InflammaDry® External Controls
Positive and Negative

QUIDEL

For *in vitro* diagnostic use. Rx ONLY

INTENDED USE

InflammaDry external controls are only to be used with the InflammaDry Test. They are intended to verify that the test reagents are working and that the test is correctly performed.

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.

REAGENTS AND MATERIALS SUPPLIED

- Positive Control (1): Buffered solution containing detergent and recombinant MMP-9 protein, as well as additional proteins to simulate biological matrix.
- Negative Control (1): Buffered solution containing detergent and proteins to simulate biological matrix. Contains 0.05% Proclin 300 as a preservative.
- Diluent (1): Deionized water
- Package Insert (1)

MATERIALS NOT PROVIDED

- InflammaDry Test
- Gloves
- Timer

EXTERNAL CONTROLS STORAGE AND STABILITY

The unopened controls are to be stored at room temperature, not to exceed 86°F/30°C, until the expiration date noted on the outer packaging. The controls are designed for one (1) use. Opened vials should be used once within the day of reconstitution, and then discarded.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Directions in the InflammaDry Package Insert must be followed for optimal results.
- Once dissolved, the controls should be clear and colorless. Controls should not be used if there is flocculation or discoloration.
- The unopened controls are to be stored at room temperature, not to exceed 86°F/30°C.
- Unopened controls may be used until the expiration date noted on the outer packaging. Do not use the controls past their expiration date.
- Controls are designed for one (1) use. Opened vials should be used within the same day of reconstitution and then discarded.

- Follow Universal Precautions when handling these controls.
- Testing should be performed in an area with adequate ventilation.
- 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.

PROCEDURE

1. Choose either the Positive or Negative Control. The InflammaDry Sample Collector, Test Cassette and Buffer can only be used once.
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. A Positive Control should show a positive result. A Negative Control should show a negative result.
8. When the correct control results are not obtained, repeat the test control, or contact Quidel Technical Support before testing patients.

DAILY QUALITY CONTROL

InflammaDry has built-in procedural controls (see Procedural Controls section of the InflammaDry Package Insert). For daily quality control, Quidel recommends documenting that these internal procedural controls were checked for the first sample tested each day.

PROCEDURAL CONTROLS

The unused test has two (2) faint orange lines in the control zone. If the test flows correctly and the reagents work, a blue line will always appear in the control zone. If the control line does not appear, the test must be interpreted as invalid and should be repeated using a new InflammaDry Test.

A purple fluid wave is observed moving across the result window while the test is running. Once the background color within the result window 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.

EXTERNAL POSITIVE AND NEGATIVE CONTROLS

In addition to your facility's standard quality control procedures, it is recommended that both a positive and negative control be tested with each new lot, shipment, and every 30 days. Additional controls may be tested according to the requirements of Federal, State, and Local regulations or accrediting organizations.

TEST LIMITATIONS

As with all diagnostic tests, InflammaDry results should be interpreted along with clinical findings and results from other diagnostic methods.

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support Number 800.874.1517 (n 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.

RPS-DESTD – InflammaDry External Controls

MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

Quidel Corporation
10165 McKellar Court
San Diego, CA 92121
quidel.com

1337601EN00 (04/18)

REF Catalogue number	CE CE mark of conformity
EC REP Authorized Representative in the European Community	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
Rx ONLY Prescription use only	 Consult instructions for use
IVD For *In Vitro* diagnostic use	CONT Contents/Contains
CONTROL + Positive control	CONTROL – Negative control