



InflammaDry[®]

For the visual, qualitative detection of elevated levels of MMP-9 protein in human tears.

Read the Package Insert and quality control procedures completely before using the product. Carefully follow the instructions when performing the test. **NOTE:** Do not discard this Package Insert. There is only one (1) Package Insert per dispenser box. Additional copies of the Package Insert can be found at quidel.com/InflammaDry.



INTENDED USE

InflammaDry is a rapid, immunoassay test for the visual, qualitative, *in vitro* detection of elevated levels of the MMP-9 protein in tear fluid, 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 professional use at point-of-care sites.

Store between 4°C to 25°C (39°F to 77°F). Not to be taken internally. Keep out of reach of children.

SUMMARY AND EXPLANATION

Dry eye, or dysfunctional tear syndrome, as defined by the second Dry Eye Work Shop (DEWS II), is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.¹ Inflammation has been shown to be an underlying cause of chronic dry eye.¹

Dry eye is an extremely common condition that is often under diagnosed. Dry eye may range in severity from episodic symptoms of ocular discomfort, to a chronic condition requiring therapeutic intervention. Inflammatory mechanisms are believed to be one possible underlying cause of chronic dry eye.^{1,4} Currently, the diagnosis of dry eye is based upon a clinical exam and supported by some ancillary testing.

The clinical diagnosis of dry eye includes utilizing a combination of symptoms and signs.¹ Typically, physicians ask patients to report on the presence of burning, stinging, discomfort, tearing, foreign body sensation, and fluctuating vision. The Ocular Surface Disease Index (OSDI) was developed to target and quantify the most common symptoms associated with dry eye. This is a standard instrument used in screening patients with dry eyes for therapeutic dry eye studies.^{1,2}

The clinical signs of dry eye include corneal staining and reduced tear break up time (TBUT). In many cases, a Schirmer tear test is performed to confirm the presence of reduced tear production.¹ Other dry eye tests that measure tear osmolarity or lactoferrin are also available.

Dry eye involves the relationship between the amount of tears produced, rate of tear evaporation, and the presence or absence of inflammation. Matrix metalloproteinases (MMP) are proteolytic enzymes that are produced by stressed epithelial cells on the ocular surface. MMP-9, in particular, is a nonspecific inflammatory marker that has consistently been shown to be elevated in the tears of patients with dry eyes.³⁻¹⁹ Studies have demonstrated that greater levels of MMP-9 are present in patients with more severe

dry eyes, and that the levels correlate with clinical exam findings and contrast sensitivity.⁴ Identifying the presence of ocular surface inflammation through objective measures can significantly impact the treatment algorithm for dry eye.

MMP-9 IN TEARS

MMP-9 is a nonspecific inflammatory marker that has consistently been shown to be elevated in the tears of patients with dry eyes. The normal levels of MMP-9 (ng/mL) in human tears range from 3 ng/mL to 40 ng/mL.³⁻⁸

Elevated MMP-9 levels in patients with moderate to severe dry eye disease correlate with clinical exam findings.⁴ Altered corneal epithelial barrier function is the cause for ocular irritation and visual morbidity in dry eye disease. MMP-9 appears to play a physiological role in regulating corneal epithelial desquamation. The increased MMP-9 activity in dry eyes may contribute to deranged corneal epithelial barrier function, increased corneal epithelial desquamation, and corneal surface irregularity.¹⁶ InflammADry detects elevated levels of MMP-9 \geq 40 ng/mL in tears to confirm the diagnosis of dry eye in patients with suspected dry eye disease in conjunction with other methods of clinical evaluation.

Normal Levels of MMP-9 in Tears				
Study	Normal Control	Average MMP-9 Levels (ng/mL)	Standard Deviation (ng/mL)	Upper Range (ng/mL)
Acera et al. ³	18	23.6	17.4	41.0
Chotikavanich et al ⁴	16	8.4	4.7	13.0
Solomon et al ⁵	17	7.2	2.1	9.0
Leonardi et al ⁶	10	10.5	0.2	11.0
Lema et al ⁷	20	6.9	1.4	8.0
Honda et al ⁸	28	22.7	14.0	37.0
Markouilie et al ⁹	38	11.6	15.2	N/A
Total/Avg/Range	147	12.9	–	41.0

PRINCIPLE OF THE PROCEDURE

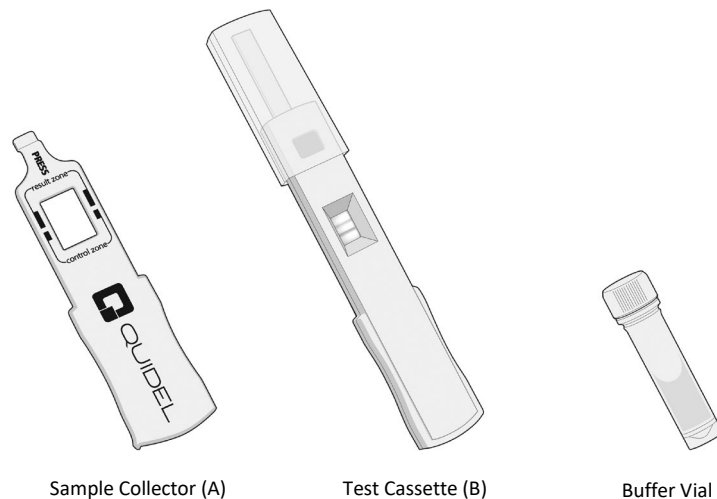
InflammADry utilizes Direct Sampling Micro-Filtration technology, based on the principle of lateral flow immunoassay. MMP-9, if present in the tear sample, is captured between MMP-9 specific mouse monoclonal and goat polyclonal antibodies at concentrations \geq 40 ng/mL. This antigen-antibody complex is captured by NeutrAvidin immobilized as the test line.

REAGENTS AND MATERIALS SUPPLIED

20-Test Kit:

- Individually Packaged Sample Collectors (20)
- Individually Packaged Test Cassettes (20)
- Buffer Vials (20): buffered salt solution containing 0.1% Sodium Azide, as a preservative
- Package Insert (1)

The Sample Collector (A) is a separately packaged sterile component that can easily be assembled onto the Test Cassette (B). Additionally, the Test Cassette (B) guarantees correct sample transfer onto the lateral flow assay strip.



Sample Collector (A)

Test Cassette (B)

Buffer Vial

MATERIALS NOT SUPPLIED IN KIT

- Timer
- Gloves
- Quality control materials (see section on external controls)

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.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- 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.
- 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.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- 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.

KIT STORAGE AND STABILITY

Store InflammDry between 4°C to 25°C (39°F to 77°F). Both InflammDry and the buffer are stable until the expiration dates marked on their outer packaging and containers.

QUALITY CONTROL

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

Procedural Controls

An unused InflammaDry device has a purple flow indicator on the test strip in the sample transfer window (G).

The unused device also has two (2) faint orange lines in the result window (H).

If the test is valid, a **BLUE** line will appear in the control zone.



The appearance of the control line indicates the correct application of adequate sample volume. The control line must appear for all tests to be considered as valid tests. If the control line does not appear, the test must be interpreted as invalid and has to be repeated by resampling the eye using a new InflammaDry test. **DO NOT** report invalid test results. Repeat the test after waiting 60 minutes.

A purple fluid wave is observed moving across the result window (H) while the test is running. Once the background within the result window (H) is white and 10 minutes have elapsed, the test may be accurately 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 running time prior to interpretation.**

External Controls

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.

Please refer to the external controls Package Insert for instructions on how to run the external controls. External controls will have an individual expiration date printed on each package. **DO NOT** use past the expiration date.

When the correct control results are not obtained, repeat the test control or contact Quidel Technical Support at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.).

External Controls may be obtained separately by contacting Quidel's Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.).

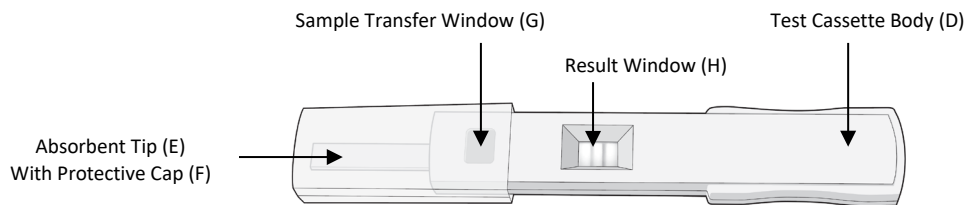
TEST PROCEDURE

Expiration date: Check expiration on all packaging. Make sure there is no damage to the foil pouches. Do not use if foil pouches are damaged. *Do not use any test past the expiration date on the label.*

Preparing the Test

Tear open each foil pouch at the indicated perforation and remove the contents. Do not touch the sterile sampling fleece (C) prior to collecting the patient sample.





Taking a Sample

1. Locate the sampling fleece (C) on the underside of the Sample Collector (A).
2. If ocular anesthetic or any other topical medication has been applied to the eye, wait at least **2 hours** before collecting a sample. Gently lower the patient's eyelid to expose the inside of the lower lid (palpebral conjunctiva).

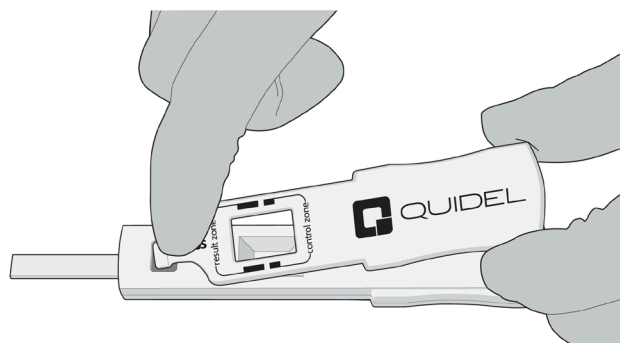


3. Gently dab the sampling fleece (C) 6-8 times in multiple locations along the inside of the patient's lower eyelid (palpebral conjunctiva). To ensure sufficient tear sample collection:
 - Dab the sampling fleece in a temporal to nasal direction along the palpebral conjunctiva.
 - Release the lid every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

In more severe dry eye states, additional dabbing may be necessary to moisten the sampling fleece. Upon saturation with tear fluid, the fleece will glisten. Based on tear volume and composition, the fleece may appear white or patchy pink in color.

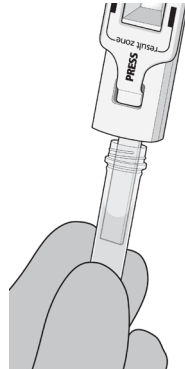
Assembling the Test

1. Locate the Test Cassette (B) with the Test Cassette body (D) and the protective cap (F). Remove the protective cap (F) from the test. The opened Test Cassette should be used within **1 hour**.
2. Assemble the test by gently placing the sampling fleece (C) of the Sample Collector (A) into the sample transfer window (G) of the Test Cassette body (D).
3. Press firmly where indicated until the test feels secure. A double-click means the test is properly assembled.



Running the Test

1. Open the Buffer Vial.
2. Immerse the absorbent tip (E) into the Buffer Vial for a minimum of **20 seconds**, ensuring that the absorbent tip is not bent in any manner.



3. Remove the absorbent tip (E) from the Buffer Vial, replace the protective cap (F), and lay the test flat on a horizontal surface for **10 minutes**.

INTERPRETATION OF RESULTS

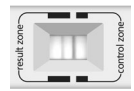
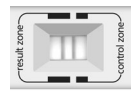
NOTE: Do not interpret the test results before completing at least 10 minutes of development time. A purple fluid wave may be observed moving across the result window (H) while the test is running.

Once the background within the result window (H) is white and 10 minutes have elapsed, the test may be accurately 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 running time prior to interpretation.** The test should be read within **6 hours** of test completion. After this period of time, it is possible that the results may change. Accurate visual interpretation requires examination under brightly lit conditions.

The results of the test are indicated through two (2) lines, which appear in the result window (H): the control line and the result line. The control line appears as a **BLUE** line in the control zone. The control line 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. An uneven or incomplete **RED** line is due to an uneven distribution of tear fluid on the sampling fleece (C). 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.



POSITIVE



NEGATIVE

The results should be evaluated with all clinical and laboratory data available. If the results do not agree with the clinical evaluation, additional tests should be performed.

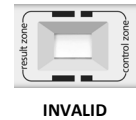
Negative Result

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.

The results should be evaluated with all clinical and laboratory data available. If the results do not agree with the clinical evaluation, additional tests should be performed.

Invalid Result

If a **BLUE** line does not appear, the test may be invalid. Re-immers the absorbent tip (E) 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. **DO NOT** report invalid test results. Although the test requires only 10 µL of fluid, if a second sample is needed, repeat dabbing may result in reducing the available tear fluid required for collecting an adequate sample. Each additional sample collection may reduce or alter the MMP-9 antigen load transferred to the test. If a second sample is needed, the sampling may be repeated **60 minutes** later.



LIMITATIONS

- MMP-9 is a nonspecific indicator for the presence of inflammation. A positive test result should not be used as the sole basis for treatment or other management decision.
- Patients with severe aqueous deficient dry eye, who produce a sample volume of less than 6 µL, may yield a false negative result.
- InflammDry should not be used within 20 minutes of performing a Schirmer tear test, as this may stimulate degranulation of MMP-9 and cause a false positive result.
- A recent history of ocular surgery or infection, allergic conjunctivitis, or other ocular surface diseases may lead to elevated levels of MMP-9 and cause a false positive result.
- Certain medications such as systemic immunomodulators, topical or oral steroids, cyclosporine, tetracycline, and topical azithromycin, are known to inhibit metalloproteinase activity. Use of these medications may lead to false negative results.
- Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
- Running the test in an environment with a temperature of 45°C or above, and humidity of 60% or above, may increase sensitivity and cause a false positive result.
- InflammDry should be performed prior to instilling ocular anesthetic, topical dyes, or performing Schirmer testing.
- Slit-lamp biomicroscopy is required to eliminate patients with active intraocular inflammation.
- Patients with a history of contact lens use or recent ocular surgery were not studied; no data supports any claims for safety and efficacy in these populations.

EXPECTED VALUES

Normal levels of MMP-9 (ng/mL) in human tears range from 3 ng/mL to 40 ng/mL.³⁻⁸

The prevalence of dry eye ranges from 5% to 30% in people aged > 50 years and dry eye is estimated to affect 21 million people in the United States.^{1,20-21} A national survey of 2,003 individuals found that nearly 40% of Americans experience dry eye symptoms, which may include dryness, burning, irritation, blurred vision, foreign body sensation and tearing.^{1,22}

The prevalence of dry eye increases with age and is far more common in women. Other risk factors include the use of certain medications, autoimmune inflammatory diseases, contact lens wear, LASIK and refractive surgery, and menopause.¹

PERFORMANCE CHARACTERISTICS

In seven (7) clinical sites, InflammDry's sensitivity and specificity was compared to clinical assessment, as defined by commonly used dry eye diagnostic criteria, composed of a combination of: necessary clinical history reflected by a high Ocular Surface Disease Index (OSDI) score ≥ 13 , and the presence of a reduced Schirmer tear test < 10, reduced Tear Break Up Time (TBUT) < 10, and the presence of keratoconjunctival staining. Normal, healthy controls without signs and symptoms of dry eye were also tested and these patients had an OSDI < 7, Schirmer tear test ≥ 10 , TBUT ≥ 10 , and no keratoconjunctival staining.

Clinical results are summarized below:

N-206		Critical Criteria		P-Value
		+	-	
InflammaDry	+	121	4	P < 0.0001
	-	22	59	
Sensitivity		85% (121/143) 95% CI (78.7-90.5)		P < 0.0001
Specificity		94% (59/63) 95% CI (87.6-99.7)		P < 0.0001
Overall Agreement		87% (180/206) 95% CI (82.9-91.9)		
Positive Predictive Value		97% (121/125) 95% CI (93.7%-99.9%)		
Negative Predictive Value		73% (59/81) 95% CI (63.2%-82.5%)		

CUT-OFF

The InflammaDry Cut-off (C_{50}) was determined to be 40 ng/mL through a series of dilutions of human MMP-9 in human tears. The C_{50} level is defined as the concentration near the cut-off that yields 50% positive results and 50% negative results when many replicates of a single sample at the concentration are tested.

CROSS REACTIVITIES

Various infectious ocular pathogens generated in a cell culture and important ocular enzymes were applied in the laboratory to determine potential cross reactivities with InflammaDry:

- Staphylococcus aureus
- Methicillin-resistant Staphylococcus aureus (MRSA)
- Moraxella catarrhalis
- Haemophilus influenzae
- Staphylococcus epidermis
- Staphylococcus pneumoniae
- Pseudomonas aeruginosa
- Matrix metalloproteinase 1, 2, and 3
- Tissue inhibitor of MMP: MMP-1, MMP-2

All isolates were cultured from human specimen. The concentrations of the suspensions were between 500,000 and 1,500,000 microorganisms (virus, bacteria) per mL of supernatant. No positive test lines developed, and no cross-reactivities to these species occurred when 10 μ L of the culture suspension was tested. No ocular enzymes caused any cross-reactivity.

INTERFERING SUBSTANCES

The following eye medications were tested for interference with InflammaDry and did not show any interference. To check specificity, undiluted blank medication was applied to the sampling fleece. Sensitivity was checked with 1:1 mixtures of recombinant MMP-9 protein in human tears at the cutoff level and the respective medication.

- | | |
|--------------------|--------------------------|
| ■ Alcon, Alcaine | ■ AMO, Blink Tears |
| ■ Alcon, Azopt | ■ AVS, Thera Tears |
| ■ Alcon, Econopred | ■ Bausch + Lomb, Alrex |
| ■ Alcon, Nevanac | ■ Bausch + Lomb, Lotemax |
| ■ Alcon, Pataday | ■ Bausch + Lomb, Zylet |

- Alcon, Systane
- Alcon, Tobra Dex
- Alcon, Travatan
- Alcon, Vigamox
- Allergan, Acular LS
- Allergan, Alphagan
- Allergan, Combigan
- Allergan, Elestat
- Allergan, FML
- Allergan, Lastacaft
- Allergan, Lumigan
- Allergan, Optive
- Allergan, Pred Forte
- Allergan, Refresh Liquigel
- Allergan, Refresh Tears
- Allergan, Zymar
- Falcon, Gentamicin Sulfate
- Falcon, Polymyxin B Sulfate
- Falcon, Timolol
- Inspire, AzaSite
- Ista, Bepreve
- Ista, Xibrom
- Medpoint, Optivar
- Novartis, GenTeal
- Novartis, Voltaren
- Novartis, Zaditor
- Pfizer, Visine
- Pfizer, Xalatan
- Sigma-Aldrich, Human IgA (1 mg/mL)
- Sigma-Aldrich, Human Lactoferrin (1 mg/mL)
- Sigma-Aldrich, Transferrin (1 mg/mL)
- Vistakon, Betimol

However, the following medications show false positive or false negative results; therefore, patients should not be tested with InflammDry if the following medications are administered into the eyes within 2 hours of testing with InflammDry.

Interferences medications:

- Merck, Trusopt
- Vistakon, Iquix
- Vistakon, Quixin
- Wilson, Proparacaine

Caution: Topical ophthalmic medications come in different formulations and some formulations (i.e., gels, ointments, etc.) may persist on the tear film longer than others. Therefore, caution should be used when using the InflammDry test on a subject who may be on such a medication, since certain medications may cause erroneous results if present on the ocular surface. In addition, certain medications may cause erroneous results if used immediately before taking a sample. If ocular anesthetic or any other topical medication has been applied to the eye, wait at least 2 hours before collecting a sample.

REPRODUCIBILITY STUDY

Samples were prepared in stabilizing buffer with purified MMP-9 protein. Eight (8) samples, consisting of a combination of weak positive and weak negative samples, as well as positive and negative controls, were tested. A total of 160 tests were performed by laboratory technicians and interpreted by non-laboratory persons over 20 consecutive days. The inter-assay precision in the non-laboratory persons' ability to detect positive and negative samples was 100%, although their interpretation of the strength of the signal varied for the weak positive samples.

Lot-to-lot reproducibility was tested with three (3) different InflammDry lots. There was no variability among the three (3) lots, as assessed by testing in triplicates with seven (7) different concentrations of MMP-9 ranging from 0 to 160 ng/mL.

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support Number 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.), Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the United States contact your local distributor or technicalsupport@quidel.com.

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REF RPS-ID-20 InflammaDry – 20 Test

IVD



EC REP

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1344303EN00 (07/20)

REF

Catalog number



CE mark of conformity

EC REP

Authorized Representative in the European Community

LOT

Batch code



Use by



Manufacturer



Temperature limitation



Intended use

R_x ONLY

Prescription use only

STERILE R

Sterilized using irradiation



Caution



Do not reuse



Consult instructions for use

IVD

For *In Vitro* diagnostic use



Contains sufficient for 20 determinations

CONT

Contents/Contains
