

LipidPro[™] Testing System



Manufactured Exclusively for

INFOPIA USA,LLC

P.O. Box 5532 Titusville, FL 32783 TEL: 888-446-3246 www.infopiausa.com

REF CL-LP1-1A0-01

LP-CL1-1B0-01 Rev. 2008-10



Instructions for use

Testing items:

- Total Cholesterol
- HDL-Cholesterol
- Triglyceride
- Calculated LDL-Cholesterol
- Blood Glucose Test

ınfopia www.infopiausa.com



Dear LipidPro™Testing System Owner

Thank you for your choosing the LipidPro[™]Testing System. This instruction for use includes important information you need know about the LipidPro[™]Testing System. Please read it carefully.

Our goal for LipidPro™ Testing System is attributed to provide the best quality healthcare products coupled with superior customer service.

Important information

The LipidProTM Testing System is intended for use of outside the body (in vitro diagnostic use only). It should be used for testing lipid profile and monitoring glucose level in a sample. The lipid profile includes total cholesterol, HDL-cholesterol (often called good cholesterol), LDL-cholesterol (often called bad cholesterol) and triglycerides.

This meter is available in two types of strips: one type of strips is measuring glucose level by the method of electrochemistry and the other is testing lipid profile by the spectroscopy method.

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Test Principle

LipidPro™ Testing System has two kinds of test principle according to test items: one for blood glucose and the other for lipid profile.

Lipid profile test result is based on a reading of reflection density. When the blood is applied, the color changes in test area through an enzyme reaction. The meter records this change in color and converts the measurement signal to the displayed result using the data previously entered via the code. The deeper the color, the higher the lipid level.

Glucose in the blood sample will react to the electrodes in the glucose test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by LipidPro™ meter and displayed as your blood glucose result.

How to use Instructions for use

This guide includes all the information you need to use LipidPro™ for self testing or professional use. For additional information and specific information for each individual test, please make sure you read the package insert included with the test strips.

If you have questions about this system, please contact Infopia Customer Service. Customer Service assistance is available 09:00 AM - 06:00 PM, Monday through Friday. If you need help interpreting your test results, please contact your healthcare provider.

For questions or assistance with LipidPro $^{\!\top\!\!}$ call :

Infopia Customer Service Hours: 09:00 AM - 06:00 PM

Monday - Friday Tel. +82-31-423-6170 Fax. +82-31-423-6171 Email : sales@infopia21.com

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LipidPro™Testing System Kit Contents



5. Two AAA batteries 1. LipidPro™ Meter 2. Instructions for Use 6. Lancing Device 3. Warranty Card 7. Lancet 4. Carrying Case

Your LipidPro™ Testing System has been sealed to protect the contents. If you find your seal has been broken, please return it to the place of purchase.

Required but not provided

- LipidPro™ Triglyceride test strip
- LipidPro™ glucose test strip
- LipidPro™ glucose control solution
- Log book for test record of glucose
- LipidPro[™] Total choresterol test strip LipidPro[™] HDL-choresterol test strip
 - LipidPro™ lipid profile test strip
 - Capillary rod
 - LipidPro™ lipid control solution

Lipidpro



LipidPro™ Testing Meter



Strip Connector

Glucose strip measurement connector

Strip discard function

Strip discard function by push toward outside

LCD Screen

Display measurement level of glucose, TC, HDL, TG, including time and message $\,$

Up button

Maneuvering button for choice of function in each mode **Down button**

Maneuvering button for choice of function in each mode & RFID operation button

Mode button

Memory mode, Setting mode, Cholesterol measurement mode, On and off button.

Cholesterol Testing part

Cholesterol strip inserting part

Buzzer sound print part

Printing part for Warning sound, Fixed sound and buzzer sound

Battery Cover

Purpose for Battery replacement and fixed cover

Caution

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- Do not use LipidPro[™] meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
- 2. Do not use LipidPro™ meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electronic or electrical equipment that are sources of electromagetic radiation, as these may interfere with the proper operation of the meter.

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LipidPro™Testing Meter Display



GLU Test item is blood glucose

CHOL Test item is TC(Total Cholesterol)

TG Test item is TG(Triglyceride)

HDL Test item is HDL(High Density Lipoprotein)

Test item is LDL(Low Density Lipoprotein)

Blood insertion for glucose test

Sample blood

Blood insertion for cholesterol test

CODE Displaying code number of Test Strips

Short of batteries

Alarm

mmol/L mg/dL Testing unit

Temperature & date of test

Hour & Data of test

AVR Average Test Results

Control Solution Sysmbol

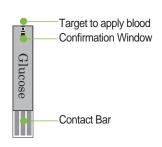
DAY . MON Day & Month

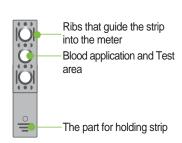
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LipidPro™ Test Strip Information

Use only LipidPro[™] Test Strips with your LipidPro[™] meter.





1. Lipid Profile test strip



This test strip enables to test TC, HDL, TG and calculated LDL.

2. HDL-Cholesterol test strip



This test strip is for HDL-Cholesterol.

3. Total Cholesterol test strip



This test strip is for Total Cholesterol.

4. Triglyceride test strip



This test strip is for Triglyceride.

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LipidPro™Test Strip Information

5. Glucose test strip



Caution

- Store the LipidPro[™] test strip vials in a cool and dry place. Keep out of direct sunlight. Do not freeze.
- Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
- Immediately replace the vial cap and close tightly after removing the LipidPro™test strip
- 4. Make a note of the discard date which is three months from the date you first open a new vial of strips. Throw LipidPro™ test strip and vial away after the discard date.
- 5. Avoid getting dirt, food, and water on the test strip. Do not handle test strips with wet hands.
- Do not use the test strips after the expiry date printed on the package or vial since it may cause inaccurate results.
- 7. Do not bend, cut, or alter the test strip.
- 8. LipidPro™ test strips are for single use only. Do not re-use.
- 9. Do not test at the following temperature condition:
- Lipid Profile strip: below 18°C(64°F) or above 30°C(86°F).
- glucose strip: below 10°C(50°F) or above 40°C(104°F)
- 10. Do not test with humidity below 10% or above 90%.
- 11. Refer to additional information in the LipidPro™ test strip package.
- Avoid getting dirt, food, and water on the color-coding label (backside of glucose test strip).
- 13. Discard the used test strips carefully according to the local regulations.

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LipidPro™Test Strip Information

LIMITATIONS OF SYSTEM (for lipid profile test):

Lipid Profile Test Strips provide accurate results when the following constraints are observed:

· Do not use neonate samples

Physicians - Please note the following interferences that may affect the results:

- Extremes in hematocrit may affect test results. Hematocrit levels less than 30 % may cause falsely high reading and hematocrit levels greater than 55 % may cause falsely low reading. If you do not know your hematocrit level, consult your healthcare professionals.
- Interferences: Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- · Antiglycolysis and anticoagulants in blood samples may affect the test results
- Total cholesterol may be decreased by dopamine and gentisic acid.
- · HDL-cholesterol may be decreased by dopamine.
- Triglyceride may be decreased by dopamine and Methyldopa.

Performance Characteristics:

The performance of the lipid profile test strips has been evaluated in laboratory and in clinical tests (Please refer to strip instructions for use in for more details). Testing Range: The test range of LipidPro $^{\text{TM}}$, is 100 ~ 400 mg/dL (2.59-10.36mmol/L) for total cholesterol, 25~80mg/dL (0.65- 2.08mmol/L) for HDL-cholesterol and 70~600 mg/dL (0.80-0.86mmol/L) for Triglyceride.

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LipidPro™Test Strip Information

LIMITATIONS OF SYSTEM (for Glucose test):

The LipidPro™ Glucose Test Strips provide accurate results when the following constraints are observed:

- · Do not use neonate samples.
- Inaccurate results may occur when in shock, hypotensive, hyperglycemic, or hyperosmolar state, with or without ketosis.
- Glucose test strips used above altitudes of 10,000 feet will have an effect on test results.

Physicians - Please note the following interferences that may affect test results:

- Extremes in hematocrit may affect test results. Hematocrit levels less than 20 % may cause falsely high reading. Hematocrit levels greater than 60 % may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professionals.
- Interferences: Acetaminophen, Uric and, Ascorbic acid (Vitamin C), and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations in may cause inaccurately high results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dl do not significantly affect the results. Values beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- EDTA containing tube is recommended as an anticoagulant tube.

Performance Characteristics:

The performance of the glucose test strips has been evaluated in laboratory and in clinical tests (Please refer to strip instructions for use for more details).

Measurement Range: The measurement range of the LipidPro™ Glucose Testing is 10 to 600 mg/dL (0.6-33.3mmol/L).

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Setting Your Meter

Battery Use

The LipidPro™ requires two(2) AAA 1.5 volt alkaline batteries.

When to replace the batteries:

The meter will give you an indication on the display that the batteries need to be changed. When the display reads battery sign, no more tests can be run until the batteries are changed. Always replace the batteries with high quality alkaline batteries. It is recommended to keep a spare set of batteries on hand. To extend battery life, remove the Test Strip as soon as a result is displayed.

How to install /replace the batteries:

- 1. Open the battery door on the back of the Lipid Pro^{TM} .
- 2. Remove old batteries from the compartment and safely discard.
- 3. Insert the new batteries into the battery compartment as marked on the inside compartment.
- 4. Replace the battery door. To make sure the batteries were installed correctly, push either one of the two buttons on the front of the meter to turn the LipidPro™ on.

<Follow Action>

- 1. Check your meter with the control solution
- 2. Perform your test again
- If you are experiencing symptoms that are not consistent with your test results of glucose or cholesterol, call your healthcare professional.

Caution

Remove both batteries from the battery compartment and dispose of them according to your institution's guidelines.

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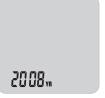
Setting Your Meter

Setting Mode

It is recommended to set your LipidPro™ meter properly before using.



The meter enters setting mode with a beep sound by pressing the mode button for 3 or more seconds in the stand-by status. Press mode (() button for the next step.



By pressing $\blacktriangle \nabla$, adjust year and press MODE (\circlearrowleft) button.



By pressing $\blacktriangle \blacktriangledown$, adjust date, month and time, and then press MODE (\circlearrowleft) button.

Caution

Make sure that the date and time are set properly to enable your data to be stored and downloaded properly.

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Setting Your Meter





By pressing $\blacktriangle \blacktriangledown$, select testing unit and press MODE (\circlearrowleft) button.





By pressing ▲▼, select temperature unit and press MODE ((少) button.



By pressing $\blacktriangle \blacktriangledown$, select average date and press MODE (\circlearrowleft) button. (3 average date is available.)



By pressing ▲▼, select Alarm ON/OFF and press MODE (乜) button. If you select Alarm ON, you can set the time by pressing ▲▼ and press MODE (乜) button(you can set 5 alarms). If you select Alarm OFF, this setting mode is completed.

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Before Testing - Coding Your Meter

LipidPro[™] has two coding systems:

Lipid Profile test - each vial of test strip has RFID-tag which enables the meter to recognize its code number automatically.

Glucose test - each test strip has color-tag on the back of the strip which enables the meter to recognize its code number automatically.

Coding for Lipid Profile test



Press RFID (▼) button.



Place the RFID-tag on the strip bottle to the area of the RFID symbol $\frac{\mathbf{r}\mathbf{r}}{((\mathbf{r}\cdot))}$ on the meter.

Caution

The radiation of RFID recognition is within 2 cm.

The meter will be back to stand-by status if there is no operation within 5 seconds.

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Before Testing - Coding Your Meter



Once it recognizes the code number, the meter displays the code value for 1 second and return to the stand-by status.



Make sure the code number matches the code on the strip bottle.

Before Testing-Coding the Meter

• Coding for Glucose test



 Firmly insert the glucose test strip into the test port of LipidPro™ meter, and then the power will automatically turn on with the code number, temperature and time.



2. Make sure the code number on the display of the meter correspond with that on the test strip bottle. The color tag of the back on the test strip automatically recognizes the code number in this system.

Caution

- If the code is not displayed after 3 seconds, pull the test strip out of the port and re-start the procedure from the beginning.
- If the code on the display and on the test vial does not match, try another new strip. If the mismatch persists, please contact your local representative for help.
- 3. If the meter does not power on, pull the test strip out of the port and re-insert the test strip.
- 4. Avoid testing under direct sunlight, for a more accurate test result.
- If you apply your sample too early, Error message will appear on the display(refer to page 49).

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Before Testing

Quality control by control solution

Control testing, also known as quality control testing, is used to ensure all the parts of the test system are working properly together and the test results are accurate and reliable within the limits of the system. As a quality control, or control solution, commercial human serum control can be used. It is available online at sales@infopia21.com or call at +82-31-423-6170 of Infopia Customer Service.

The users should follow their facility's policies on when controls should be tested (for example: with each new Test strip lot; monthly as a continued check on storage conditions; whenever issues (storage, operator, or other) are identified or there are questions about the results).

The control solution should be used

- Whenever you suspect the meter or test stirp is not functioning properly.
- If your blood glucose test results are not consistent with your symptoms or if you think they are not accurate.
- If you have dropped the meter
- · For quality control in the point of care
- For Teaching or learning the system

Checking the system with control solution

Check the expiry date before performing a control solution test. Do not use if expired.



Caution

Once the control solution for glucose test is opened, it expires after 3 months, while if the control solution for lipid profile is mixed with distilled water, it expires after 3 days.

LipidPro™ control solution is sold separately.

It is recommended that the control solution is stored at room temperature before testing.

Lipid Profile test

Testing procedure

 Press ▼ button and the meter enters RFID mode.



2. Place of the RFID-tag on the strip bottle to the area of the RFID symbol (((--))) on the meter.



Caution:

The radiation of RFID recognition is within 2cm.

The meter will revert back to stand-by status if there is no operation within 5 seconds.

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Checking the system with control solution

Check the code number on the display of the meter with that on the strip bottle.



Insert the test strip and press mode button.
 Press ▲ button and the meter displays the symbol of control solution.



5. Press mode (🖒) button again and the symbol of sample blood is blinking.



6. Take a drop of control solution on clean bowl (ex. Aluminium foil).





Apply the prepared control solution to the test strip by using capillary rod.





8. The test result will come after 1~2 minutes.



Checking the system with control solution

Testing tips:

- Please make a test after reading the instructions for use of control solution thoroughly.
- · Keep clean of the test area on the meter.
- Keep test strips and control solutions in proper condition according to the instructions for use provided, such as expiry date, storage condition and so forth.
- Before testing, make sure that the test strips and the meter are at the temperature of 18-30 °C (64-86°F).

Caution

If your control solution test falls out of range, please follow the next steps before contacting customer support:

- Check the expiry dates on all the products you are using. Be sure you are using LipidPro™ control solution.
- Try another control solution test.
- If this test falls out of range, try another control solution test with a new unopened bottle of strips.
- After following the appropriate steps and the control solution test still falls out of range, do not perform a test. Please contact the Infopia customer service at +82-31-423-6170 or sales@infopia21.com.
- The control solution range is not the recommended range for your test.
- Discard the used control solution and the test strips carefully according to the local regulations.
- Glucose test

Testing procedure

1. Shake the control solution before use.



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Checking the system with control solution

2. Discard the 1st drop of control solution, this will eliminate any residue.



3. Place a drop of control solution on a clean, dry surface(ex. The lid of the test strip vial).



4. Insert a test strip into the port firmly and press ▲ button. The symbol of control solution will appear on the display of meter. This will allow you to differentiate between a control solution test and an actual blood test for future reference.



5. Dip the test strip into the control solution.



6. Results appear in 3 seconds. Compare the result to the range printed on the test strip vial, the results should fall within that range.



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Testing Your Blood - Preparation

Blood testing

A strip instructions for use is included with each box of test strips. Please read the test strip package insert along with this section completely and carefully before testing.

Testing supplies



To perform a blood test you need:

- LipidPro[™] meter
- Test strips
- Sterile lancet
- Capillary rod
- · Lancing device

Caution

1)To reduce the chance of infection.

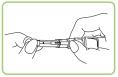
- The Lancing Device and sterile lancets should NOT be shared with others.
- · Always use a new, sterile lancet.
- · Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the Lancets and the Lancing Device
- 2) Do not operate the meter in direct light.
- Practice using the lancing device and become accustomed with its use. Wash your hands with warm, clean water and soap. Dry your hands completely before testing.

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Collecting a Drop of Blood

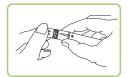
Performing Your Test



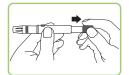
1. Unscrew the lancing device and insert a lancet firmly into the carrier.



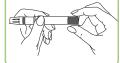
2. Pinch the lancet and twist off the protective cover. Do not discard the cover.



3. The tip of the lancing device offers 5 different levels of skin penetration. To select the best depth: Use 1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused



 Hold the tip in one hand and pull on the sliding barrel with other hand. Pull the ends apart and you will feel a click. This indicates that the lancing device is in a locked position ready for lancing.



5. Release the sleeve. It will automatically contract and move back to its original position near the trigger hub.



3. The tip of the lancing device offers 5 different levels of skin penetration. To select the best depth: Use 1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused

Caution

Use a new sterile lancet every time you test. Do not use lancet if protective cover has been removed or damaged.

Never share a lancet with anyone.

Maintaining your Lancing Device

- Unscrew the lancing device tip. Carefully stick the protective disk cover back on the used lancet.
- Grip the holder firmly and pull the lancet safely out of holder. Screw the tip back on the lancing device.
- Properly discard the used lancet. Clean the lancing device if blood or stain remains.

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Testing Your Blood

1. Lipid Profile test

Capillary blood process

When you collect the sample, please use the capillary rod provided with the test strip package. Make sure enough sample has been collected to the capillary rod.









Caution:

If blood is stained outside the sample area, carefully wipe the stain out with a tissue. Do not allow the wiping tissue to touch the open end of the sample area of the collecting leg.

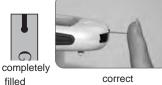
2. Glucose test



Place your fingertip to the top edge of glucose test strip.

Correct: Completely filled





poorly

filled



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Testing Your Blood

This is for professtional use

venouse whole blood and serum process for Lipid Profile test

For venous whole blood and serum, acceptable anti-coagulants are EDTA, heparin, citrate and fluoride/oxalate, and these samples may be stored at $4\,^{\circ}\text{C} \sim 20\,^{\circ}\text{C}$ (39 $^{\circ}\text{F} \sim 68\,^{\circ}\text{F}$) for three days.

Please follow the procedure below.

- 1. Allow blood sample to reach room temperature.
- 2. Anti-coagulated blood should be mixed well prior to testing.
- 3. Remove the stopper from the holder and collect the sample of 5 ul by using pipette.

Optional method

- Take out a drop of blood sample on a clean container.
- Collect the sample of 5 ul by using capillary rod, instead of pipette.
- 4. Apply the sample to the test strip.







Caution:

Do not freeze the samples, but store at 4° C instead and test quickly. Please test freshly collected samples. If the samples are not fresh, LPL(lipoprotein lipase) or LCAT(lecithin cholesterol acyltransferase) may affect the form of lipoprotein.

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Quick reference of test procedure -Lipid test



1) After code recognition, press mode (ひ) button again



Prick the finger with a lancing device for the sample blood.



Collecting the sample blood to the capillary rod.



4) Make sure the enough sample has been collected to the capillary rod.



5) Contact the capillary rod with the sample to the test area of the strip so as to start the test.

Caution

- If the test result is out of the test range, the Hi/Lo message will be shown on the LCD.
- Safely discard used test strips and lancets.

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Quick reference of test procedure -Glucose test



 Insert the glucose test strip. Code number is automatically displayed. Compare with code number printed on test strip vial. If not identical discard the test strip and restart.



2) Prick the finger with a lancing device for the sample blood.



3) Apply blood sample until confirmation window is completely filled. Meter automatically begins to countdown. If the countdown does not start, do not add more blood to the test strip! Discard the test strip a restart testing.



4) Test results appear in 3 seconds.

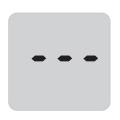
Caution

- If the test result is out of the test range, the Hi/Lo message will be shown on the LCD.
- Safely discard used test strips and lancets.

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Test Procedure

1. Lipid test - Test for multi items



Press mode ((b)) button after a test strip is inserted and confirm if the meter recognizes the right test strip by checking out the corresponding symbol on its display.



The meter displays the code number and the testing symbols ($\fbox{\textbf{CHOL}}$, $\fbox{\textbf{HDL}}$, $\fbox{\textbf{TG}}$) together and then, press mode button.



The symbol of blood is blinking.



Please apply the sample to the first test area of test strip until you hear beep sound. Then, the symbol, **[CHOL]** disappears.

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Please apply the sample to the second test area of test strip until you hear beep sound. Then, the symbol, **HDL** disappears.



Please apply the sample to the third test area of test strip until you hear beep sound. Then, the symbol, **[TG]** disappears.



The meter displays --- , blinking in order, which means it is under test.



In the case of LDL-cholesterol, if density of triglyceride is over 350mg/dL, it can't be measured.

In order to check each test item, please press up or down button. You can check out each result of Total Cholesterol, HDL-Cholesterol and Triglyceride.

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Test Procedure

2. Test for each single item1) Total Cholesterol test



Press mode (ტ) button after a test strip is inserted and confirm if the meter recognizes the right test strip by checking out the corresponding symbol on its display.



The meter displays the code number and the testing symbols (**CHOL**) together and then, press mode button.



The symbol of blood is blinking.



Please apply the sample to the test area of test strip until you hear beep sound.

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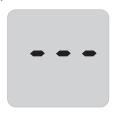


The meter displays --- , blinking in order, which means it is under test.



When the test is completed (in about maximum 2 minutes), the meter displays the test result of **CHOL** with the symbol.

2) HDL-Cholesterol test



Press mode (\circlearrowleft) button after a test strip is inserted and confirm if the meter recognizes the right test strip by checking out the corresponding symbol on its display.



The meter displays the code number and the testing symbols (\fbox{HDL}) together and then, press mode button.

Test Procedure



The symbol of blood is blinking.



Please apply the sample to the test area of test strip until you hear beep sound.



The meter displays --- , blinking in order, which means it is under test.

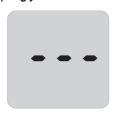


When the test is completed (in about maximum 2 minutes), the meter displays the test result of **[HDL]** with the symbol.

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3) Triglyceride test



Press mode ((b)) button after a test strip is inserted and confirm if the meter recognizes the right test strip by checking out the corresponding symbol on its display.



The meter displays the code number and the testing symbols ($\boxed{\mathbf{TG}}$) together and then, press mode button.



The symbol of blood is blinking.



Please apply the sample to the test area of test strip until you hear beep sound.

Test Procedure



The meter displays --- , blinking in order, which means it is under test.



When the test is completed (in about maximum 2 minutes), the meter displays the test result of **TG** with the symbol.

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3. Glucose test



When the test strip is inserted, the meter displays the code number for 3 seconds.



The symbol of blood is blinking.



Once the sample is applied, the meter displays 3, 2, 1 in order.



Then, the meter completes the test with the test result.

Glucose test strip Discard Function







- After checking your test result, slide the ejector button twice forward to remove the test strip from the meter.
- Discard the used strip and lancet to a proper place, according to the local regulation.

Caution

- 1. If you push the discard button forward too much, it may be damaged.
- 2. Do not give strong impact to meter.

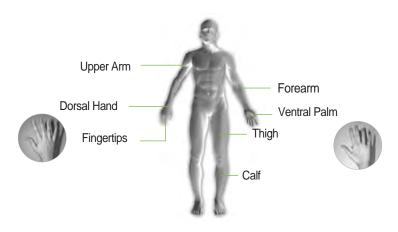
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Alternate site testing

Note: This alternate site testing is applied to glucose testing only.



The LipidPro™Testing System gives you the ability to obtain a blood sample for testing your glucose level from different areas of your body. The figure shown above displays the areas where you can test using your LipidPro™Testing System.

You may test your blood glucose from your forearm, upper arm, palm(ventral palm or dorsal hand), fingertips, thigh, or calf.

It is recommended that alternate site testing be used when glucose values are stable: before meals and before bedtime. However, when blood glucose is changing, blood from the finger tip may show these changes sooner than blood from other sites.

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Performing a Blood Test using an Alternate site

Important:

We recommend that you test on your fingertip if you are testing for hypoglycemia (low blood glucose) or if you have a history of reoccurring hypoglycemia.



To ensure accurate results when lancing your forearm, upper arm, hand, thigh, or calf, wash the test site with soap and water.

Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

Caution

- To ensure accurate results when lancing your arm (Upper arm or forearm), leg (calf or thigh) or palm (ventral palm or dorsal hand), wash your hand and test site with soap and water.
- To receive accurate test results, at least 0.3ul minimum sample volume is required.

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Reviewing Your Results

Every test result is stored with its date and time of test.

Following is the memory capacity of each test item in the meter.

Glucose 100 memories
TC 50 memories
HDL 50 memories
TG 100 memories
LDL 50 memories

When the test results is over the capacity memory, the recent test result will replace with the oldest test result.

In order to enter into Memory mode, please press mode button when no test strip is inserted.



When there is no memory in the meter

How to enter into Memory Mode

In order to enter into Memory mode, please press the mode button when no test strip is inserted. By using $\blacktriangle \blacktriangledown$, you can recall each Total Cholesterol, HDL-Cholesterol, Triglyceride, LDL-Cholesterol and glucose. Press the mode button after you select the item you would like to review.

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Reviewing Your Results

1. Total Cholesterol



Press mode (🖰) button.



Press ▲▼ for reviewing the rest result.

2. HDL-Cholesterol



Press mode (🖰) button.



Press ▲▼ for reviewing the rest result.

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Reviewing Your Results

3. TG Cholesterol



Press mode (🖰) button.



Press ▲▼ for reviewing the rest result.

4. LDL Cholesterol



Press mode (🖒) button.



Press $\blacktriangle \blacktriangledown$ for reviewing the rest result.

Reviewing Your Results

5. Glucose



Press mode (🖰) button.



Press mode (\circlearrowleft) button and the meter displays the average data and the symbol (AVR) you had set previously. If you set 3 kinds of average data, please press $\blacktriangle \blacktriangledown$, button for reviewing.

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Deleting your Results



deleting individual test result

To delete any individual test result in the memory press \triangle or \blacktriangledown button for 3 seconds, while the test result to delete is displayed. Then, dEL is blinking. After the second beep sound the test result is deleted.



deleting all test results

To delete all test results press \blacktriangle and \blacktriangledown button at the same time for 3 seconds, while any test result is displayed. Then, ALL is displayed and dEL is blinking. After the third beep sound all test results are deleted.

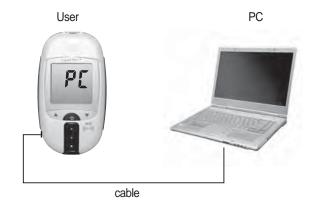
LipidPro™Testing System Software

You can transfer test results from the LipidPro™Testing System meter to a computer.

You can download the software from our web site.

(http://www.infopia21.com)

You can purchase the computer communication cable separately from a local representative.



Caution

The deleted test results can't be recovered. Please be careful in deleting the test results.

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Cleaning Your Meter and Maintenance

Meter

Your meter does not require special maintenance or cleaning. Avoid getting dirt, dust, blood, control solution, or liquids on the meter, the test port, or data port. Your meter operation temperature is $18^{\circ}\text{C} \sim 30^{\circ}\text{C}(64 \sim 86^{\circ}\text{F})$.

It is recommended that you store the meter in its carrying case after each use. A cloth dampened with water and mild detergent can be used to wipe down the outside of the meter. Your LipidPro™ meter is a precision instrument. Please handle it with care.

- 1) Do not disassemble or modify the meter.
- 2) Do not place the meter in places with high humidity.
- 3) Do not place the meter in polluted or dusty areas.
- 4) Do not expose the meter to impact, shock, vibration, inclination, etc. and keep it in a safe place.
- 5) Do not place the meter with chemical products or with gases.
- 6) Keep it away from direct sunlight.
- 7) Close the vial, immediately after taking out the Test Sensor for the test.
- 8) Keep the Test Sensor away from children.
- 9) Keep the lancing device clean by using alcohol or soap and water.
- 10) The meter should be cleaned with soft cloth or paper tissue, in case of dirt.

Lancet Device:

Clean the lancet device and caps with soap and luke warm water. To disinfect the lancet device, prepare a disinfectant solution of one part household bleach to 10 parts water. Dampen a cloth with this solution and wipe the lancet device thoroughly. Soak only the cap for at least 30 minutes in the disinfectant solution. Do not soak the lancet device in liquid. Rinse the lancet device and cap with water and dry thoroughly. Properly discard the used lancet.

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Troubleshooting

Message	Probable cause	Action required
iviessage		Action required
E P 1 12:00 AM	This message appears when the hardware defects. Ex) The Flash ROM write/read function does not work. Oxidization voltage is out of range, etc.	Reboot the meter by placing the batteries again when no test strip is inserted. Please contact your local representative or customer support when the problem persists.
E 200m	This message appears when test strip may be contaminated or reused. This message appears when the raw data of strip higher than 8 before injection blood.	Please insert a new test strip and perform your test again.
BAY. MON (200AM	This message appears when the sample blood is insufficient amount on the lipid test.	Please apply the sufficient sample blood to the test strip.
BAY. MON	This message appears when strip signals without any Blood or Control solution or other sample applying. This message appears when the raw data of test result is lower than 3.	Please insert a new test strip and perform your test again.

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Troubleshooting

Message	Probable cause	Action required
E-5	This message appears when blood sample is input before the symbol for blood blinks.	Please wait for the meter displays the icon blinking before applying your blood sample.
E-5 DRY - MON (1 (200 AM	This message appears when the color bar of the strip is dirty or not good or there is too much light. Action required.	Please insert a new test strip and perform your test again.
DRY . MON	This message appears when Lipid strip is removed during testing.	Test again with a new test strip and make sure the test strip to be inserted into the right port of each item. Do not discard the test strip from the meter during the test.
BAY MON (2:117am	The test result is higher than the following.	more than 600mg/dL (33.3mmol/L) TC : more than 400mg/dl TG : more than 600mg/dl HDL : more than 80mg/dl

Troubleshooting

Message	Probable cause	Action required
GLU DAY . MON	The test result is lower than the following	glucose: less than 10mg/dL (0.6mmol/L) TC: less than 100mg/dl TG: less than 70mg/dl HDL: less than 25mg/dl
H 1 1 1 1 1 1 1 1 1 1	The ambient temperature is over 30°C	Place the meter at the temperature between 18 and 30°C for more than 10 minutes and test again.
LoC	The ambient temperature is less than 18℃	Place the meter at the temperature between 18 and 30℃ for more than 10 minutes and test again.

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Troubleshooting

Inconsistent or unexpected test results

If you continue to get unexpected results, check your system with control solution. If you experience symptoms that are not consistent with your lipid and glucose results, first be sure you have followed all instructions in this Instructions for use, then contact your doctor. Never ignore symptoms or make significant changes to your control program without speaking to your doctor.

Product Specification

	Devision	Content
	Sample type	Capillary whole blood, Venous blood, Plasma
	Testing Types	Total cholesterol HDL-cholesterol Triglyceride LDL-cholesterol
	Testing method	Enzymatic-colorimetric method
LipidPro™ test	Testing range	Total cholesterol : 100~400mg/dL, Triglyceride :70~600mg/dL, HDL-cholesterol : 25~80mg/dL
	Testing time	About 1 ~ 2 minute
	Calibration	Plasma_Equivalent
	Sample volume	5uL
	Operating Humidity	10 ~ 90 %
	Storage Temperature	2 ~ 30°C (36 ~ 86 °F)
	Hct influence	35 ~ 50%

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Product Specification

	Devision	Content
	Sample type	Capillary whole blood
	Testing Types	Glucose
	Test range	10~600mg/dL
	Sample volume	0.3uL
Glucose test	Testing time	3sec
	Calibration	Plasma - Equivalent
	Operating Humidity	10 ~ 90 %
	Storage Temperature	2~ 30℃ (36~86℉)
	Hct influence	20 ~ 60%
RFID	Standard Supported	ISO/IEC 15693
	Nominal Read/Write Range	< 2cm
	Antenna	Integrated
	Frequency	13.56 MHz

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Product Specification

Devision	Content
Measuring principle	Electrochemical, Spectroscopy
Storage memory	350
Operation Temperature	18~30°C (36~86°F)
Operation Humidity	10 ~ 90%
Display Type	LCD
Size(W*D*H)	60.38 x 109 x 22.9 (mm)
Weight	77.5g (including battery) ± 1g
Power supply	(AAA) 1.5V x 2
Battery life time	Running over 1,000 times
PC Port	The connection between Computer and cable

Warranty

Manufacturer's Warranty:

Infopia Co., Ltd., warrants to the original purchaser that this instrument will be free from defects in workmanship for 3 years from the date of original purchase.

Limitations of Warranty:

This warranty is subject to the following exceptions and limitations:

- Infopia Co., Ltd. shall not be required to replace any unit which are damaged or malfunction due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than Infopia Co., Ltd., or failure to operate in accordance with the instructions.
- Infopia Co., Ltd. reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
- 3. Infopia Co., Ltd. has no knowledge of the performance of the instrument when the test strip is altered or modified in any manner.

For warranty service:

Purchaser must contact the local representative for assistance and/or instructions for obtaining service of this instrument.

Important:

Speak to the Infopia Co., Ltd. local representative before returning your instrument for any reason. She/he will give you the information needed to resolve your problem correctly and efficiently.



Declaration of Conformity	Memo
THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES. Operation is subject to the following two conditions; (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. CAUTION: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.	
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician for help.	

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