

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

A. 510(k) Number:

k062521

B. Purpose for Submission:

New device

C. Measurand:

Calibrator and control materials for oxalate,

D. Type of Test:

Calibrator and control materials

E. Applicant:

Thermo Electron Corporation

F. Proprietary and Established Names:

Oxalate Urine Controls (Normal & Elevated)

Oxalate Standard

G. Regulatory Information:

1. Regulation section:

21 CFR §862. 1150, Calibrator

21 CFR §862. 1660, Quality Control Material

2. Classification:

Class II and Class I, respectively

3. Product Code:

JIT and JJW, respectively

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The Oxalate Normal and Elevated Controls are for use in the quality control of the Thermo Oxalate method for the quantitative determination of urine

oxalate. The control is used for monitoring accuracy and precision on automated clinical chemistry analyzers and for manual operation. It is for in vitro diagnostic use only.

The Oxalate Standard is intended for the calibration of Oxalate assays using the Thermo Oxalate Reagent. It is for in vitro diagnostic use only.

3. Special condition for use statement(s):
Prescription Use Only
4. Special instrument Requirements:
Roche Cobas Mira

I. Device Description:

The Oxalate Urine Controls (Normal & Elevated) are aqueous synthetic urine preparations, formulated for monitoring the accuracy and precision of urine oxalate assays.

The Oxalate Standard is prepared gravimetrically from a certified primary reference material, and is supplied as an aqueous preparation with preservative. The standard contains 0.50 mmol/L Oxalate.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Oxalate Urine Controls, Sigma Chemical Co.
Oxalate Standard (0.5 mmol/L)
2. Predicate K number(s):
k842366
k883525
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The Oxalate Urine Controls (Normal & Elevated) are for use in the quality control of the Thermo Oxalate method for the quantitative determination of urine oxalate. The control is used for monitoring accuracy and precision on automated clinical chemistry analyzers and for manual operation. It is for	It is designed for use as a control in the determination of Oxalate according to Trinity Biotech Procedure No. 591

Similarities		
Item	Device	Predicate
	in vitro diagnostic use only. The Oxalate Standard is intended for the calibration of Oxalate assays using the Thermo Oxalate Reagent. It is for in vitro diagnostic use only.	
Matrix	Lyophilized powder - reconstituted	Liquid
Storage	2 to 8°C	2 to 8°C

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

None were reference in the submission.

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 (controls, calibrators, or method):*

The Thermo Oxalate Standard and control materials are prepared gravimetrically from an in-house primary standard that is traceable to NIST SRM # 40h. The target value for the standard is 0.5 mmol/L. Target values for the control materials are 0.3 mmol/L and 1.0 mmol/L. Values for the control materials are provided in the labeling for the Roche Cobas Mira.

Stability testing protocols and acceptance criteria were described and found to be acceptable. Accelerated stability testing was performed to support the expiration date. Real time studies are on going.

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:

Target values for the control materials are provided in the labeling for the Roche Cobas Mira. The labeling includes a recommendation that each laboratory establish its own mean and acceptable range.

N. Proposed Labeling:

The labeling is sufficient and satisfies the requirement of 21 CFR part 809.10

O. Conclusion:

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