

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

A. 510(k) Number:

K050823

B. Purpose for Submission:

New Device

C. Measurand:

High-density lipoprotein cholesterol

D. Type of Test:

Quantitative

E. Applicant:

Teco Diagnostics

F. Proprietary and Established Names:

Direct HDL Cholesterol
Direct HDL/LDL Cholesterol Calibrator

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1475 – Lipoprotein test system
21 CFR 862.1150 – Calibrator

2. Classification:

Class I (meets limitation to exemption 862.9(c)(4))
Class II

3. Product code:

LBR – HDL, LDL & VLDL precipitation

JIS – Primary calibrator

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

The Direct HDL Cholesterol Reagent is for the quantitative determination of high-density lipoprotein (HDL) in human serum or plasma on automated analyzer. For *in vitro* diagnostic use only.

The Direct HDL/LDL Cholesterol Calibrator is for the calibration of Teco Diagnostics' Direct HDL and Direct LDL Cholesterol Reagent Set in serum or plasma. For *in vitro* diagnostic use only.

2. Indication(s) for use:

Teco Direct HDL/LDL Calibrator for the calibration of Teco Diagnostics' Direct HDL and Direct LDL Cholesterol Reagent Set in serum or plasma and with Teco Direct HDL Cholesterol Reagent for the quantitative determination of high-density lipoprotein cholesterol (HDL-C) in human serum or plasma. HDL Cholesterol is recognized as a useful tool in identifying patients who are at a higher risk for coronary heart diseases. Low HDL cholesterol levels are associated with an increased risk. This reagent set is intended for *in vitro* diagnostic use only. For prescription use.

3. Special conditions for use statement(s):

These devices are for prescription use.

4. Special instrument requirements:

The Direct HDL Cholesterol Reagent requires an automated clinical chemistry analyzer capable of accommodating two-reagent assays.

I. Device Description:

The Direct HDL Cholesterol Reagent Kit consists of 3 x 60 mL Reagent 1 and 3 x 20 mL Reagent 2. Reagent 1 contains magnesium chloride, aminoantipyrene, buffer, and preservative. Reagent 2 contains peroxidase (Horseradish), cholesterol oxidase (Norcardia), cholesterol esterase (Pseudomonas), HDAOS (N-(2-Hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline, sodium salt), buffer, surfactant, and preservative.

The Direct HDL/LDL Cholesterol Calibrator is a preparation of lyophilized human serum containing lipoproteins from the various lipoprotein classes including high-density lipoproteins. Target concentrations for HDL and LDL are 53 mg/dL and 114 mg/dL, respectively.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Pointe Scientific AutoHDL Cholesterol
 Pointe Scientific Auto HDL/LDL Cholesterol Calibrator

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

K981978
 K992002

3. Comparison with predicate:

Similarities		
Item	Device	Predicates
Intended Use	Quantitative detection of HDL	Same
Specimens	Serum and plasma (heparin or EDTA)	Same
Test Principle	Enzymatic colorimetric reaction	Same

Differences		
Item	Device	Predicate
Linearity	5-150 mg/dL	2-150 mg/dL

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

NCCLS EP5-A – Evaluation of Precision Performance of Clinical Chemistry Devices
 NCCLS EP6-P – Evaluation of Linearity of Quantitative Analytical Methods
 NCCLS EP9-A – Method Comparison and Bias Estimation Using Patient Samples

L. Test Principle:

The test employs enzymatic colorimetric reaction. Results are determined

photometrically by measuring the color intensity of a dye, which is generated during the reaction and is directly proportional to the cholesterol concentration of the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-run precision for the Direct HDL Cholesterol Reagent was determined following a modification of NCCLS document EP5-T2. Two commercial serum controls were assayed 25 times on the Hitachi 717. The following results were obtained:

	Control 1	Control 2
Mean	38.1 mg/dL	83.5 mg/dL
SD	1.54	1.94
CV	4%	2.3%

Run-to-run precision for the Direct HDL Cholesterol Reagent was also determined following a modification of NCCLS document EP5-T2. Two commercial serum controls were assayed on the Hitachi 717 five times per day for five days, for a total of 25 values. The following results were obtained:

	Control 1	Control 2
Mean	38.2 mg/dL	83.6 mg/dL
SD	1.74	2.2
CV	4.5%	2.6%

b. *Linearity/assay reportable range:*

Linearity studies were designed using NCCLS EP6-P. Serial dilutions of high serum samples were used. Each concentration was tested twice to determine the mean concentration. The results of this study demonstrate that the linearity of this test is 5 – 150 mg/dL. The Direct HDL Cholesterol values were plotted versus the sample dilutions, and an appropriate line fitted by standard linear regression: $y = 1.14x - 1.97$, $r = 0.999$.

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

The calibrator is prepared from lyophilized human serum. Each plasma donor unit used in the preparation of this product has been tested by an FDA-approved method and found non-reactive for the presence of HbsAg, HCV,

and antibody to HIV-1/2.

The value of this calibrator was assigned by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL).

d. Detection limit:

The analytical sensitivity of the Direct HDL Cholesterol Reagent was determined on the Hitachi 717 as 2 mg/dL of HDL Cholesterol. The sensitivity was determined by reading the change for a saline sample and serum sample with known concentrations (Hitachi 717). The 2 mg/dL sample, as opposed to the 1 mg/dL sample, results were all within the 95% confidence interval.

e. Analytical specificity:

The interference studies were conducted according to the procedures recommended in NCCLS guideline EP7-P. Two samples spiked with interferant were each tested three times. The mean sample results with and without interferant were evaluated. Hemoglobin levels up to 100 mg/dL, triglyceride levels up to 1800 mg/dL, and bilirubin levels up to 20 mg/dL were found to exhibit negligible interference (<5%) on this method.

f. Assay cut-off:

See "Detection limit" above.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison experiments were designed using NCCLS EP9-A. The comparison study was performed on the Hitachi 717 Chemistry Analyzer. Fifty-two (52) serum samples, ranging from 22.3 to 96.8 mg/dL, were evaluated by the predicate device and the Teco Direct HDL Cholesterol Reagent Set. The results of this study yielded the following regression equation: $y = 0.93x + 0.73$, with a correlation coefficient of 0.916.

b. Matrix comparison:

Six samples were split into serum and plasma (sodium heparin, lithium heparin, and EDTA) to perform matrix comparison. The three correlation coefficients were ≥ 0.998 .

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 expected values were based on literature.

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.