
Prolactin	Abbott Axsym	ng/mL	8 (6-10)	23 (19-29)	37 (32-48)
PSA	Beckman Access	ng/mL	0.9 (0.5-1.5)	3.4 (3-4)	30 (27-37)
PTH, Intact	Roche Elecsys	pg/mL	14 (10-35)	36 (34-75)	761 (700-1250)
Quinidine	Abbott Axsym	µg/mL	1 (0.9-1.5)	3.2 (2-4)	5.2 (4.8-7)
Salicylate	Siemens Dimension RxL	mg/dL	7 (5.5-9.5)	33 (29-39)	58 (52-68)
T3	Abbott Axsym	ng/mL	0.5 (0.4-0.8)	0.9 (0.7-1.6)	1.1 (1-2.2)

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Closed vial (shelf life) of 3 years at the recommended storage

temperature (-25 to -15ºC) was demonstrated based on accelerated stability studies. Real-time shelf-life stability studies for the Omni-IMMUNE solutions at -25 to -15ºC are ongoing. Studies also demonstrated that if a closed vial is thawed, remains closed, and is stored at 2 to 8ºC, the control solutions are stable for 30 days. Open vial stability of 30 days was also demonstrated at the recommended storage temperature of 2 to 8ºC. All storage recommendations are provided in the labeling.

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.