

Quick Setup - TearLab Reader & Pen

Quality Control Test



TearLab Reader

Plug the power cord into a normal wall outlet. Then plug the cord into the reader. There is a power switch on the back of the reader. Turn the switch to "on." For information on the Accessory Tray, refer to 930095 Installation Guide.

TearLab Pen

Place each pen in its dock on the reader so that the pens are in the position shown in the photo. The pens need to charge for at least one hour before you use them. Make sure the reader is plugged in and turned to "on" when charging the pens.

Using The Reader Keypad

- Press the MENU Key (⏏) once to enter the Menu Mode.
- Press (⬅) under the "up" or "down" arrows to scroll.
- Press (OK) to choose a menu item.
- Press MENU Key to return to the main screen.
- When in Test Mode, pressing the RECALL Key (⏪) will show the last test result.

Test Cards



Each Test Card can be used only once. The number code printed on top of the Test Card should be entered into the Reader during the test. Test Cards should be stored in the Test Card Accessory Tray attached to the Reader to ensure accurate results.

Control Solutions



Control Solutions confirm that the Osmolarity Test Cards are working correctly. The glass bottles (ampules) should be kept at room temperature. Do not refrigerate or keep in a hot place.

Electronic Check Cards



Electronic Check Cards are blue. Two identical cards come in each box. They can be reused to check the performance of the Reader and Pen. Test the blue Electronic Check Card once a day before testing a patient or if a Pen has been dropped or mishandled.

When testing the control solution or the electronic check cards, make sure the results match the expected values shown in the instruction sheets. If they do not match, the quality tests have FAILED. Stop testing. Contact TearLab Technical Support in your area or call TearLab at (858) 455-6006.

Electronic Check Card

Read the electronic check card instruction sheet for expected values. Be sure to test the blue electronic check cards on both Pens once a day before patient testing. Do NOT collect tears or control solutions with the electronic check cards.

- Attach Electronic Check Card onto Pen.
- The Pen will beep and a green light will turn on.
- Wait for the light to turn off and for the Pen to beep again.
- When the light turns off, dock the Pen in the Reader.
- Press (OK).
- If results FAIL, stop testing. Contact TearLab Technical Support in your area or call TearLab at (858) 455-6006.

Control Solutions

Test both levels of control solution with each new shipment of test cards (even if the lot number is the same), with each new lot number, and monthly to check storage. Read the control solution instructions sheet for expected values.

- Attach a test card to the pen (refer to the back side of this guide).
 - Do NOT collect tears.
 - Instead of collecting tears, use a control solution.
 - Use the blue sleeve to snap off the top of an ampule.
 - Turn the ampule upside down (the fluid will not spill out).
 - Touch the tip of the pen to the control solution.
 - Return the Pen to the reader, enter the code.
 - Check control result to the expected value.
 - If within the expected range patient testing may proceed.
 - If not within the expected range you should not perform patient testing.
- Contact TearLab Technical Support in your area or call TearLab at (858) 455-6006.

FDA MedWatch. Report a serious adverse event, product quality problem, product use error, or therapeutic inequivalence/failure that you suspect is associated with the use of the TearLab Osmolarity System to TearLab Customer Support (Tel: (858) 455-6006) and/or to FDA MedWatch (Tel: (800) FDA-1088, Fax: (800) FDA-0178, or www.fda.gov/medwatch).

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For more information, refer to the TearLab User Manual.



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One or more of the following patents may apply: U.S. Patents 7,017,394; 7,051,569; 7,111,502; 7,129,717; 7,204,122; 8,020,433; 7,987,702; 7,905,134; 7,810,380; 7,574,902

CLIA CONSIDERATIONS

The TearLab Osmolarity System is a CLIA-waived test system for human tears. Each laboratory or testing site using the TearLab Osmolarity System must have a CLIA Certificate of Waiver before starting testing. To obtain a Certificate of Waiver, call your state department of health or TearLab Customer Support at (858) 455-6006 for an application (Form CMS-116). TearLab can provide the phone number of your state department of health and assist you in filling out the application. The TearLab Osmolarity System is a waived test so long as it is used according to the instructions set in the Package Insert. Refer to the package insert for more complete information. User should read the complete test procedure, including recommended quality control procedures, before performing the TearLab Osmolarity test. Any modification by the laboratory to the test system or the test system instructions will result in this test no longer meeting the requirements for waived categorization. A modified test is considered to be high complexity and is subject to all applicable CLIA requirements.



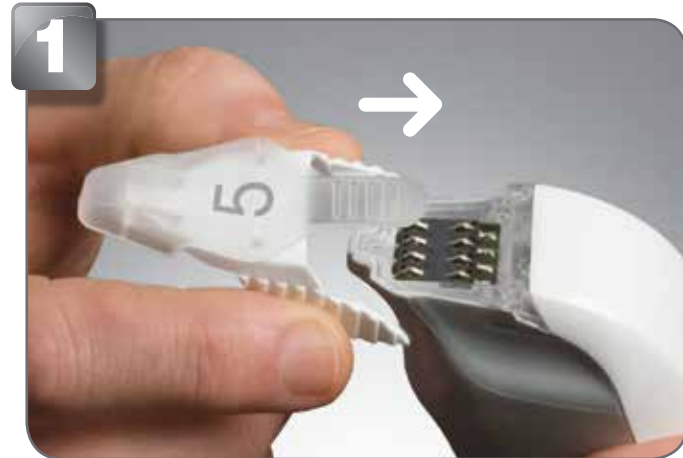
QUICK REFERENCE GUIDE



TearLab Test Procedure

Use good hygiene when collecting tears. Throw away used test cards in an appropriate container.

Frequently Asked Questions



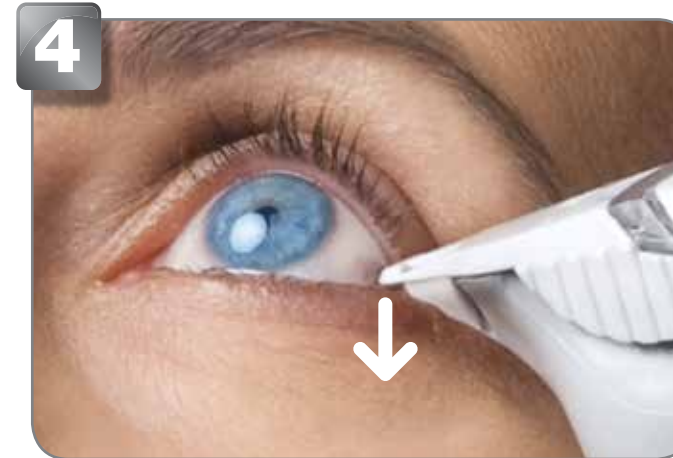
- Attach Test Card.



- Hold wings, remove cover.



- Seat patient with head back and eyes up.
- **Do NOT pull the eyelid away from the eye.**





- Lower Pen until the bottom of the tip touches the line of moisture on top of the eyelid.
- When tears are collected, the Pen will beep.



- Dock the Pen to the Reader.



- Enter the code on top of the card by pressing  below the "up" or "down" arrows.
- Press .



- Record the test result in the patient's chart.



- Remove the Test Card with your thumb.

1. What is a test card code?

The test card code is a number printed on top of the test card and allows the test cards to be read correctly. When a pen is placed in the dock, the number must be entered into the reader within eight seconds.

2. What does it mean if the green light on the pen does not turn on?

It means do not test unless the green light is on.

3. How do I know if I have successfully collected a tear sample?

The green light will turn off and the pen will beep.

4. Why does the pen start beeping again after I collect a tear?

The pen is about to "time out." This means that you have just ten seconds to place the pen in the dock before the test information is lost.

5. How do I know if the pen is successfully docked?

The reader will beep.

6. How can I determine if a test card is used?

A test card without a protective cover should always be considered a used test card.

7. How often should I test the blue check card?

Test the blue electronic check card once a day before testing a patient or if a pen has been dropped or mishandled.

8. How often should I test the control solutions?

Test both levels of control solution with each new shipment of test cards (even if the lot number is the same), with each new lot number, and monthly to check storage.

9. After collecting a tear, does it matter on which side I dock the pen?

No. You will see the test results on the LCD screen on the side where the pen is docked.

10. What is proper hygiene for testing?

Always wash your hands and keep the TearLab clean. Read the TearLab Test Card Insert for more information.

11. How should I store the test cards?

Test cards should be stored in the Test Card Accessory Tray attached to the Reader to ensure accurate results. Store extra Test Cards at room temperature. Pay attention to the expiration date printed on the box and on each package. Never use a test card after the expiration date.

12. What if the Quality Controls FAIL?

Stop testing. Contact TearLab Technical Support in your area or call TearLab at (858) 455-6006. Refer to the User Manual for information on troubleshooting and maintenance.