VivaDiag

Lipid Testing System

User's Manual

IVD

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Section 1 Introduction

The **VivaDiag** Lipid Testing System is intended or the quantitative determination of Total Cholesterol (TC), High Density Lipoprotein Cholesterol (HDL), Triglycerides (TG), the calculated ratio of TC/ HDL and Low Density Lipoprotein Cholesterol (LDL) in capillary and venous human whole blood, plasma, and serum. The system consists of a portable meter that analyzes the intensity and color of the reagent area of a test device, ensuring quick and accurate results.

The **VivaDiag** Lipid Testing System provides results in less than 2 minutes. The meter can store up to 200 results and records can be transferred to a computer for further analysis using the USB port. The meter can be operated by 3 AAA (1.5V) batteries.

To ensure accurate results:

- Read instructions carefully and complete any necessary training before use.
- Use the code chip that is included in each box of test devices.
- Only use the **VivaDiag** Lipid Test Devices with the **VivaDiag** Lipid Meter.
- For in vitro diagnostic use only.
- For professional use only.
- Sample type: Fresh capillary blood, heparinized or EDTA venous whole blood, serum and heparinized plasma can be tested.
- Please test within the expired date of all components.

Note:

*Throughout this User's Manual, meter parts or functions will appear in **bold**. Items appearing on displays are identified in **bold italics**.*

Section 2 Getting Started

Before testing, read the instructions carefully and learn about all the components of the **VivaDiag** Lipid Testing System. Depending on the package type, some of the components may need to be purchased separately. Please check the list of contents on the outer box for details on which components are included with your purchase. The following items are needed to perform a test:

Lipid Meter

Test Device

Control Device

Code Chip

Capillary Transfer Tube

AAA Batteries

Lancing Device

Safety Lancets

Or

Sterile Lancets

Lipid Meter: Reads the test devices and displays the concentrations of TC, HDL, TG, and calculated LDL and TC/HDL values.

Test Devices: Part of the system, work with the meter to measure the concentrations of TC, HDL, TG and calculated LDL and TC/HDL values.

Code Chip: Automatically calibrates the meter when inserted into the meter.

Capillary Transfer Tubes: Collects capillary blood from fingertip for accurate results (10μL for an individual test and 25μL for a 3-in-1 test).

AAA Batteries: Provides power for the meter.

Carrying Case: Provides portability for testing.

User's Manual: Provides detailed instructions on using the Lipid Testing System.

Test Devices Package Insert: Provides detailed instructions on using the Cholesterol Test Devices.

Lancing Device: Used with sterile lancets to prick the fingertip for blood specimen collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort. It can also eject the used lancets.

Sterile Lancets: Used with the lancing device to draw blood specimens for individual test. Sterile lancets are inserted into the lancing device for each blood draw and discarded after use.

Safety Lancets: Used to draw blood specimens. Discard after use.

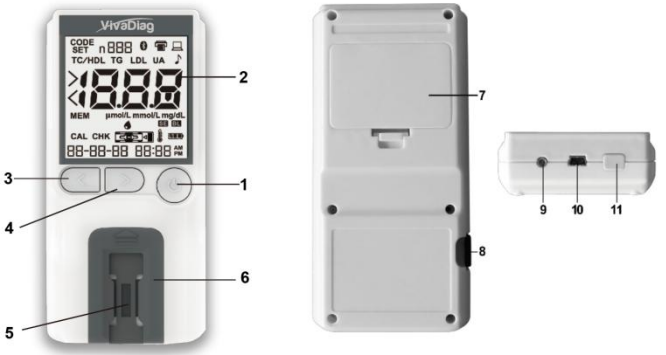
Control Device: Verifies the proper operation of the meter by checking that the meter can detect a pre-calibrated value.

Warranty Card: Should be completed and returned to the distributor to qualify for the 2-year meter warranty.

Section 3 Components

The Lipid Meter reads the test devices and displays the concentrations of TC, HDL, TG, the calculated value of LDL and the ratio of TC/HDL. Use the below diagram to become familiar with all the parts of the meter.

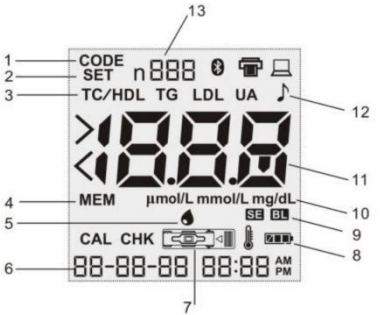
Meter



1	On/ Off ⏻ Button	7	Battery Cover
2	Liquid Crystal Display (LCD)	8	Code Chip Slot
3	Left Arrow ◄ Button	9	Printer interface
4	Right Arrow ► Button	10	USB interface
5	Strip Channel	11	Setup Button
6	Test Strip Holder		

Meter Display

During testing, the Lipid Meter will display icons showing the status, options available, and prompts for testing:



1	Code	8	Battery
2	SET option	9	Sample type
3	Test Item	10	Measurement Units
4	Memory	11	Test result area
5	Blood Drop Symbol	12	Sound Icon
6	Date	13	Test number
7	Test Device Symbol		

Code: Shows the code number of the test devices.
SET option: Setup the meter functions.
Test Item: Shows which item is being tested.
Memory: Indicates a test result is being recalled from memory.
Test Device and Blood Drop Symbols: Indicates when to insert test device or apply specimen.
Date: Shows the current date or date tested.
Battery: Appears when the battery should be replaced.
Sample type: Displays the type of blood.
Measurement Units: Displays the units of the test result.
Test Result Area: Displays the test result or menu options.
Sound Icon: Appears when the sound is turned on.
Test Number: Indicates the assigned test number.

Meter Use and Precautions

- Do not get water or other liquids on or inside the meter.
- Keep the Device Channel clean.
- Keep the meter dry and avoid exposing it to extreme temperatures and humidity.
- Do not drop the meter or get it wet. If the meter is dropped or has gotten wet, ensure the meter is working properly by running an Optical Check. Refer to Optical System Check for details.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to Maintenance for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note:

Follow proper precautions and all local regulations when disposing of the meter and used batteries.

All Lipid Testing Systems Preventive Warnings with Regard to EMC

1. This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause may cause erroneous results.

2. This instrument and immunity requirements described in EN 61326-1 and EN 61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the meter.

3. For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

Test Devices

The Lipid Test Devices are plastic devices that work with the Lipid Meter to measure the lipid concentration in whole blood, plasma and serum.

Test devices including TC Total cholesterol test devices, HDL High Density Lipoprotein test devices, TG Triglycerides test devices and 3-1 Lipid Panel test device.

3-1 Lipid Panel test devices can detect TC, HDL and TG with one device at the same time. The ratio of TC/HDL and the value of LDL can also be calculated by meter at the same time.

Insert Arrow: Located on the front of the test device, the arrows indicate the direction in which the test device should be inserted into the meter.

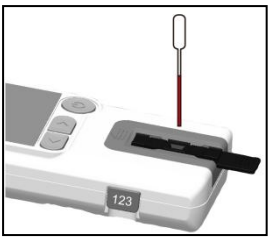
Specimen Application Area: After the device is inserted into the Device Channel, apply the correct specimen volume (10 µL for individual test devices or 25 µL for 3-1 test devices) to the region in the center of the test device.

Handle: Located on the end of the test device, the handle is used to insert and remove the test device from the meter.

Test Area: Located on the back of the test device. The meter will detect and read this area to give results of lipid levels.

Specimen Application

For best results, fill the Specimen Application Area with the correct specimen volume (10 µL for individual test devices or 25 µL for 3-1 test devices). Incorrect results may occur if the specimen is not applied correctly or if the Specimen Application Area is not filled with the correct amount.



After applying the specimen, ensure that the Specimen Application Area is completely covered. The Specimen Application Area should remain covered throughout the entire test. If the Specimen Application Area is not covered or if there is too much specimen covering the Specimen Application Area, repeat the test with a new test device.

Note:

If the specimen applied to the Specimen Application Area is not enough, do not add more specimen to the test device. Instead, retest with a new device. If the E-5 Error or another error appears on the display, please discard the used device and retest with a new device.

Code Number

Printed on each package of test devices is a code number CODE, lot number LOT, unopened expiration date, and test quantity ▽.

Test Device Precautions and Instructions for Use

- Test Devices should be stored in their canister to keep them in working condition.
- Do not store test devices outside of their package. Test devices must be stored in the original package.
- Do not transfer test devices to a new package or any other container.
- For *in vitro* diagnostic use. Test devices are to be used only outside the body for testing purposes.
- Use the test device immediately after removing it from the canister.
- Do not use test devices that are torn, bent, or damaged in anyway. Do not reuse test devices.
- Before performing a test, make sure that the code number on the meter display matches the number shown on the test device canister and on the ink-jet printing on the code chip.
- Refer to the test device package insert for more details.

Control Devices

The Lipid Control Devices are devices containing a reference pad, which work with the Lipid Meter to ensure the optical system is working properly. After the control device is inserted into the meter, the meter's optical system detects the color intensity of the control device. The meter displays ***YES*** or ***no*** to indicate whether the meter is functioning properly. Refer to Optical System for details.

Precautions

- Store in the closed canister at room temperature or in the refrigerator within 2-30 °C (36-86 °F). Avoid exposure to direct sunlight, extreme temperatures, and humidity.
- Control devices should be stored in their tightly capped canister to keep them in working condition.
- Do not freeze or refrigerate.
- Keep the control devices clean. Do not touch the test area of the device.
- Remove the control device for immediate use. Put the control device back and close the canister immediately after use. Do not use contaminated, discolored, or damaged control devices.
- Do not use after the expiration date.
- For *in vitro* diagnostic use only.

Storage and Handling

- Store test devices in a cool, dry place. Store away from heat and direct sunlight.
- Transport and store in its closed canister within 2-30°C (36-86°F) temperature and less than 90% humidity.
- Do not freeze or refrigerate.
- Replace the cap on the devices canister immediately after removing a device. Expired devices may cause incorrect test results.

Note:

The expiration date is printed in a Year-Month format. For example, 2016-01 is January, 2016.

Section 4 Initial Setup

Before testing, ensure the following procedures are followed.

Turn on Meter

The meter can be operated using 3 AAA batteries (1.5V).

To use the meter with batteries, insert 3 AAA batteries (1.5V) into the battery compartment on the back of the meter.

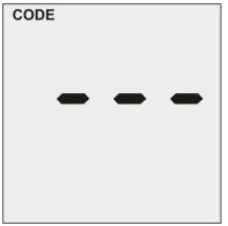
Press ⏻ to turn the meter on after the batteries are inserted. The screen will briefly display all of the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on. After the power-on diagnostic check, the Initial Screen will be displayed.

The meter will automatically turn off after 5 minutes of inactivity.

Coding the Meter

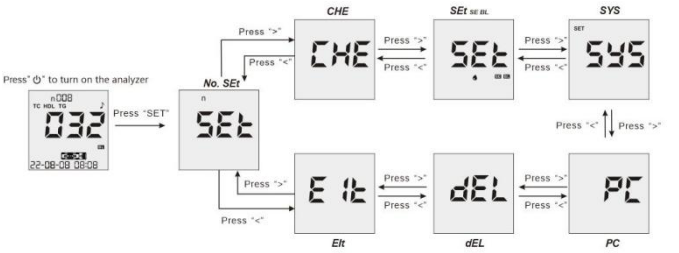
Each time a new box of test devices is used, the new **code chip** included in the box must be inserted into the meter. Compare the code number on the **code chip** from the box with the code number printed on the test device canister label. Results may be inaccurate if the two numbers are not identical. Insert the new **code chip** into the **code chip slot** of the meter. The **code chip** should remain in the meter. Do not take it out until a new box of test devices is needed. The code number will appear on the Initial Screen after startup.

If the **code chip** is not properly inserted into the **code chip slot** or if it is missing, the meter will display ***three dashes*** as shown below.



Section 5 Meter Setup and Options

With the meter turned on, press **SET** button to enter the **Meter Setup** mode.
Press ◄ or ► to display several setup sub-modes:

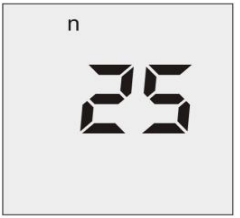


No. SEt	Test number setup. The test number can be set from 1 to 999.
CHE	**Optical Check** mode. Refer to Optical System Check.
SEt *SE BL*	Specimen type setup.
SYS	System setup, including date, time, test number reset, units, and sound.
PC	**Data Transfer** mode. Refer to Data/ Communication.
dEL	**Memory Delete** mode. Refer to Data/ Communication.
Elt	Exit setup modes and save changes when ⏻ is pressed. The meter will automatically return to the Initial Screen.

Press ⏻ to enter the mode when the desired sub-mode is displayed.
Press **SET** button to exit **Meter Setup** mode.

Test Number Setup

From the ***No. SEt*** screen, press ⏻ to enter **Test Number Setup.**
The test number can be set to any number from 1 to 999.



Press ◄ or ► until the correct test number is displayed. To quickly cycle to the desired test number.
Press ⏻ to save and return to the **Meter Setup** screen.

Optical Check

From the **No. *SEt*** screen, press ► to enter the **CHE Setup.**

Note:

The control strip is intended for checking the optical system.

Press ⏻ to enter Check control strip mode. Insert a control strip into the strip channel in the same direction as the arrows indicate on the strip. Ensure that the test strip is inserted all the way, then press ⏻ to confirm.

If the meter displays ***YES***, the meter is normal. If the meter displays no, the meter is abnormal as show below.

If the meter displays no, check if the control strip is contaminated, bent or damaged. If there are any visible signs of damage or contamination, discard the control strip and retest a new control strip.

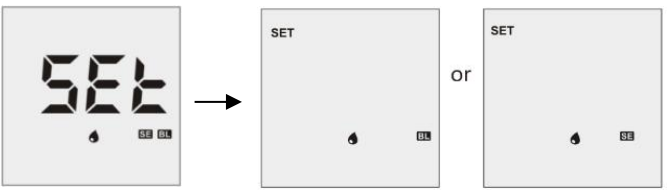
Press the ⏻ button to return to the Setup Screen.

Specimen Type Set Up

From the ***No.SEt*** screen, press ► till the ***SEt SE BL*** screen.

Press ⏻ to set specimen type.

Press ◄ or ► to set specimen type to either ***BL*** or ***SE***. When specimen type is set to ***BL***, control solution, fresh capillary blood, EDTA or heparinized venous whole blood can be used. When specimen type is set to ***SE,*** serum and heparinized plasma can be used. Press ⏻ to save and return to the setup screen.



Note:

bL *means Whole Blood,* ***SE*** *means Plasma and Serum.*

System Setup

From the **No.** ***SEt*** screen, Press ► till to enter the ***SYS*** **Setup** screen.

Press ⏻ to start system setup.

The first option sets the clock to either 12 or 24 hour mode. Press ◄ or ► to switch between the two settings.

Press ⏻ to save and move to **Date Setup** .

The second option sets the date according to Y-M-D.

The year will appear at the bottom of the display with **Y** indicating year setup. Press ◄ or ► until the correct year is displayed.

Press ⏻ to save and move to the **Month and Date Setup**.

Month and Date Setup

The month and date will appear at the bottom of the display separated by a single dash (**-**), with the month flashing. **M** will also appear indicating month setup. Press ◄ or ► until the correct month is displayed.

Press ⏻ to save. The day will flash and **d** will appear indicating day setup. Press ◄ or ► until the correct day is displayed.

Press ⏻ to save and proceed to **Time Setup.**

Time Setup

The hour and minute will appear at the bottom of the display separated by a colon, with the hour flashing.

Press ◄ or ► until the correct hour is displayed. Press ⏻ to save and move to **Minutes.**

***Note**:*

*The meter will display **AM** or **PM** if the 12H time setting is chosen.*

Minutes will flash. Press ◄ or ► until the correct **Minutes** are displayed. Press ⏻ to save and move to Test Number Reset Setup.

Test Number Reset Setup

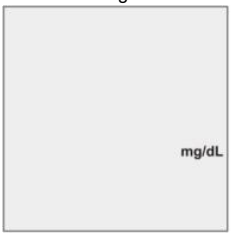
Press ◄ or ► to turn the test number reset ***On*** or ***OFF.*** The test number will reset to 1 for each new day of testing when the test number reset is turned on.

or

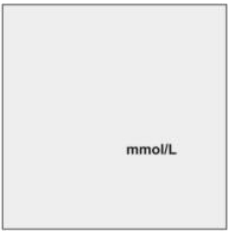
Press ⏻ to save and move to **Unit Setup**.

Unit Setup

Set the units to either **mg/dL** or **mmol/L.** Press ◄ or ► to switch between the two settings.



or



Press ⏻ to save and move to **Sound Setup**.

Sound Setup

Press ◄ or ► to select sound either ***On*** or ***OFF.*** The ***Sound Symbol*** will appear on the display when the sound is turned on.

or

Press ⏻ to save and return to Num Setup.

PC transmission Setup

From the **No.*SEt*** screen, Press ► till to enter the **PC Setup.**

Press ⏻ to select **PC Setup.**

Press ⏻ again to transfer data.

It will automatically return to **Num setup** when the transmission is completed.

Del Data Setup

Press ► till to enter the **Del Setup**.

Press ⏻ to select **Del Setup** .

Press ⏻ again to delete the MEM data.

It will automatic return to **Num setup** when the mem data is deleted.

Section 6 Testing

Before performing any test, the user should review the **VivaDiag** Lipid Testing System's User's Manual for detailed instructions. The following steps show how to use each component to measure the lipid concentration.

Specimen Collection

1. Use fresh capillary blood from the fingertip.
2. Use heparinized or EDTA venous whole blood, serum and heparinized plasma specimens. Please refer to Professional Testing below.

Note:

Before testing, choose a clean, dry work surface. Review the procedure and make sure all of the items needed to obtain a sufficient amount of blood are available.

Testing with heparinized or EDTA venous whole blood, serum and heparinized plasma

For heparinized or EDTA venous whole blood, serum and heparinized plasma, mix the specimen well, then collect specimen (10 µL for individual test, 25 µL for 3-1 test) into a plastic/glass capillary transfer tubes or pipette. Apply it to the center region of the Specimen Application Area of the device. Do not touch the test devices with the pipette or tube.

- Specimen must be tested within 8 hours of collection.
- Mix the specimens well before testing in order to ensure the cellular components are evenly distributed.
- Allow the specimen to come to operating temperature (15-40°C or 59-104°F) for approximately 15 minutes if the specimen has been refrigerated.
- Anticoagulants other than EDTA and heparin are not recommended.

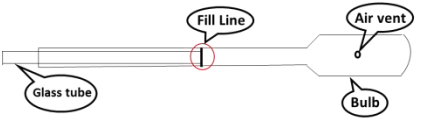
Note:

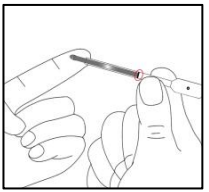
Refer to NCCLS Documents H3-A6, Collection of Diagnostic Blood Specimens by Venipuncture.

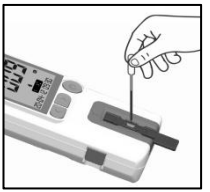
Testing with fingertip blood

Wipe away the first drop of blood. Apply light pressure to obtain a second drop of blood. Collect capillary blood (10 µL for individual test, 25 µL for 3-1 test) using a Capillary Transfer Tube or pipette.

For use with the Capillary Transfer Tube, hold the tube slightly downward and touch the tip of the Capillary Transfer Tube to the blood specimen. Capillary action will automatically draw the specimen to the fill line and stop.







Note:

The Capillary Transfer Tube will fill automatically. Make sure the blood reach the fill line. Never squeeze the capillary transfer tube or cover the air vent while sampling.

Align the tip of the Capillary Transfer Tube with the center hole of the Specimen Application Area of the test devices. Cover the air vent and Squeeze the bulb to apply the blood sample to the sample well.

Note:

Do not touch the test device with the Capillary Transfer Tube or pipette. The capillary blood should be tested immediately after collected. Use of a Capillary Transfer Tube or pipette is recommended for accurate results.

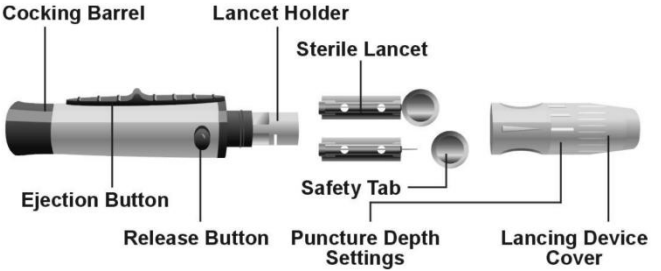
Blood specimens can be obtained by using a lancing device or a safety lancet.

Note:

For 3-in-1 test, please use the safety lancet.
For individual tests, you can use either the lancing device or the safety lancet.

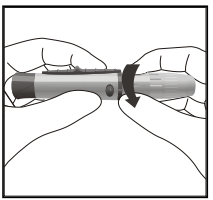
Lancing Device (For individual tests)

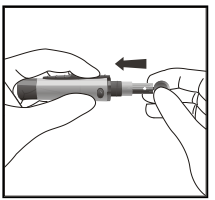
Refer to the instructions below for details.



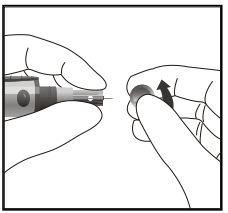
For obtaining a drop of blood from the fingertip, adjust the penetration depth on the lancing device to reduce discomfort.

Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.

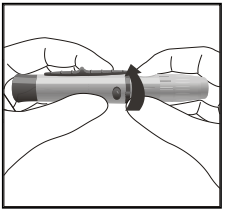




Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens. Then pull the safety tab off the lancet. Save the safety tab for lancet disposal.

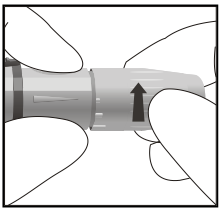


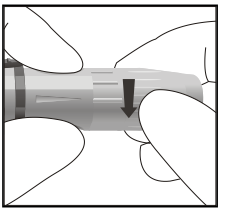
Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully seated on the lancing device.



Adjust the puncture depth by rotating the lancing device cover. There are a total of 6 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.

Use settings 1 and 2 for delicate skin, 3 and 4 for normal skin, or 5 and 6 for calloused or thick skin.

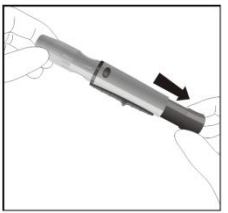




Note:

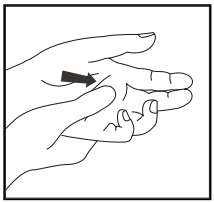
Greater pressure of the lancing device against the finger will also increase the puncture depth.

Pull the cocking barrel back to set the lancing device. A click may be heard. The device is now loaded and ready to obtain a drop of blood.

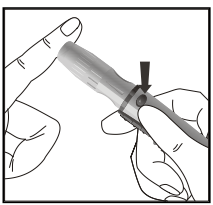


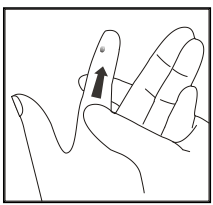
Prior to testing, make sure the patients hand is warm and relaxed before collecting the capillary blood specimen. Use warm water to increase blood flow if necessary. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

Clean the testing site with an alcohol swab or by washing the hands with warm soapy water and then dry the testing site thoroughly.



Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick the fingertip. A click should be heard as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood. For the greatest reduction in pain, lance the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make the fingers sore and callused.





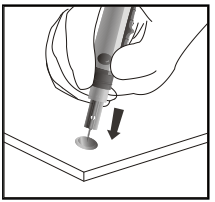
Note:

Make sure the patient's hand is warm and relaxed before collecting a capillary blood specimen. Use warm water to increase blood flow if necessary.

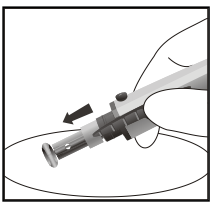
Don' t use an infection swab containing iodine. This can give inaccurate results.

Disposal of the Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface. Carefully insert the lancet needle into the safety tab.



Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to eject the used lancet. Place the lancing device cover back on the lancing device.

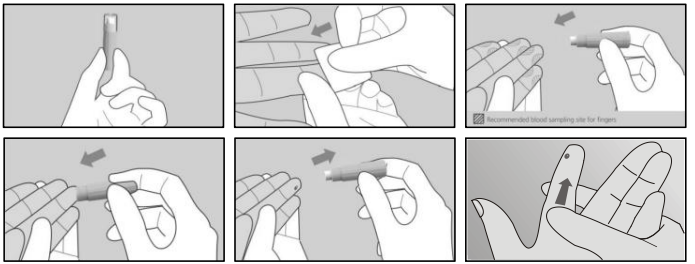


Note:

For professional use, please refer to NCCLS Documents H04-A6, Collection of Diagnostic Capillary Blood Specimens.

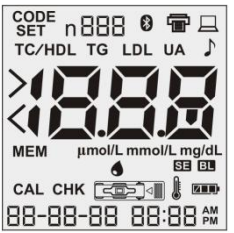
Safety Lancets (For 3-1 test and individual tests)

Carefully rotate and pull off the protective cap.
After cleaning the skin, hold the lancet firmly against the puncture site.
Press the lancet against the puncture site tightly to lance the skin. Discard the lancet in an appropriate sharps container.
Gently massage the surrounding area toward the puncture site to collect the required blood volume.

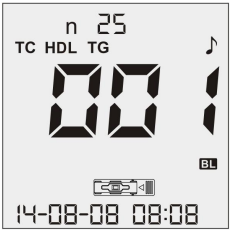


Test Processing

Ensure the meter is set up properly, as described in previous sections. Turn the meter on. The screen will briefly display all the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on. There should be no missing icons or elements. The meter will briefly show a blank display.



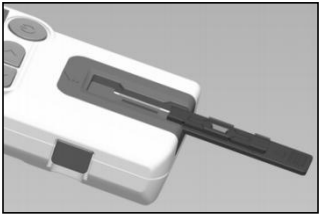
After startup, the Initial Screen will be displayed. Ensure the code chip is inserted. Compare the number showed in the display with the code number printed on the foil pouch. Refer to Initial Setup. The ***test device symbol*** will flash when the meter is ready for the device to be inserted.



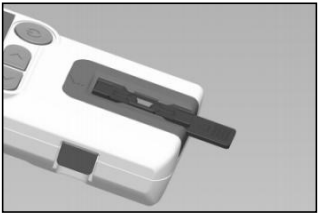
Check the specimen type displayed on the meter LCD is same as the specimen type tested. If not, set the correct specimen type. Refer to Section 5 Specimen Type Set Up.

Testing

Insert a device into the Device Channel in the same direction as the arrows indicate on the device.



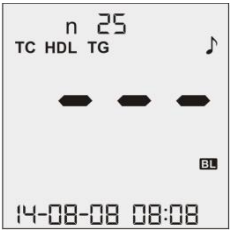
Ensure that the test device is inserted to the end of the Device Channel. The ***blood drop symbol*** will flash when the meter is ready for the specimen to be applied.



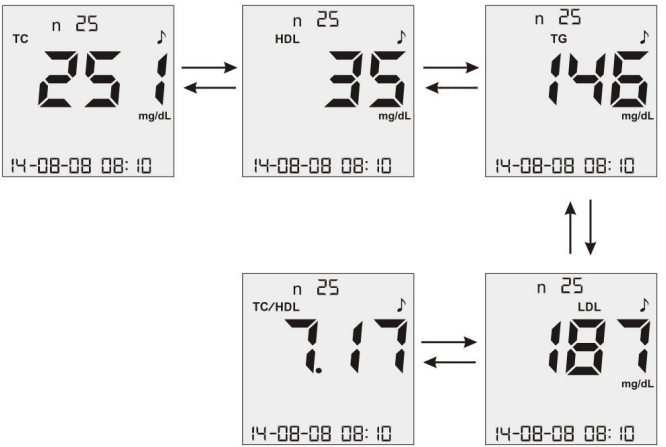
Apply the blood specimen (10 µL for individual test, 25 µL for 3-1 test) to the center of the Specimen Application Area on test device.

Note:

For testing capillary blood, use the second drop of blood for accurate results. The meter will begin testing automatically with ***three dashes*** *in a line flashing on the display indicating the test is in progress.*



Results will be displayed within 2 minutes. Press ► to view the results.



Remove the used test device. The meter will return to the Initial Screen and ready to perform a new test.

Note:

Discard all blood specimens, used test devices, and materials carefully.
Follow proper precautions and obey all local regulations when discarding blood specimens and materials.

Perform daily cleaning when testing is completed for the day. Refer to the Maintenance section.

The meter will automatically turn off after 5 minutes of inactivity or when ⏻ is pressed. Remove the batteries if the meter will not be used for an extended period.

Section 7 Data/Communication

Data Transmission

Plug the USB cable into the USB port located on the top of the meter and connect the other end of the USB cable to a PC.

Note:

The PC must have a compatible software installed to receive and process the data transmitted from the meter.

For transferring data to a PC, from the Setup screen, press ◄ or ► until ***PC*** is displayed. Refer to Meter Setup and Options for more details. Press ⏻ to enable the Data Communication mode. ***MEM*** will be displayed.

Press ⏻ again to transfer data to an external certified PC.
After data Transmission is complete, the meter will return to the Setup Menu.

Note:

Up to 200 test records are automatically stored in the memory. After 200 test records are stored, the oldest test record will be replaced by a new record. For example, if 200 records are stored in the memory, the next test result (201) will replace the first result in the memory.

Deleting Data

To delete all data from the meter database, enter the Setup Menu. Refer to Meter Setup and Options for more details. Press ◄ or ► until ***dEL*** is displayed.

Press ⏻ to enable data deletion, ***MEM*** will be displayed.

Press ⏻ until the meter returns to the Setup Menu.

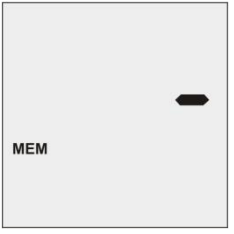
Memory/Database

From the initial test screen, press ◄ or ► to proceed to the memory/database.

Press ◄ or ► to view the memory from corresponding tests: individual or 3-1. Press ⏻ to enter the selected memory screen. The screen will show the latest results. Press ◄ or ► to choose the No. of results and view each record in the date/time sequence.

To view the 3-1 test results, press ⏻ to proceed to the record. Then press ◄ or ► to view results of TC, HDL, TG, TC/HDL and LDL. Press ***SET*** button to exit.

If no data is stored, the meter will display ***one dash*** (**-**) and ***MEM***. Press top setup button or ⏻ to return to the testing screen.



Section 8 Optical System Check

Press ◄ or ► from the Setup Screen to select the Optical Check mode, as shown below.

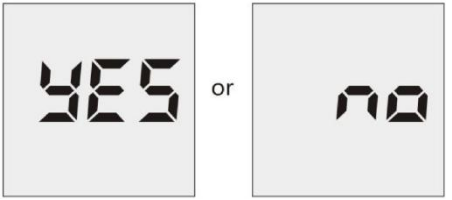
Note:

- The control device is intended to check the optical system.
- Allow the control devices and the meter to reach operating temperature (15-40° C or 59-104°F) prior to testing.
- The optical check should be performed under normal lab lighting conditions. Do not perform under sunlight or extreme lighting conditions.

Press to enter this mode. The meter will flash the test device symbol, as shown below.

Insert a control device into the Device Channel. Follow the direction of the arrows indicated on the device. Ensure that the control device is inserted all the way.

Press ⏻ to start the optical check. If the meter displays ***YES***, the meter is normal. If the meter displays ***no***, the meter is not functioning properly.



If the meter displays ***no***, check the control device for contamination or to check if it is damaged. If there are any visible signs of damage or contamination, discard the control device and retest using a new device. Press ⏻ to return to the Setup Screen.

Section 9 Quality Control

Each lab should use its own standards and procedures for performance. Test known specimens/controls at each of the following events in accordance with local, state, and/or federal regulations or accreditation requirements:

- Each new day of testing
- When a new package of test devices is opened
- When a new operator uses the meter
- When test results seem inaccurate
- After performing maintenance or service on the meter

If QC tests do not provide expected results, perform the following checks:

- Ensure that the test devices used are not expired.
- Ensure that the test devices are fresh from a new package.
- Ensure that the controls are not expired.
- Repeat the test to ensure no errors were made during the test.

Control Solution Testing

Cholesterol Control Solution testing is performed in same method as blood tests. Cholesterol Control Solution is used instead of blood.

Note:

Make sure the control solution and all the test materials reach operating temperatures of 20-40°C (68-104°F) prior to testing. Tests can only be accurately performed when the control solutions and test materials are within this temperature range.

1. Turn on the meter, and press ◄ or ► from the Setup Screen to confirm the ***bL*** mode is selected, as shown below. Refer to *Specimen Type Set Up* in the User's Manual for more details.
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. 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.
4. 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.
5. 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 25 µL of control solution for the 3-1 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 3-1 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, 3-1 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. Avoid touching the device with the tip of the bottle to finish an incomplete drop.*

6. For the 3-1 test, two kinds of control solutions (one for TC and TG, one for HDL) 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.

Interpreting 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 Lipid Testing System is working correctly and the procedures are being performed properly.

If the results do not fall within the respective range(s), refer to the Control Solution Package Insert for further instructions.

Section 10 Maintenance

Proper maintenance is recommended for best results.

General Cleaning

For best results, the meter should be cleaned after each day of testing.

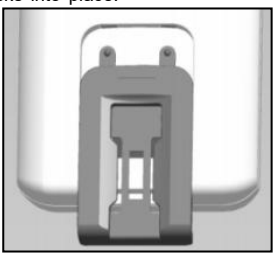
Meter Surface

A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary.

A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use. Avoid getting liquids, residue, or control solutions in the meter through the **Device Channel, Code Chip Slot**, or **USB Port**.

Test Device Holder

Remove the **Test Device Holder** by pressing in on the middle of the **Test Device Holder** and sliding it out from the meter. Wipe it down with a damp cloth or a mild detergent. Dry it with a dry, soft cloth. Slide the **Test Device Holder** back into the meter by laying it flat on the meter. Firmly press down on the two sides of the **Test Device Holder** with your thumb and push it in until it clicks into place.



Note:

Do not use organic solvents, such as gasoline or paint thinner. This will cause damage to the meter.

Meter Sensor Area

Remove the **Test Device Holder** as described in the previous section. Wipe down the **Meter Sensor Area** with a cotton swab. Do not scratch the transparent window covering the sensors.

Note:

*Do not use bleach or alcohol to clean the **Meter Sensor Area.** This will cause damage to the meter.*

Disinfection Process

The disinfection process should be performed before each test to prevent potential infectious disease Transmissions through blood-borne pathogens.

Cleaning Before Disinfection and How to Disinfect

Before disinfection, use EPA Registered towelette/wipes with active ingredients of Isopropyl alcohol to clean the meter. Use these towelette/wipes to remove any stains/debris. The cleaning before disinfection ensures stains or debris are removed before disinfection for an effective sterilization.
For disinfection, please use a fresh EPA Registered towelette/wipe with active Isopropyl alcohol to wipe the meter. Be sure to wet the entire outer meter surface thoroughly. The outer meter surface must remain visibly wet for one full minute. After wiping, allow the meter to air dry completely before using the meter again.

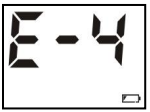
Note:

*Avoid inserting the towelette/wipe into the inside of the **Code Chip Slot** and the **USB Port** when performing cleaning before and during disinfection.*

Disinfection Frequency

The meter disinfection process should be performed for the first 2 years of the meter usage. This ensures that your meter will operate properly with regular disinfection for the first 2 years of the meter's life. Check normal meter electronic operations regularly. Do this by ensuring the LCD display shows all segments once the meter is turned on before testing.

Replacing the Batteries



When the battery icon is flashing, the batteries are low and should be replaced as soon as possible. An ***E- 4*** error message will appear if the batteries are too low to perform any more tests. The meter will not function until the batteries are replaced.

Make sure the meter is off before removing the batteries. Turn the meter over to locate the battery cover. Press the battery cover tab on the top and lift the cover to open it. Remove and discard the old batteries. Insert three new AAA batteries into the battery compartment, alternating orientation up and down as indicated in the bottom of the battery compartment.

Close the battery cover and make sure that it snaps shut. Recheck and reset the clock setting if necessary, after replacing the batteries to ensure that the time is correctly set. Refer to Initial Setup.

Note:

Do not discard batteries with household waste. Follow local regulations for disposal.

Section 11 Precautions

Follow the precautions listed below to ensure accurate results and proper operation of the meter.

- The protection provided by the equipment may be impaired if used in a manner not defined in this instruction manual.
- Wear gloves to avoid contact with potentially hazardous biological specimens during testing.
- Avoid storing or operating the meter in direct sunlight, excessive temperatures, or high humidity. Refer to Appendix 1 Meter Specifications for operating condition requirements.
- Keep the unit clean. Wipe it frequently with a soft, clean, and dry cloth. Use a damp cloth when needed.
- Do not clean the unit with substances, such as gasoline, paint thinner or other organic solvents to avoid any damage to the meter.
- Do not clean the LCD or sensor area with water. Lightly wipe with a soft, clean, dry cloth.
- The device channel must be kept clean. Lightly wipe with a soft, clean, dry cloth each day. Use a damp cloth as needed. Refer to the Maintenance section.
- Follow all local regulations when discarding the unit or its accessories.
- Do not use the unit or the devices outside of the operating temperature ranges: 15-40°C (59-104°F); ≤ 90% RH.

Section 12 Troubleshooting

Display	Causes	Solution
	The sensor area is damaged, dirty, or blocked at turn-on, such as a used test device left in the meter.	Ensure the sensor area is clean and that there are no objects covering the sensor area. Refer to Maintenance. Restart the meter. Contact your local distributor if the sensor area window is broken
	Test device was removed during the test.	Repeat the test and ensure the test device remains in place.
	Specimen was applied to the test device too soon.	Repeat the test and apply specimen after blood drop symbol appears.
	Batteries are discharged but have enough power to run 20 more tests.	Test results will still be accurate, but replace the batteries as soon as possible.
	Batteries are low and meter will not allow more tests until the batteries are replaced.	Replace the batteries then repeat the test.
	Insufficient specimen.	Repeat the test. Apply enough specimen. Use around 10 µL (for individual tests) and 25 µL (for 3-1 test) of specimen.
	Expired test device or incorrect date entered .	Ensure the test devices are within the expiration date printed on the package label. If the test devices are still within the expiration date, check to see if the date was entered correctly.
	Code chip was removed during testing.	Insert proper code chip. Confirm the code chip matches the test device code and repeat the test.
	The test device type does not match the code chip.	Use the proper device which its type matches the code chip.
	The environment temperature is higher than 40 ºC (104ºF).	Get the meter in a proper environment where the temperature is between 15-40ºC (59-104ºF) .
	The environment temperature is lower than 15 °C (59ºF)	
	No code chip in the meter. Code chip is damaged or inserted incorrectly.	Insert the code chip that accompanied the package of test devices. If the code chip is damaged, use a new code chip with the correct code number. If the code chip is inserted incorrectly, remove the code chip and insert it into the code chip slot.

Appendix 1 Meter Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Test Time	≤ 2 min
Measurement Range	TC: 100-500 mg/dL (2.59-12.93 mmol/L, 1 mmol/L=38.66 mg/dL) HDL: 15-120 mg/dL (0.39-3.10 mmol/L, 1 mmol/L=38.66 mg/dL) TG: 45-650 mg/dL (0.51-7.34 mmol/L, 1 mmol/L=88.6 mg/dL)
Specimen	Whole blood, plasma, and serum
Specimen Volume	10 µL for individual test; 25 µL for 3-1 test
Power Source	Batteries: 3 AAA (LR03) Mini USB, 5 V dc, 50 mA, use only AC/DC adapter or PC certified and recommended.
Battery Life	85 hours or 1,000 tests
Units of Measurement	mg/dL, mmol/L
Memory	200 records
Automatic Shut Off	5 minutes after last use
Meter Size	142 mm × 70 mm × 27 mm
Display Size	50 mm × 50 mm (1.97” × 1.97”)
Weight	130 g (without batteries)
Meter Storage Conditions	0-50°C (32-122°F); ≤ 90% RH; altitude ≤ 2000 m
Operating Conditions	15-40°C (59-104°F); ≤ 90% RH; altitude ≤ 2000 m

Appendix 2 Index of Symbols

	Consult instructions for use		*In vitro* diagnostic medical device
	Catalogue number		Serial Number
	Manufacturer		Authorized Representative
	Batch code		Use-by date
	Contains sufficient for <n> tests		Temperature limit
	Sterilized using irradiation		Code Number
	Do not discard along with household waste		USB Port
	Fragile, handle with care		This Side Up
	Keep away from sunlight and heat		Keep Dry
	Do not re-use		Model number

Appendix 3 Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within 30 days of purchase.
For your records, write the purchase date of your starter kit here:

_____

Note:

This warranty applies only to the analyzer in the original purchase. It does not apply to the other materials included with the analyzer.

Warrants to the original purchaser that this meter will be free from defects in materials and workmanship for a period of two years (24 months). The two years starts from the later of the date of original purchase or installation (except as noted below). During the stated two years period, ***VivaChek*** shall replace theunitunder warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. ***VivaChek*** shall not be responsible for shipping charges incurred in the repair of such a meter.
This Warranty is subject to the following exception and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. ***VivaChek*** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the analyzer in accordance with the operations manual, or maintenance by anyone other than ***VivaChek***. Furthermore, ***VivaChek*** assumes no liability from malfunction or damage to meters caused by the use of strips other than strips manufactured by ***VivaChek.*** ***VivaChek*** reserves the right to make changes in the design of this meter without obligation to incorporate such changes into previously manufactured meters.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by ***VivaChek***.

Limitations of Liability

In no event shall ***VivaChek*** be liable for indirect, special or consequential damages, even if ***VivaChek*** has been advised of the possibility of such damages.
For warranty service, please contact your local distributor.

VivaChek

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Effective Date: 2024-10-15