

This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10).

**Quidel Corporation provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.**

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## InflammaDry

### CLIA Complexity: Waived

For *in vitro* diagnostic use, Rx only.

A CLIA Certificate of Waiver is required to perform the test in a waived setting. 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/CLIA](http://www.cms.hhs.gov/CLIA) or from your state health department.

Read the Package Insert and quality control procedures completely before using the product. Carefully follow the instructions when performing the test. 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.

**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](http://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 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.

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

### SUMMARY AND EXPLANATION

Dry eye, or dysfunctional tear syndrome, as defined by the Dry Eye Work Shop (DEWS 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.<sup>1</sup>

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.<sup>1,4</sup> 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.<sup>1</sup> 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.<sup>1-2</sup>

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.<sup>1</sup> 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.<sup>3-19</sup> 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.<sup>4</sup>

### 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.<sup>3-8</sup>

Elevated MMP-9 levels in patients with moderate to severe dry eye disease correlate with clinical exam findings.<sup>4</sup> 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.<sup>16</sup> InflammDry detects elevated levels of MMP-9  $\geq$  40 ng/mL in tears to aid in the clinical 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. <sup>3</sup>	18	23.6	17.4	41.0
Chotikavanich et al <sup>4</sup>	16	8.4	4.7	13.0
Solomon et al <sup>5</sup>	17	7.2	2.1	9.0
Leonardi et al <sup>6</sup>	10	10.5	0.2	11.0
Lema et al <sup>7</sup>	20	6.9	1.4	8.0
Honda et al <sup>8</sup>	28	22.7	14.0	37.0
Markouillie et al <sup>9</sup>	38	11.6	15.2	N/A
Total/Avg/Range	147	12.9	–	41.0

### PRINCIPLE OF THE PROCEDURE

InflammDry 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

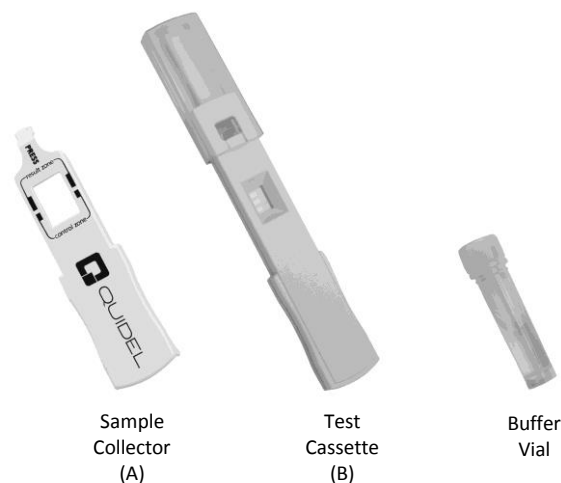
#### 20-Test Kit:

- Individually Packaged Sample Collector (20)
- Individually Packaged Test Cassettes (20)
- Buffer Vial (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.

The buffer vial contains a buffered salt solution containing:

- 200 mM Tris
- 10% Fish 81 (sea block)
- 0.8% Tergitol
- 100 mM NaCl
- 0.1% Sodium Azide
- 0.0126% Gentamycin
- pH 9.5 ± 0.05



#### **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.
- Follow Universal Precautions when handling patient samples.
- 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.
- 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](http://quidel.com).

#### **KIT STORAGE AND STABILITY**

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

## QUALITY CONTROL

InflammaDry 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 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.).

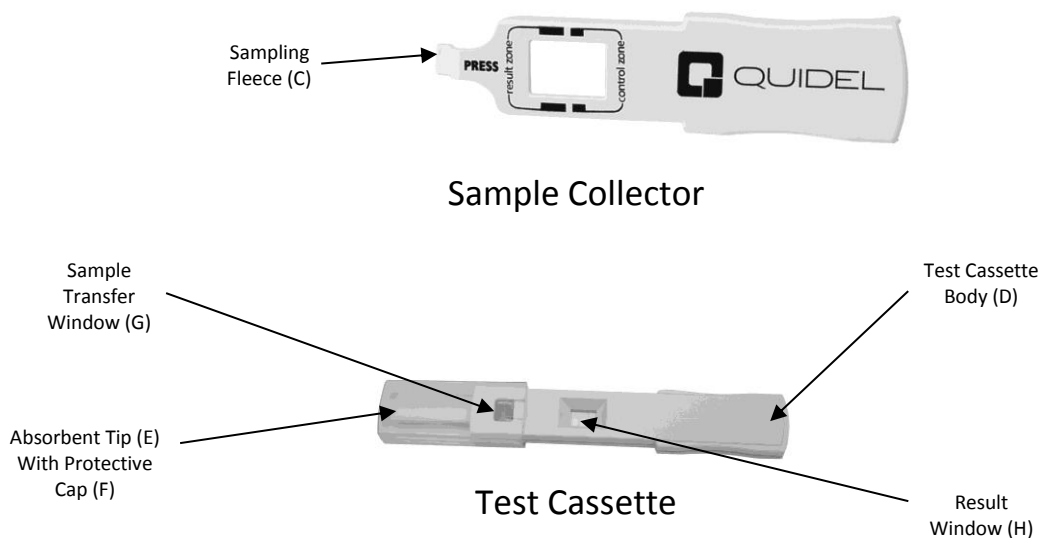
Additional External Controls may be obtained separately by contacting Quidel's Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.).

## 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).



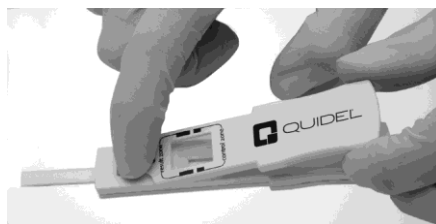
3. Gently dab the sampling fleece (C) in multiple locations along the palpebral conjunctiva, releasing the lid after every 2-3 dabs to allow the patient to blink, until the sampling fleece is saturated. Adequate saturation usually occurs when the sampling fleece is dabbed at least 6-8 times and then allowed to rest against the conjunctiva for an additional 5 seconds. In more severe dry eye states, additional dabbing may be necessary to moisten the sampling fleece. Do not use a dragging motion when collecting the sample.

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

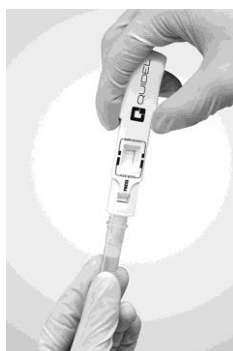
1. Locate the Test Cassette (B) with the Test Cassette body (D) and the protective cap (F). Remove the protective cap (F) from the test. The opened Test Cassette should be used within **1 hour**.
2. Assemble the test by gently placing the sampling fleece (C) of the sample collector (A) into the sample 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. Remove the protective cap (F) from the Test Cassette. 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**.

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### 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 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  $\geq 40$  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.



## 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.



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.

## Invalid Result

If a **BLUE** line does not appear, the test is 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.



Invalid

## 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.
- 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.
- 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.
- 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 not be performed in conditions which could lead to conjunctival injury, such as Stevens' Johnson Syndrome or other cicatricial conditions.
- 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.

## EXPECTED VALUES

Normal levels of MMP-9 (ng/ml) in human tears range from 3 ng/ml to 40 ng/ml.<sup>3-8</sup>

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.<sup>1,20-21</sup> 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.<sup>1,22</sup>

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.<sup>1</sup>

## **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 Quidel InflammDry Test to Quidel Technical Support at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.) and/or to FDA MedWatch (tel: 800.FDA.1088, fax: 800.FDA.0178 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)).

## **CLIA WAIVER UNTRAINED USER STUDY**

A clinical study was conducted at four (4) intended use sites and the participants were given only the test instructions. Those patients who were clinically determined by an ophthalmic clinician to meet enrollment criteria were included in the study. The study enrolled 237 patients, consisting of 164 females and 73 males, between the ages of 18 and 94 years, with an average age of 53 years. Patients presented from both private practices and academic centers, from various regions across the country.

The protocol deviation involved patients receiving topical ocular anesthetic prior to the evaluation of the tear break up time (TBUT) and corneal staining, potentially accelerating the TBUT and inducing corneal staining.

### **Inclusion Criteria**

- 18 years of age or older
- Patient voluntarily reported at least one (1) episode of any of the following ocular symptoms during the last month:
  - ▶ Burning or stinging
  - ▶ Sandy or gritty feeling
  - ▶ Foreign body sensation
  - ▶ Tearing
  - ▶ Light sensitivity
  - ▶ Intermittent or fluctuating vision
  - ▶ Tired eyes

### **Exclusion Criteria**

- Allergy to cornstarch or Dacron®
- Allergy to topical anesthetic or fluorescein dye
- Prior eye injury, trauma, or ocular surgery, within the last three (3) months
- Known blockage of the lacrimal drainage system
- Contact lens wear in the last month
- Previous corneal refractive surgery including RK, LASIK, or PRK surgery
- Have an active ocular infection or history of a recent ocular infection in the last month
- Have active intraocular inflammation or history of intraocular inflammation, e.g. uveitis
- Use of oral doxycycline, corticosteroids, or immunomodulators in the last month
- Have received topical ocular corticosteroids, topical nonsteroidal (NSAIDs) therapy, or topical ocular cyclosporine in the last month
- Pregnant or lactating
- Use of any topical ophthalmic medications, including artificial tears, 2 hours prior to enrollment

Study testing was done on the subject's more symptomatic eye. If there was no existing symptomatic difference between the two eyes, the right eye was tested. Each subject underwent the following sequence of testing: InflammDry, tear break up time (TBUT), Schirmer tear testing, and corneal staining.

The InflammDry test was compared to the clinical assessment in the following table. Derived from the DEWS criteria, the clinical assessment was developed to represent a combination of symptoms and signs. The pivotal clinical trial used the same metrics for TBUT, Schirmer tear testing, and corneal staining, as described in the DEWS criteria. However, conjunctival injection, conjunctival staining, and the presence of meibomian disease were not tested or used to characterize the severity of dry eye disease. In general, the



worst severity for any sign tested determined the overall severity. Symptoms are known to be poorly correlated with signs, with even the most severe dry eye patients often reporting little to no symptoms. Patients were categorized to the highest severity level at which all required criteria are satisfied. Patients who did not meet all the required clinical criteria for a given severity grade were considered to be the next lower grade.

InflammaDry Compared to Clinical Assessment					
Clinical Testing	Negative Control	Mild Grade 1	Moderate Grade 2	Moderately Severe Grade 3	Severe Grade 4
OSDI Score	≤ 13	≥ 13	≥ 13	≥ 13	≥ 13
TBUT (sec) <sup>8</sup>	> 10	< 10	≤ 10	≤ 5	0 (immediate)
Schirmer (mm/5 min) <sup>8</sup>	> 10	< 10	≤ 10	≤ 5	≤ 2
Staining (0-5) <sup>9</sup>	None	None	1 – 2	3	≥ 4

### CLINICAL RESULTS FROM FOUR (4) SITES

Grade is assessed based on OSDI, TBUT, Schirmer tear testing, and corneal staining, as described in the DEWS criteria. However, conjunctival injection, conjunctival staining, and the presence of meibomian disease were not tested or used to characterize the severity of dry eye disease.

- Grade 0 (negative control) is when OSDSI is ≤13, TBUT is >10 seconds, Schirmer is >10mm, staining is none.
- Grade 1 (mild) is when OSDI score is ≥ 13, TBUT is <10 seconds, Schirmer is <10 mm, staining is none.
- Grade 2 (moderate) is when OSDSI is ≥13, TBUT is ≤10 seconds, Schirmer is ≤10 mm, staining is 1-2.
- Grade 3 (moderately severe) is when OSDSI is ≥13, TBUT is <5 seconds, Schirmer is ≤5 mm, staining is 3.
- Grade 4 (severe) is when OSDSI is ≥13, TBUT is 0 seconds (immediate), Schirmer is ≤2 mm, staining is ≥4.

Site 1	Grade					Total
	4	3	2	1	0	
InflammaDry +	0	0	15	41	1	57
InflammaDry –	0	0	0	2	31	33
Total	0	0	15	43	32	90

Site 2	Grade					Total
	4	3	2	1	0	
InflammaDry +	0	7	21	1	1	30
InflammaDry –	0	0	0	8	47	55
Total	0	7	21	9	48	85

Site 3	Grade					Total
	4	3	2	1	0	
InflammaDry +	0	0	4	4	0	8
InflammaDry –	0	0	3	1	0	4
Total	0	0	7	5	0	12

Site 4	Grade					Total
	4	3	2	1	0	
InflammaDry +	1	11	20	1	0	33
InflammaDry –	0	2	13	2	0	17
Total	1	13	33	3	0	50

## DEVICE PERFORMANCE

The multicenter clinical study depicted below demonstrated the following range of performance positive agreement 66% to 97% and negative agreement 97% to 98%. At two (2) sites, negative agreement could not be calculated because there were no subjects without dry eye.

Multicenter Clinical Study N=237		Clinical Assessment OSDI** + TBUT + Schirmer + Staining		Positive % Agreement 95% / Confidence Interval	Negative % Agreement 95% / Confidence Interval
		Positive	Negative		
Site 1 InflammaDry	Positive	56	1	97% (56/58) (88%, 99%)	97% (31/32) (84%, 99%)
	Negative	2	31		
Site 2 InflammaDry	Positive	29	1	78% (29/37) (63%, 89%)	98% (47/48) (89%, 100%)
	Negative	8	47		
Site 3 InflammaDry	Positive	8	0	67% (8/12) (39%, 86%)	N/A*
	Negative	4	0		
Site 4 InflammaDry	Positive	33	0	66% (33/50) (52%, 78%)	N/A*
	Negative	17	0		

\*N/A = Not available. Specificity cannot be calculated because there were no subjects without dry eye.

\*\*11 patients were assessed to be positive for mild dry eye based on the OSDI (OSDI  $\geq$  13) without any associated positive objective test results.

## CUT-OFF STUDY

A cut-off study was performed using increments from 5 ng/mL to 70 ng/mL. The study was conducted with ten (10) operators testing ten (10) replicates of stabilizing buffer samples spiked with MMP-9. The results are presented below.

Concentration (ng/mL)	Negative	Positive
5	100	0
10 (-75%)	93	7
20 (-50%)	97	3
30 (-25%)	83	17
35	65	35
40 (cut-off)	48	52
50 (25%)	5	95
60 (50%)	0	100
70 (75%)	0	100

## CROSS-REACTIVITIES

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

- Adenovirus
- IgE
- Staphylococcus aureus
- Methicillin-resistant Staphylococcus aureus (MRSA)
- Moraxella catarrhalis
- Haemophilus influenzae

- Staphylococcus epidermis
- Streptococcus pneumoniae
- Pseudomonas aeruginosa
- Matrix metalloproteinase: 1, 2 and 3
- Tissue inhibitor of MMP: MMP-1, MMP-2

All isolates were cultured from human specimens. 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 µL 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 near the cutoff level with the respective medication. The following medications did not show any interference:

- |                              |  |
|------------------------------|--|
| ■ Alcon, Alcaine             | ■ AVS, Thera Tears                           |
| ■ Alcon, Azopt               | ■ Bausch + Lomb, Alrex                       |
| ■ Alcon, Econopred           | ■ Bausch + Lomb, Lotemax                     |
| ■ Alcon, Nevanac             | ■ Bausch + Lomb, Zylet                       |
| ■ Alcon, Pataday             | ■ Falcon, Gentamicin Sulfate                 |
| ■ Alcon, Systane             | ■ Falcon, Polymyxin B Sulfate                |
| ■ Alcon, Tobra Dex           | ■ Falcon, Timolol                            |
| ■ Alcon, Travatan            | ■ Inspire, AzaSite                           |
| ■ Alcon, Vigamox             | ■ Ista, Bepreve                              |
| ■ Allergan, Acular LS        | ■ Ista, Xibrom                               |
| ■ Allergan, Alphagan         | ■ Medpoint, Optivar                          |
| ■ Allergan, Combigan         | ■ Novartis, GenTeal                          |
| ■ Allergan, Elastat          | ■ Novartis, Voltaren                         |
| ■ Allergan, FML              | ■ Novartis, Zaditor                          |
| ■ Allergan, Lastacaft        | ■ Pfizer, Visine                             |
| ■ Allergan, Lumigan          | ■ Pfizer, Xalatan                            |
| ■ Allergan, Optive           | ■ Sigma-Aldrich, Human IgA (1 mg/ml)         |
| ■ Allergan, Pred Forte       | ■ Sigma-Aldrich, Human Lactoferrin (1 mg/ml) |
| ■ Allergan, Refresh Liquigel | ■ Sigma-Aldrich, Transferrin (1 mg/ml)       |
| ■ Allergan, Refresh Tears    | ■ Vistakon, Betimol                          |
| ■ Allergan, Zymar            |  |
| ■ AMO, Blink Tears           |  |

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

- |                   |                        |
|-------------------|------------------------|
| ■ Merck, Trusopt  | ■ Vistakon, Quixin     |
| ■ Vistakon, Iquix | ■ 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 InflammaDry 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

A reproducibility study was performed in three (3) point-of-care sites using the intended operator over five (5) days. A total of 720 samples (120 samples for each of the six (6) concentrations) were prepared in stabilizing buffer containing six (6) different concentrations of purified MMP-9 protein. The concentrations were chosen to be close to the assay cutoff (40 ng/ml). The results for each sample over the entire study are summarized in the table below.

Reproducibility Study Negative – / +		Negative – / +	–50% – / +	–25% – / +	Cut-off – / +	+25% – / +	+50% – / +
Site 1	Operator 1	20/0	19/1	18/2	4/16	0/20	0/20
	Operator 2	20/0	19/1	10/10	4/16	2/18	0/20
Site 2	Operator 1	20/0	20/0	17/3	10/10	3/17	0/20
	Operator 2	20/0	20/0	18/2	12/8	2/18	3/17
Site 3	Operator 1	20/0	20/0	19/1	10/10	2/18	0/20
	Operator 2	20/0	20/0	18/2	12/8	2/18	0/20
Combined		120/0	118/2	100/20	52/68	11/109	3/117

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](mailto:technicalsupport@quidel.com).

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# InflammaDry®

*Record Built-in Procedural Controls on the first patient tested each day.*

	Date	Patient ID	Valid Procedural Control	Test Results At 10 minutes	Lot Number and Expiration Date	Technician Initials
1						
2						
3						
4						
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14						
15						

Facility Name: \_\_\_\_\_



InflammaDry®

*Quidel recommends that positive and negative controls be run once for each untrained operator, once for each new shipment of kits — provided that each different lot received in the shipment is tested — and as deemed additionally necessary by your internal quality control procedures, and in accordance with local, state, and federal regulations or accreditation requirements. If you have any questions or concerns, please contact Quidel Technical Support at 800.874.1517 or at [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com).*

	Date MM/DD/YY	Kit Lot #	Positive Control passed?	Negative Control passed?	Comments	Technician Initials
1						
2						
3						
4						
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