

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k072640

B. Purpose for Submission:

This submission is for the addition of a new control material containing ascorbic acid (CC) to the previously cleared IRISpec™ CA and CB urine chemistry control set. The new product is named IRISpec™ CA/CB/CC.

C. Measurand:

Quality control material for urine chemistry

D. Type of Test:

Not applicable

E. Applicant:

Iris International Inc.

F. Proprietary and Established Names:

IRISpec™ CA/CB/CC

G. Regulatory Information:

1. Regulation section:

CFR § 862.1660 Quality Control Material (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJW

4. Panel:

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

IRISpec™ CA/CB/CC is an assayed QC material for monitoring of the urine chemistry analytes and devices as listed on the package insert. For *in vitro* diagnostic (IVD) use only.

3. Special conditions for use statement(s):

Not applicable

4. Special instrument requirements:

iChem 100®, Aution AX-4280®, Aution AJ-4270®

I. Device Description:

IRISpec™ CA/CB/CC controls are based on a synthetic matrix simulating human urine with preservatives. Bovine-sourced biological material is added for serum albumin, hemoglobin, and bilirubin. L-ascorbic acid is in the CC control material only. It does not contain human sourced materials.

IRISpec™ CA/CB/CC will be marketed as a set. IRISpec™ CC is not intended to be marketed as a stand-alone product.

J. Substantial Equivalence Information:

1. Predicate device name(s):

IRISpec™ Urine Chemistry Control CA and CB

Note: The predicate device, IRISpec™ CA and CB, has been re-labeled as IRISpec™ CA/CB.

2. Predicate K number(s):

k945913

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Name	IRISpec™ CA/CB/CC Control	IRISpec™ CA/CB Control
Composition	CA and CB are identical to CA and CB of the predicate device. CC matrix is the same as CA/CB.	Synthetic matrix simulating human urine, with preservatives and bovine-sourced biological material for serum albumin, hemoglobin, and bilirubin. No human sourced materials.
Form	Same	Liquid, ready to use
Packaging-container	Same	Glass bottle with plastic screw cap
Packaging-fill volume	Same	100 mL
Preservative	Same	0.0048% gluteraldehyde
Storage	Same	2° to 8°C until expiration date
Stability-closed vial	Same	6 months at 2° to 8°C
Stability-open vial	Same	15 days at 2° to 8°C

Differences		
Item	Device	Predicate
Name	IRISpec™ CA/CB/CC Control	IRISpec™ CA/CB Control
Intended Use	IRISpec™ CA/CB/CC is an assayed QC material for monitoring of urine chemistry analytes and devices as listed on the package insert	The IRISpec Urine Chemistry Controls are intended to be used as a quality control material for all Chemstrip™ urine reagent strips
Analytes	Contains ascorbic acid in CC control	No ascorbic acid

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

None

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):*

Ascorbic acid was added gravimetrically to the control material to obtain a positive result of approximately 40 mg/dL. Values were confirmed with repeat testing on each instrument.

Comparison testing was performed on three lots of the proposed CC control material and compared to human urine spiked with ascorbic acid at 40 mg/dL. Testing was performed in triplicate on the iChem 100 Urine Analyzer. No measurement differences were found.

Real time, open vial, and accelerated stability protocols were reviewed and found to be acceptable. The material has a 6 month shelf life.

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:

Not applicable

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.