Lipid Test Devices
Package Insert

CE IVD

3-in-1		English
MODEL LS-101	REF LS-103-2	

For testing cholesterol in human whole blood, plasma or serum.
For in vitro diagnostic use only.
For professional use only.

INTENDED USE

The *VivaDiag* Lipid Test Devices work with the *VivaDiag* Lipid Meter to measure the lipid concentration in whole blood, plasma and serum during professional testing.
The 3-in-1 Lipid Test Device is used to measure the concentrations of Total Cholesterol (TC), High Density Lipoprotein (HDL) and Triglycerides (TG) simultaneously. It is also used to calculate LDL and TC/HDL.
Note: *Three separate test devices are also available, which can measure the concentrations of TC, HDL, and TG individually. Lipid measurements are used in the diagnosis and treatment of atherosclerotic coronary artery disease and in the diagnosis of metabolic disorders involving lipids and lipoproteins.*

MEASUREMENT RANGE

Test Type	Measurement Range
Total Cholesterol	100-500 mg/dL (2.59-12.93 mmol/L)
High Density Lipoprotein	15-120 mg/dL (0.39-3.10 mmol/L)
Triglycerides	45-650 mg/dL (0.51-7.34 mmol/L)

For total cholesterol and high density lipoprotein, 1 mmol/L =38.66 mg/dL; for triglycerides, 1 mmol/L=88.6 mg/dL.
Results below the ranges will show "<_", and results above the ranges will show ">_". When concentrations of specimens are above the test ranges, values for TC/HDL, LDL will display "- -".

PRINCIPLE AND REFERENCE VALUES

VivaDiag Lipid Test Devices use a timed-endpoint method to measure the Total Cholesterol (TC)/High Density Lipoprotein (HDL)/Triglycerides (TG) concentrations in whole blood, serum or plasma. The concentration of Low Density Lipoprotein (LDL) is calculated by the values of TC, TG and HDL. The system monitors the change in absorbance at 635 nm at a fixed-time interval. The change in absorbance is directly proportional to the concentration of lipid in the specimen.
TC: In the reaction, cholesterol esterase hydrolyzes cholesterol esters to free cholesterol and fatty acids. The free cholesterol is oxidized to cholesten-3-one and hydrogen peroxide by cholesterol oxidase. Peroxidase catalyzes the reaction of hydrogen peroxide with 4-aminoantipyrine and phenol to produce a colored quinoneimine product.
HDL: The dextran sulphate/Mg^{2+} on the test device precipitates the chylomicrons, VLDL and LDL, leaving HDL in the specimen. The cholesterol concentration of this HDL is then determined enzymatically, the same as TC.
TG: Triglycerides in the specimen are hydrolyzed to glycerol and free fatty acids by the action of lipase. A sequence of three coupled enzymatic steps using glycerol kinase (GK), glycerophosphate oxidase (GPO), and horseradish peroxidase (POD) causes the oxidative coupling of 4-aminoantipyrine to form a blue dye.
LDL: When the concentration of TG in the specimen is equal to or lower than 400mg/dL, LDL concentration can be calculated by the meter with the following equation[2]:
LDL = TC – HDL - TG/2.2 (mmol/L); LDL = TC– HDL -TG/5 (mg/dL)
Calculated LDL is an estimation of LDL.
Reference values are listed in the chart below[3,4]:

Tests	Desirable	Borderline High	High
Total Cholesterol (TC)	<5.2 mmol/L (<200 mg/dL)	5.2-6.2 mmol/L (200-240 mg/dL)	>6.2 mmol/L (240 mg/dL)
High Density Lipoprotein (HDL)	≥1.5 mmol/L (≥60 mg/dL)	Men: 1.5-1.0 mmol/L (60-40 mg/dL) Women: 1.5-1.3 mmol/L (60-50 mg/dL)	Men: <1.0 mmol/L (40 mg/dL) Women: <1.3 mmol/L (50 mg/dL)
Triglycerides (TG)	<1.7 mmol/L (<150 mg/dL)	1.7-2.3 mmol/L (150-200 mg/dL)	>2.3 mmol/L (200 mg/dL)
Low Density Lipoprotein (LDL)	<3.4 mmol/L (<130 mg/dL)	3.4-4.1 mmol/L (130-160 mg/dL)	>4.1 mmol/L (160 mg/dL)

Reference ranges may vary between laboratories. Every laboratory should establish its own reference range as needed.[1]
Blood lipid levels will have big physiological fluctuations depending on food consumed or exercise.

REAGENTS AND PERFORMANCE CHARACTERISTICS

Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances.

Tests	Components
Total Cholesterol	Cholesterol esterase>0.25U; Cholesterol oxidase>0.12U; POD(horseradish)>0.5U; Ascorbate oxidase>0.5U; 4-aminoantipyrine>0.05mg; MAOS>0.03mg; buffer
High Density Lipoprotein	Magnesium chloride>0.1mg; Dextran sulphate>0.4mg; Ascorbate oxidase>0.5U; Cholesterol esterase>0.25U; Cholesterol oxidase>0.12U; POD(horseradish)>0.5U; 4-aminoantipyrine>0.05mg; MAOS>0.03mg; buffer
Triglycerides	Lipoprotein lipase>0.27U; Glycerol kinase>0.38U, Glycerol phosphate oxidase>0.08U, POD(horseradish)>0.5U; ATP>0.2mg; Ascorbate oxidase>0.5U 4-aminoantipyrine>0.08mg; MAOS>0.03mg; buffer

The performance characteristics of these optical lipid devices have been determined in both laboratory and clinical tests. This test has been developed to be specific for the parameters to be measured with the exception of the interferences listed. Refer to the **Limitations** section for detailed information.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- The test devices should remain in the original package until use.
- Do not use after the expiration date.
- Use the test device immediately after removing it from the foil pouch or the canister.
- Do not touch the reagent area of the test device.
- Discard any discolored or damaged test devices.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to local regulations after testing.
- Check the code chip before performing a test. Make sure to use the code chip that is included with the package of test devices. Insert the code chip into the code chip slot. The code chip slot is located on the left side of the meter.
- Check that the specimen type displayed on the meter LCD is the same as the specimen type tested. Whole blood samples have a two-digit test number "***BL***" displayed on the screen. Serum or plasma samples have the letter "***SE***". Decisions of medical relevance are not to be taken without consultation of a doctor. Changes to treatment should only be made after proper training.

STORAGE AND STABILITY

Store as packaged in the sealed pouch/canister, either at room temperature or refrigerated (2-30°C). Keep out of direct sunlight. Test devices are stable through the expiration date printed on the test device foil pouch. The open-bottle shelf life is 3 months. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Fresh capillary blood; heparinized or EDTA venous whole blood; serum and heparinized plasma specimens.
- Heparinized or EDTA venous whole blood, serum and heparinized plasma must be kept in a closed container and must be used within 8 hours of collection. Mix stored specimens adequately before testing.
- Use fresh capillary blood immediately after collection.
- Capillary Transfer Tube or pipette must be used to collect capillary specimens for accurate results.

MATERIALS

Materials Provided

- Test Devices
- Code Chip
- Capillary Transfer Tubes
- Package Insert

Materials Required But Not Provided

- Meter
- Safety Lancets or Lancing Device with Sterile Lancets
- Gauze for Puncture Site
- Latex Gloves
- Alcohol Swab

DIRECTIONS FOR USE

Allow the test device, specimen, and/or controls to reach operating temperature (15-40ºC) prior to testing. Refer to the *VivaDiag* Lipid Testing System User's Manual for detailed instructions.
1. Insert the code chip into the meter and code the meter correctly. Refer to Coding the Meter section in the User's Manual for details. Compare the code number on the code chip with the code number printed on the test device foil pouch / canister label and ensure the two numbers are identical to avoid inaccurate results.
2. Check that the specimen type displayed on the meter LCD is same as the specimen type tested. If not, set the correct specimen type. Refer to the User's Manual for details.
3. Remove the test device from the foil pouch/canister.
4. Wait for the meter to flash the test device symbol. Insert the test device completely into the test device channel in the same direction as the arrow printed on the test device.
5. For venous whole blood/plasma/serum specimens: Samples should be tested right after collection. If the testing is not conducted at the time of collection, mix the specimen for 15 minutes before testing.
6. For capillary blood specimens: wipe away the first drop of blood. Collect 25µL (10µL for individual tests) of capillary blood specimen using a Capillary Transfer Tube or pipette. Refer to the User's Manual for details. Hold the tube slightly downward and touch the tip of the Capillary Transfer Tube to the blood drop. The specimen will automatically be drawn into the tube. Stop drawing blood when the specimen reaches the fill line. Do not squeeze the capillary transfer tube and/or cover the air vent while collecting the blood specimen.
7. While the meter is flashing the blood drop symbol, apply 25uL (10uL for individual tests) of specimen to the Specimen Application Area of the test device using a pipette or Capillary Transfer Tube. Align the tip of the pipette or Capillary Transfer Tube with the Specimen Application Area to apply the blood. Three dashed lines will appear on the meter screen to indicate that the test is in progress.
8. Read the results on the screen in 2 minutes. Refer to the User's Manual for detailed test procedures.

Note: *Blood specimens for the 3-in-1 test or the individual tests can be obtained by using a safety lancet. (For individual tests only, a lancing device may also be used.). Avoid an environment with strong lighting during the test. Be sure the alcohol dries completely before pricking finger. Hand lotions or creams on the finger should be completely removed from the skin prick site before testing or the TG results will be abnormally high. Excessively squeezing the finger may alter the results. For best results, fasting for at least 12 hours is recommended. Add 25µL (10µL for individual tests) of specimen to the test device all at one time.*

INTERPRETATION OF RESULTS

The meter automatically measures concentrations of TC, HDL, and TG. In the event of unexpected or questionable results, the following steps are recommended:
- Confirm that the test devices have been used within the expiration date printed on the foil pouch/canister.
- Compare results to controls with known levels and repeat the test using a new test device.
- If the problem persists, discontinue using the test devices immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

Linearity

Five replicate assays were drawn from three test device lots and tested on the Lipid Testing Systems (y), using five concentration levels of heparin preserved venous whole blood specimens. Several Lipid Testing Systems were used to perform tests at each concentration (n=5). The same specimens were also tested using a reference method (x). Linearity results are presented below:

Total Cholesterol

Test Device Lot	Linearity Equation	R
Lot 1	y = 0.9672x + 2.6989	0.9992
Lot 2	y = 0.9757x + 3.3939	0.9985
Lot 3	y = 0.9748x + 1.3249	0.9985

High Density Lipoprotein

Test Device Lot	Linearity Equation	R
Lot 1	y = 0.99x - 0.5190	0.9982
Lot 2	y = 0.9981x - 0.3746	0.9984
Lot 3	y = 0.9775x + 0.543	0.9983

Triglycerides

Test Device Lot	Linearity Equation	R
Lot 1	y = 0.98x + 0.1054	0.9992
Lot 2	y = 0.985x - 1.1291	0.9993
Lot 3	y = 0.983x - 0.7096	0.9990

Reproducibility and Precision

Ten replicate assays were tested. Fresh heparin preserved venous whole blood specimens at three concentration levels were used with three test device lots, producing the following within-run precision and total precision estimates.
Within-run precision using whole blood specimens statistical analysis gives the mean, standard deviations (SD), and coefficients of variation (CV%) listed below:

Total cholesterol

Precision	Level I (n=10)			Level II (n=10)			Level III (n=10)		
Lot Number	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (mg/dL)	150.2	150.0	150.9	241.5	241.8	241.0	335.3	335.2	341.3
SD (%CV)	2.9%	2.3%	3.3%	2.0%	1.7%	1.6%	1.9%	1.3%	1.3%

Total precision is listed below:

Total Precision	Level I (n=30)	Level II (n=30)	Level III (n=30)
Mean (mg/dL)	150.4	241 .4	337.3
SD (%CV)	2.7%	1.7%	1.7%

High Density Lipoprotein

Precision	Level I (n=10)			Level II (n=10)			Level III (n=10)		
Lot Number	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (mg/dL)	22.4	22.8	22.2	54.0	54.3	54.9	79.4	78.5	79.8
SD (mg/dL) or %CV	1.2	0.8	0.6	4.8%	4.0%	2.8%	2.9%	3.4%	3.3%

Total precision is listed below:

Total Precision	Level I (n=30)	Level II (n=30)	Level III (n=30)
Mean (mg/dL)	22.5	54.4	79.2
SD (mg/dL) or %CV	0.90	3.8%	3.2%

Triglycerides

Precision	Level I (n=10)			Level II (n=10)			Level III (n=10)		
Lot Number	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (mg/dL)	75.0	74.0	74.2	256.9	254.0	260.1	328.1	339.1	330.8
SD (mg/dL) or %CV	2.0	1.4	2.3	1.8%	2.1%	0.8%	1.9%	1.0%	1.9%

Total precision is listed below:

Total Precision	Level I (n=30)	Level II (n=30)	Level III (n=30)
Mean (mg/dL)	74.4	257.0	332.7
SD (mg/dL) or %CV	1.9	1.9%	2.1%

Accuracy

The Lipid Test Devices were used by a trained technician to test heparin preserved venous whole blood specimens from 100 participants. The same specimens were analyzed using a reference method (x). The results are compared below:

Total Cholesterol

Specimen	Slope	Intercept	R	N
Venous whole blood	1.0092	3.0701	0.9869	100

High Density Lipoprotein

Specimen	Slope	Intercept	R	N
Venous whole blood	1.0367	-1.4891	0.9928	100

Triglycerides

Specimen	Slope	Intercept	R	N
Venous whole blood	1.0203	-0.5208	0.9950	100

QUALITY CONTROL

For best results, performance of test devices should be confirmed by testing known specimens/controls whenever a new test is performed or whenever a new package is first opened. Each laboratory should establish its own goals for adequate standards of performance.

LIMITATIONS

The following substances do not interfere with test results:

Substance	Amount	Substance	Amount
Acetaminophen	1324 µmol/L (20 mg/dL)	Cholesterol	12.9 mmol/L (500 mg/dL)
Ascorbic Acid	568 µmol/L (10 mg/dL)	Triglyceride	7.3 mmol/L (650 mg/dL)
Conjugated Bilirubin	240 µmol/L (20 mg/dL)	Uric Acid	0.6 mmol/L (10 mg/dL)
Creatinine	442 µmol/L (5 mg/dL)	Hemoglobin	2 g/L (200 mg/dL)
Ibuprofen	2425 µmol/L (50 mg/dL)	Dopamine	5.87 umol/L (0.09 mg/dL)
Methyldopa	71 µmol/L (1.5 mg/dL)		

High concentrations of uric acid and ascorbic acid can lead to low measurements. Anticoagulants, such as heparin and EDTA, are recommended for use with venous whole blood. Do not use EDTA plasma, which lead to higher results. Do not use other anticoagulants, such as iodoacetate, sodium citrate or those containing fluoride. Arterial blood isn't recommended for use. Hemolyzed blood or thrombolytic therapy blood may lower the results. Venous occlusion may increase the results, and it is not recommended that blood be drawn from sites where veins are occluded.

BIBLIOGRAPHY

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2. Friedewald et al. Clin Chem. 1972. 18(6): 499-502
3. National Cholesterol Education Program 2001 Guidelines, National Institutes of Health, May 2001.
4. ATP III NCEP Guidelines for CHD Risk. JAMA.2001. 285:2486-2509

INDEX OF SYMBOLS

	Consult instructions for use		Use by	30°C 2°C	Store between 2-30°C
IVD	For *in vitro* diagnostic use only	LOT	Lot number	CODE	Code number
Σ	Contents sufficient for <n> tests		Manufacturer	REF	Catalog #
EC REP	Authorized representative	MODEL	Model number		Do not reuse

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