skyla Hi Lipid Panel Plus

IVD

CE

Product Code：801-110

For professional use

Rev：E

========== **Be sure to read and follow the instructions before use** ==========

1. Intended Use

The skyla Hi Lipid Panel PLUS used with skyla Hi Analyzer is intended to be used for the quantitative determination of Blood Glucose (GLU), High-Density Lipoprotein (HDL), Total Cholesterol (TC), and Triglyceride (TG) in both of finger-prick whole blood, venous whole blood, Plasma or Serum. The calculated values of Low-Density Lipoprotein (LDL),Very Low-Density Lipoprotein (VLDL) and Chol / HDL ratio (TC / HDL) can then be obtained.

Precaution/Warning

1. This product is for in vitro diagnostic use only
2. The product must not be used individually for diagnostic purpose. The users should consult a physician and make a diagnosis after all clinical and laboratory findings are evaluated.
3. The Reagent kit should be stored at 2-8 °C (35.6-46.4 °F).
4. Please wear the gloves when performing the test.
5. Do not re-use any part of the test kit.
6. Dispose all waste in accordance with applicable national and/or local regulations.

2. Principles

The skyla Hi Lipid Panel PLUS contains a total of 4 types of dried reagents located in the respective detection wells of the analysis disc. The user only needs to inject the blood specimens into the blood inlet of the disc, and places the disc into the analyzer. The test will be done automatically within 13 minutes. Two additional calculated values are also obtained after the test. For the detail description of disc, please refer to “skyla Hi Analyzer Operator’s Manual”.

Clinical Significance:

Glucose (GLU)

GLU can be used for the diagnosis of diabetes and diseases related to the carbohydrate metabolism. Diabetes, chronic pancreatitis and certain endocrine diseases may lead to hyperglycemia. Abnormal glucose metabolism, islet cell tumors, pancreatic tumors and severe liver diseases may lead to hypoglycemia.

High-Density Lipoprotein (HDL)

HDL is an important substance that helps the human body to prevent arteriosclerosis. HDL can be used to determine the ischemic heart diseases, cerebral arteriosclerosis, stroke and other illnesses caused by excessively low HDL.

Total Cholesterol (TC)

TC test can be used to assess the metabolic state of lipids. When there is an excessive amount of TC in the serum, atherosclerosis or hypertension are a likely cause and could lead to myocardial infarction or stroke. The lipoprotein is also an important marker to determine the risk of atherosclerosis.

Triglyceride (TG)

TG test can be used to assess the metabolic state of lipids. When there is an excessive amount of TG in the serum, atherosclerosis or hypertension are a likely cause and could lead to myocardial infarction or stroke. Other possible causes of elevated TG include poorly controlled diabetes, nephrotic syndrome, hypothyroidism, hereditary hypertriglyceridemia or alcohol.

#Low-Density Lipoprotein (#LDL)

This parameter is calculated from HDL, TC, and TG. Excessive LDL is a warning sign of cardiovascular diseases, which in turn may cause hyperlipoproteinemia, nephrotic syndrome, obstructive hepatitis, and hypothyroidism. Excessively low LDL may lead to β hyperlipoproteinemia and liver cell failure. LDL is also an important indicator of coronary heart disease.

#Very Low-Density Lipoprotein (#VLDL)

VLDL is calculated from TG and is closely associated with TG. Diabetes, pancreatitis, uremia, nephritis, pregnancy, taking birth control pills, alcohol, obesity can lead to elevated VLDL value.

#Chol / HDL ratio (#TC / HDL)

Total cholesterol / HDL is calculated from TC and HDL, it is an important indicators of vascular risk. This ratio reflects two powerful components of risk. An increase in total cholesterol concentration is an atherogenic lipid maker, whereas low HDL cholesterol is correlated with numerous risk factors, including the metabolic syndrome and probably involves some independent risk.

Method:

GLU

GLU is determined through the endpoint enzymatic reaction approach. The Glucose reacts with Glucose Oxidase yielding o-D-gluconolactone and Peroxide (H2O2).The following Peroxidase reaction

with H2O2 results in a wine-red colored product that has an absorbance at wavelength of 510 nm. The original GLU concentration is directly proportional to the absorbance maximum in this end-point reaction.

HDL

HDL is determined through the endpoint enzymatic reaction approach. MgCl2 and Dextran Sulfate form insoluble compounds with LDL, VDL and Chylomicrons that are removed by centrifugal force. The remaining HDL is hydrolyzed by Cholesterol Esterase into Cholesterol and Fatty Acids. Cholesterol reacts with Cholesterol Oxidase yielding Cholest-4-En-3-One and Peroxide (H2O2). The following Peroxidase reaction with H2O2 results in a wine-red colored product that has an absorbance at wavelength of 510 nm. The original HDL concentration is directly proportional to the absorbance maximum in this end-point reaction.

TC

TC is determined enzymatically by an endpoint reaction. It is hydrolyzed by Cholesterol Esterase into free Cholesterol and Fatty Acids. Cholesterol reacts with Cholesterol Oxidase yielding Cholest-4-En-3-One and Peroxide (H2O2). The following Peroxidase reaction with H2O2 results in a wine-red colored product that has an absorbance at wavelength of 510 nm. The original TC concentration is directly proportional to the absorbance maximum in this end-point reaction.

TG

TG is determined enzymatically. Lipase converts the Triglycerides to Glycerol and Fatty Acids. In a subsequent step, Glycerol Kinase converts Glycerol into Glycerol Phosphate, which is oxidized, producing Dihydroxyacetone Phosphate and Peroxide (H2O2) in the process. The Peroxidase reaction with H2O2 results in the production of a wine-red colored product that has an absorbance maximum at 510 nm. The original TG concentration is directly proportional to the absorbance maximum in this end-point reaction.

#LDL (Calculated)

The skyla Hi analyzer automatically calculates the concentration of LDL in each sample using the directly determined values for total cholesterol, HDL, and triglycerides and the standard Friedewald equation.6 This equation is not valid for triglyceride concentrations above 400 mg/dL, non-fasting patients, and patients with Type III hyperlipoproteinemia (dysbetalipoproteinemia).6, 7 An LDL value is not reported for samples with triglycerides greater than 400 mg/dL or if any of the directly measured analyte values is unavailable. On the printout, the calculated value for LDL is prefixed "#" to indicate that it is calculated.

#VLDL (Calculated)

The skyla Hi analyzer automatically calculates the concentration of VLDL in each sample using the standard triglycerides/5 (if units in mg/dL) equation.6 This equation is not valid for triglyceride concentrations above 400 mg/dL, non-fasting patients, and patients with Type III hyperlipoproteinemia (dysbetalipoproteinemia).6, 7 Of course, no VLDL value is calculated if no triglyceride value is available. On the printout, the calculated value for VLDL is prefixed "#" to indicate that it is calculated.

Reaction pathway：

GLU

$$\text{Glucose} + O_2 \xrightarrow{\text{Glucose Oxidase}} \text{o-D-gluconolactone-6-Phosphate} + H_2O_2$$

$$H_2O_2 + \text{4-Aminoantipyrine} + \text{TBHBA} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 2H_2O$$

HDL

$$\text{CM,LDL,VLDL,and HDL} + \text{Dextran Sulfate} + MgCl_2 \longrightarrow \text{HDL} + \text{Insoluble Complexes}$$

$$\text{Insoluble Complexes} \xrightarrow{\text{Centrifugal force}} \text{Insoluble Complexes Pelleted in Precipitate Well}$$

$$\text{HDL-Cholesterol Esters} + H_2O \xrightarrow{\text{Cholesterol Esterase}} \text{Cholesterol} + \text{Fatty Acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol Oxidase}} \text{Cholest-4-En-3-One} + H_2O_2$$

$$H_2O_2 + \text{4-Aminoantipyrine} + \text{TBHBA} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 2H_2O$$

TC

$$\text{Cholesterol Esters} + H_2O \xrightarrow{\text{Cholesterol Esterase}} \text{Cholesterol} + \text{Fatty Acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol Oxidase}} \text{Cholest-4-En-3-One} + H_2O_2$$

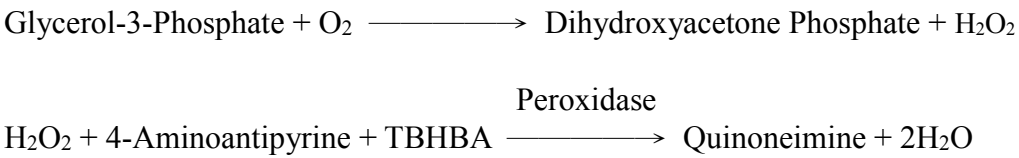
$$H_2O_2 + \text{4-Aminoantipyrine} + \text{TBHBA} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 2H_2O$$

TG

$$\text{Triglycerides} + H_2O \xrightarrow{\text{LPL}} \text{Glycerol} + \text{Fatty Acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow[Mg^{2+}]{\text{GK}} \text{Glycerol-3-Phosphate} + \text{ADP}$$

$$\xrightarrow{\text{GPO}}$$



3. Reagents

Included:

Each panel contains dried reagents. ,.

Reagent Composition:

Test marker	Composition	Quantity/Panel
GLU	4-Aminoantipyrine	0.02 mg
	Peroxidase	0.58 U
	Glucose Oxidase	4.6 U
	TBHBA	0.02 mg
HDL	Cholesterol Esterase	0.25 U
	Peroxidase	0.48 U
	Cholesterol Oxidase	0.40 U
	TBHBA	0.02 mg
	4-Aminoantipyrine	0.01 mg
	Dextran Sulfate	0.02 mg
	Magnesium chloride	0.08 mg
TC	4-Aminoantipyrine	0.01 mg
	Cholesterol Esterase	0.65 U
	Cholesterol Oxidase	0.65 U
	Peroxidase	0.65 U
	TBHBA	0.01 mg
TG	4-Aminoantipyrine	0.003 mg
	Lipoprotein Lipase	0.78 U
	Glycerol Kinase	0.62 U
	L-alpha-Glycerophosphate Oxidase	0.1 U

Test marker	Composition	Quantity/Panel
	Peroxidase	1.885 U
	Magnesium chloride	0.001 mg
	ATP	0.015 mg
	TBHBA	0.025 mg

Reagent Storage:

- The analysis disc should be stored at 2～8°C.
- The test kit can be stored in unopened pouch at room temperature (15-25°C) for 12 weeks.
- The expiry date of the reagent is printed on the outside of the sealed pouch of analysis disc. Do not use if the reagents have expired.

4. Specimen Collection and Preparation

The product is suitable for specimen, including fingertip whole blood, lithium heparinized venous whole blood, lithium heparinized plasma or Serum. The minimum required specimen volume for each test is 30 μL, but no more than 40 μL injected the specimen into blood inlet on the analysis disc.

Whole blood venipuncture samples should be run within 10 minutes of collection.[8, 9] Glucose concentrations are affected by the length of time since the patient has eaten and by the type of sample collected from the patient. To accurately determine glucose results, samples should be obtained from a patient who has been fasting for at least 12 hours. The glucose concentration decreases approximately 5-12 mg/dL in 1 hour in uncentrifuged samples stored at room temperature.[10]

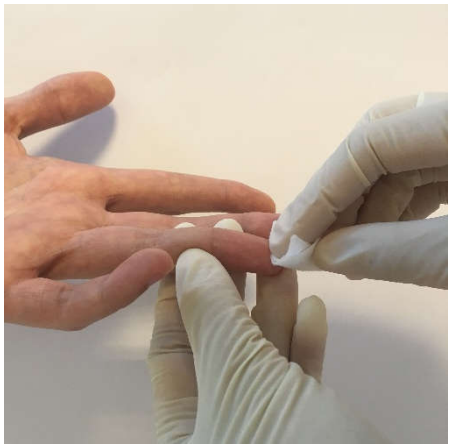
NOTE:

1. Do not use specimens containing other anti-coagulants. That would cause in incorrect test results.

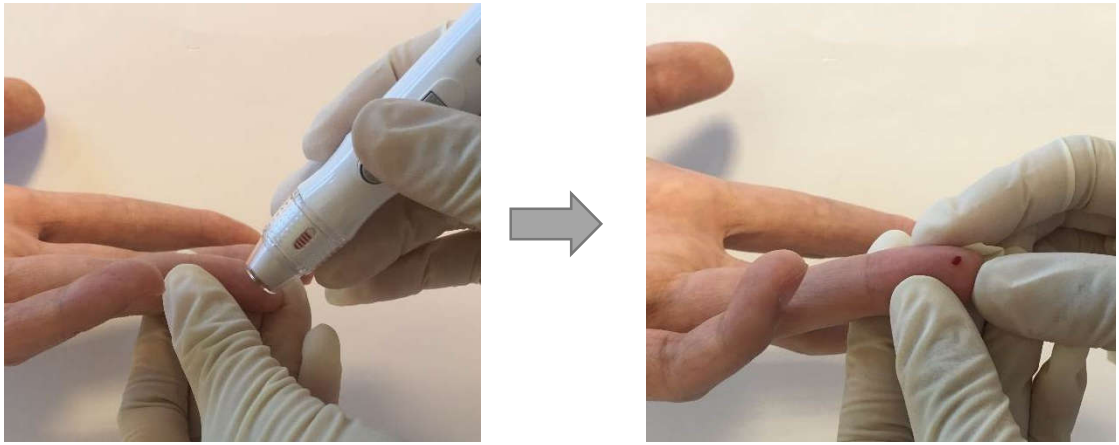
2. Make sure that blood collection channel on the analysis disc is completely filled with specimen and it must flow to the position of the check-window.
3. Once the blood collection channel on the analysis disc is filled with the specimen, analysis must begin within 5 mins.
4. The use of whole blood specimens with hematocrits (Hct) higher than 60% may affect the test results.

Steps for Fingertip Whole Blood Collection

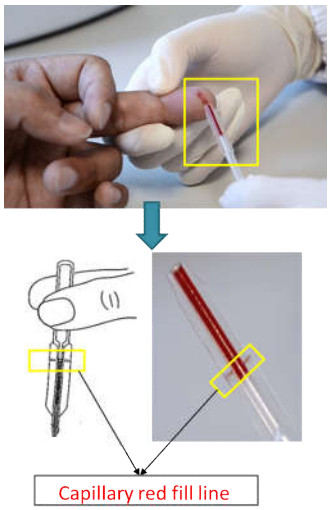
- Fingertip whole blood can be collected either by healthcare provider or by the person who need the blood test under healthcare provider's guidance.
- Ask the person who need blood test to massage the distal 2/3 of the finger for about 30 seconds with an alcohol wipe. Thoroughly dry the site with gauze pad while massaging the finger for approximately 30 more seconds.



- Prick fingertip by using lancet for site selected.



- The first drop contains excess tissue fluid and must be wiped away.
- Use a capillary to collect blood sample.



For further information in specimen collection and preparation, please refer to “skyla Hi Analyzer Operator’s Manual”.

5. Test Procedures

Material Preparation:

1 pieces of the analysis disc of **skyla** Hi Lipid Panel PLUS.

Required materials not included in the kit:

skyla Hi Analyzer

Sample collection container with heparin anticoagulant (for venous whole blood)

Finger lancets

Quality control solution

Test Conditions:

Test should be carrying out in an environment with temperatures of 10°C~32°C (50.0-89.6 °F). Each test will take about 13 minutes. During the test, chamber in the analyzer keeps the temperature at 37°C for stable assay

Test Steps:

1. Open the aluminum pouch and remove the analysis disc.
2. Place and fix the analysis disc onto the analysis carrier
3. Drop the blood sample in to blood inlet on the analysis disc.

Note:Make sure that blood collection channel on the analysis disc is completely filled with sample as shown in figure (a) adequate. the specimen must flow to the labeled Blood Checkpoint. If the specimen did not flow to the labeled Blood Checkpoint as shown in figure (b), please inject/drop more blood samples into the blood inlet.

If the blood inlet exterior has excess blood buildup, use non-ciliated tissues to wipe away the excess blood outside the blood inlet.

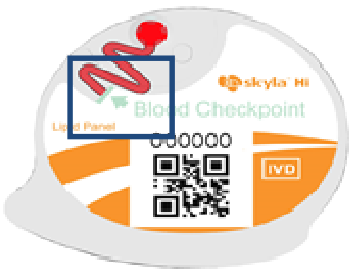


Fig. (a) adequate

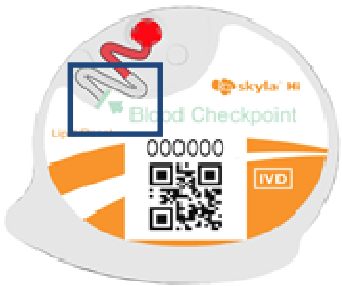


Fig. (b) inadequate

4. Place the analysis carrier to the analyzer drawer.

5. Press the “start” button on the screen to initiate testing.

For details on the operating steps and instrument setting, refer to “the skyla Hi Analyzer Operator’s Manual.”

Note: 1. To operate the analysis disc or instrument, please wear lab gloves and other protective gear to avoid contamination by specimen.

2. The used analysis disc, tips should be discarded as biomedical waste.

3. Testing should be performed within 20 minutes after the pouch is opened.

4. Do not place the analysis disc at the environment more than 25°C and longer than 48 hours prior to use.

5. If the analysis disc or its package is damaged or is over the expiry date, do not use it.

6. Calibration

The barcode on every manufactured analysis disc contains all information required for calibration of the test items. The analyzer will automatically read the barcode information during testing.

Traceability information

The calibrators are traceable to Siemens ADVIA Chemistry analyzer method calibration to below reference material or method：

method	Traceable to reference material / method
GLU	The ADVIA Chemistry GLUH_3 assay is traceable to the Standard Reference Material 965a from the National Institute of Standards and Technology (NIST).
HDL	The D-HDL method is traceable to the NCEP Designated Comparison Method (reference method) via patient sample correlation.
TC	The ADVIA CHOL_2 method is traceable to the NCEP/CDC reference method, which uses reference materials from the National Institute of Standards and Technology (NIST), via patient sample correlation.
TG	The ADVIA TRIG method measures total glycerols and is traceable to a reference method, which uses reference materials from the National Institute of Standards and Technology (NIST), via patient sample correlation.

7. Quality Control

External quality control materials can be used for the accuracy monitor of skyla system. The recommended frequency of QC testing is as follows. (External quality control materials are not provided by LITE-ON)

- At least every 30 days.
- Before a new batch of reagents is used for testing.
- When the analyzer is moved or the operating environment significantly changes.

8. Reference interval

The table below shows the reference interval for each test item. These ranges are provided as a reference only. It is recommended that every laboratory or test site should establish its own reference interval from its particular patient population.

Test Item	Reference Interval	Reference Interval (SI Unit)
GLU	70 – 110 mg/dL	3.9 – 6.1 mmol/L
HDL	> 40 mg/dL	> 1.0 mmol/L
TC	< 200 mg/dL	< 5.2 mmol/L
TG	< 150 mg/dL	< 1.7 mmol/L

9. Limitation

Interference studies:

1. Effect of endogenous substances

   Physiological interferents in blood include hemolysis, icterus, and lipemia. For every test item, 2 Levels human serum pool supplemented with known concentrations of the endogenous substances were used for the testing. Significant interference is defined as a >10% shift in the test result.

Test Item	substance concentration with interferences of less than 10%			
	Hemolysis [Hemoglobin]	Icterus [Bilirubin (unconjugated)]	Icterus [Bilirubin (conjugated)]	Lipemia [Intralipid]
GLU	400 mg/dL	4.08 mg/dL	13.01 mg/dL	543.7 mg/dL
HDL	527.9 mg/dL	1.83 mg/dL	0.49 mg/dL	484mg/dL
TC	400 mg/dL	12.9 mg/dL	9.5 mg/dL	774 mg/dL
TG	113 mg/dL	1.78 mg/dL	4.24 mg/dL	---

2. Effect of exogenous substances

Ten exogenous substances were selected as potential interferents for the study. For every test item, human serum pool supplemented with a known concentration of the substances was used for the testing. Significant interference is defined as a >10% shift in the test result.

Substance	Test Concentration	Affected Test Item	Effect
Acetaminophen	20 mg/dL	No significant interference	
Acetylsalicylic acid	65 mg/dL	No significant interference	
Ampicillin	5 mg/dL	No significant interference	
Ascorbic acid	6 mg/dL	No significant interference	
Caffenine	6 mg/dL	No significant interference	
Cephalothin	30 mg/dL	No significant interference	
Cimetidine	2 mg/dL	No significant interference	
Ibuprofen	50 mg/dL	No significant interference	
Salicylic acid	60 mg/dL	No significant interference	
Theophylline	4 mg/dL	No significant interference	

3.The description for the condition NA. of HDL and #LDL #VLDL

Test Item	NA. possible condition
HDL	TG or TC over the upper dynamic range TG>400mg/dL TC>350mg/dL
LDL	HDL or TC or TG is out of dynamic range HDL,TC,TG any NA
VLDL	TG is out of dynamic range TG is NA

4. The description for the calculation of #LDL, if HDL or TG is out of dynamic range

Test Item	calculation
LDL	◆ When TG <35 mg/dL & 20<=HDL<=100 LDL calculated by TG as 35 mg/dL ◆ When HDL<20 mg/dL LDL calculated by TG as 35 mg/dL, HDL calculated by 20 mg/dL ◆ When HDL>100 mg/dL LDL calculated by TG as 35 mg/dL, HDL calculated by 100 mg/dL

10. Performance Characteristics

Dynamic range:

The dynamic range was determined by linearity study, as follows:

Test Item	Dynamic Range	Dynamic Range (SI Unit)
GLU	30 – 600 mg/dL	1.7 – 33.3 mmol/L
HDL	20 – 100 mg/dL	0.5 – 2.6 mmol/L
TC	50 – 540 mg/dL	1.3 – 14.0 mmol/L
TG	35 – 600 mg/dL	0.4 – 6.8 mmol/L

Analytical Sensitivity:

The sensitivity (limits of quantitation) was determined according to the lowest concentration of the dynamic range which had an acceptable CV (CV<20%). The sensitivity of each test item is shown in the table below.

Test Item	Limit of Detection	Test Item	Limit of Detection
GLU	30 mg/dL	TC	50 mg/dL
HDL	20 mg/dL	TG	35 mg/dL

Precision:

Precision studies adopt serum pool of high and low concentrations as test samples. Tests are performed twice a day for a total of 20 days. Results for repeatability and reproducibility of each test item are shown in the table below.

Level 1					
Test Item	Mean	Within-Run		Total	
		SD	%CV	SD	%CV
GLU	86.1 mg/dL	3.6	**4.2**	3.8	**4.4**
HDL	58.9mg/dL	1.2	**2.0**	1.3	**2.1**
TC	248.0 mg/dL	6.3	**2.5**	7.2	**2.9**
TG	182.2 mg/dL	8.8	**4.8**	9.1	**5.0**

Level 2					
Test Item	Mean	Within-Run		Total	
		SD	%CV	SD	%CV
GLU	284.0 mg/dL	9.5	**3.4**	9.5	**3.4**
HDL	31.1 mg/dL	1.0	**3.4**	1.2	**3.8**

Level 2					
Test Item	Mean	Within-Run		Total	
		SD	%CV	SD	%CV
TC	110.1 mg/dL	1.5	**1.4**	2.3	**2.1**
TG	96.2 mg/dL	7.5	**7.8**	8.1	**8.4**

Method Comparison:

The automatic clinical chemistry analyzer in clinical laboratory was used as comparative method in the study. The tests are performed by using the same clinical serum sample for two methods. Correlation between two methods can be determined through statistical analysis.

Test Item	Correlation Coefficient (R)	Slope	Intercept	SEE	N	Sample range
GLU	0.9983	1.006	-0.6	8.4	48	31 – 585 mg/dL
HDL	0.9902	1.011	-0.3	3.4	46	18-104 mg/dL
TC	0.9976	1.003	0.4	5.1	46	54 – 330 mg/dL
TG	0.9972	0.997	0.7	7.9	47	30 – 467 mg/dL

Matrix Comparison:

The Correlation between WB, plasma and serum was determined. The clinical sample was used in the study.

Test Item	N	Matrix type	Correlation Coefficient (R)	Slope	Intercept
GLU	10	Fingertip WB vs WB	0.9767	1.085	-8.8

Test Item	N	Matrix type	Correlation Coefficient (R)	Slope	Intercept
		Fingertip WB vs Plasma	0.9884	1.081	-7.9
		Fingertip WB vs Serum	0.9829	1.097	-10.0
		WB vs. Plasma	0.9782	0.998	0.8
		WB vs. Serum	0.9906	1.012	-1.1
		Serum vs. Plasma	0.9939	0.986	1.9
HDL	15	Fingertip WB vs WB	0.9932	1.012	0.5
		Fingertip WB vs Plasma	0.9947	1.040	-0.5
		Fingertip WB vs Serum	0.9939	1.025	0.2
		WB vs. Plasma	0.9989	1.028	-1.1
		WB vs. Serum	0.9985	1.013	-0.4
		Serum vs. Plasma	0.9987	1.015	-0.7
TC	10	Fingertip WB vs WB	0.9845	1.146	-23.4
		Fingertip WB vs Plasma	0.9765	1.192	-31.2
		Fingertip WB vs Serum	0.9871	1.247	-40.5
		WB vs. Plasma	0.9946	1.038	-6.5
		WB vs. Serum	0.9968	1.087	-14.9
		Serum vs. Plasma	0.9920	0.955	7.8
TG	10	Fingertip WB vs WB	0.9994	0.946	6.8
		Fingertip WB vs Plasma	0.9978	0.965	3.1
		Fingertip WB vs Serum	0.9989	0.891	10.0
		WB vs. Plasma	0.9992	1.020	-3.8
		WB vs. Serum	0.9995	0.942	3.6
		Serum vs. Plasma	0.9994	1.083	-7.7

11. Reference

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Symbol Index			
REF	Catalogue number		Consult instruction for use
LOT	Batch code		Use by
	Manufacturer	EC REP	Authorized representative in the European Community
IVD	In Vitro diagnostic medical device	CE	CE mark
	Temperature limitation		Caution
	Do not reuse		

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