

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k050983

B. Purpose for Submission:

New Device

C. Analyte:

Creatinine

D. Type of Test:

Control Material

E. Applicant:

International Technidyne Corp.

F. Proprietary and Established Names:

IRMA TRUpoint™ Creatinine Control Kit

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1660 Quality control material (assayed and unassayed).
2. Classification:
Class I, Reserved
3. Product Code:
JJX
4. Panel:
75, Chemistry

H. Intended Use:

1. Intended use(s):
See Indications for Use Below
2. Indication(s) for use:
The IRMA TRUpoint™ Creatinine Control Kit is for use on the IRMA TRUpoint™ Blood Analysis System to perform Quality Control assays for Creatinine on the IRMA TRUpoint™ Blood Analysis System.
3. Special condition for use statement(s):
For Prescription Use Only
4. Special instrument Requirements:
IRMA TRUpoint™ Blood Analysis System

I. Device Description:

The IRMA TRUpoint™ Creatinine Control Kit is an assayed bi-level control used on the IRMA TRUpoint™ Blood Analysis System. The kit contains three capped luer lock syringes for each level. The control contains no human or biological materials. The IRMA TRUpoint™ Creatinine Control Kit is an aqueous based solution of creatinine and sucrose.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Bionostics Inc. RNA 823 Controls and Medical Analysis Systems Moni-Trol H Controls
2. Predicate K number(s):
k943754 and k030942
3. Comparison with predicate:

Similarities			
Item	Device	Predicate #1	Predicate #2
Intended Use	The IRMA TRUpoint™ Creatinine Control Kit are assayed quality control materials and are intended to be used to perform Quality Control assays for Creatinine on the IRMA TRUpoint™ Blood Analysis System.	RNA Medical Brand QC Blood Gas Electrolyte Metabolite Bun control is an assayed quality control material used for monitoring the performance of blood gas, electrolyte, metabolite, and BUN (urea) instrumentation for analytes and analyzers.	Moni-Trol H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations.
Form	Aqueous	Aqueous	Aqueous
Differences			
Item	Device	Predicate #1	Predicate #2
Open Stability	1 Hour	Immediately	14 days
Levels	Two	Three	Three
Closed Stability	2-8 °C	2-8 °C	-20 °C
Analytes	Creatinine	pH, pCO ₂ , pO ₂ , iCa, Na, K, Cl, iMg, Glucose, Lactate and Urea	Creatinine plus 69 other analytes

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

NCCLS EP-14A Evaluation of Matrix Effects

L. Test Principle:

N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
N/A
 - b. *Linearity/assay reportable range:*
N/A

c. *Traceability (controls, calibrators, or method):*

The IRMA TRUpoint™ Creatinine Control kit is composed of non-biological creatine anhydrous, sucrose and dye.

The range and value assignment was based on ANSI ASQ Z1.4 standard and is dependant on lot size. For a lot size of 600, thirteen were tested to determine the range mean. The derived mean and range is fixed according to CAP/HCFA criteria of +/- 0.03 mg/dL or +/-15%, whichever is greater. The assigned values are chosen to span the expected medically relevant decision point (approximately 1.5 mg/dL) and to incorporate the upper region of the reportable range (approximately 7.5 mg/dL).

Closed Container Stability

Closed container stability testing was conducted on 4 lots of each control level. Each lot was stored at different temperatures 4, 10, 22 and 30 °C and analyzed at its 4 week shelf-life. The sponsor reports significant shifts at un-refrigerated temperatures in the mean results. The sponsor recommends refrigeration storage of 2-8 °C.

Open Container Stability

Open container stability testing was conducted on 3 lots of each control level. Two lots were evaluated through 2 hours and one lot through 3 days. No significant changes in mean or variability were observed and support the sponsors' claim of 1 hour open container stability.

d. *Detection limit:*

N/A

e. *Analytical specificity:*

N/A

f. *Assay cut-off:*

N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:

a. *Clinical sensitivity:*

N/A

b. *Clinical specificity:*

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

N. Conclusion:

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