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

A. 510(k) Number:

k092051

B. Purpose for Submission:

Addition of value assignments for Apolipoprotein A (APO A), Apolipoprotein B (APO B), and Lipoprotein A (LpA) to control material previously cleared in k030942. The analytes are found endogenously in the source material (human serum).

C. Measurand:

Quality control material

D. Type of Test:

N/A

E. Applicant:

Microgenics Corporation, Thermo Fisher Scientific, Clinical Diagnostics Division

F. Proprietary and Established Names:

Thermo Scientific MAS® chemTRAK® H Liquid Assayed Chemistry Controls

Thermo Scientific Moni-Trol® H Liquid Assayed Controls

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1660 Quality Control Material (assayed and unassayed)

2. Classification:

   Class I, reserved

3. Product code:

   JJY

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   chemTRAK® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include chemTRAK® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

   Moni-Trol® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include Moni-Trol® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Siemens Advia Chemistry Systems, Siemens Dimension Vista Systems, Roche Cobas 6000, Roche Cobas Integra Systems, Olympus AU Systems, and Beckman Coulter Immage Systems.

I. Device Description:

MAS® chemTRAK® H is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various animal extracts and other non-protein materials including drugs. drug metabolites, and purified chemicals. Preservatives and stabilizers are added to maintain product integrity. chemTRAK® H is prepared from human source 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. The product is supplied as 3 levels (Level 1, Level 2 and Level 3) with 6 x 5 mL vials for each level.

Moni-Trol® H is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various animal extracts and other non-protein materials including drugs, drug metabolites, and purified chemicals. Preservatives and stabilizers are added to maintain product integrity. chemTRAK® H is prepared from human source 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. The product is supplied as 3 levels (Level 1, Level 2 and Level 3) with 6 x 5 mL vials for each level.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   MAS® chemTRAK® H, Dade Moni-Trol® H, Olympus Chemistry Control

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

   k030942

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include chemTRAK® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	same
Matrix	liquid	same
Storage	-20º C	same

Differences		
Item	Device	Predicate
Analyte list	Multi-analyte with Apolipoprotein A (APO A), Apolipoprotein B (APO B), and Lipoprotein A (LpA) value assignments added	Multi-analyte without value assignments for Apolipoprotein A (APO A), Apolipoprotein B (APO B), and Lipoprotein A (LpA)

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):

Value assignment ranges for the additional analytes Apolipoprotein A (APO A), Apolipoprotein B (APO B), and Lipoprotein A (LpA) were established based on data from three different laboratories over three separate days. The control material was tested on Siemens Advia Chemistry Systems, Siemens Dimension Vista Systems, Roche Cobas 6000, Cobas Integra Systems, Olympus AU Systems, and Beckman Coulter Immage Systems. Value assignments are established at ± 20 % of the mean value.

The protocols for establishing shelf-life for the additional analytes Apolipoprotein A (APO A), Apolipoprotein B (APO B), and Lipoprotein A (LpA) and open-vial stability were reviewed and are adequate. An accelerated stability study was performed to simulate a shelf life of 2.5 years frozen at -20 º C. Real time frozen stability data studies for the 3 additional analytes are on-going. The refrigerated stability claims (2-8º C) are 30 days unopened and 7 days opened.

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:

Values are provided in the package insert for each specific instrument.

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.