

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

A. 510(k) Number:

k113177

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for 25-Hydroxyvitamin D assay

D. Type of Test:

Quality Control Materials

E. Applicant:

Quantimetrix

F. Proprietary and Established Names:

Quantimetrix Complete D 25-OH Vitamin D Control

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR§862.1660	75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Complete D 25-OH Vitamin D control is intended to monitor the performance of clinical assays used to quantitate total 25-OH Vitamin D.

3. Special conditions for use statement(s):

- For *in vitro* diagnostic use only
- For prescription use only
- DiaSorin Liaison users should dilute Level 1 and Level 2 by 75 % (3 parts control to 1 part Liaison® Vitamin D Specimen Diluent).

4. Special instrument requirements:

None

I. Device Description:

The Quantimetrix Complete D 25-OH Vitamin D Control is supplied liquid in two levels and consists of a human serum matrix containing preservatives.

The Quantimetrix Complete D 25-OH Vitamin D Control is supplied in two levels; each kit contains 3 vials of level 1 or level 2 per box. The controls are supplied as a ready-to-use liquid, requiring no reconstitution. They are prepared in human serum matrix spiked with 25-Hydroxyvitamin D₂ and 25-Hydroxyvitamin D₃ in order to achieve the two levels. The preservatives have been added to inhibit microbial growth.

The Quantimetrix Complete D 25-OH Vitamin D Control is prepared in a human serum matrix and contains other human source materials. All blood donor units comprising the serum pool have been tested and found nonreactive for hepatitis B surface antigen, Hepatitis C and HIV 1 and 2 antibodies when tested by FDA accepted methods. Handle these controls with the same precautions used when handling any potentially infectious material.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Fujirebio Diagnostics Vitamin D Control

2. Predicate K number(s):

k110641

3. Comparison with predicate:

Similarities		
	Predicate Device	New product
Control Name	Fujirebio Diagnostics, Inc.'s Vitamin D Control (k110641)	Complete D 25-OH Vitamin D Control
Intended Use	Fujirebio Diagnostics Vitamin D Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of Vitamin D.	same
Analyte	25-OH Vitamin D	same
Matrix	Human serum, protein (bovine), purified biochemical materials, and chemicals. Proclin 300 and Gentamicin as preservatives.	Vitamin D depleted human serum, reagent grade chemicals and preservatives.
Differences		
	Predicate Device	New product
	Fujirebio Diagnostics, Inc.'s Vitamin D Control	Complete D 25-OH Vitamin D Control
Volume	2.0mL (reconstituted)	3mL
Number of Levels	3	2
Storage (unopened)	12 months at 2 to 8° C	24 months at 2 to 8° C
Form	Lyophilized	Liquid

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 25-OH Vitamin D2 and D3 are purchased from commercial vendors. The Complete D® 25-OH Vitamin D Control is traceable to NIST reference material SRM972.

Stability

Shelf life and open vial stability:

Real-time testing at 2-8°C was conducted and is still on-going. The stability study protocol and acceptance criteria have been reviewed and found to be acceptable. The current real time and accelerated stability test results support two year shelf life stability, one year open vial stability when stored at 2-8°C and 30 days open vial stability when stored at room temperature (18-25°C).

Value Assignment

The control ranges as determined using LC-MS-MS, DiaSorin Liaison, LC-MS-MS Isotope Dilution, IDS EIA and IDS-RIA assays are provided in the assigned value sheet for each lot release. Control range was determined from replicate measurements using IDS-RIA, IDS-EIA, LC-MS-MS Isotope Dilution, DiaSorin Liaison, and LC-MS-MS. The ranges were determined as mean +/- 2 SD around the mean for LC-MS-MS and DiaSorin Liaison; and as +/- 20% CV around the mean for LC-MS-MS Isotope Dilution, IDS-EIA and IDS-RIA assays.

In the labeling the sponsor recommends that each end user laboratory establish its own means and acceptable ranges and use the assigned value sheet as guidance only.

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 control ranges for each assay are provided in the assigned value sheet for each lot release.

The expected ranges have been established from inter-laboratory data. Each laboratory should establish its own precision parameters.

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.