120x175mm

High Density Lipoprotein Cholesterol Test Strip (DryChemistry)
Package Insert

REF HLS-101	English

INTENDED USE

The High Density Lipoprotein Cholesterol Test Strip (Dry Chemistry) work with the Blood Lipid Analysis Meter or Dry Biochemical Analysis Meter to measure the High Density Lipoprotein Cholesterol (HDL) concentration in whole blood, plasma and serum. For professional use.

MEASUREMENT RANGE

Test Type	Measurement Range
High Density Lipoprotein Cholesterol	0.39-2.59 mmol/L (15-100 mg/dL)

Note: for high density lipoprotein cholesterol test, 1mmol/L=38.66mg/dL.
Results below the ranges will show “Lo”, and results above the ranges will show “HI”.

PRINCIPLE AND REFERENCE VALUES

The High Density Lipoprotein Cholesterol Test Strip (Dry Chemistry) use a timed-endpoint method to measure the High Density LipoproteinCholesterol (HDL) concentrations in whole blood,serum or plasma. The system monitors the change in absorbance at 620 nm at a fixed-time interval. The change in absorbance is directly proportional to the concentration of lipid in the specimen.
HDL: The dextran slulphate/Mg^{2+}on the test strip 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.

Reference values are listed in the chart below:

Tests	Desirable	Borderline High	High
High Density Lipoprotein Cholesterol (HDL)	≥1.5mmol/L(60mg/dL)	Men: 1.5 -1.0 mmol/L (60-40mg/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)

Reference ranges may vary between laboratories. Every laboratory should establish its own reference range as needed.
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
High Density Lipoprotein Cholesterol	Dextran Sulfate>0.1mg; Magnesium Chloride>0.1mg; Cholesterol Esterase>0.3U; Cholesterol Oxidase>0.2U; Peroxidase>0.6U; Ascorbate Oxidase>0.1U; 4-aminoantipyrine>0.006mg

The performance characteristics of these optical strips 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 strips should remain in the original package until use.
- Do not use it after the expiration date.
- Do not touch the reagent area of the test strips.
- Discard any discolored or damaged test strips.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test strips 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 strips. 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 is same as the specimen type tested.
- 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 or canister, either at room temperature or refrigerated (2-30℃). Keep out of direct sunlight. Test strips are stable through the expiration date printed on the test strip canister or foil pouch.

Remove only enough test strips for immediate use. Replace the cap on the strips canister immediately and tightly.

Do not freeze. Do not use it beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- For professional use: 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 with 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 Strips •Code Chip •Package Insert

Materials Required But Not Provided

•Meter •Safety Lancets •Capillary Transfer Tubes •Latex Gloves • Alcohol Swab

DIRECTIONS FOR USE

Allow the test strip, specimen, and/or controls to reach operating temperature (10-35℃) prior to testing. Refer to the Blood Lipid Monitoring System or Dry Biochemical Monitoring 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 strip canister or foil pouch and ensure the two numbers are identical to avoid inaccurate results.
2. Check that the specimen type is same as the specimen type tested. If not, set the correct specimen type. Refer to the User’s Manual for details. Remove the test strip from the test strip canister or foil pouch.
3. Wait for the meter to display Insert Strip. Insert the test strip completely into the test strip channel in the same direction as the arrows printed on the test strip.
4. Prepare the specimen to be tested. For venous whole blood/plasma/serum specimens: mix the specimen for about 15minutes. For capillary blood specimen: wipe away the first drop of blood. Collect 10μL of the second or third drop 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.
   Draw the specimen and stop drawing when the specimen comes to the fill line.
5. While the meter is flashing the blood drop symbol, apply 10μL specimen to the Specimen Application Area of the test strip 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. 4 dashed lines will appear on the meter to show the test is in progress.
6. Read the results on the screen in 2 minutes. Refer to the User’s Manual for detail test procedures.

Note: Use safety lancets for test. Avoid an environment with strong lighting during the test. Be sure the alcohol dries completely before picking the finger. Excessively squeezing the finger may alter the results. For best results, fasting for at least 12 hours is recommended. Add 10μL specimen to the test strip at one time.

INTERRELATION OF RESULTS

The meter automatically measures concentrations of HDL. In the event of unexpected or questionable results, the following steps are recommended:

- Confirm that the test strips have been used within the expiration date printed on the canister or foil pouch.
- Compare results to controls with known levels and repeat the test using a new test strip.
- If the problem persists, discontinue using the test strips immediately and contact your local distributor.

PERFORMANCE CHARACTERIALS

Linearity

Ten replicate assays were drawn from three test strip lots and tested on the Cholesterol Monitoring Systems (y), using ten concentration levels of heparin preserved venous whole blood specimens. Several Cholesterol Monitoring 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:

High Density Lipoprotein Cholesterol

Test Strip Lot	Linearity Equation	R
Lot 1	y = 0.9538x+0.0552	0.992
Lot 2	y = 0.965x + 0.0677	0.995
Lot 3	y = 1.0018x + 0.0023	0.995

Reproducibility and Precision

Twenty replicate assays were tested. Fresh heparin preserved venous whole blood specimens at three concentration levels were used with three test strip 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:

High Density Lipoprotein Cholesterol

Precision	Level I (n=20)			Level II (n=20)			Level III (n=20)		
Lot Number	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (mmol/L)	0.78	0.78	0.79	1.24	1.23	1.21	1.63	1.65	1.64
SD(%CV)	0.03	0.03	0.03	4.57%	3.06%	4.22%	3.57%	3.73%	4.03%

Total precision is listed below:

Total Precision	Level I (n=60)	Level II (n=60)	Level III (n=60)
Mean (mmol/L)	0.78	1.23	1.64
SD(%CV)	0.03	4.06%	3.74%

Accuracy

The High Density Lipoprotein Cholesterol Test Strip (Dry Chemistry) 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:

High Density Lipoprotein Cholesterol

Specimen	Slope	Intercept	R	N
Venous whole blood	1.0144	-0.0071	0.993	100

QUALITY CONTROL

For best results, performance of test strips 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. Contact your local distributor for information on specific controls for this product.

LIMTATIONS

The following substances do not interfere with test results:

Substance	Amount	Substance	Amount
Acetaminophen	1324μmol/L(20mg/dL)	Triglyceride	7.3 mmol/L(650mg/dL)
Ascorbic Acid	568 μmol/L(10mg/dL)	Uric Acid	0.6mmol/L(10mg/dL)
Conjugated Bilirubin	240 μmol/L(20mg/dL)	Hemoglobin	2 g/L(200mg/dL)
Creatinine	442 μmol/L(5mg/dL)	Dopamine	5.87 μmol/L(0.09mg/dL)
Ibuprofen	2425 μmol/L(50mg/dL)		
Methyldopa	71 μmol/L(1.5mg/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 is not recommended to draw the blood.

BIBLIOGRAPHY

1. Henry, J.B. Clinical Diagnosis and Management by Laboratory Methods.15-290,2001.
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℃ 2℃	Store between 2-30℃
IVD	For in vitro diagnostic use only	LOT	Lot number	REF	Catalog #
Σ	Contents sufficient for <n> tests		Manufacturer		Do not reuse
EC REP	Authorized representative				

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