IDS SARS-CoV-2 IgG

IVD

Product Name	IDS SARS-CoV-2 IgG	REF	IS-ID6502
Abbreviated Product Name	IDS SARS-CoV-2 IgG		
System	IDS-iSYS Multi-Discipline Automated System	REF	IS-310400

Changes: § 12
Deletions: §

For *In Vitro* Diagnostic Use

Use Under Emergency Use Authorization Only

For prescription use only.

1. Intended Use

The IDS SARS-CoV-2 IgG is a chemiluminescent immunoassay intended for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (tripotassium EDTA, lithium heparin and sodium citrate), using the IDS-iSYS Multi-Discipline Automated System. The IDS 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 IDS 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 IDS 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 for IDS SARS-CoV-2 IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

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

2. Summary and Explanation

Coronaviruses cause illnesses in mammals and birds, such as the common cold, severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). A new coronavirus was identified and named severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) in 2019 in China.[1]

SARS-CoV-2 is a positive sense, single strand RNA virus belonging to the family *Coronaviridae* and has four structural proteins: Spike (S), Envelope (E), Membrane (M) and Nucleocapsid (N).[2] The N protein holds the RNA genome, and the S, E, and M proteins together create the viral envelope.[2]

Coronavirus disease-2019 (COVID-19) results from an infection with SARS-CoV-2 and was declared a pandemic by the World Health Organization in March 2020.[3,4] COVID-19 symptoms range from no apparent symptoms to severe respiratory distress necessitating the use of mechanical ventilation.

The presence of SARS-Cov-2 antibodies may be helpful in tracking disease spread.

3. Method Description

The assay is based on chemiluminescence technology. Four microliters (4µL) of patient sample or control are incubated with magnetic particles coated with recombinant SARS-CoV-2 nucleocapsid (N) and spike (S) antigens. Following the washing step after the first incubation, a specific anti-SARS-CoV-2 labelled with acridinium, followed by a subsequent incubation step. The magnetic particles are captured using a magnet and a wash step performed to remove any unbound analyte. Trigger reagents are added; the resulting light emitted by the acridinium label is directly proportional to the concentration of analyte in the original sample.

4. Warnings and Precautions

For in vitro diagnostic use only

For use under Emergency Use Authorization (EUA) Only

This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by 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.

This test has been authorized only for detecting the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this test 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The IDS SARS-CoV-2 IgG is not for internal use in humans or animals. This product must be used strictly in accordance with the instructions set out in these Instructions For Use (IFU). Do not use product beyond the expiration date printed on the product labelling. Immunodiagnostic Systems Limited (IDS) will not be held responsible for any loss or damage (except as required by statute), howsoever caused, arising out of non-compliance with the instructions provided.

Rx only.

CAUTION: This kit contains material of animal origin. Handle kit reagents as if capable of transmitting an infectious agent. Appropriate precautions and good laboratory practice must be used in the storage, handling and disposal of the kit reagents. Disposal of kit reagents should be in accordance with local regulations.

Human materials
Human material used in the preparation of this product has been tested by FDA recommended assays for the presence of antibody to Human Immunodeficiency Virus (HIV I and II), Hepatitis B surface antigen, antibody to Hepatitis C, and found negative. As no test can offer complete assurance that infectious agents are absent, the reagents should be handled according to Biosafety Level 2.

Reagents containing Sodium Azide
Some reagents in this kit contain sodium azide (NaN_3) <0.1 % (w/w) which may react with lead, copper or brass plumbing to form highly explosive metal azides. On disposal, flush with large volumes of water to prevent azide build up.

Reagents containing ProClin® 300
Some reagents in this kit contain ProClin® 300 as a preservative.

Classification under CLP:
Skin Sens. 1: H317

Hazard statements:
H317: May cause an allergic skin reaction

Precautionary statements:
P261: Avoid breathing dust/fumes/gas/mist/vapours/spray
P272: Contaminated work clothing should not be allowed out of the workplace
P280: Wear protective gloves/protective clothing/eye protection/face protection
P302+352: IF ON SKIN: Wash with plenty of water
P321: Specific treatment (see instructions on this label)
P333+313: If skin irritation or rash occurs: Get medical attention

5. Handling Precautions

The reagents provided in the kit are ready to use. Store the cartridge and calibrators in an **upright** position in the dark at 2 - 8 °C. **Do not freeze** the cartridge or the calibrators.

Reagent shelf life	Cartridge	Calibrators
Before opening at 2 - 8 °C	To the expiry date	
After opening at 2 - 8 °C	14 Days	14 Days, 4 Usages
On board the system *	14 Days	1 Hour per usage

* Continuous on-board stability

6. Sample Collection and Storage

The correct specimen type must be used in the assay. The following matrices have been tested (refer to Section 13.2 for the study results) and may be used.

- Serum;
- Potassium K_3 EDTA plasma:
- Lithium heparin plasma;
- Sodium citrate plasma

Blood should be collected aseptically by venipuncture and the serum or plasma should be separated from clot, red cells or gel separator, after centrifugation, carefully following the tube manufacturers' instructions and according to good laboratory practices.[7]

- Follow the blood collection tube manufacturer's recommendations for handling and processing the samples.
- Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Follow the blood collection tube manufacturer's recommendations for handling and processing the samples.

- Samples can be stored for a maximum of 8 hours at room temperature (18 - 22 °C) or up to 7 days at 2-8°C. If longer time is required between separation and testing, the samples should be stored at -20°C.
- Do not freeze samples more than once. Samples should be completely thawed and mixed well prior to loading onto the system.
- Samples are stable on-board the system for a maximum of 6 hours.
- Samples containing particulate matter must be centrifuged before performing the assay. Centrifuged samples with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified samples without the lipemic material.
- The minimum volume required for a single determination is 100 µL of specimen (4 µL specimen + dead volume).
- Before performing assays, make sure that samples, calibrators and controls are at room temperature (18 - 22 °C).
- To minimize possible evaporation effects, samples, calibrators and controls should be measured within 30 minutes of being placed on the system.
- Do not use heat-inactivated samples.

7. Materials

System: **IDS-iSYS Multi-Discipline Automated System using software version 14.10 or higher**

Materials Provided

Reagent Cartridge

REAG	1	MP	2.5 mL

Magnetic particles coated with recombinant SARS-CoV-2 antigens in phosphate buffer with ProClin 300 sodium and azide as preservative (<0.1 %), 1 bottle, 2.5 mL

REAG	2	CONJ	25 mL

Mouse Monoclonal anti-human IgG antibody labelled with an acridinium ester derivative, in phosphate buffer containing stabilisers, surfactant and sodium azide (< 0.1%) as preservative, 1 bottle, 25 mL

REAG	3	DIL	25 mL

Phosphate Buffer containing bovine serum albumin, a surfactant, an inert blue colouring agent, with Pro-Clin 300 and Gentamicin SO4 as preservatives. 1 bottle, 25 mL.

Calibrators

REAG	4	CAL A	1.6 mL

Human serum with low concentration of anti-SARS-CoV-2 antibodies in phosphate buffer containing bovine serum albumin, a surfactant, an inert blue colouring agent, with Pro-Clin 300 and Gentamicin SO4 as preservatives. 1 vial, 1.6 mL.

REAG	5	CAL B	1.6 mL

Human serum with high concentration of anti-SARS-CoV-2 antibodies in phosphate buffer containing bovine serum albumin, a surfactant, an inert blue colouring agent, with Pro-Clin 300 and Gentamicin SO4 as preservatives. 1 vial, 1.6 mL.

Mini CD

DATA DISK

Contains documents for the reagents.

Materials Required But Not Provided

Standard Materials

IS-310400	IDS-iSYS Multi-Discipline Automated System
IS-ID6530	IDS SARS-CoV-2 Control Set
IS-CC100	IDS-iSYS Cuvettes
IS-CS100	IDS-iSYS System Liquid (Syst. l)
IS-CW100	IDS-iSYS Wash Solution (Wash S)
IS-CT100	IDS-iSYS Trigger Set
IS-6010	IDS-iSYS Cartridge Check System (CCS)
IS-DS200	IDS-iSYS D-SORB Solution
IS-IM100	IDS Immunocleaner
IS-CAP300	IDS Top Cap Set
IS-XP01	IDS-iSYS XPrep

Optional equipment / materials

IS-CSC105	Sample Cups (500 µL)
IS-HS100	IDS-iSYS Cleaning Solution

8. Assay Procedure

8.1 Preparation of the Reagent Cartridge

The reagents provided in the cartridge are ready to use. Before a cartridge is loaded on-board the system, mix the magnetic particles container with a brisk rotation between the palms of the hands in a back-and-forth motion or via the IDS XPrep device. Avoid foam formation. Refer to the instructions in the System User Manual for loading and managing the reagent cartridge on-board the system.

If the cartridge is removed from the system, store the cartridge upright at 2 - 8 °C in the dark.

8.2 Preparation of the Calibrators

The calibrators are supplied with the kit; calibrators from another lot must not be used.

The calibrators are ready to use. Leave the calibrator vials at room temperature for 10 minutes. Gently mix the vials by hand; do not shake or turn the vials upside down. Care should be taken to avoid the formation of foam.

When using the calibrators for the first time:

- Remove the safety seal and white sealing cap.
- Place the calibrator vials into the appropriate rack and insert onto the system. Proceed according to the instructions in the System User Manual.
- To minimize possible evaporation effects, calibrators should be measured within 30 minutes of being placed on the system.
- The calibrator should be removed from the system within 60 minutes (1 hour) after use.
- Upon removing the calibrator vials from the system, they should be capped with the IDS Top Cap Set (IS-CAP300) and returned to 2 – 8 °C storage. Do not re-use the caps after use, to avoid contamination.
- The calibrators can be used for a maximum of 4 times.

When re-using the stored calibrator vials:

- Leave the calibrator vials at room temperature for 10 minutes. Gently mix the vials by hand; do not shake or turn the vials upside down. Care should be taken to avoid the formation of foam.
- Remove the Top Cap before placing the calibrator vials into the appropriate rack and insert onto thesystem.
- Calibrators should be placed on the system within 10 minutes after reaching room temperature. Proceed according to the instructions in the System User Manual.
- To minimise possible evaporation effects, calibrators should be measured within 30 minutes of being placed on the system.
- The calibrator should be removed from the system within 60 minutes (1 hour) after use.
- Upon removing the calibrator vials from the system, they should be capped with the IDS Top Cap Set (IS-CAP300) and returned to 2 - 8°C storage. Do not re-use the caps after use, to avoid contamination.

8.3 Assay Calibration

No international standard is available for Anti-SARS-CoV-2. The IDS SARS-CoV-2 IgG assay has been standardized against in-house reference standards.

All levels of IDS SARS-CoV-2 IgG calibrator should be measured in 3 replicates and 1 replicate of all levels of IDS SARS-CoV-2 control at the same time to calibrate the IDS SARS-CoV-2 IgG assay. The IDS SARS-CoV-2 Control Set is supplied separately. Refer to the IDS SARS-CoV-2 Control Set IFU for preparation and handling instructions. Verification of the calibration is automatic and managed by the system.

Perform the assay calibration according to the instructions in the System User Manual

8.4 Calibration Frequency

A new calibration is required:

- Upon loading each new lot of cartridges.
- When the control values do not fall within the defined ranges.
- When the calibration interval of 14 days has expired.
- After system service.

8.5 Detection of Sample anti-SARS-CoV-2 IgG

Process the samples according to the instructions in the System User Manual.

9. Quality Control

Use the IDS SARS-CoV-2 Control Set (IS-ID6530) for quality control. Controls should be tested at (or near) the beginning of every run containing patient samples in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory's quality procedure.

The control values must be within the specified acceptable ranges. If a control is out of its specified range, the associated test results are invalid, samples results should not be reported, and samples must be retested. Recalibration may be required.

Refer to the IDS SARS-CoV-2 Control Set IFU for preparation and handling instructions.

10. Calculation of Results

The system automatically calculates the IDS SARS-CoV-2 IgG output expressed as arbitrary units (AU/mL) and grades the qualitative results

- 'NEG' code will be displayed / printed for outputs <10.0 AU/mL
- 'POS' code will be displayed / printed for outputs ≥ 10.0 AU/mL.

11. Interpretation of Results

Assessment of IDS SARS-CoV-2 IgG results should be performed after the IDS SARS-CoV-2 Control results have been reviewed and determined to be valid and acceptable. The IDS-iSYS Multi-Discipline system automatically interprets the IDS SARS-CoV-2 Control values. If the controls are not valid, the patient results cannot be interpreted, and samples must be retested.

Output (AU/mL)*	Interpretation	Description
< 10.0	Negative	The sample should be considered Negative for the presence of anti-SARS-CoV-2- IgG antibodies.
≥ 10.0	Positive	The sample should be considered Positive for the presence of anti-SARS-CoV-2- IgG antibodies

* Results reported outside the laboratory should be reported qualitatively as positive or negative. Numerical values should not be reported outside the laboratory.

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

12. Limitations of Use

- As in the case of any diagnostic procedure, results must be interpreted in conjunction with the patient's clinical presentation and other information available to the physician.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.[6] Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed.
- This device should not be used to diagnose or exclude acute SARS-CoV-2 infection. Direct testing for SARS-CoV-2 with a molecular assay should be performed to evaluate acute infection in symptomatic individuals.
- Performance characteristics have not been established for the assay used in conjunction with other manufacturers' assays for specific SARS-CoV-2 serological markers.
- Performance has only been established with specimen types listed in the Intended Use. Other specimen types have not been evaluated.
- The performance of the assay has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than the specimen types listed in the Intended Use.
- Results obtained with the assay may not be used interchangeably with results obtained with different manufacturers' test methods.
- 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 adaptive immune response.
- A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2-specific IgG 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 quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or if the antibodies are not present during the stage of disease in which a sample is collected.
- Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.
- A reactive (positive) test result does not exclude past or present infection by other coronaviruses, such as SARS-CoV-1, MERS-CoV, HKU1, 229E, NL63, or OC43.
- SARS-CoV-2 antibodies may not be detectable in patients with recent infections (7–10 days or less) or in samples collected from patients less than 7 days from a positive polymerase chain reaction (PCR) result. Patient specimens may be nonreactive if collected during the early (pre-seroconversion) phase of illness or due to a decline in concentration over time. In addition, the immune response may be depressed in elderly, immunocompromised, or immunosuppressed patients.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to infection.
- This test should not be used for donor screening.
- 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.
- 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 LABORATORIES

The IDS SARS-CoV-2 IgG Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, 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 IDS SARS-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:

• Authorized laboratories* using IDS SARS-CoV-2 IgG 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.

• Authorized laboratories using IDS SARS-CoV-2 IgG must use IDS SARS-CoV-2 IgG as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use IDS SARS-CoV-2 IgG are not permitted.

• Authorized laboratories that receive IDS SARS-CoV-2 IgG must notify the relevant public health authorities of their intent to run IDS SARS-CoV-2 IgG prior to initiating testing.

• Authorized laboratories using IDS SARS-CoV-2 IgG must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

• Authorized laboratories must collect information on the performance of IDS SARS-CoV-2 IgG and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and (info.uk@idsplc.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of IDS SARS-CoV-2 IgG of which they become aware.

• All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use IDS SARS-CoV-2 IgG 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.

• Immunodiagnostic Systems, Ltd., 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."

13. Analytical Performance

Representative performance data are shown. Results obtained at individual laboratories may vary.

13.1 Interference

Four (4) serum samples (1 negative and 3 positive samples), tested in singlicate, were spiked with potential endogenous interference substances commonly found in serum and plasma specimens, including haemoglobin, conjugated bilirubin, unconjugated bilirubin and triglycerides. Study results demonstrated a ≤ 10% change for each substance at the indicated concentration; all positive samples remained positive, and all negative samples remained negative:

Potentially Interfering Agent	Threshold Concentration
Bilirubin, conjugated	20 mg/dL
Bilirubin, unconjugated	20 mg/dL
Haemoglobin	1000 mg/dL
Triglyceride	3000 mg/dL

Biotin-streptavidin amplification methods are not contained within this test system; therefore, biotin interference was not evaluated.

13.2 Matrix Equivalency Study

A study was performed to assess the performance of different serum and plasma sample types following the CLSI EP9-A3 guideline. Matrix sets were collected from ten (10) donors negative for SARS-CoV-2 IgG when tested by the IDS SARS-CoV-2 IgG assay. A serum tube, a K_3 EDTA plasma tube, a Lithium Heparin plasma tube, and a Sodium Citrate plasma tube were collected from each donor at one time point. Each sample was used to create two (2) contrived samples with analytes at the following levels: Negative (no spike), Low Positive (spiked with known positive serum), and Positive (spiked with known positive serum). The positive serum for spiking was collected from a single donor who had tested positive for SARS-CoV-2 using an FDA-authorized PCR method. Each of the native (no spike) and contrived samples was tested in singlicate with the IDS SARS-CoV-2 IgG.

Results were consistent across all evaluated matrices; all positive samples were positive, and all negative samples were negative. Passing Bablok analysis was performed against the serum results; the summary is tabulated below:

Sample type	N	Slope	95% CI	Intercept (AU/mL)	95% CI	Corr. Coeff. (r)
K_3 EDTA	30	1.00	0.96 to 1.03	0.11	-0.13 to 0.33	0.998
Lithium Heparin	30	0.98	0.94 to 1.02	0.30	-0.24 to 0.52	0.997
Sodium Citrate	27*	1.03	1.00 to 1.06	0.24	-0.37 to 0.73	0.998

* One Sodium Citrate plasma was excluded from the study due to accidental spillage of the negative sample during spiking process.

13.3 Analytical Specificity - Cross-reactivity

The IDS SARS-CoV-2 IgG assay was evaluated for potential cross-reactivity using specimens containing antibodies to other pathogens and other disease states using the IDS SARS-CoV-2 IgG assay in singlicate with the IDS-iSYS Multi-Discipline Automated System. No false positive results were observed with the potential cross-reactants listed in the following summary table:

Cross-reactants	Number of tested samples	Number of Positive samples
Human Coronavirus 229E	3	0
Human Coronavirus 229E and NL63	1	0
Human Coronavirus NL63	3	0
MERS-CoV Glycoprotein (S1) IgG	3	0
Influenza A	19	0
Influenza B	11	0
Mycoplasma Pneumonia	8	0
Chlamydia Pneumoniae	35	0
Respiratory Syncytial Virus (RSV) IgM	4	0
Hepatitis B core antigen (HBcAg)	12	0
Hepatitis B surface antigen (HBsAg)	10	0
Hepatitis C virus (HCV) Antibody	6	0
Human Immunodeficiency Virus (HIV)	30	0
Herpes Simplex Virus (HSV) 1/2 IgG	3	0
Epstein Barr Virus Capsid Antigen (VCA) IgG	2	0
Epstein Barr Virus Nuclear Antigen-1 (EBNA-1) IgG	1	0
Toxoplasma IgG	2	0
Cytomegalovirus (CMV) IgG	2	0
Cytomegalovirus (CMV) IgM	2	0
Rubella IgG	2	0
Varicella Zoster Virus (VZV) IgG	2	0

Autoimmune disease states

Cross-reactants	Number of tested samples	Number of Positive samples
Antinuclear Autoantibodies (ANA)	10	0
SS-A/Ro 52kDa Autoantibodies	1	0
Double-Stranded Deoxyribonucleic Acid (dsDNA) IgG	2	0
Liver Kidney Microsomal Type 1 (LKM-1) IgG	2	0

14. Clinical Performance

14.3 Positive Percent Agreement (PPA)

The PPA between the IDS SARS-CoV-2 IgG assay and the PCR comparator was determined by investigating 141 samples collected from 141 subjects who tested positive for SARS-CoV-2 by an EUA-authorized polymerase chain reaction (PCR) method from nasopharyngeal swab who presented with COVID-19 symptoms.

Each specimen was tested using the IDS SARS-CoV-2 IgG assay. The results were compared to the RT-PCR results and are presented in the following table, stratified by days between the positive PCR test and the blood sample draw. The PPA point estimate and 95% confidence interval (CI) were determined by the Wilson Score method.

Days After PCR Method	Total Samples	No. Negative	No. Positive	Positive Percent Agreement (95%CI)
$\leq$ 7	43	20	23	53.5% (38.9 - 67.5)
8-14	38	0	38	100.0% (90.8 – 100.0)
$\geq$ 15	60	0	60	100.0% (94.0 - 100.0)
Total Subjects	141			N/A

A subset of the cohort contained data from onset of symptoms. These data are summarized comparing results from the IDS SARS-CoV-2 IgG to the PCR comparator, stratified by days from onset of symptoms.

Days after symptom onset	No. Subjects	No. Negative	No. Positive	Positive Percent Agreement	
				point est.	(95% CI)
≤7	23	9	14	60.9%	(40.8; 77.8%)
8–14	39	4	35	89.7%	(76.4; 95.9%)
≥15	42	1	41	97.6%	(87.7; 99.6%)
Total Subjects	104			N/A	N/A

14.4 Negative percent Agreement (NPA)

The NPA of the IDS SARS-CoV-2 IgG assay was evaluated in a study of 554 samples collected prior to December 2019 in Europe and the United States. Based on this evaluation, the overall negative percent agreement of the IDS SARS-CoV-2 IgG assay is 99.6% (552/554), with a 95% confidence interval of 98.7 - 99.9% determined by the Wilson Score method. The results are presented in the following table:

Population	Total Samples	No. Negative	No. Positive	NPA (95%CI)
Blood Donor Samples (Italy)	212	212	0	100.0% (98.2 – 100.0)
Blood Donor Samples (Germany)	64	64	0	100.0% (94.3 – 100.0)
Diagnostic Samples (Belgium)	79	79	0	100.0% (95.4 – 100.0)
Diagnostic Samples (USA)	199	197	2	99.9% (96.4 - 99.7)
Total	554	552	2	99.6% (98.7 - 99.9)

15. Symbols used

REF Catalogue Number

Manufacturer

IVD *In Vitro* Diagnostic Device

Rx Only Caution: Federal law restricts this device to sale by or on the order of a physician (Only for US)

16. Bibliography

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