



InflammaDry[®]

CLIA Complexity: Waived for tear fluid samples.

Store between 39°F to 77°F (4°C to 25°C)

QUICK REFERENCE INSTRUCTIONS

InflammaDry is a CLIA-waived test for the visual, qualitative, *in vitro* detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye. A CLIA Certificate of Waiver is required to perform the test in a waived setting. Laboratories with a CLIA Certificate of Waiver must follow the manufacturer's instructions for performing the test. To obtain a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CUA or from your state health department. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

Test Contents



InflammaDry



Sample Collector



Test Cassette



Buffer Vial

Note: An unused InflammaDry device has two faint orange lines in the result window.



Test Procedure

1 Sample Prep

Gently dab the sampling fleece in multiple locations along the inside of the patient's lower eyelid (palpebral conjunctiva), releasing the lid every 2 to 3 dabs to allow the patient to blink. Do not use a dragging motion when collecting the sample.



2 Sample Prep

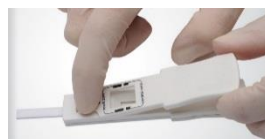
After completing a minimum of 6 to 8 dabs along the conjunctiva, allow the sampling fleece to rest against the conjunctiva for an additional 5 seconds. Upon saturation with tear fluid, the fleece will glisten and may turn patchy pink in color, depending on the patient's tear composition.

3 Assembly

Assemble the test by gently placing the sampling fleece of the Sample Collector into the sample transfer window of the Test Cassette body.

4 Snap Together

Press firmly where indicated until the test feels secure. A double click means the test is properly assembled.



5 Buffer Step

Open the buffer vial and immerse the absorbent tip for a minimum of 20 seconds.



6 Running the Test

Remove the absorbent tip from the buffer vial, replace the protective cap, and lay the test flat on a horizontal surface for 10 minutes.

External Control Procedure

- InflammaDry external controls are available directly through Quidel. InflammaDry external controls consist of two (2) vials (a positive control containing recombinant MMP-9 protein and a negative control) and diluent. InflammaDry external control testing should be performed with each new lot, each new shipment, and every 30 days.
- Choose either the positive or negative control. Only one (1) control may be run on each InflammaDry test at a time.
- Remove the cap and rubber stopper from the selected control vial and add 5 drops of diluent from the Diluent Bottle, 1 drop at a time.
- Recap the control vial and gently shake the vial to dissolve the lyophilized powder. Let the vial with the liquid sit for at least 2 minutes prior to use.

- Open the control vial and pour the entire liquid contents of the vial into the inside of the black cap.
- Open the Sample Collector pouch from an unused InflammaDry Test.
- Dip the sampling fleece into the control liquid in the black cap.
- Run and read the InflammaDry results per the instructions provided in the InflammaDry Package Insert.
- A positive control should show a positive result. A negative control should show a negative result.
- When the correct control results are not obtained, repeat the test control or contact Quidel Technical Support at 800.874.1517 before testing patients.

Interpretation of Results

Once the background within the result window is white and 10 minutes have elapsed, the test may be read. If there is a streaky fluid wave in the background, or if the test is negative after 10 minutes, allow an additional 5 to 10 minutes of running time prior to interpretation.

The results of the test are indicated through two (2) lines which appear in the result window: the control line and the result line. The control line appears as a BLUE line in the control zone. It indicates the correct application and performance of the test, and must appear for the test to be valid.

POSITIVE RESULT

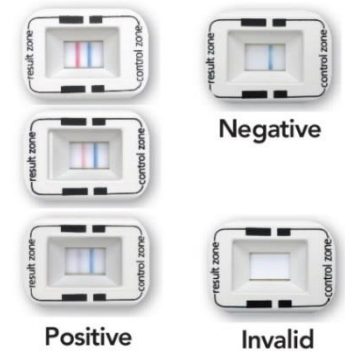
The presence of both a BLUE line in the control zone and a RED line in the result zone indicates a positive result. Even if the RED line is faint in color, incomplete over the width of the test strip, or uneven in color, it must be interpreted as a positive. A positive result indicates the presence of MMP-9 \geq 40 ng/mL.

NEGATIVE RESULT

The presence of only a BLUE line in the control zone indicates a negative result. A negative result is indicative of an MMP-9 level $<$ 40 ng/mL.

INVALID RESULT

If a BLUE line does not appear, the test may be invalid. Re-immerses the absorbent tip into the Buffer Vial for an additional 10 seconds. If a BLUE line still does not appear, the test must be discarded and the subject retested by resampling the eye using a new InflammDry test.



Warnings and Precautions

- For *in vitro* diagnostic use only. For prescription use.
- Keep the Test Cassette and Sample Collector in their foil pouches until just before use.
- The Dacron® material used in the sampling fleece may cause allergic reactions for some people.
- Do not use InflammDry past the expiration date.
- Follow Universal Precautions when handling patient samples.
- Wear disposable gloves while handling samples and wash hands after the test is complete.
- Both InflammDry and the Buffer Vial are single-use items. Do not reuse with multiple specimens.
- InflammDry requires a visual readout. Do not interpret the test result if you have color-impaired vision.
- Result interpretation requires a brightly lit environment.
- Do not use the same InflammDry Test on more than one patient.
- Slit-lamp biomicroscopy is required to eliminate patients with active intraocular inflammation.
- InflammDry should be performed prior to instilling ocular anesthetic, topical dyes, or performing Schirmer testing.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

ASSISTANCE

If the InflammDry Test does not perform as expected, contact Quidel Technical Support 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.), technicalsupport@quidel.com, or your local distributor.

Reference the Package Insert for *Warnings and Precautions, Specimen Collection and Handling, and Quality Control.*

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Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.



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