DIAZYME DZ-LITE SARS-CoV-2 IgG CLIA KIT

For Emergency Use Authorization Only
For Prescription Use Only
For in vitro Diagnostic Use Only

CONFIGURATION
The DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit is provided in the following kit configuration (100 tests) and is used in conjunction with the fully automated DZ-lite 3000 Plus Chemiluminescence Analyzers:

<table>
<thead>
<tr>
<th>Component</th>
<th>Catalog #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Microbeads</td>
<td>130219015M</td>
</tr>
<tr>
<td>ABEI Label</td>
<td>2.5 mL</td>
</tr>
<tr>
<td>Diluent</td>
<td>23.5 mL</td>
</tr>
<tr>
<td>Buffer</td>
<td>23.5 mL</td>
</tr>
<tr>
<td>Negative Control</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>Positive Control</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>Calibrator Low</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>Calibrator High</td>
<td>1.0 mL</td>
</tr>
</tbody>
</table>

INTENDED USE
The DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit is a chemiluminescent immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (potassium EDTA, disodium EDTA and lithium heparin). The DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

Results are for the detection of SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. The sensitivity of DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. False positive results for DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit may occur due to cross-reactivity from pre-existing antibodies or other possible causes. The DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit is only for use under the Food and Drug Administration’s Emergency Use Authorization.

CLINICAL SIGNIFICANCE
The 2019-nCoV virus was first named by the World Health Organization on January 7, 2020. On February 11, 2020, the virus was renamed Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses (ICTV). On the same day, the World Health Organization (WHO) announced that SARS-CoV-2-associated respiratory disease will be officially named COVID-19.

The novel coronavirus (SARS-CoV-2) that is causing an acute respiratory syndrome in humans belongs to the family coronaviridae and the genus Betacoronavirus. The virus has an envelope and its particles are round or oval, often polymorphic, with a diameter between 60 and 140 nm. The genetic characteristics of the virus are significantly different from those of SARS-CoV and MERS-CoV. Current research shows that SARS-CoV-2 has more than 85% homology with the bat SARS-like coronavirus (bat-SL-CoVZC45).

SARS-CoV-2 is mainly transmitted through respiratory droplets and can also be transmitted through contact. The sources of infection seem mainly consist of patients with pneumonia infected by the novel coronavirus. Research has shown that IgM and IgG antiviral antibodies can be detected in the serum samples of infected patients. After infection with SARS-CoV-2, the virus antigen stimulates the immune system to produce antibodies that can be detected in the blood. Among these antibodies, SARS-CoV-2 IgM antibodies generally appear early and are mostly positive 8 to 14 days after onset of symptoms depending on the IgM assay used. The SARS-CoV-2 IgM titer then decrease while the SARS-CoV-2 IgG antibody titer start to rise rapidly.

ASSAY PRINCIPLE
The DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit is an indirect chemiluminescence immunoassay. The sample, buffer and magnetic microbeads coated with a SARS-CoV-2 recombinant antigen are mixed thoroughly and incubated, forming immune-complexes. After precipitation in a magnetic field and decanting of the supernatant, wash cycles are performed. Subsequently, ABEI-labeled anti-human IgG antibody is added and incubated to form additional complexes. After precipitation in a magnetic field and decanting of the supernatant, wash cycles are performed. Subsequently, the Starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier in relative light units (RLUs), which is evaluated against the established cutoff to determine the final result.

KIT CONTENTS
• Magnetic Microbeads: Magnetic microbeads coated with SARS-CoV-2 recombinant antigen, PBS buffer containing BSA, NaN3 (<0.1%).
• ABEI Label: Anti-human IgG antibody labeled with ABEI, Tris-HCl buffer containing Mouse IgG, Goat IgG, and BSA, NaN3(<0.1%).
• Buffer: PBS buffer containing BSA, NaN3 (<0.1%).
• Negative Control: PBS buffer containing BSA, NaN3 (<0.1%).
• Positive Control: SARS-CoV-2 IgG, PBS buffer containing BSA, NaN3 (<0.1%).
• Calibrator Low: SARS-CoV-2 IgG, PBS buffer containing BSA, NaN3 (<0.1%).
• Calibrator High: SARS-CoV-2 IgG, PBS buffer containing BSA, NaN3 (<0.1%).

All components of the kit are provided ready-to-use.

MATERIALS REQUIRED BUT NOT PROVIDED
DZ-lite 3000 Plus Chemiluminescence Analyzer

Reaction Modules
• Starter 1 + 2: REF: 630003
• Wash Concentrate: REF: 130299005M
• Light Check: REF: 130299006M

STORAGE AND STABILITY
Store at 2-8°C. Do not freeze.
Keep upright for storage to facilitate later proper resuspension of magnetic microbeads.
Keep away from sunlight.
The stability study is still on-going, the following data is obtained by referring to similar products:

Stability of the reagent
Unopened at 2-8°C: until the stated expiration date
Opened at 2-8°C: 6 weeks
Onboard Kit: 4 weeks

To ensure the best kit performance, it is recommended to place opened kits in the refrigerator after the end of the intraday test work.

SPECIMEN COLLECTION AND HANDLING
• Human serum or plasma may be used with the DIAZYME DZ-Lite SARS-CoV-2 IgG CLIA Kit. For serum samples, standard serum tubes, tubes containing clot activator, or tubes containing clot activator and separating gel could be applied for the assay. For plasma samples, the anticoagulants including K2-EDTA, K3-EDTA, Na2-EDTA, Li- Heparin were tested and found acceptable.
• Please pay attention to the risk of infection during sample collection and preparation.
• According to the “Diagnosis and treatment program of novel coronavirus pneumonia” issued in China, heat inactivation of the samples should be performed at 56°C for 30 minutes before testing. Please refer to the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-guidelines.html as well as your local, state and federal government’s mandated requirements.
• Ensure that complete clot formation in specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time.
• If the specimen is centrifuged before complete clotting, the presence of fibrin may cause erroneous results. Samples must be free of fibrin and other particulate substances.
• Do not use grossly hemolyzed specimens as well as specimens containing particulate matter or exhibiting obvious microbial contamination. Inspect all specimens for bubbles and remove bubbles before analysis for optimal results.
• All samples (patient specimens and controls) should be tested within 3 hours of placing on board the DZ-Lite System. Refer to the instrument manual for more detailed discussion on onboard sample storage constraints.
• Specimens removed from the separator gel, cells or clot may be stored 3 days at 2-8°C. If longer storage is required, freeze the specimens at -20°C or colder.
Avoid repeated freezing and thawing. Frozen specimens must be mixed thoroughly after thawing by low speed vortexing or by gentle end-over-end rotation.

For optimal results, specimens should be free of fibrin, red blood cells, or other particulate matter. Such specimens may give inconsistent results and must be transferred to a centrifuge tube and centrifuged at ≤ 10,000 RCF (Relative Centrifugal Force) for 10 minutes. Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Before shipping specimens, it is recommended that specimens be removed from the separator, red blood cells or clot. When shipped, specimens should be packaged and labeled to comply with applicable local, state, federal and international regulations covering the transport of clinical specimens and infectious substances. It is recommended specimens should be shipped frozen.

The sample volume required for a single determination is 10 µL.

PRECAUTIONS

For use under an Emergency Use Authorization Only.

For in vitro Diagnostic Use Only.

This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.

This test has been authorized only for the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 366bb-3(b)(1), unless the declaration is terminated by the Secretary sooner.

Follow the package insert carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the 29 CFR 1910.1030 Occupational exposure to blood borne pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that are or are suspected of containing infectious agents.

All samples, biological reagents and materials used in the assay should be considered potentially able to transmit infectious agents. They should therefore be disposed of in accordance with the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

This product contains Sodium Azide. Dispose of contents and container must be in accordance with local, regional and national regulations.

Refer to safety data sheets, which are available on request.

Handling Precautions

Do not use reagent kits beyond the expiration date.

Do not interchange reagent components from different reagents or lots.

Properly load the Reagent Kit on the system for the first time, the Reagent Kit requires mixing to re-suspend magnetic microbeads that have settled during shipment. For magnetic microbeads mixing instructions, refer to the Preparation of the Reagent section of this package insert.

To avoid contamination, wear clean gloves when operating with a reagent kit and sample.

Over time, residual liquids may dry on the septum surface. These are typically dried salts which have no effect on assay efficacy.

To avoid cross-contamination between kits, reagent kits with the same lot number should be kept separate and the lot number verified before use.

For detailed discussion of handling precautions during system operation, refer to the instrument manual.

WARNINGS


ASSAY PROCEDURE

Preparation of the Reagent

• Take the reagent kit out of the box and check the sealing film and other parts of the reagent kit for any signs of leakage. In case of leakage, please contact Diazyme technical support immediately. Open the assay tray door; hold the reagent handle to get the RFID label close to the RFID reader (for about 2 seconds); the power will be on; keep one sound indicates successful sensing.

• Keep the reagent cartridge upright and straight, insert to the bottom along the blank recessed track.

• Observe whether the reagent information is displayed successfully in the software interface, otherwise repeat the above steps.

• Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are resuspended and homogenous prior to use. Resuspension should be allowed for at least 30 minutes prior to the testing of controls and samples.

Assay Calibration

Click <Calibration> or <Batch Calibration> button to execute calibration operation. For specific information on ordering calibrations, refer to the Calibration Section of the Operating Instructions.

Execute recalibration according to the calibration interval required in this package insert.

Recalibration is recommended any of the following conditions occurs:

• After each exchange of lots (Reagent or Starter 1+2).

• Every week and/or each time a new reagent kit is used.

• After instrument service.

• If controls fall outside the expected range.

Quality Control

The Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit Negative Control and Positive Control provided with the kits are required for quality control of the Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit to ensure that the kit performs properly and to monitor system performance. The Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit Negative Control contains no IgG antibodies to SARS-CoV-2; test results should be < 0.70 AU/mL and reported as non-reactive (-). The Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit Positive Control contains IgG antibodies to SARS-CoV-2; results are typically within the expected range of 2.80 to 5.20 AU/mL and reported as reactive (+).

Follow government regulations or accreditation requirements for quality control frequency. Internal quality control is only applicable to this system. Treat all quality control samples with the same level of care as patient samples. A satisfactory level of performance is achieved when obtained quality control results match expected results. If the quality control results do not match expected results, quality controls should be repeated. If the quality control results still do not match expected results, do not report results and take the following actions:

• Verify that the materials are not expired.

• Verify that required instrument maintenance was performed.

• Verify that the assay was performed according to the instruction for use.

• Determine if the assay was performed with fresh quality control samples.

• If necessary, contact customer service for assistance.

For specific information on ordering quality controls, refer to the Quality Control Section of the Operating Instructions.

Sample Testing

Order the samples in the Sample Area of the software and click the <Start> button to execute testing. For specific information on ordering patient specimens, refer to the Sample Ordering Section of the Operating Instructions.

To ensure proper test performance, strictly adhere to the Operating Instructions of the fully automated chemiluminescence immunoassay analyzer.

INTERPRETATION OF RESULTS

The analyzer automatically determines the final result by comparing the RLU for each sample against the established cutoff. Results are reported as either Reactive (+) or Non-Reactive (-). For further information please refer to the Operating Instructions of the fully automated chemiluminescence immunoassay analyzer.

Result Interpretation

Results obtained with the Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit is interpreted as follows:

<table>
<thead>
<tr>
<th>Cutoff</th>
<th>Result Message</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1.0</td>
<td>Negative for SARS-CoV-2 IgG antibodies</td>
<td>Reactive</td>
</tr>
<tr>
<td>≥ 1.0</td>
<td>Positive for SARS-CoV-2 IgG antibodies</td>
<td>Non-Reactive</td>
</tr>
</tbody>
</table>

The magnitude of the measured result above the cutoff is not indicative of the total amount of antibody present in the sample. The individual immune response following SARS-CoV-2 infection varies considerably and may vary differently across manufacturers. Results of assays from different manufacturers should not be used interchangeably.

LIMITATIONS

For use under an Emergency Use Authorization Only

This test is suitable only for investigating single samples, not for pooled samples.

Bacterial contamination or repeated freeze-thaw cycles may affect the test results. Assay results should be interpreted only in the context of other laboratory findings and the total clinical status of the patient.

A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.

A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. A negative result can occur if the antibody levels are not present during the stage of disease in which a sample is collected.

Assay results should not be used for the diagnosis or exclusion of acute novel coronavirus infection.

It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.

This test is for qualitative detection of anti-COVID-19 antibody in human serum or plasma and does not measure the quantity of the antibodies.

Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

It is recommended to be used in conjunction with SARS-CoV-2 IgM testing to improve clinical sensitivity.

If the SARS-CoV-2 IgG results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

Diazyme Laboratories, Inc.

60900 Rev. B

Effective: 07/08/2020

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**Performance Characteristics**

Precision for Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit was determined as described in the CLSI EP5-A3. Two controls and 3 samples containing different concentrations of analyte were assayed in duplicate at three sites over five days, with 3 runs per day, one lot and was excluded from analysis. The obtained results show that the Diazyme DZ-Lite SARS-CoV-2 IgG CLIA test does not cross-react to the following:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Negative Specimens</th>
<th>Positive Specimens</th>
<th>Cross-Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Rheumatoid factor</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Anti-IgM Oncobeads</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>HAMA</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Total IgG</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Total IgM</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Interferon α</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Ribavirin</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Oseltamivir</td>
<td>Serum</td>
<td>Serum</td>
<td>Serum</td>
</tr>
</tbody>
</table>

**Levofloxacin** 1.776 mg/dL
**Azithromycin** 1.201 mg/dL
**Ceftriaxone sodium** 81.03 mg/dL
**Mepolizumab** 40.15 mg/dL
**Tobramycin** 2.4 mg/dL
**Diphenhydratone Hydrochloride** 4.5 mg/dL
**Oxytetrazolamine** 2.5 mg/dL
**Sodium chloride** 45 mg/dL
**Beclomethasone** 2.5 mg/dL
**Dexamethasone** 18 mg/dL
**Tramcinolone acetonide** 5.5 mg/dL
**Budesonide** 3.2 mg/dL
**Mometasone** 2.5 mg/dL
**Fluticasone propionate** 2.5 mg/dL

**Clinical Sensitivity**

A total of 77 samples from 51 patients with PCR-confirmed SARS-CoV-2 infections were tested with the Diazyme DZ-Lite SARS-CoV-2 IgG CLIA assay. One or more consecutive specimens from these patients were collected after PCR confirmation at various time points. Both serum and plasma sample types were used in the study. Results were as follows:

<table>
<thead>
<tr>
<th>Days Post Symptom Onset</th>
<th>n</th>
<th>Positive</th>
<th>Negative</th>
<th>Sensitivity, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤7</td>
<td>23</td>
<td>10</td>
<td>13</td>
<td>43.5 (25.6-63.2)</td>
</tr>
<tr>
<td>&gt;8 to 14</td>
<td>24</td>
<td>22</td>
<td>2</td>
<td>91.7 (74.2-97.7)</td>
</tr>
</tbody>
</table>

A patient who did not seroconvert died after having a positive PCR result for SARS-CoV-2 and was excluded from analysis.

**Clinical Specificity**

The clinical specificity was determined using non-novel coronavirus infected specimens collected before December 2019. The results are shown in the following table:

<table>
<thead>
<tr>
<th>Source/sample</th>
<th>n</th>
<th>Positive</th>
<th>Negative</th>
<th>Specificity, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza A</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza B</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza C</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza D</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza E</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza F</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza G</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza H</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza I</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza J</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Influenza K</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>97.4 (91.0-98.1)</td>
</tr>
</tbody>
</table>

Diazyme Laboratories, Inc.

Effective: 07/08/2020

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Class Specificity

Upon treatment with DTT, five SARS-CoV-2 patient samples (initially positive for both IgG and IgM) remained positive for IgG when tested with the Diazyme DZ-Lite SARS-CoV-2 IgG CLIA assay and became negative for IgM when tested with the Diazyme DZ-Lite SARS-CoV-2 IgM CLIA assay. This establishes the specificity of the Diazyme DZ-Lite SARS-CoV-2 IgG CLIA kit to the IgG class of antibodies.

Hook effect

The assay has a hook effect tolerance up to 1000 AU/mL.

REFERENCES

2. Diagnosis and treatment program of novel coronavirus pneumonia (Trial version 7).
4. Prevention and control program of novel coronavirus pneumonia (version 5).