Cholesterol Control Solution Package Insert

REF C121-2011	English

For validating cholesterol testing.
For *in vitro* diagnostic use only.

PRINCIPLE AND INTENDED USE

The *Mission*® Cholesterol Control Solution is intended for validating cholesterol testing while using the *Mission*® Cholesterol Monitoring System. The control solution contains stabilizers, preservatives and added chemicals. High-density lipoprotein (HDL) and triglyceride (TRIG) are included in the same control solution. Total Cholesterol (CHOL) is an individual control solution. The control solution is applied into the specimen well of the *Mission*® Cholesterol Test Device which has been already inserted in the meter. The onscreen result confirms that the test device and meter are working together properly and that the test is being performed correctly. The control solution is available in two levels and is ready for validating the testing of CHOL, HDL and TRIG. It is for self-testing and professional use.

PRECAUTIONS

- For *in vitro* diagnostic use only. Use before the expiration date printed on the bottle label.
- Make sure the control solution and all the test materials reach operating temperature of 20 - 40°C (68 - 104°F) prior to testing. The control solutions and test materials are only accurate within this temperature range.
- All materials should be considered potentially hazardous and handled in the same manner as infectious agents.
- This product is not intended for use as a calibrator.
- Discard the control solution if it appears cloudy.
- Use the quality control materials before blood testing as an objective method to assess the techniques or practices in use.
- Use the *Mission*® Cholesterol Control Solution with the *Mission*® Cholesterol meter and test devices.
- The used 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 box of test devices.

COMPONENTS

CHOL Control Solution Level 1 contains less than 0.2% cholesterol; CHOL Control Solution Level 2 contains less than 0.4% cholesterol. HDL/TRIG Control Solution Level 1 contains less than 0.06% cholesterol and 0.2% sodium glycerophosphate, HDL/TRIG Control Solution Level 2 contains less than 0.1% cholesterol and 0.4% sodium glycerophosphate. Every control solution is an aqueous mixture that includes preservatives and stabilizers.

STORAGE AND STABILITY

- Store the control solution either refrigerated or at room temperature 2 - 30°C (36 – 86°F).
- Use before the expiration date shown on the bottle label.
- Each control solution will expire 4 months after the bottle is opened for the first time. Record this open expiration date on the bottle label.

MATERIALS REQUIRED

- CHOL Control Solution 1
- CHOL Control Solution 2
- HDL/TRIG Control Solution 1
- HDL/TRIG Control Solution 2
- Package Insert

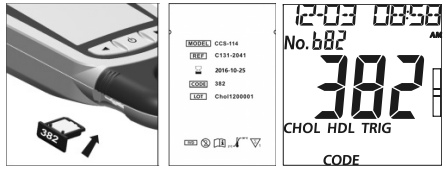
MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Test Devices

INSTRUCTIONS FOR USE

Allow all test materials to reach an operating temperature of 20 - 40°C (68 - 104°F) prior to testing. Refer to the *Mission*® Cholesterol Monitoring System User's Manual for detailed instructions.

1. Turn on the meter.
2. Insert the code chip into the meter. Refer to *Coding the Meter* in the User's Manual for details. Make sure the control solution is tightly closed before use.
3. Check that the specimen type shown on the meter is set to blood (***bL***).
4. Compare the code number on the code chip with the code number printed on the test device pouch label and ensure the two numbers are identical to avoid inaccurate results.



5. Wait for the meter to flash the test device symbol. Insert a test device completely into the device channel in the same direction as the arrows printed on the device until it cannot be inserted any further.

6. When the meter is flashing the blood drop symbol, open the screw cap of the control solution bottle and turn the bottle upside down. Squeeze the control solution bottle gently and discard the first drop. If there are bubbles in the previous drop, squeeze the bottle and discard another drop until there are no bubbles in the drop. Apply the next drop to the specimen well on the test device while keeping the bottle vertically upside down. Use about 35 µL of control solution for the 3-in-1 test device or about 10 µL of control solution for an individual test device. Make sure the control solution is applied directly into the specimen well and that there is no bubble in the solution drop. Because the required sample volume of the 3-in-1 test device is much larger than that required for the individual test device, there are two kinds of bottles with different dropper tips. Check the labels on the control solution bottle and kit box to make sure that you are using the correct bottle for each device type, 3-in-1 or individual.

   Note:
   - Make sure the bottle is completely vertical when applying the solution to the device. The volume will be inconsistent if the bottle is not completely vertical.
   - Gently squeeze so that the solution makes a complete drop on the tip of the bottle and falls freely into the specimen well. Avoid touching the device with the tip of the bottle to finish an incomplete drop.
7. For the 3-in-1 test, two kinds of control solutions need to be tested on two separate test devices. Remember to switch to a new test device after the control solution has been tested on the first device.
8. The results will appear on the screen within 2 minutes. Refer to the User's Manual for detailed test procedures.
9. Make sure to choose the correct specimen type setting to continue with cholesterol testing.

EXPECTED RESULTS

The results should fall within the range(s) printed on the bottle label and are specific for each lot of controls. If the results fall within the specified control range, it indicates the *Mission*® Cholesterol Monitoring System is working correctly and the procedures are being performed properly.

If the results do not fall within the respective range(s):

- Check the expiration date of the test device and the control solution. Make sure they are within the expiration date. Discard any expired devices and control solution.
- Make sure the control solution is tightly closed before use.
- Confirm that you are using the *Mission*® brand control solution.
- Make sure that all test procedures are followed correctly.
- Make sure the meter is not contaminated.
- Make sure the code chip number matches the code number printed on the device pouch label and the number that appears on the meter screen.
- Make sure the control solution is tested using the blood (***bL***) setting on the meter.
- Make sure the test device is 3-in-1 or individual, and then choose the correct control solution bottle according to the printed labels.
- Make sure the operating temperature is 20 - 40°C (68 - 104°F). Testing at 15 - 20°C will lead to higher results. Please move the meter, test device and control solution to a warmer room with temperature ≥20°C, and wait for at least 30 minutes before repeating the test.

After checking all of the above, please repeat the test with a new test device. You can also use a transfer tube to collect the control solution. Please gently squeeze the control solution on a clean nonabsorbent surface. Use a transfer tube to collect the control solution and then apply it to the Specimen Application Area of the test device in the repeated test. Please only use the *Mission*® capillary transfer tubes, and use 35 µL of control solution for a 3-in-1 test device or 10 µL of control solution for an individual test device.

After repeating the control solution test with a new test device, if the results still fall outside of the control range(s), the meter may not be working properly. Contact your local distributor for further assistance.

INDEX OF SYMBOLS

	Consult instructions for use		Use-by date	EC REP	Authorized Representative in the European Community
IVD	*In vitro* diagnostic medical device	LOT	Batch code	CTRL	Control Range
REF	Catalogue number		Manufacturer	30°C 2°C	Temperature limit
CONTROL 1	Normal Level Control	CONTROL 2	High Level Control		Health hazard

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