BioPlex 2200

SARS-CoV-2 IgG

Instructions For Use

REF **12014192**

Σ 200

IVD

For use under an Emergency Use Authorization (EUA) Only

For Prescription Use Only.

For *In Vitro* Diagnostic Use Only.

The results of this semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from infection.

This IFU is effective beginning with Lot # 301258 (BioPlex 2200 SARS-CoV-2 IgG) and above, and BioPlex 2200 Software Version 4.3 and above.

UNITED STATES: Bio-Rad Laboratories, Inc., 4000 Alfred Nobel Drive, Hercules, CA 94547

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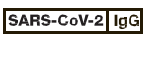
SYMBOLS LEXICON

					
Catalog Number	WARNING	Lot Number	Manufactured by	Number of Tests	Temperature Limit
					
Use by (YYYY-MM-DD)	Sample Diluent	Consult Instructions For Use	Contains	Version	Caution, consult accompanying documents
					
Bead Set	Conjugate	SARS-CoV-2 IgG Reagent Pack	For In Vitro Diagnostic Use		

INTENDED USE

The BioPlex 2200 SARS-CoV-2 IgG is a bead-based immunoassay intended for the qualitative and semi-quantitative detection of IgG class antibodies to SARS-CoV-2 in human serum and plasma (dipotassium EDTA, tripotassium EDTA, lithium heparin, sodium heparin, and sodium citrate). The BioPlex 2200 SARS-CoV-2 IgG is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The BioPlex 2200 SARS CoV-2 IgG should not be used to diagnose or exclude acute SARS-CoV-2 infection. At this time, it is unknown for how long antibodies persist following infection, and if the presence of antibodies confers protective immunity. 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 IgG 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 results to the appropriate public health authorities.

The sensitivity of the BioPlex 2200 SARS-CoV-2 IgG 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 with the BioPlex 2200 SARS-CoV-2 IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The BioPlex 2200 SARS-CoV-2 IgG is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

Coronavirus (CoV) is an enveloped virus that contains a single-stranded positive-sense RNA. SARS-CoV-2, formerly known as 2019-nCoV, is a newly emerging coronavirus that affects the respiratory tract. The underlying disease caused by this virus is COVID-19. Coronaviruses have been responsible for several outbreaks in the world during the last two decades. In 2003 and 2014, coronaviruses caused outbreaks mainly in Asia (SARS-CoV) and in the Middle East (MERS-CoV), respectively. Before the new SARS-CoV-2 emergence, six coronaviruses were known to affect humans (SARS-CoV, MERS-CoV, and four other coronaviruses that cause mild upper and lower respiratory syndromes).

SARS-CoV-2 was first identified in December 2019, in Wuhan City, Hubei Province, China, after several patients developed severe pneumonia similar to that caused by SARS-CoV. The virus has since rapidly spread worldwide, and in March 2020, WHO officially announced COVID-19 as a pandemic. Person-to-person transmission of the virus leads to the quick spreading of COVID-19, and a high number of patients requiring intensive care urged authorities around the world to set up containment measures. The incubation period ranges from 2 to 14 days.

The virus has been detected in respiratory specimens, and respiratory droplets are considered the primary means of transmission. Once viral particles enter the respiratory tract, the virus attaches to pulmonary cells via the ACE-2 receptors, followed by endocytosis. SARS-CoV-2 might also be transmitted via the fecal route.

Diagnosis of acute SARS-CoV-2 infection mainly relies on real-time reverse transcription - polymerase chain reaction (RT-PCR) testing of respiratory specimens. Symptoms can vary drastically and notably include fever, dry cough, anosmia, sputum production, headaches, dyspnea, fatigue, nausea, and diarrhea. While some cases can be asymptomatic, others can lead to acute respiratory distress syndrome (ARDS) and even death.

The BioPlex 2200 SARS-CoV-2 IgG assay is designed to detect IgG antibodies to SARS-CoV-2 using the Spike protein S1 subunit (including the RBD) of the SARS-CoV-2 virus. Results can be reported qualitatively or semi-quantitatively in U/mL.

In conjunction with other diagnostic tests, the BioPlex 2200 SARS-CoV-2 IgG assay can be used to determine if a patient has a recent or prior exposure to the SARS-CoV-2 virus.

PRINCIPLE OF THE PROCEDURE

The BioPlex 2200 SARS-CoV-2 IgG assay employs fluoromagnetic, dyed beads coated with Spike protein S1 subunit (including the RBD) to identify the presence of IgG antibodies to SARS-CoV-2 virus in a two-step assay format.

The BioPlex 2200 System combines an aliquot of patient sample, sample diluent, and bead reagent into a reaction vessel. The mixture is incubated at 37°C. After a wash cycle, murine monodonal anti-human IgG conjugated to

phycoerythrin (PE) is added to the dyed beads, and this mixture is incubated at 37°C. The excess conjugate is removed in another wash cycle, and the beads are re-suspended in sheath fluid. The bead mixture then passes through the detector. The identity of the dyed beads is determined by the fluorescence of the dyes, and the amount of antibody captured by the antigen is determined by the fluorescence of the attached PE. Raw data are calculated in relative fluorescence intensity (RFI).

Two additional dyed beads, an Internal Standard Bead (ISB) and a Serum Verification Bead (SVB), are present in each reaction mixture to verify detector response and the addition of serum or plasma to the reaction vessel, respectively. Refer to the BioPlex 2200 System Operation Manual for more information.

The system is calibrated using a set of six (6) distinct calibrator vials supplied separately by Bio-Rad Laboratories. Five (5) levels of antibody affinity are included, which are used for establishing a 4PL calibration curve. The semi-quantitative results for the IgG SARS-CoV-2 antibodies are expressed in U/mL. A direct relationship exists between the amount of SARS-CoV-2 IgG antibody present in the patient sample and the RFI calculated by the system. The qualitative assay results are reported as negative if < 10 U/mL or positive if ≥ 10 U/mL.

KIT COMPONENTS

SARS-CoV-2 IgG (REF 12014192). The reagent pack contains supplies sufficient for 200 tests.

Vial	Description
Bead Set BEAD	One (1) 10 mL vial, containing dyed beads coated with SARS-CoV-2 antigen, Internal Standard (ISB), and Serum Verification (SVB), with glycerol and protein stabilizers (bovine) in a MOPS (3-[N-Morpholino] propanesulfonic acid) buffer. ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) are added as preservatives.
Conjugate CONJ	One (1) 5 mL vial, containing murine monoclonal anti-human IgG/phycoerythrin conjugate and murine anti-human FXIII/phycoerythrin conjugate in a phosphate buffer with protein stabilizers (bovine). ProClin 300 (≤ 0.3%) and sodium azide (< 0.1%) are added as preservatives.
Sample Diluent DIL	One (1) 10 mL vial, containing protein stabilizers (bovine and murine) in a triethanolamine buffer. ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%), and sodium azide (< 0.1%) are added as preservatives.

ADDITIONAL REQUIRED ITEMS, AVAILABLE FROM BIO-RAD

REF	Description
12014193	BioPlex 2200 SARS-CoV-2 IgG Calibrator Set: Six (6) 500 µL vials, in a human serum matrix made from defibrinated plasma with added known analyte concentrations of SARS-CoV-2 antibodies. All calibrators contain ProClin (≤ 0.3%), sodium benzoate (≤ 0.1%), and sodium azide (<0.1%) as preservatives.
12014195	BioPlex 2200 SARS-CoV-2 IgG Control Set: Positive Controls - Four (4) 1.5 mL positive control vials that are provided in a human serum matrix made from defibrinated/delipidated plasma, with known analyte concentrations of SARS-CoV-2 antibodies. Negative Controls – Two (2) 1.5 mL negative control vials that are provided in a human serum matrix made from defribrinated/ delipidated plasma.
60-0817	BioPlex 2200 Sheath Fluid: Two (2) 4 L bottles containing Phosphate Buffered Saline (PBS). ProClin 300 (0.03%) and sodium azide (< 0.1%) are added as preservatives.
660-0818	BioPlex 2200 Wash Solution: One (1) 10 L bottle containing Phosphate Buffered Saline (PBS) and Tween 20. ProClin 300 (0.03%) and sodium azide (< 0.1%) are added as preservatives.
660-0000	BioPlex 2200 Instrument and Software Version 4.3 and above.

PRECAUTIONS/WARNINGS

1. For use under an Emergency Use Authorization (EUA) only.
2. For *In Vitro* Diagnostic (IVD) Use only.
3. For prescription use only.
4. This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized 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.
5. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
6. This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
7. WARNING: This product is preserved with ProClin 300.

WARNING
H317

Contains ≤ 0.3% ProClin 300

H317: May cause an allergic skin reaction.

H412: Harmful to aquatic life with long lasting effects.

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.

P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.

P501: Dispose of contents and container in accordance with local, regional, national, and international regulations.

8. Each unit of human serum used in the manufacture of the BioPlex 2200 SARS-CoV-2 IgG (including calibrator and control sets) was tested by FDA-accepted methods and found non-reactive for Hepatitis B surface antigen (HBsAg), antibody to HIV-1, HIV-2, and Hepatitis C (HCV). No test method can offer complete assurance that products containing human source materials will be absent of these and other infectious agents. In accordance with good laboratory practice (GLP), all human source material should be considered potentially infectious for Hepatitis B (HBV), Hepatitis C (HCV), HIV-1, HIV-2, and all other infectious agents; therefore, handle the BioPlex 2200 SARS-CoV-2 IgG assay (including calibrator and control sets) with the same precautions used with patient specimens. It is recommended that these reagents and human specimens be handled in accordance with the Biosafety in Microbiological and Biomedical Laboratories, WHO Laboratory Biosafety Manual, Biosafety Level 2, or other appropriate biosafety practices for materials which contain or are suspected of containing infectious agents.
9. Consider any materials of human origin as infectious and handle them using typical biosafety procedures and Universal Precautions according to 29 CFR 1910.1030 and in accordance with local, regional, and national regulations.
10. Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled.
11. Do not pipette by mouth.
12. Wear personal protective equipment while handling all reagents and samples and while operating the BioPlex 2200 System.
13. Dispose of all wastes in accordance with applicable national and/or local regulations.
14. Waste material containing patient samples or biological products should be considered biohazardous when disposing or treating.
15. Chemical reagents should be handled in accordance with Good Laboratory Practices.
16. Refer to the kit and additional required component Safety Data Sheets (SDS) for more safety information and warnings about chemical and biological hazards. The Safety Data Sheets are available at bio-rad.com and on request.
17. Clean up all spills immediately and thoroughly. Decontaminate the area for any spills involving biohazardous materials with an effective disinfectant. Dispose of all contaminated materials appropriately.
18. Do not use tests beyond their expiration date. The date is printed on all boxes.
19. Do not interchange vial or bottle caps and stoppers; this will lead to cross-contamination of reagents.
20. Adherence to the protocol specified herein is necessary to ensure the proper performance of this product. If aberrant results are obtained, contact Bio-Rad Technical Service.

21. Never mix the contents from different bottles of the same reagent. Doing so may lead to reagent contamination and compromise the performance of the product.
22. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.

SPECIMEN COLLECTION AND HANDLING

Specimen Collection Precaution
Consider any materials of human origin as infectious and handle them using typical biosafety procedures.

Specimen Type
Serum (including serum separator tubes) and plasma (dipotassium-EDTA, tripotassium-EDTA, lithium heparin, sodium heparin, and sodium citrate) are the recommended sample types for the BioPlex 2200 SARS-CoV-2 IgG. Avoid lipemic, icteric, and hemolyzed samples.

Specimen Storage
Serum and plasma may be stored at room temperature (25°C) for up to 5 days or under refrigeration (2 – 8°C) for up to 7 days. For long-term storage of samples, keep at -20°C or colder.

Specimen Preparation
Thoroughly mix thawed specimens; it is also recommended to centrifuge thawed specimens to remove gross particulate matter. Avoid multiple freeze/thaw cycles (up to 5 cycles is acceptable).

Specimen Shipping
All specimens and other samples of human origin must be shipped in accordance with national and international transportation regulations.

Note: Bio-Rad has established assay performance according to the specimen handling and storage parameters described in this IFU. If a laboratory uses handling and storage information criteria outside of the guidance listed here, it is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for their procedures.

PREPARATION AND STORAGE OF REAGENTS

- Do not freeze the reagents of BioPlex 2200 SARS-CoV-2 IgG.
- Reagents in the BioPlex 2200 SARS-CoV-2 IgG are ready to use. After initial use, the opened reagents are stable for 60 days if refrigerated or on the instrument at 2 – 8°C. Store the unopened kits at 2 – 8°C.
- Do not use reagents beyond expiration dates.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

Store all reagents at the labeled temperature and do not use past their expiration dates. Do not use any reagents which have any indications of discoloration, cloudiness, or precipitation. Do not use any reagents that show any signs of leakage.

PROCEDURE

In order to obtain reliable and consistent results, strictly adhere to the instructions in this Instructions for Use. Do not modify the handling and storage conditions for kit reagents or patient samples.

Operating instructions, including calibration, quality control, and maintenance for the BioPlex 2200 System are further described in the BioPlex 2200 System Operation Manual. Prior to using the BioPlex 2200 SARS-CoV-2 IgG, ensure that the BioPlex 2200 System is powered on and loaded with reagent packs and bulk solutions, and that all required maintenance has been performed. Please refer to the BioPlex 2200 System Operation Manual for more information regarding these activities.

Any lot numbers of the BioPlex 2200 System Sheath Fluid and BioPlex 2200 System Wash Solution can be interchanged.

A) Calibration

The BioPlex 2200 SARS-CoV-2 IgG Calibrator Set should be loaded and assayed, at a minimum, in duplicate every 30 days or with each new Reagent Pack lot. A 4PL curve is used to calculate results corresponding to the cutoff concentration. Refer to the BioPlex 2200 System Operation Manual for more information.

B) Quality Control

At the beginning of each day that the BioPlex 2200 SARS-CoV-2 IgG is to be used, load and process the BioPlex 2200 SARS-CoV-2 IgG Control Set as indicated in the BioPlex 2200 System Operation Manual. The BioPlex 2200 SARS-CoV-2 IgG Control Set should be run at least once per day and with each new Reagent Pack lot.

The BioPlex 2200 SARS-CoV-2 IgG Control Set includes a negative control and two positive controls in a human serum matrix made from defibrinated plasma. The Positive Controls are manufactured to give positive results, with values above the cutoff. The Negative Control is manufactured to give negative results with values below the cutoff. The Negative Control must have a negative result, and the Positive Controls must have positive results.

Note: The Negative and Positive Controls of the BioPlex 2200 SARS-CoV-2 IgG Control Set are intended to monitor for substantial reagent failure. The Positive Controls will not ensure precision at the assay cutoff.

Lot specific values for the Positive Controls are loaded into the BioPlex 2200 System database via the provided media or by manual input. After identifying a control via the barcoded vial, the BioPlex 2200 System compares the control results to the expected lot specific control values stored in the BioPlex 2200 System database.

Failure to obtain the appropriate values for controls will invalidate the assay and indicates procedural error, improper sample handling, or deterioration of reagents. Additional controls may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and laboratory quality control policies.

IMPORTANT QC TROUBLESHOOTING

At low frequency, reagent packs may exhibit falsely low signals and generate QC errors. The following troubleshooting steps should be followed when observing the noted QC behavior:

1. **QC Warning - low:**

   Repeat QC testing. If the QC Warning repeats, remove the pack with the flagged QC results and do not use. Please call Bio-Rad Technical Support to report the suspected low signal pack. Run QC with a new reagent pack. If QC results are within the acceptable range on the new reagent pack, discard the affected reagent pack with the QC Warning - Low results and do not report patient test results from that reagent pack. Retest any samples that were tested using the affected reagent pack. If the QC Warning repeats on the new reagent pack, please call Bio-Rad Technical Support for assistance with troubleshooting. If multiple packs for a particular BioPlex 2200 assay are on-board the instrument, the reagent pack (kit) serial number associated with the QC Warning - low results can be determined by viewing the Control Result dialog for the corresponding QC Event.

2. **QC Warning - high:**

   Recalibrate the reagent pack with the QC Warning - high and rerun QC. Verify that QC results are within the acceptable range before proceeding. Once QC results are within acceptable range after calibration, all samples tested using the pack with the QC Warning - high must be retested. The affected pack may be used to generate valid patient results after calibration has occurred.

   If a control result is out of its specified range, any test results generated since the last acceptable control results must be evaluated to determine if test results may have been adversely affected. Adversely affected results are invalid, and these samples must be retested.

C) Traceability to a Certified Reference Material (CRM)

The BioPlex 2200 SARS-CoV-2IgG is not traceable to a CRM (National / International Standard).

D) Load/Process Samples

Load samples into the racks provided with the BioPlex 2200 System as indicated in the BioPlex 2200 System Operation Manual. Sample processing on the BioPlex 2200 System is fully automated. Refer to the BioPlex 2200 System Operation Manual for appropriate software setup.

INTERPRETATION OF RESULTS

Calculation

All calculations necessary to interpret the results are performed automatically by the BioPlex 2200 System Software. Results are compared against the assay cutoff of 10 U/mL. If the result is less than the cutoff, the BioPlex 2200 SARS-CoV-2 IgG result is reported as negative. If the result is equal to or above the cutoff, the BioPlex 2200 SARS-CoV-2 IgG result is reported as positive. A semi-quantitative result can also be reported in U/mL.

BioPlex 2200 SARS-CoV-2 IgG Data Analysis

BioPlex 2200 SARS-CoV-2 IgG qualitative results are reported as Negative or Positive, and semi-quantitative results are expressed as U/mL. Results of <10 U/mL are Negative and ≥ 10 U/mL are reported as Positive. The analytical measuring range for the assay is 2-100 U/mL. If a numerical result is below 2 U/mL, the Bio-Plex 2200 system will report it as "<2 U/mL". Since this is below 10 U/mL, it is a negative result. Numeric results below 10 U/mL should not be reported outside of the laboratory. If a result is greater than 100 U/mL, the BioPlex 2200 system will report it as ">100 U/mL". Samples should be tested undiluted.

Interpretation of Results:

Result	Interpretation	Report
< 10 U/mL	Non-reactive SARS-CoV-2 IgG antibodies NOT detected	Negative for SARS-CoV-2 IgG antibodies. Numerical results are not reported outside the laboratory
10 U/mL ≤ x ≤ 100 U/mL	Reactive SARS-CoV-2 IgG antibodies detected	Positive for SARS-CoV-2 IgG antibodies; reactive results with numeric U/mL are reported outside the laboratory
> 100* U/mL	Reactive. SARS-CoV-2 IgG antibodies detected; Value above ULMI* is not reported	Positive for SARS-CoV-2 IgG antibodies; reactive results are reported outside the laboratory as >100 U/mL

* ULMI: upper limit of measuring interval.

In conjunction with these results, a patient's immune response should be evaluated based on their clinical status, related risk factors, and other diagnostic test results.

Assay Cut-Off:

The assay cut-off value was established using sera from various sample populations collected prior to November of 2019 (N=1619) and was then verified by concordance testing and Receiver Operator Characteristic (ROC) analysis, with the clinical status of the samples as the standard. The analysis was used to evaluate negative and positive agreement. Based on the results, calibrator values were adjusted such that the cut-off value is equal to 10 U/ml.

LIMITATIONS OF THE PROCEDURE

- The clinical applicability of a quantitative or semi-quantitative result is currently unknown and cannot be interpreted as an indication or degree of immunity nor protection from reinfection, nor compared to other SARS-CoV-2 antibody assays.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to infection.
- The performance of this test has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
- Results obtained with the assay may not be used interchangeably with values obtained with different manufacturers' test methods.
- This test should not be used to diagnose or exclude acute SARS-CoV-2 infection. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.
- The BioPlex 2200 SARS-CoV-2 IgG assay results should be considered along with the clinical presentation of the patient. Only a physician should interpret the results.
- Heterophilic antibodies in serum samples may cause interference in immunoassays. These antibodies may be present in patients regularly exposed to animals or to animal serum products.
- A negative result does not exclude a recent (within the last 14 days) SARS-CoV-2 infection. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

- 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.
- Contaminated, icteric, lipemic, hemolyzed, or heat-inactivated sera may cause erroneous results and should be avoided.
- This test should not be used for screening of donated blood.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Conditions of Authorization for the Laboratory

The BioPlex 2200 SARS-CoV-2 IgG Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: : https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Authorized laboratories using the BioPlex SARA-CoV-2 IgG ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instrument, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Bio-Rad Laboratories, Inc. (TechSupport.USSD@bio-rad.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Bio-Rad Laboratories, Inc., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

* The letter of authorization refers 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" as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

Limit of Detection / Limit of Quantitation

The detection capability LoB (Limit of Blank) of the BioPlex 2200 SARS CoV-2 IgG assay was evaluated using dilution series of 5 blank serum samples (serum samples with no analyte), while the LoD (Limit of Detection) and LoQ (Limit of Quantitation) of the BioPlex 2200 SARS-CoV-2 IgG assay were evaluated using dilution series of 5 serum positive samples. Two lots of reagents/calibrator were tested to determine the LoB, LoD and LoQ. All samples were run in replicates of 10 for five days for a total of 50 replicates per sample. Data were analyzed for LoB using the classical approach, and LoD and LoQ were analyzed using the precision approach per CLSI EP17-A2. If the calculated LoQ is < LoD, based on LoQ criteria, the final LoQ = LoD. If the calculated LoQ is outside the linear range, the final LoQ is the lower end of the assay measuring interval (AMI)

Results are summarized in Table 1.

Table 1. Maximum Detection Limits

BioPlex 2200 SARS-CoV-2 IgG	Units (U/ml)
Limit of Blank	0.0748
Limit of Detection	0.090
Limit of Quantitation	2

Linearity Study

A linearity study was conducted to validate the reportable semi-quantitative range of the BioPlex 2200 SARS-CoV-2 IgG. The testing protocol was performed as per CLSI guideline EP6-A. Five high positive patient serum samples were diluted to prepare high positive samples with test results between 100 and 120 U/ml. Per sample, each dilution level was evaluated in replicates of four. The BioPlex 2200 SARS-CoV-2 IgG assay demonstrated linearity throughout the analytical measuring interval of 2 to 100 U/ml.

Within Laboratory Precision Study

The precision of the BioPlex 2200 SARS-CoV-2 IgG assay was evaluated. Two BioPlex 2200 SARS-CoV-2 IgG reagent/calibrator lots were used over 5 days on three instruments using samples prepared in five claimed matrices (serum, dipotassium EDTA, sodium heparin, lithium heparin and sodium citrate). Samples spanning the assay range were prepared by spiking high positive patient samples into each matrix in order to obtain the target concentrations. Testing was conducted internally at Bio-Rad Laboratories. All samples were tested in replicates of four (4), at two runs per day, over 5 days on three instruments (4 replicates per run x 2 runs per day x 5 days x 3 instruments x 2 lots = 240 total replicates). Data were analyzed for repeatability, between-run, between-day, between-lot, between-instrument, and total (within laboratory precision) according to CLSI EP5-A3. The mean U/ml, standard deviation (SD), and percent coefficient of variation (%CV) for each sample were calculated. The results of the testing are summarized Table 2.

Table 2. BioPlex 2200 SARS-CoV-2 IgG Precision with Serum Samples

Panel Members	N	Mean (U/ml)	Within Run		Between Run		Between Day		Between Lot		Between Instrument		Within Laboratory Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative	240	6	0.40	6.3%	0.19	2.9%	0.13	2.1%	1.02	16.2%	0.00	0.0%	1.12	17.7%
Near Cut-Off	240	10	0.50	5.2%	0.36	3.8%	0.00	0.0%	1.10	11.4%	0.00	0.0%	1.26	13.1%
Low Positive	240	25	1.01	4.1%	0.67	2.7%	0.00	0.0%	1.79	7.2%	0.00	0.0%	2.16	8.7%
Positive	240	48	1.61	3.4%	1.26	2.6%	0.00	0.0%	4.33	9.0%	0.00	0.0%	4.78	10.0%

Table 2.2 BioPlex 2200 SARS-CoV-2 IgG Positive Controls Precision

	N	Mean (U/ml)	Repeatability		Between Run		Between Day		Between Instrument		Within Laboratory Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Positive control 1 (tested with lot 1)	120	29	1.01	3.5%	1.77	6.1%	0.00	0.0%	1.78	6.1%	2.71	9.3%
Positive control 2 (tested with lot 2)	120	33	1.14	3.5%	1.23	3.7%	0.00	0.0%	1.26	3.8%	2.10	6.4%

Matrix Comparison

To evaluate performance of the BioPlex 2200 SARS-CoV-2 IgG in the different claimed matrices: serum and plasma (dipotassium-EDTA, tripotassium-EDTA, lithium heparin, sodium heparin, and sodium citrate), SARS-CoV-2 antibody negative paired serum and plasma samples drawn from > 40 individual donors were spiked with SARS-CoV-2 IgG positive samples at various levels that span the dynamic assay range. All samples were evaluated in replicates of two (2) and the mean values were used for data analysis in U/mL. Regression analysis comparing the performance of all matrices against serum samples is shown in Table 3.

Table 3. BioPlex 2200 SARS-CoV-2 IgG Matrix Comparison- Data Analysis

Parameter	Serum Separator	K2 EDTA	K3 EDTA	Lithium Heparin	Sodium Heparin	Sodium Citrate
Slope	0.99	1.01	1.00	0.99	0.98	0.98
Intercept	-0.07	-0.14	-0.06	-0.24	0.19	0.33
Correlation	0.998	0.998	0.998	0.998	0.999	0.998

Analytical Specificity

Potential Cross-Reactivity

A total of 1078 samples from patients with potentially cross-reactant antibodies or conditions other than SARS-CoV-2 were tested, representing 41 different analytes/conditions. All samples were collected prior to November 2019 and are presumed negative for antibody to SARS-CoV-2. All samples were tested with the BioPlex 2200 SARS-CoV-2 IgG in singlicate.

Negative agreement results for each potentially cross-reactive sample tested with the BioPlex 2200 SARS-CoV-2 IgG assay are shown in Table 4. One (1) sample (ANA positive) was reactive for an overall specificity of 99.9% (1077/1078). No significant cross-reactivity was observed for any cross-reactive group of samples that were tested.

Table 4. Potential Cross-Reactivity

Potential Cross-Reactants	Number Tested	Number Positive	Number Negative	Overall % Specificity
Anti-influenza A	34	0	34	100.0%
Anti-influenza B	26	0	26	100.0%
Anti-HCV	14	0	14	100.0%
Anti-HBV	49	0	49	100.0%
Anti-*Haemophilus influenzae*	25	0	25	100.0%
Anti-229E (alpha coronavirus)	20	0	20	100.0%
Anti-NL63 (alpha coronavirus)	20	0	20	100.0%
Anti-OC43 (beta coronavirus)	20	0	20	100.0%
Anti-HKU1 (beta coronavirus)	20	0	20	100.0%
ANA	192	1	191	99.5%
Anti-RSV	20	0	20	100.0%
Anti-HIV	23	0	23	100.0%

Potential Cross-Reactants	Number Tested	Number Positive	Number Negative	Overall % Specificity
Pregnant women	110	0	110	100.0%
Rheumatoid Factor positive	47	0	47	100.0%
Anti-adenovirus	11	0	11	100.0%
Anti-parainfuenza virus 1-4	20	0	20	100.0%
Anti-human metapneumovirus	5	0	5	100.0%
Anti-enterovirus	10	0	10	100.0%
Anti-rhinovirus	5	0	5	100.0%
Anti-Epstein-Barr virus IgG	23	0	23	100.0%
Anti-Epstein-Barr virus IgM	22	0	22	100.0%
Anti-*Mycoplasma pneumoniae*	15	0	15	100.0%
Anti-MERS	5	0	5	100.0%
Anti-SARS	5	0	5	100.0%
Common Cold	9	0	9	100.0%
Flu Vaccinated	7	0	7	100.0%
2008 Flu Vaccine BioAssay Validation Panel	36	0	36	100.0%
Streptococcus pneumoniae Immunity control	20	0	20	100.0%
Anti-HSV 2	15	0	15	100.0%
Anti-HSV 1	15	0	15	100.0%
Anti-CMV	22	0	22	100.0%
Anti-Rubella	20	0	20	100.0%
Anti-Toxoplasma	22	0	22	100.0%
Anti-Measles	20	0	20	100.0%
Anti-Mumps	20	0	20	100.0%
Anti-Syphilis	19	0	19	100.0%
Anti- VZV	19	0	19	100.0%
Anti-Hepatitis A	20	0	20	100.0%
Elevated IgG	20	0	20	100.0%
Elevated IgM	19	0	19	100.0%
HAMA	34	0	34	100.0%
Total	1078	1	1077	99.9%

Potentially Interfering Substances

Interference testing was performed to measure the effects of unrelated substances such as endogenous serum components (hemoglobin, bilirubin, lipids, immunoglobulin, and total protein) and exogenous molecules (ascorbic acid and anticoagulants) on BioPlex 2200 SARS-CoV-2 IgG assay performance. Negative serum was spiked with three levels of SARS-CoV-2 IgG antibody to create samples that were high negative, low positive, and high positive, and they were tested, in singlicate, with each of the potentially interfering substances. Testing was conducted according to CLSI Protocol EP7-ED3 2018. No significant interference was observed with any of the substances tested at the concentrations listed in Table 5.

Table 5. Interfering Substances

Potential Interferent	Test Concentration
Hemoglobin	1000 mg/dL
Bilirubin, Unconjugated	20 mg/dL
Bilirubin, Conjugated	30 mg/dL
Cholesterol	500 mg/dL
Gamma Globulin	6 g/dL
Triglyceride	3300 mg/dL

Potential Interferent	Test Concentration
Total Protein (albumin)	12 g/dL
Ascorbic Acid	6 mg/dL
K2 EDTA	800 units/dL
K3 EDTA	800 units/dL
Sodium Heparin	8000 units/dL
Lithium Heparin	8000 units/dL
Sodium Citrate	1000 mg/dL

Clinical Agreement Study

Negative Percent Agreement (NPA)

A total of 1557 samples from 1015 presumed healthy subjects (individuals tested during routine checkups) and 542 blood bank donors were purchased and tested with the BioPlex 2200 SARS-CoV-2 IgG assay. All samples were collected prior to November 2019. The BioPlex 2200 SARS-CoV-2 IgG assay exhibited an overall specificity of 99.9% (1556/1557). Results are summarized in Table 6.

Table 6. BioPlex 2200 SARS-CoV-2 IgG NPA

Population	Number Tested	BioPlex 2200 SARS-CoV-2 IgG			
		Number Positive	Number Negative	NPA	95% Confidence Interval
Healthy Subjects	1015	1	1014	99.9% (1014/1015)	99.4% to 100.0%
Blood Bank Donors	542	0	542	100.0% (542/542)	99.3% to 100.0%
Total	1557	1	1556	99.9% (1556/1557)	99.64% to 99.99%

Positive Percent Agreement (PPA)

A total of 305 samples from subjects who had been identified as positive for SARS-CoV-2 by FDA-authorized RT-PCR testing, were evaluated with the BioPlex 2200 SARS-CoV-2 IgG assay. The population of subjects consisted of hospitalized (47), non-hospitalized (154), and unknown hospitalization status (104) subjects. One sample was tested per patient, and the patients were not followed over time to monitor change in antibody status. Results are summarized Table 7.

Table 7. BioPlex 2200 SARS-CoV-2 IgG PPA

Days between symptom onset and sample collection	Number Tested		BioPlex 2200 SARS-CoV-2 IgG		
		Number Positive	Number Negative	PPA	95% Confidence Interval
0-7 days	32	26	6	81.3 % (26/32)	64.7% to 91.1%
8-14 days	27	26	1	96.3 % (26/27)	81.7% to 99.3%
≥15 days	246	231	15	93.9 % (231/246)	90.1% to 96.2%

The SARS-CoV-2 IgG PPA for all samples (N=305) was 81.3% (26/32) at 0-7 days, 96.3% (26/27) at 8-14 days, and 93.9% (231/246) at ≥15 days.

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TRADEMARK INFORMATION

BioPlex is a trademark of Bio-Rad Laboratories, Inc. in certain jurisdictions.

TECHNICAL INFORMATION CONTACTS

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665-0566A
June 2021

BIO-RAD

REF 12014193

IVD 6 x 0.5 mL

BioPlex 2200 SARS-CoV-2 IgG Calibrator Set

For US Customers Only

For use under an Emergency Use Authorization (EUA) Only

Prescription Use Only

For *In Vitro* Diagnostic Use Only

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

For laboratory professional use only.

EN

INTENDED USE

The BioPlex 2200 SARS-CoV-2 IgG Calibrator Set is intended for the calibration of the BioPlex 2200 SARS-CoV-2 IgG Reagent Pack in the BioPlex 2200 System.

SUMMARY AND PRINCIPLE

The BioPlex 2200 SARS-CoV-2 IgG Reagent Pack is calibrated using a set of six (6) distinct serum-based calibrators. Calibrators are used in a test system to establish points of reference that are used in the determination of the presence of substances in human specimens.

MATERIALS PROVIDED

Reagents: SARS-CoV-2 IgG Calibrators: 6 x 0.5 mL vials.

The calibrators are provided in a human serum matrix made from defibrinated plasma with added known analyte concentrations of SARS-CoV-2 recombinant antibodies and antibodies derived from inactivated human disease state plasma. All calibrators contain ProClin (≤ 0.3%), sodium benzoate (≤ 0.1%), and sodium azide (<0.1%) as preservatives.

Analytes: Antibodies to SARS-CoV-2.

Components: One (1) package insert providing instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED

12014194 – BioPlex 2200 SARS-CoV-2 IgG Calibrator Lot Data CD-ROM.

WARNINGS AND PRECAUTIONS FOR USERS

- For use under Emergency Use Authorization only.
- For In Vitro Diagnostic Use only.
- For prescription use only.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized 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.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- This product is for use with the BioPlex 2200 SARS-CoV-2 IgG test that is authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- This product should not be used past the expiration date.
- If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.
- Do not interchange vial caps. This may lead to cross-contamination of calibrators.
- For professional use only.

Caution, consult accompanying documents. Biological source material. Treat as potentially infectious. SDS: www.bio-rad.com.

Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human agents capable of transmitting infectious disease. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

WARNING

Contains ≤ 0.3% ProClin 300

H317: May cause an allergic skin reaction. • H412: Harmful to aquatic life with long-lasting effects. • P273: Avoid release to the environment. **• P280:** Wear protective gloves/protective clothing/eye protection/ face protection. **• P302 + P352:** IF ON SKIN: Wash with plenty of soap and water. **P333 + P313:** If skin irritation or rash occurs: Get medical advice/attention. **P501:** Dispose of contents and container in accordance with local, regional, national, and international regulations.

STORAGE AND STABILITY

This product is stable until the expiration date when stored unopened at 2 to 8°C. Once opened, the calibrators are stable for 60 days when stored tightly capped at 2 to 8°C.

PROCEDURE

This product should be run in accordance with the instructions accompanying the BioPlex 2200 Instrument and BioPlex 2200 SARS-CoV-2 IgG Reagent Pack.

Before sampling calibrators, allow the vials to reach room temperature (18 to 25°C) and gently mix to ensure homogeneity. After each use, promptly cap the reagents and return to 2 to 8°C storage.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

LIMITATIONS

This product is intended for use with the BioPlex 2200 Instrument. Any other use has not been evaluated.

ASSIGNMENT OF VALUES

Calibrator assignment is established using a Master Set of calibrators and a specific lot of BioPlex 2200 SARS-CoV-2 IgG Reagent Packs on multiple BioPlex 2200 instruments.

A BioPlex 2200 SARS-CoV-2 IgG Calibrator Lot Data CD-ROM or 2D barcode (SW 4.4 and above) on the outer box of the calibrator set is required in order to load the necessary value assignment data into the instrument. Refer to the BioPlex 2200 System Operation Manual for more information regarding this activity.

For In Vitro Diagnostic Use


Temperature Limit


Consult Instructions for Use

Lot Number


Date of Manufacture

Contains


Manufactured by

Catalog Number

Calibrator / Level


Use by (YYYY-MM-DD)


WARNING

Technical Information Contacts:
USA & Puerto Rico: 1-800-2-BIORAD (224-6723).

- **Outside the U.S.A., please contact your regional Bio-Rad office for assistance.**

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BIO-RAD

REF 12014195

CTRL + 4 x 1.5 mL

CTRL − 2 x 1.5 mL

IVD

BioPlex 2200 SARS-CoV-2 IgG Control Set

For US Customers Only

For use under an Emergency Use Authorization (EUA) Only

Prescription Use Only

For In Vitro Diagnostic Use Only

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

For laboratory professional use only.

EN

INTENDED USE

The BioPlex 2200 SARS-CoV-2 IgG Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and BioPlex 2200 SARS-CoV-2 IgG Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 SARS-CoV-2 IgG Control Set has not been established with any other SARS-CoV-2 assays.

SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices.

MATERIALS PROVIDED

Reagents: All reagents contain preservatives including ≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate.

BioPlex 2200 SARS-CoV-2 IgG Positive Controls – Four (4) 1.5 mL positive control vials that are provided in a human serum matrix made from defibrinated/delipidated plasma, with known analyte concentrations of SARS-CoV-2 recombinant antibodies and antibodies derived from inactivated human disease state plasma.

BioPlex 2200 SARS-CoV-2 IgG Negative Controls – Two (2) 1.5 mL negative control vials that are provided in a human serum matrix made from defibrinated/delipidated plasma.

Analytes: Antibodies to SARS-CoV-2.

Components: One (1) package insert providing instructions for use. One (1) assignment of values sheet.

OPTIONAL MATERIALS NOT PROVIDED

REF 12014196 – BioPlex 2200 SARS-CoV-2 IgG Control Lot Data CD-ROM.

WARNINGS AND PRECAUTIONS FOR USERS

- For use under Emergency Use Authorization only.
- For In Vitro Diagnostic Use only.
- For prescription use only.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized 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.
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- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- This product should not be used past the expiration date.
- If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.
- Do not interchange vial caps. This may lead to cross-contamination of controls.
- For professional use only.

Caution, consult accompanying documents. Biological source material. Treat as potentially infectious. SDS: www.bio-rad.com.

Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/HIV-2. This product may also contain other human agents capable of transmitting infectious disease. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

WARNING

Contains ≤ 0.3% ProClin 300

H317: May cause an allergic skin reaction. • H412: Harmful to aquatic life with long-lasting effects. • P273: Avoid release to the environment. • **P280:** Wear protective gloves/protective clothing/eye protection/ face protection. • **P302 + P352:** IF ON SKIN: Wash with plenty of soap and water.

• **P333 + P313:** If skin irritation or rash occurs: Get medical advice/attention.

• **P501:** Dispose of contents and container in accordance with local, regional, national, and international regulations.

STORAGE AND STABILITY

This product is stable until the expiration date when stored unopened at 2 to 8°C. Once opened, all controls are stable for 60 days when stored tightly capped at 2 to 8°C

PROCEDURE

This product should be treated the same as clinical specimens and run in accordance with the instructions accompanying the BioPlex 2200 Instrument and the BioPlex 2200 SARS-CoV-2 IgG Reagent Pack.

Before sampling, allow the controls to reach room temperature (18 to 25°C) and gently mix by inverting the tube to ensure homogeneity. After each use, promptly cap the reagents and return to 2 to 8°C storage.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to the packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

LIMITATIONS

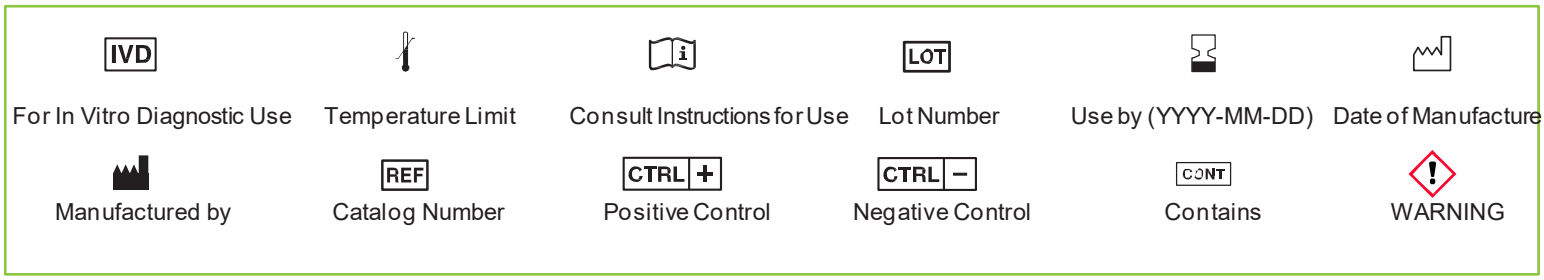
1. This product is intended for use with the BioPlex 2200 SARS-CoV-2 IgG test. Any other use has not been evaluated.
2. This product is intended for use with the BioPlex 2200 Instrument. Any other use has not been evaluated.
3. This product is intended to monitor for substantial reagent failure. The Positive Controls will not ensure precision at the assay cutoff.

ASSIGNMENT OF VALUES

The BioPlex 2200 SARS-CoV-2 IgG Control Set contains antibodies present for analytes within the BioPlex 2200 SARS-CoV-2 IgG Reagent Pack.

A BioPlex 2200 SARS-CoV-2 IgG Control Lot Data CD-ROM or 2D barcode (SW 4.4 and above) located on the outer box of the control set is available to load the necessary value assignment data into the Instrument. Refer to the BioPlex 2200 System Operation Manual for more information regarding this activity.

The mean values were derived from replicate analyses and should fall within the corresponding standard deviation.



Technical Information Contacts:

USA & Puerto Rico: 1-800-2-BIORAD (224-6723).

- Outside the U.S.A., please contact your regional Bio-Rad office for assistance.

BioPlex is a trademark of Bio-Rad Laboratories, Inc. in certain jurisdictions.

BIO-RAD

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BioPlex 2200 SARS-CoV-2 IgG

REF 12014192

FOR IN VITRO DIAGNOSTIC USE.
FOR USE UNDER AN EMERGENCY USE AUTHORIZATION (EUA) ONLY.
FOR PRESCRIPTION USE ONLY.

This is not the full Instructions for Use.

The full Instructions for Use can be downloaded from the Bio-Rad website at:
www.bio-rad.com/bioplex2200-sarscov2-igg

Please contact Bio-Rad Laboratories (1-800-424-6723, option 2) if you require a printed copy of the Instructions for Use free of charge.

- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.