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

A. 510(k) Number: K033278

B. Analyte: Uric Acid

C. Type of Test: Method used is based on UV detection.

D. Applicant: Randox Laboratories Ltd.

E. Proprietary and Established Names: Randox Uric Acid

F. Regulatory Information:

1. Regulation section: 21 CFR §862.1775 Uric acid test system
2. Classification: Class I
3. Product Code: CDO
4. Panel: 75

G. Intended Use:

1. Intended use(s):

The Randox Uric Acid Test Kit used on the Dimension® clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of uric acid in serum.

2. Special condition for use statement(s): None

3. Special instrument Requirements:

Dade Dimension Clinical Chemistry Analyzer.

H. Device Description:

The Randox Uric Acid Test Kit used on the Dimension Clinical Chemistry System consists of two liquid reagents ready for use. The reagents provided are Glycine Buffer (0.1 mmol/L pH 9.4) and Uricase Reagent (Bacterial) 8 IU/L. Store reagents at +2 to +8 °C.

I. Substantial Equivalence Information:

1. Predicate device name(s):

The Randox Uric Acid Test Kit is substantially equivalent to the currently marketed Dade Behring Dimension clinical chemistry system Uric Acid Flex reagent cartridge (K862359).

2. Predicate K number(s): K862359
3. Comparison with predicate:

Similarities between Predicate Device and Proposed Randox Uric Acid

Characteristics	Predicate Device (K862359)	Proposed Product
Device Brand Name	Dade Behring Dimension® Uric Acid Flex reagent cartridge	Randox Uric Acid Test Kit
Immunoassay System	Dade Dimension clinical chemistry system	Dade Dimension ® clinical chemistry system
Format	Liquid and ready to use.	Liquid and ready-to-use.
Storage Conditions	2 – 8 °C	2 – 8 °C
Intended Use	The Dade Uric Acid method used on the Dimension clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of uric acid in serum.	The Randox Uric Acid method used on the Dimension clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of uric acid in serum.

J. Standard/Guidance Document Referenced (if applicable): N/A

K. Test Principle: UV Detection.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

The within run and total run precision was determined by testing 20 replicates of 3 different control sera or patient samples in one assay. Where possible, control sera or patient samples within the normal range and at the decision making level were used. The mean concentration, the number of determinations, the standard deviation and the percentage coefficient of variation are listed below:

	Level 1	Level II	Level III
Mean	165.1	328	522.2
SD	4.217	6.358	10.370
% CV	2.55%	1.94%	1.99%
n	20	20	20

   b. Linearity/assay reportable range:

The linearity of this method was evaluated by comparing the recovery of serial diluted linearity sera and the observed value was compared to the known expected or calculated expected result. The linearity claim is based on a percentage

deviation of ≤5% at the 2 highest analyte concentrations. The uric acid assay was found to be linear up to 1145 µmol/l.

c. Traceability (controls, calibrators, or method): N/A

d. Detection limit:

The minimum detectable level has been determined as 23 µmol/l (0.39 mg/dl). Sensitivity is determined for each analyte and is expressed as the lowest measurable concentration that can be distinguished from zero with a %CV ≤ 20.

e. Analytical specificity:

Interference was evaluated by spiking human serum pools with hemoglobin, unconjugated bilirubin, conjugated bilirubin, and triglycerides concentrate, and triglyceride intralipid.

The following interferents were tested up to the indicated levels and found not to interfere:

Bilirubin (conjugated and unconjugated0	152 µmol/l
Hemoglobin	1000 mg/dl
Triglyceride (concentrate)	834 mg/dl
Triglyceride (intralipid)	1600 mg/dl

f. Assay cut-off: N/A

2. Comparison studies:

a. Method comparison with predicate device:

A comparison of 40 normal and abnormal patient samples, which span the analytical range, is made using the Randox method and a comparable, commercially available test kit- the Predicate Device. The results obtained are correlated using least-squares regression analysis.

Linear regression analysis of the data resulted in the equation:

Y = 1.01 X + 3.9, with a correlation coefficient r = 1.00

Matrix comparison: Only Serum Samples were evaluated

3. Clinical studies:

a. Clinical sensitivity:

Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Clinical studies are not typically submitted for this device type.

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

4. Clinical cut-off: Not Applicable

5. Expected values/Reference range:

Reference ranges provided are cited from those quoted in the appropriate literature. A warning statement accompanies all reference ranges to indicate that they are provided for GUIDANCE ONLY and that individual laboratories are advised to establish their own reference range to reflect the age, sex, diet and geographical location of the specific population encountered in the daily course of laboratory operation.

Normal Values		
Serum: (5)	Men	208 - 428 µmol/l 3.5 - 7.2 mg/dl
	Women	155 - 357 µmol/l 2.6 – 6.0 mg/dl

M. Conclusion:

Based on the information provided in this 510(k) submission, I recommend that the Randox Uric Acid Test Kit for use on the Dade Dimension® clinical chemistry system is substantially equivalent to the currently marketed Dade Behring Dimension clinical chemistry system Uric Acid Flex reagent cartridge (K862359).