QUICK REFERENCE GUIDE

InflammaDry®
AN RPS DIAGNOSTIC SOLUTION

IMPORTANT

See the package insert, including the quality control section, for complete instructions for use, warnings and precautions, limitations, and study results. For questions and technical support, call +1.941.556.1850.

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, to aid in the diagnosis of dry eye, in conjunction with other methods of clinical evaluation. This test is intended for professional use at point-of-care sites.

TEST CONTENTS

InflammaDry®

Sample Collector


Test Cassette


Buffer Vial

TEST PROCEDURE

NOTE: An unused InflammaDry device has two (2) faint orange lines in the result window. If an ocular anesthetic or any other topical medication has been applied to the eye, wait at least **two (2) hours** before collecting a sample.

1. Gently lower the patient's eyelid to expose the inside of the lower lid (palpebral conjunctiva).

2. Gently dab the sampling fleece six to eight (6-8) times in multiple locations along the inside of the patient's lower eyelid (palpebral conjunctiva). To ensure sufficient tear sample collection:
   - Dab the sampling fleece in a temporal to nasal direction along the palpebral conjunctiva.
   - Release the lid after every two to three (2-3) dabs to allow the patient to blink.
   - After completing six to eight (6-8) dabs, allow the sample collector to rest along the inferior nasal palpebral conjunctiva for an additional five (5) seconds.
   - Dab when collecting the sample. Do not drag.

   The sampling fleece will glisten when it is sufficiently saturated, and may turn slightly pink 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 10 minutes.

Information is only applicable to product distributed outside the U.S.

To place an order, call 1.855.651.4934,
email orders@labtician.com, or visit www.labtician.com

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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 result window background, or if the test is negative after 10 minutes, allow an additional 5-10 minutes of development 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

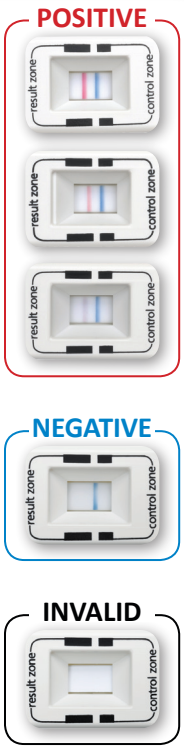
The presence of both a **BLUE** line in the control zone and a **RED** line in the result zone indicates a positive result. Even if the **RED** line is faint in color, incomplete over the width of the test strip, or uneven in color, it must be interpreted as positive. A positive result indicates the 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. Reimmerse 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.



WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
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 local, state, and federal 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 kit on more than one patient.
11. InflammaDry should be performed prior to instilling ocular anesthetic, topical dyes, or performing Schirmer testing.

LABTICIAN™ ophthalmics

Commercialized in Canada by Labtician Ophthalmics, Inc.
Manufactered Rapid Pathogen Screening, Inc.
7227 Delainey Court • Sarasota, FL 34240 USA • +1.941.556.1850 • RPSdetectors.com

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