Mission®

Cholesterol Test Devices
Package Insert

3-1 Lipid Panel	CHOL Total Cholesterol	TRIG Triglycerides	HDL High Density Lipoprotein	English
REF C131-2041	REF C131-2011	REF C131-2021	REF C131-2031	
MODEL CCS-114	MODEL CCS-111	MODEL CCS-112	MODEL CCS-113	

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

INTENDED USE

The *Mission*® Cholesterol Test Devices work with the *Mission*® Cholesterol Meter to measure the lipid concentration in whole blood, plasma and serum. For professional use or self-testing using fingertip blood.
The 3-1 Lipid Panel is used to measure the concentrations of Total Cholesterol (CHOL), High Density Lipoprotein (HDL) and Triglycerides (TRIG). It is also used to calculate LDL, CHOL/HDL and CHD values.
Note: CHD calculation function is only for professional use, refer to the *Mission*® Cholesterol Monitoring System User's Manual for detailed instructions.
3 separate test devices can measure the concentrations of CHOL, HDL, and TRIG 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	15-100 mg/dL (0.39-2.59 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 CHOL/HDL, LDL will display "- -".

PRINCIPLE AND REFERENCE VALUES

Mission® Cholesterol Test Devices use a timed-endpoint method to measure the Total Cholesterol (CHOL)/High Density Lipoprotein (HDL)/Triglycerides (TRIG) concentrations in whole blood, serum or plasma. The concentration of Low Density Lipoprotein (LDL) is calculated by the values of CHOL, TRIG 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.
CHOL: 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 slulphate/Mg2+ 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 CHOL.
TRIG: 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 (HPO) causes the oxidative coupling of 4-aminoantipyrine to form a blue dye.
LDL: When the concentration of TRIG 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 = CHOL – HDL - TRIG/2.2 (mmol/L); LDL = CHOL – HDL -TRIG/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 (CHOL)	<5.2 mmol/L (<200 mg/dL)	5.2-6.2 mmol/L (200-240 mg/dL)	>6.2mmol/L (240mg/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 (TRIG)	<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>0.3U; cholesterol oxidase>0.16U; POD(horseradish)>0.6U; ascorbate oxidase>0.6U; 4-aminoantipyrine>0.06mg; Maos>0.06mg; buffer
High Density Lipoprotein	Magnesium chloride>0.1mg; dextran sulphate>0.01mg; ascorbate oxidase>0.6U; Cholesterol esterase>0.3U; cholesterol oxidase>0.16U; POD(horseradish)>0.6U; 4-aminoantipyrine>0.06mg; Maos>0.06mg; buffer
Triglycerides	Lipoprotein lipase>0.35U; glycerol kinase>0.5U, glycerol phosphate oxidase>0.1U, POD(horseradish)>0.6U; ATP>0.2mg; ascorbate oxidase>0.5U 4-aminoantipyrine>0.09mg; Maos>0.06mg; 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.
- 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 same as the specimen type tested. "**b**" before the two digitals' test number equals to whole blood and "***S***" equals to serum and plasma.
- 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°C). Keep out of direct sunlight. Test devices are stable through the expiration date printed on the test device canister or foil pouch. Remove only enough test devices for immediate use. Replace the cap on the devices canister immediately and tightly. DO NOT FREEZE. Do not use 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.
- For self-testing: Fresh capillary blood.
- 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 *Mission*® Cholesterol 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 device canister or foil pouch 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 test device canister or foil pouch.
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 arrows printed on the test device.
5. Prepare the specimen to be tested. For venous whole blood/plasma/serum specimens: mix the specimen for about 15 minutes. For capillary blood specimens: wipe away the first drop of blood. Collect 35µL (10µl for individual test) 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.
6. While the meter is flashing the blood drop symbol, apply 35ul (10ul for individual tests) 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. 3 dashed lines will appear on the meter to show the test is in progress.
7. Read the results on the screen in 2 minutes. Refer to the User's Manual for detailed test procedures.

Note: Use lancing device with sterile lancets for individual tests; use safety lancets for 3-1 test and individual tests. Avoid an environment with strong lighting during the test. Be sure the alcohol dries completely before pricking the finger. Hand lotions or creams on the finger should be cleaned enough before testing or the results of TRIG will be abnormally high. Excessively squeezing the finger may alter the results. For best results, fasting for at least 12 hours is recommended. Add 35µL (10µl for individual test) specimen to the test device at one time.

INTERPRETATION OF RESULTS

The meter automatically measures concentrations of CHOL, HDL, and TRIG. 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 canister or foil pouch.
- 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

Ten replicate assays were drawn from three test device 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:

Total Cholesterol

Test Device Lot	Linearity Equation	R
Lot 1	Y=0.9985x + 0.7805	0.998
Lot 2	Y=0.9992x + 0.4052	0.997
Lot 3	Y=x+0.0062	0.998

High Density Lipoprotein

Test Device Lot	Linearity Equation	R
Lot 1	Y=1.0137x – 1.121	0.994
Lot 2	Y=1.002x – 0.2461	0.997
Lot 3	Y=0.9962x+0.2157	0.998

Triglycerides

Test Device Lot	Linearity Equation	R
Lot 1	Y=0.9996x + 0.2864	0.996
Lot 2	Y=1.0055x – 5.9755	0.998
Lot 3	Y=1.0096x – 10.233	0.998

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=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 (mg/dL)	149	140	140	250	239	238	305	303	318
SD (%CV)	3.60%	3.70%	3.90%	3.30%	2.40%	1.70%	2.70%	4.10%	3.50%

Total precision is listed below:

Total Precision	Level I (n=60)	Level II (n=60)	Level III (n=60)
Mean (g/dL)	143	243	309
SD (%CV)	4.80%	3.30%	4.00%

High Density Lipoprotein

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 (mg/dL)	28	28	28	52	52	51	83	84	83
SD (mg/dL) or %CV	1.00	1.19	0.88	3.80%	3.40%	3.50%	4.50%	3.70%	2.60%

Total precision is listed below:

Total Precision	Level I (n=60)	Level II (n=60)	Level III (n=60)
Mean (g/dL)	28	52	83
SD (mg/dL) or %CV	1.03	3.70%	3.60%

Triglycerides

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 (mg/dL)	91	90	89	196	192	189	326	321	317
SD (mg/dL) or %CV	3.89	4.23	3.50	2.10%	3.90%	2.40%	2.10%	3.70%	4.10%

Total precision is listed below:

Total Precision	Level I (n=60)	Level II (n=60)	Level III (n=60)
Mean (g/dL)	90	192	321
SD (mg/dL) or %CV	3.89	3.20%	3.60%

Accuracy

The Cholesterol Test Devices were used by a trained technician to test heparin preserved venous whole blood specimens from 78 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	1.0243	-2.7846	0.994	78

High Density Lipoprotein

Specimen	Slope	Intercept	R	N
Venous whole blood	0.9728	1.6124	0.991	78

Triglycerides

Specimen	Slope	Intercept	R	N
Venous whole blood	0.9991	1.4849	0.993	78

In another study, heparinized venous whole blood, serum and heparinized plasma were collected from each patient and tested using a Cholesterol Test Device by a trained technician. A total of 40 patients took part in this study and results compared to those tested on the serum from same patients by the Abell-Kendall method (For CHOL) and DCM method (For HDL) in a Cholesterol Reference Method Laboratory Network (CRMLN) laboratory. The results were listed below:

Total Cholesterol

Specimen	Slope	Intercept	R	N
Venous whole blood	1.0286	- 6.5223	0.998	40
Plasma	1.0336	- 4.4486	0.998	40
Serum	1.0402	- 6.145	0.999	40

High Density Lipoprotein

Specimen	Slope	Intercept	R	N
Venous whole blood	1.0334	-0.6386	0.995	40
Plasma	1.0441	- 0.7255	0.995	40
Serum	1.0438	- 0.8096	0.995	40

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. Contact your local distributor for information on specific controls for this product.

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

ACON Laboratories, Inc.
10125 Mesa Rim Road,
San Diego, CA 92121, USA

CE 0123

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150685903
Effective date: 2013-xx-xx