Reimbursement code
The assigned CPT® (Current Procedural Terminology)® code for the InflammaDry test is 83516, “immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semi-quantitative, multiple step method.” The 2020 CMS national limit for this code is $11.53. Offices submitting reimbursement for claims are required to have a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver.²

Compliance
Concept of chief complaint and medical necessity
In order to make your medical record compliant for clinical lab testing, it is important to have a complaint, symptom or clinical sign that is recorded in the record to provide the basis for ordering the test. This would help to establish a “chief complaint” for the lab test. It is also critical to have a statement of medical necessity in the file that ties together the basis for ordering and performing the tests. This carries additional weight when ordering sequential tests over time.

Modifiers and their use
Medicare and Medicaid claims
The modifier “QW” is added to the CPT code to report the use of a CLIA-waived test. The RT and LT modifiers are also used to specify laterality of the test to correspond with the appropriate ICD-10 codes used. CPT code 83516QW is paid from the Clinical Laboratory Fee Schedule (not the Physician Fee Schedule as with other CPT codes).

Bilateral testing
Ocular surface inflammation often presents asymmetrically, and therefore testing both eyes with the InflammaDry test is recommended. The InflammaDry test is a single use item, so bilateral testing requires two separate InflammaDry tests.

When billing for bilateral testing, it is necessary to use a modifier. Given the many and varied payers and policies, it is possible that certain payers may have different coding requirements; Quidel offers reimbursement support to assist you with questions about InflammaDry coding, compliance and reimbursement.

<table>
<thead>
<tr>
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<th>Medicare/Medicaid</th>
<th>Commercial Payers</th>
<th>2020 National Limit</th>
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<tbody>
<tr>
<td>1st Eye</td>
<td>83516QW-RT/LT</td>
<td>83516-RT/LT</td>
<td>$11.53</td>
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<tr>
<td>2nd Eye</td>
<td>83516QW-RT/LT</td>
<td>83516-RT/LT</td>
<td>$11.53</td>
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Another option when coding is to use the -59 modifier. The -59 modifier denotes a distinct procedural code. Providers should check with their payers to determine preferred coding.
Bilateral alternative
83516QW-50 (when using the -50 modifier, leave the number of units as “1” but double the price)

Related diagnostic codes
There can be many ICD-10 codes that will be related to your need to provide clinical lab testing for a dry eye diagnosis and/or dry eye symptoms. It is important when providing diagnoses related to the testing performed, that you provide the most specific diagnoses that you can in accordance with ICD rules and guidelines. That means relating both laterality and severity if possible. Generalized diagnoses may get reimbursed but are more difficult to defend should your record be scrutinized.

Advance Beneficiary Notice of Noncoverage (ABN)
The Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, is issued by providers (including independent laboratories, home health agencies, and hospices), physicians, practitioners, and suppliers to Original Medicare (fee for service – FFS) beneficiaries in situations where Medicare payment is expected to be denied. The ABN is issued in order to transfer potential financial liability to the Medicare beneficiary in certain instances.³

An ABN form in its original format must be used for all Medicare Part B patients. If your patient is a Medicare Part C (Medicare Advantage) patient, each carrier may have their own specific format that they will require you to use. Please check with the individual carrier for specifics. Commercial carriers will generally accept the CMS format for having an ABN on file.

Please remember that the ABN must be completed prior to the procedure being performed.

Visit quideleyehealth.com/compliance to access the ABN template specific to Quidel’s InflammaDry test, pre-filled out for Medicare Part B patients.

Reimbursement support
Quidel has a Reimbursement Support Team available to assist you with questions about InflammaDry coding and reimbursement. For reimbursement support, please contact technicalessupport@quidel.com or call 800.874.1517.

This information is being provided as a reference, for informational purposes only, with no expressed or implied warranty and does not purport to provide legal or certified coding advice. It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-10-CM codes to accurately reflect patient condition(s) and testing procedure(s). Any review, retransmission, dissemination or other use of this information by persons or entities other than the intended recipient is prohibited.

¹CPT is a copyright and registered trademark of the American Medical Association (AMA). Please consult the current CPT Manual for full descriptors and instructions regarding the use of CPT codes.
²CLIA stands for Clinical Laboratory Improvement Amendments and is a registration with the U.S. Department of Health and Human Services that allows physicians or medical office personnel to collect a sample and perform a laboratory test within their office.
³https://www.cms.gov/medicare/medicare-general-information/bni/abn.html

Under Federal and State law, it is the individual provider’s responsibility to determine appropriate coding, charges and claims for a particular service. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.