Purpose

InflammaDry is a rapid immunoassay test for the qualitative detection of elevated levels of MMP-9 protein in human tears from patients suspected of having dry eye.

Clinical Significance

MMP-9 protein in human tears has been shown to be elevated in the tears of patients with dry eye. The prevalence of dry eye ranges from 5%-30% in people age >50 years and causes dryness, burning, itching, irritation, blurred vision, foreign body sensation and tearing. InflammaDry detects elevated levels of MMP-9 >40 ng/mL which, along with other clinical exam findings, can aid in the diagnosis of dry eye.

Scope

All staff performing InflammaDry testing.

The laboratory maintains all KPNW POCT/PPMP oversight responsibilities and authority to intervene when there is non-compliance or quality-of care concern. Refer to the Point of Care Testing, Quality Assurance Program.

Specimen Requirements

Human tears collected using the sampling fleece of the Quidel InflammaDry Sample Collector.

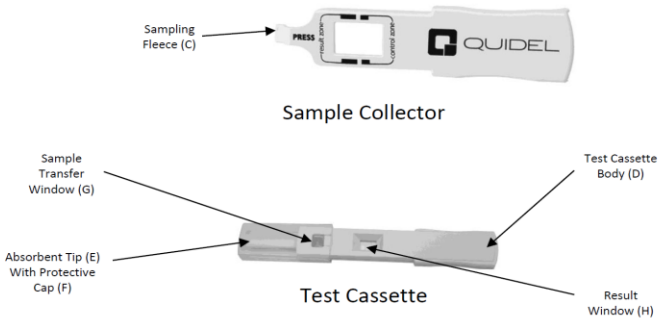
Equipment and Materials

Kit/Reagent	Storage	Unopen Stability	Open Stability
InflammaDry Test Kit	4°C-25°C	Until Expiration Date on kit	Until Expiration Date on kit
InflammaDry External Controls	Room temperature (not >30°C)	Until Expiration Date on kit	Reconstitute with the Diluent provided.

			One use only-use and discard

- Gloves
- Timer

Procedure-Quality Control and Patient Testing



External Quality Control

A positive and negative control should be run with each new InflammaDry test kit opened and at least every 30 days of testing.

1. Reconstitute one vial of positive and one vial of negative control by removing the cap and the rubber stopper from the control vial and adding 5 drops of the Diluent from the diluent bottle one drop at a time.
2. Recap the control vials and gently shake to dissolve the lyophilized powder.
3. Allow the vials to sit for at least 2 minutes prior to use.
4. Open one vial at a time, and pour the entire control liquid from the vial into the inside of the black cap.

5. Open the Sample Collector pouch, label the collector as "positive" or "negative," and dip the sampling fleece {C} into the control liquid in the black cap until the fleece glistens.
6. Follow the steps for Assembling the Test below.

Patient Sample Collection

Refer to the package insert for patient exclusion criteria.

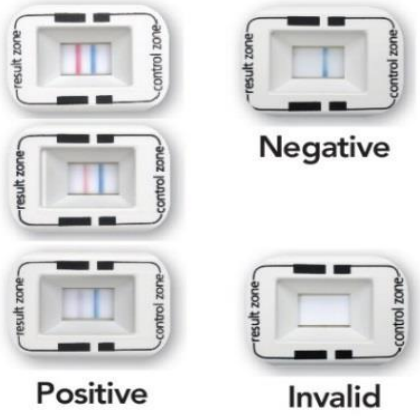
1. If ocular anesthetic or any other medication has been applied to the eye, wait at least 2 hours prior to sample collection.
2. Open 1 Sample Collector and label with patient ID. Make sure not to touch the sterile sampling fleece on the Sample Collector prior to collecting the patient sample.
3. Gently lower the patient's lower eyelid to expose the inside palpebral conjunctiva.
4. Gently dab (do not use a dragging motion) the sampling fleece {C} in multiple locations along the palpebral conjunctiva. Release the lid every 2-3 dabs to allow the patient toblink. Dab the fleece at least 6-8 times and then allow it to rest for an additional 5 seconds.
5. Continue until the sampling fleece {C} is saturated. In severe dry eye additional dabbing may be necessary. The fleece will glisten when saturated and can appear white or patchy pink in color.
6. Follow the steps for Assembling the Test below.

Assembling the Test

1. Remove the protective cap {F} from the Test Cassette. This is the end with the absorbent tip {E}. Once opened the Test Cassette must be used within one hour.
2. Place the sampling fleece {C} of the Sample Collector into the sample transfer window {G} of the Test Cassette body.
3. Press firmly where indicated. A double-click means the test is assembled properly.
4. Open 1 buffer vial and immerse the absorbent tip {E} of the Test Cassette into the buffer vial for 20 seconds.
5. Remove the absorbent tip and replace the protective cap on the Test Cassette.

6. Lay flat on a horizontal surface and set a timer for 10 minutes.
7. If there is a streaky fluid wave in the background of the result window or if the test is negative, allow an additional 10 minutes of running time prior to interpretation.
8. Read the results within 6 hours of completion.

Interpretation



Positive Result: Indicates the presence of MMP-9 of >40 ng/mL.

The presence of a blue line in the control zone and a red line in the result zone indicates a positive result. The presence of any red line-faint, incomplete over the length of the test area or uneven in color is considered as positive.

Negative Result: Indicates the presence of MMP-9 < 40 ng/mL. Normal levels of MMP-9 in human tears range from 3 ng/ml-40 ng/ml.

The presence of only a blue line in the control zone indicates a negative result.

Invalid Result: Do not report

If the blue control line does not appear, the test is invalid. Re-immerse the absorbent tip into the Buffer Vial for an additional 10 seconds. If a blue line does not appear, discard the test and repeat patient sampling after allowing 60 minutes between collections. Do not report invalid test results.

Reporting

Internal Quality Control

1. The appearance of a blue line in the control zone confirms the correct application of sample volume. The control line must appear for the test results to be considered valid.
2. If the blue line does not appear in the control zone, the test must be repeated. DO NOT report invalid test results.
3. The background of the test window should be white. 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.
4. Internal QC is documented with each patient test result in KPHC.

External Quality Control

1. External Quality Control is reported as Positive or Negative.
2. The blue line in the control zone must be present for external QC to be valid.
3. External QC is documented on the attached QC Log.

Patients

1. Patients are reported as Positive or Negative in KPHC.
2. Internal QC is documented with each patient result in KPHC.

Limitations of Procedure

- MMP-9 is a non-specific indicator for diagnosis of inflammation and should not be used as the sole basis of diagnosis or treatment.
- Patients with severe dry-eye may yield a false-negative result due to low volume (<6 uL) of tears.

- InflammaDry should not be used within 20 minutes of performing a Schirmer tear test as this can cause a false-positive result.
- False positive results can occur due to elevated levels of MMP-9 post recent ocular surgery, infection, allergic conjunctivitis or ocular surface diseases.
- False negative results may occur with the use of the following medications: immunomodulators, topical or oral steroids, cyclosporine, tetracycline and topical azithromycin as they inhibit metalloproteinase activity.
- InflammaDry should not be used in Stevens' Johnson Syndrome or other cicatricial conditions as it could lead to conjunctival injury.
- InflammaDry should not be used prior to instilling ocular anesthetic, topical dyes or performing Schirmer testing.
- Patients with a history of contact lens use have not been studied.
- Running the test in an environment with a temperature of 45°C or above and a humidity of 60% or above many increase sensitivity and cause a false positive result.

References

- Quidel Corporation, InflammaDry Package Insert 1337401EN00 10/17
- Quidel Corporation, InflammaDry External Controls Package Insert 1337601EN00 04/18
- Quidel Corporation, InflammaDry Quick Reference Instructions 13441000EN00 10/17

Attachments

- InflammaDry QC Log
- Point of Care Testing, Quality Assurance Program

Training Criteria

Training Method:

- MTS or HealthStream Ishihara color vision screening.
- MTS or HealthStream competency quiz for the InflammaDry test.
- Hands-On training

Evaluation Criteria:

- Successful completion of color vision screening.
- Successful completion of InflammaDry curriculum.
- Successful completion of hands-on training checklist