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

A. 510(k) Number:

k150819

B. Purpose for Submission:

New Device

C. Measurand:

Triglyceride

D. Type of Test:

Quantitative, colorimetric

E. Applicant:

Randox Laboratories Limited

F. Proprietary and Established Names:

Triglycerides (TRIGS)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CDT	Class I, meets the limitation of exemption 21 CFR §862.9(c)(4)	21 CFR §862.1705 Triglyceride Test System	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below

2. Indication(s) for use:

   For the quantitative in vitro determination of Triglycerides in serum. Triglyceride measurements are used in the diagnosis and treatment of diseases involving lipid metabolism and various endocrine disorders *e.g.,* Diabetes mellitus, nephrosis and liver obstruction.

   This in vitro diagnostic device is intended for prescription use only.

3. Special conditions for use statement(s):

   For Prescription Use Only

4. Special instrument requirements:

   For use with the RX Daytona Plus Chemistry analyzer

I. Device Description:

The Randox Triglycerides (TRIGS) test system is a one reagent system. The reagent (R1) is supplied in liquid ready-to-use form and contains pipes buffer, 4-chlorophenol, ATP, 4-aminophenazone, lipoprotein lipase (bacterial), glycerol kinase (bacterial), glycerol-3-phosphate oxidase (bacterial), peroxidase (horseradish), magnesium (Mg2+) and sodium azide.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Triglycerides GPO-PAP
2. Predicate 510(k) number(s):
   k923508
3. Comparison with predicate:

Similarities and Differences		
Item	Triglycerides (TRIGS) (New Device)	Triglycerides GPO-PAP (Predicate device, k923508)
Intended Use	For the quantitative in vitro determination of Triglycerides in serum. Triglyceride measurements are used in the diagnosis and treatment of diseases involving lipid metabolism and various endocrine disorders e.g Diabetes mellitus, nephrosis and liver obstruction	Same
Assay Methodology	Quantitative, colorimetric method	Same
Measuring Range	12.4 to 1000 mg/dL	11.5 to 1133 mg/dL
Sample type	Serum	Serum, heparinized plasma and EDTA plasma samples are suitable

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

CLSI EP5-A2: *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition*

CLSI EP6-A: *Evaluation of the Linearity of Quantitative Measurement Procedures*

CLSI EP17-A: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second Edition*

CLSI C28-A3: *Defining, Establishing, and verifying Reference Intervals in the Clinical Laboratory; Approved Guideline*

CLSI EP9-A2: *Method Comparison and Bias Estimation Using Patient Samples*

L. Test Principle:

Triglycerides are hydrolyzed by a lipase to glycerol and fatty acids. In the presence of ATP and glycerol kinase, the glycerol is phosphorylated to glycerol-3-phosphate, which is then oxidized by glycerol-3-phosphate-oxidase to produce hydrogen peroxide (H_2O_2). H_2O_2 reacts with 4-aminophenazone and 4-chlorophenol under the catalytic action of peroxidase to form a colored quinoneimine complex. The absorbance of the quinoneimine complex at 510 nm is proportional to the concentration of triglycerides in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision of the Triglycerides (TRIGS) test system was determined in accordance with the Clinical and Laboratory Standards Institute (CLSI) EP5-A2 guideline. Two reagent lots, 2 RX Daytona Plus analyzers and 2 operators were utilized in the study. Two replicates of each of the control and serum samples were tested on two separate runs per day for 20 days, leading to the generation of 80 data points for each sample. The mean, SD, and %CV calculated for within-run and total imprecision for each lot yielded similar results. The results from one representative lot is shown below.

Sample	**Mean (mg/dL)**	**Within-run**		**Total**	
		SD	**%CV**	**SD**	**%CV**
Serum Pool 1	13.3	0.88	8.0	4.42	13.4
Serum Pool 2	96.4	1.77	1.9	1.77	2.1
Control Pool 1	96.5	1.77	1.8	1.77	2.3
Native Patient Pool 3	104	1.77	2.1	2.65	2.5
Native Patient	117	2.65	2.3	2.65	2.5

Sample	Mean (mg/dL)	Within-run		Total	
		SD	%CV	SD	%CV
Pool 4					
Serum Pool 5	237	4.42	1.9	7.08	2.1
Control Pool 2	240	3.54	1.5	4.42	2.0
Control Pool 3	259	3.54	1.3	3.54	1.5
Serum Pool 6	326	4.42	1.4	4.42	1.6

b. *Linearity/assay reportable range:*
Two linearity studies were performed. For both studies, samples were prepared by mixing a high spiked serum sample with a low diluted serum sample to obtain 11 concentrations. In Study 1, the samples spanned the range of 19.8 to 1017 mg/dL and in Study 2, the samples spanned the range of 12.04 mg/dL to 995.60 mg/dL, with each sample assayed in 5 replicates. The results of linear regression analyses for each study are summarized below:

Study 1: y = 1.02x - 0.25; r=0.999

Study 2: y = 0.96x + 3.30; r= 1.000.

The RX Daytona Plus analyzer is capable of auto diluting with a 1:15 dilution factor, and an auto-dilution study was conducted against a manual dilution and all results were within a pre-specified acceptance criteria.

The reportable range of the assay is 12.4 to 1000 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The controls and calibrators to be used with this assay are manufactured by Randox Laboratories. The Randox Calibration Serum Level 3 has previously been cleared under k053153, and the control under k942458.

Value Assignment for Calibrators
A 2 point calibration is recommended every 28 days or with change of reagent lot. 0.9% NaCl as zero calibrator and Randox Calibration Serum Level 3 are recommended for calibration. The Randox Calibration Serum Level 3 is a lyophilized calibrator prepared with human serum at a target value of 241 mg/dL. Value assignment is done in-house by testing 2 lots of the calibrator against the master lot in replicates of 5 on the Triglycerides (TRIGS) test system. The protocol and acceptance criteria were reviewed and found acceptable.

d. *Detection limit:*

A detection limit study was performed according to CLSI EP17-A2 guideline. Limit of Blank (LoB) was determined by running 4 blank samples in 20 replicates across 3 days giving 60 determinations in total on the RX Daytona Plus analyzer, and LoB was the value at the 95^{th} percentile. The limit of detection (LoD) was determined

using 4 diluted patient serum sample pools in 20 replicates across 3 days for a total of 60 data points on the RX Daytona Plus analyzer. Limit of Quantitation (LoQ) was determined by running 4 diluted patient serum sample pools in 12 replicates across 5 days yielding a total of 60 results. The LoQ was defined by the mean concentration of the lowest sample that met the performance goal (intermediate precision of ≤ 20% CV).

LoB	2.65 mg/dL
LoD	3.96 mg/dL
LoQ	12.4 mg/dL

The claimed measuring range for the triglyceride assay is 12.4-1000 mg/dL.

e. Analytical specificity:

Interference testing was performed at 2 different concentrations of triglycerides (150 mg/dL and 496 mg/dL) using one RX Daytona Plus analyzer and one reagent lot. Samples with added potential interferents were tested in replicates of 10, and compared to a sample without interferent. The sponsor defined no significant interference as < 10 % difference from the control sample.

Results are summarized in the table below:

Interferent	**Concentration at which no interference was observed**
Ascorbic acid	3 mg/dL
Hemoglobin	750 mg/dL
Unconjugated bilirubin	60 mg/dL
Total bilirubin	60 mg/dL

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed following the recommendations in CLSI EP9-A2 comparing testing on the Randox Triglycerides (TRIGS) reagent on a Rx Daytona Plus analyzer to the predicate device. A total of 109 serum samples covering the range 14.2 to 986 mg/dL were assayed in singlicate. Of these, 10 were spiked or diluted samples. Linear regression analysis yielded the following results:

$y = 0.97x + 1.22$, $r = 0.999$

95% CI of slope = 0.96 to 0.97

95% CI of y-intercept = -0.03 to 2.47

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 NCEP (American National Cholesterol Education Program) has established the following classification for triglyceride levels according to the risk of developing coronary heart diseases:

Normal < 150 mg/dL

Borderline-high 150 – 199 mg/dL

High 200 – 499 mg/dl

Very High ≥ 500 mg/dl

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.