

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

A. 510(k) Number:

k052242

B. Purpose for Submission:

Marketing of a laboratory control

C. Measurand:

Microalbumin

D. Type of Test:

The product is used as a quality control serum to monitor the precision of laboratory testing procedures.

E. Applicant:

Bayer HealthCare LLC

F. Proprietary and Established Names:

ADVIA® Chemistry Microalbumin Controls

G. Regulatory Information:

1. Regulation section:
21CFR862.1660 Quality control material (assayed and unassayed).
2. Classification:
Class I (reserved)
3. Product code:
JJY
4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The ADVIA Chemistry Microalbumin Control is intended for in vitro diagnostic use in the control of ADVIA[®] Chemistry systems for the microalbumin method.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

Values are listed for several analyzers

I. Device Description:

The ADVIA Chemistry Microalbumin Control is a human urine based solution containing various constituents.

Human source materials have been screened by FDA approved methods and found to be negative for HBsAg and antibodies to HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Randox Urine Controls

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

k043266

3. Comparison with predicate:

Item or Characteristic	Device	Predicate
Format	Lyophilized mixture of human urine base to which appropriate constituents have been added to achieve specific	Same

Item or Characteristic	Device	Predicate
	concentration	
Constituent Analytes	Microalbumin values only	Multiple analytes
Stability	Reconstituted, capped and stored at 2-8° C stable for 28 days 24 months shelf life	Reconstituted urine controls are stable for 8 hours at 25° C and 5 days at 4° C if kept capped in original container and free from contamination or 14 days at -20° C
Levels	Two levels	Same

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

None were referenced 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, Stability, Expected values (controls, calibrators, or methods):

The value assignment of the Controls for the two levels were done by a Fitness-For-Use (FFU) study over a period of 4 days. The FFU data was collected with two lots of the Reagents, Calibrators and Controls on two ADVIA® 1650 systems for a total of 128 replicates.

The mean System Specific Values (SSVs) of the two Controls, Level 1 and 2, were then validated by value assignment using a nested testing protocol on the ADVIA® 1650. The nested tested derived mean SSVs compared well with FFU derived mean SSVs and were within 4.8%.

The FFU study was also done on the ADVIA[®] 2400 and 1200 systems to compare the 1650 derived mean SSVs with the SSVs derived on the ADVIA[®] 1200 and the ADVIA[®] 2400.

Shelf life stability: 24 months.

Open vial stability: 28 days at 2 to 8°C.

- 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.