InflammaDry®
An RPS Diagnostic Solution
CLIA-waived

QUICK REFERENCE GUIDE

A CLIA-waived, Point-of-care Test to Aid in Dry Eye Diagnosis

For U.S. use only.
InflammaDry® is a CLIA-waived test for human tears. A CLIA Certificate of Waiver is required to perform the test in a waived setting. To obtain a Certificate of Waiver, go to the following website: http://www.cms.hhs.gov/clia/. The form should be mailed to the address of the local state agency of the state in which the testing site resides: http://www.cms.hhs.gov/clia/ssa-map.asp. Laboratories with a CLIA Certificate of Waiver must follow the manufacturer’s instructions for performing the test. If the laboratory modifies the instructions, the test no longer meets the requirements for waived categorization. A modified test is considered to be of high complexity and subject to all CLIA requirements.

**INTENDED USE**
InflammaDry is a rapid, immunoassay 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. InflammaDry is to be used to aid in the diagnosis of dry eye, in conjunction with other methods of clinical evaluation. This test is intended for prescription use at point-of-care sites.

**QUALITY CONTROL**
InflammaDry has built-in procedural controls (see below). For daily quality control, RPS recommends documenting that these internal procedural controls were checked for the first sample tested each day.

- An unused InflammaDry device has a purple flow indicator on the test strip in the sample transfer window.
- The unused device also has two (2) faint orange lines in the result window.
- If the test is valid, a BLUE line will appear in the control zone.

**PACKAGE INSERT**
See the package insert, including the quality control section, for complete instructions for use, warnings and precautions, limitations, and study results before using the product. Carefully follow these instructions when performing the test. For questions and technical support, call RPS customer care at 844.GoToRPS (468.6777).

**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 RSP InflammaDry test to Rapid Pathogen Screening, Inc., customer care at 844.GoToRPS (468.6777) and/or to FDA MedWatch (tel: 800-FDA-1088, fax: 800-FDA-0178, or www.fda.gov/medwatch).

**TEST PROCEDURE**

**TEST 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 5-10 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 positive. A positive result indicates the presence of MMP-9 ≥ 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. Reimmers the absorbent tip into the buffer vial for an additional ten (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 InflammaDry test.

**NOTE:** InflammaDry should be performed PRIOR to instilling ocular anesthetic, topical dyes, or performing Schirmer testing.

1. Gently dab the sampling fleece in multiple locations along the inside of the patient’s lower eyelid (palpebral conjunctiva), releasing the lid after every two to three (2-3) dabs to allow the patient to blink. Do not use a dragging motion when collecting the sample.
2. After completing a minimum of six to eight (6-8) dabs along the conjunctiva, allow the sampling fleece to rest against the conjunctiva for an additional five (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. Assemble the test by gently placing the sampling fleece of the sample collector into the sample transfer window of the test cassette body.
4. Press firmly where indicated until the test feels secure. A double click means the test is properly assembled.
5. Open the buffer vial and immerse the absorbent tip for a minimum of 20 seconds.
6. Remove the absorbent tip from the buffer vial, replace the protective cap, and lay the test flat on a horizontal surface for ten (10) minutes.

**TEST CONTENTS**

- InflammaDry®
- Sample Collector
- Test Cassette
- Buffer Vial
**EXTERNAL CONTROLS**

InflammaDry external controls are available directly through RPS. 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.

1. Choose either the positive or negative control. Only one (1) control may be run on each InflammaDry test at a time.
2. Remove the cap and rubber stopper from the selected control vial and add five (5) drops of diluent from the diluent bottle, one (1) drop at a time.
3. Recap the control vial and gently shake the vial to dissolve the lyophilized powder. Let the vial with the liquid sit for at least two (2) minutes prior to use.
4. Open the control vial and pour the entire liquid contents of the vial into the inside of the black cap.
5. Open the sample collector pouch from an unused InflammaDry test.
6. Dip the sampling fleece into the control liquid in the black cap.
7. Run and read the InflammaDry results per the instructions provided in the test’s package insert.
8. A positive control should show a positive result. A negative control should show a negative result.
9. When the correct control results are not obtained, repeat the test control or contact RPS customer care at 844.GoToRPS (468.6777) before testing patients.

---

**WARNINGS AND PRECAUTIONS**

1. For *in vitro* diagnostic use only. For prescription use.
2. Keep the test cassette and sample collector in their foil pouches until just before use.
3. The Dacron® material used in the sampling fleece may cause allergic reactions for some people.
4. Do not use InflammaDry past the expiration date.
5. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. Proper handling and disposal methods should be established according to federal, state, and local regulations.
6. Wear disposable gloves while handling samples and wash hands after the test is complete.
7. Both InflammaDry and the buffer vial are single use items. Do not reuse with multiple specimens.
8. InflammaDry requires a visual readout. Do not interpret the test result if you have color-impaired vision.
9. Result interpretation requires a brightly lit environment.
10. Do not use the same InflammaDry test on more than one patient.
11. Slit-lamp biomicroscopy is required to eliminate patients with active intraocular inflammation.
12. InflammaDry should be performed prior to instilling ocular anesthetic, topical dyes, or performing Schirmer testing.