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Changes: Update of Legal Manufacturer name;
Deletions: -

LIAISON® SARS-CoV-2 IgM (REF 311470)

1. INTENDED USE

The LIAISON® SARS-CoV-2 IgM uses chemiluminescence immunoassay (CLIA) technology for the qualitative determination of specific IgM antibodies to SARS-CoV-2 in human serum or plasma samples.

The assay is intended as an aid in the diagnosis of CoVID-19 and to support the study of the immune status of patients who may have been exposed to and infected by SARS-CoV-2. Results from the LIAISON® SARS-CoV-2 IgM test should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform of an infection status.

The test has to be performed on the LIAISON® XL Analyzer only.

2. SUMMARY AND EXPLANATION OF THE TEST

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus. At the end of December 2019, Chinese public health authorities reported several cases of acute respiratory syndrome in Wuhan City, Hubei province, China. The initial outbreak in Wuhan spread rapidly, affecting other parts of China. Cases were then detected in several other countries. Since late February, the majority of cases reported are from outside China, with an increasing majority of these reported from EU/EEA countries and the US. The Director General of the World Health Organization declared COVID-19 a global pandemic on 11 March 2020[1].

The causative virus of the COVID-19 is called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). It is a new strain of coronavirus that has not been previously identified in humans. It spreads primarily through contact with an infected person through respiratory droplets generated when a person coughs or sneezes, or through droplets of saliva or discharge from the nose. Infection with SARS-CoV-2 can cause mild symptoms including a runny nose, sore throat, cough and fever. However, it can be more severe for some people and can lead to pneumonia or breathing difficulties. The elderly, and people with pre-existing medical conditions (such as, diabetes and heart disease) appear to be more vulnerable to becoming severely ill with the virus. Based on previous studies on SARS, an incubation period from three to fourteen days after onset of symptoms may be expected. The WHO, in the ad interim guidance for laboratory testing, supports the development of serological assays to be used as an aid in the investigation of an ongoing outbreak and for retrospective assessment.

The incubation period for COVID-19 is thought to range from 2-14 days following exposure, with most cases showing symptoms approximately 4-5 days after exposure[2]. The interval during which an individual with COVID-19 is infectious has not yet been clearly established. Definite COVID-19 diagnosis entails SARS-CoV-2 detection by nucleic acid amplification technology (NAAT)[3, 4, 5]. Although the underlying technology for NAAT is robust and shows excellent specificity, the outcome directly depends on the viral load acquired during sampling which, among others, can vary according to the time point of infection, the individual patient, sampling method and position as well as sample preparation time.

Consequently, a non-negligible proportion of infected individuals may be missed by screenings based on symptoms and NAAT[6, 7] and thus form an important source of continued viral spread.

Serological assays can contribute to identifying individuals exposed to the virus and assessing the extent of exposure of a population, and might thereby help to decide on the application, enforcement or relaxation of containment measures[8].

Seroconversion has been observed as early as within 5 days after symptom onset for immunoglobulin M (IgM) and within 5-7 days for IgG[9, 10]. Depending on the applied method, seroconversion is observed after a median of 10-13 days after symptom onset for IgM and 12-14 days for IgG[6, 11].

As for the detection of IgG, detection of IgM antibodies against SARS-CoV-2 can be used to assess the immune status of patients affected by CoVID-19. The production of specific antibodies, particularly anti-SARS-CoV-2 IgM and IgG, should be used as an additional non-invasive method for detecting the disease, especially in patients who present late symptoms, with a low viral load.

Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease or cancer are more likely to develop serious illness.

3. PRINCIPLE OF THE PROCEDURE

The method for qualitative determination of specific IgM to SARS-CoV2 is an indirect chemiluminescence immunoassay (CLIA). A specific antigen is used for coating magnetic particles (solid phase). During the first incubation, the SARS-CoV2 IgM antibodies present in calibrators, samples or controls bind to the solid phase. During the second incubation, mouse monoclonal antibodies to human IgM linked to an isoluminol derivative (isoluminol-antibody conjugate), react with SARS-CoV2 IgM already bound to the solid phase. After each incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and indicates the presence or absence of antibodies to SARS-CoV2 present in calibrators, samples or controls.

4. MATERIALS PROVIDED

Reagent integral

Magnetic particles (2.63 mL)	SORB	Magnetic particles coated with RBD antigen (mammalian cells), BSA, phosphate buffer, < 0.1% sodium azide.
Calibrator 1 (0.6 mL)	CAL 1	BSA, Phosphate buffer, detergents, ProClin® 300, preservatives, an inert yellow dye.
Calibrator 2 (0.6 mL)	CAL 2	Anti-SARS-CoV-2 Human IgM monoclonal antibody, BSA, phosphate buffer, detergents, ProClin® 300, preservatives, an inert blue dye.
Specimen Diluent (22 mL)	DIL SPE	Goat serum to human IgG (adsorbent reagent), BSA, phosphate buffer, ProClin® 300, preservatives.
Assay Buffer (14 mL)	BUF	BSA, phosphate buffer, EDTA, detergents, ProClin® 300, preservatives, an inert yellow dye.
Conjugate (25 mL)	CONJ	Mouse monoclonal IgG to human IgM conjugated to an isoluminol derivative, BSA, phosphate buffer, non-specific IgG, ProClin® 300, preservatives.
Number of tests		110

All reagents are supplied ready to use. The order of reagents reflects the layout of containers in the reagent integral.

Materials required but not provided

LIAISON® XL Cuvettes (REF X0016).
LIAISON® XL Disposable Tips (REF X0015) or
LIAISON® Disposable Tips (REF X0055).
LIAISON® XL Starter Kit (REF 319200) or
LIAISON® EASY Starter Kit (REF 319300).
LIAISON® Wash/System Liquid (REF 319100).
LIAISON® XL Waste Bags (REF X0025).
LIAISON® XL Cleaning Tool (REF 310995) or
LIAISON® EASY Cleaning Tool (REF 310996).

Additional required materials:

LIAISON® Control SARS-CoV-2 IgM (REF 311471)

5. WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use.

Visually inspect the integral vials for leaking at the membrane seals or elsewhere. If the vials are found to be leaking, the local customer service should be notified immediately.

6. SAFETY PRECAUTIONS

Do not eat, drink, smoke or apply cosmetics during the assay. Do not pipette by mouth.

Avoid direct contact with potentially infected material by wearing laboratory clothing, protective goggles and disposable gloves. Wash hands thoroughly at the end of each assay.

Avoid splashing or forming an aerosol. All drops of biological reagent must be removed with a sodium hypochlorite solution with 0.5% active chlorine, and the means used must be treated as infected waste.

All samples and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents; the waste must be handled with care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country. Any materials for reuse must be appropriately sterilized in compliance with the local laws and guidelines. Check the effectiveness of the sterilization/decontamination cycle.

Do not use kits or components beyond the expiration date given on the label.

Pursuant to EC Regulation 1272/2008 (CLP), hazardous reagents are classified and labeled as follows:

REAGENTS:	CAL 1, CAL 2, DIL SPE, BUF, CONJ
CLASSIFICATION:	Skin sens. 1 H317
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 GHS07 Exclamation mark
HAZARD STATEMENTS:	H317 May cause an allergic skin reaction.
PRECAUTIONARY STATEMENTS:	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P363 Wash contaminated clothing before reuse.
CONTAINS: (only substances prescribed pursuant to Article 18 of EC Regulation 1272/2008).	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) (ProClin® 300).

Pursuant to EC Regulation 1272/2008 (CLP), SORB is labeled as EUH210, safety data sheets available on request.
For additional information see Safety Data Sheets available on www.diasorin.com.

7. REAGENT PREPARATION

REAGENT INTEGRAL

Please note the following important reagent handling precautions:

Resuspension of magnetic particles

Magnetic particles must be completely resuspended before the integral is placed on the LIAISON® XL Analyzer. Follow the steps below to ensure complete suspension.

Before the seal is removed, rotate the small wheel on the magnetic particle compartment until the colour of the suspension has changed to brown. Gentle and careful side-to-side mixing may assist in the suspension of the magnetic particles (avoid foam formation). Visually check the bottom of the magnetic particle vial to confirm that all settled magnetic particles have resuspended. Carefully wipe the surface of each septum to remove any residual liquid.

Repeat as necessary until the magnetic particles are completely resuspended.

An incomplete magnetic particles resuspension may cause variable and inaccurate analytical results.

Foaming of reagents

In order to ensure the optimal performance of the integral, foaming of reagents should be avoided. Adhere to the recommendation below to prevent this occurrence:

Visually inspect the reagents, in particular the calibrators (position two and three following the magnetic particle vial), to ensure there is no foaming present before using the integral. If foam is present after the resuspension of the magnetic particles, place the integral on the instrument and allow the foam to dissipate. Load the integral into the reagent area once the foam has dissipated.

Loading the integral into the reagent area

- LIAISON® XL Analyzer is equipped with a built-in solid-state magnetic device which aids the dispersal of microparticles prior to placing a reagent integral into the reagent area of the analyzer. Refer to the analyzer operator's manual for details.
  a. Insert the reagent integral into the dedicated slot.
  b. Allow the reagent integral to remain in the solid-state magnetic device for at least 30 seconds (up to several minutes). Repeat as necessary.
- Place the integral into the reagent area of the analyzer with the label facing left and let it stand for 15 minutes before using. The analyzer automatically stirs and completely resuspends the magnetic particles.
- Follow the analyzer operator's manual to load the specimens and start the run.

8. REAGENT INTEGRAL STORAGE AND STABILITY

- **Sealed**: Stable at 2-8°C until the expiry date.
- **Opened on board or at 2-8°C**: stability up to 1 week.
- Use the storage rack provided with the LIAISON® XL Analyzer for the upright storage of reagent integral.
- Do not freeze.
- Keep upright for storage to facilitate later proper resuspension of magnetic particles.
- Keep away from direct light.

9. SPECIMEN COLLECTION AND PREPARATION

The correct specimen type must be used in the assay. Following matrices have been tested and may be used:
– serum;
– sodium and lithium heparin plasma;
– potassium EDTA.

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

Centrifugation conditions of collection tubes may vary depending on the manufacturer. A minimum of 1,000 g for 10 minutes is reported. Use of centrifugation conditions should be evaluated and validated by the laboratory.

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Specimens may be shipped on dry ice (frozen), on wet ice (for 2°-8°C), following the sample storage limitations described below.

Uncontrolled transport conditions (in terms of temperature and time) may cause inaccurate analytical results. During validation studies, specimen collection tubes commercially available at the time of testing were used. Therefore, not all collection tubes from all manufacturers have been evaluated. Blood collection devices from various manufacturers may contain substances which could affect the test results in some cases (Bowen et al., Clinical Biochemistry, 43, 4-25, 2010).

A dedicated study on storage limitations was performed on serum or plasma specimens removed from clot, red cells or gel separator. The following storage conditions showed no significant differences:
– 15°-30°C for 21 hours, in any case, room temperature storage should be avoided;
– 2°-8°C for 7 days, otherwise they should be aliquoted and stored deep-frozen (–20°C or below);
– Up to 3 freeze-thaw cycles, however multiple freeze thaw cycles should be avoided.

If samples are stored frozen, mix thawed samples well before testing.

Further centrifugation of specimens removed from red cells, clot or gel separator (suggested between 3,000 and 10,000 g for 10 minutes) is recommended to guarantee the consistency of results whenever one of the following conditions is identified:
– Samples previously centrifuged and stored at 2-8°C;
– Samples with particulate matter, fibrin, turbidity, lipaemia or erythrocyte debris;
– Samples frozen and thawed;
– Samples requiring repeat testing.

Specimens with a lipid layer on the top should be transferred into a secondary tube, taking care to transfer only the clarified material.

Grossly haemolyzed or lipaemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination should not be tested. Heat inactivation of the specimens may affect the test results. Check for and remove air bubbles before assaying.

The minimum volume required for a single determination is 164 µL of specimen (14 µL specimen + 150 µL dead volume).

10. CALIBRATION

Testing of assay specific calibrator allows the detected relative light unit (RLU) values to set the cut-off.

Each calibration solution allows 4 calibrations to be performed.

Recalibration in triplicate is mandatory whenever at least one of the following conditions occurs:
– A new lot of Starter Kit is used.
– The previous calibration was performed more than 1 week before.
– Each time a new lot of integral is used.
– The analyzer has been serviced.
– Control values lie outside the expected ranges.

11. ASSAY PROCEDURE

Strict adherence to the analyzer operator's manual ensures proper assay performance. Each test parameter is identified via information encoded in the reagent integral Radio Frequency IDentification transponder (RFID Tag). In the event that the RFID Tag cannot be read by the analyzer, the integral cannot be used. Do not discard the reagent integral; contact your local DiaSorin technical support for instructions.

The analyzer operations are as follows:
1. Dispense specimens (calibrator or control), coated magnetic particles, specimen diluent and assay buffer into the reaction cuvettes
2. Incubate and wash
3. Dispense the Conjugate into the reaction cuvettes
4. Incubate and wash
5. Add the Starter Reagents and measure the light emitted.

Warning - Maintenance with the LIAISON® XL Cleaning Tool (REF 310995) or LIAISON® EASY Cleaning Tool (REF 310996) must be performed (refer to pertinent instruction for use for details).

12. QUALITY CONTROL

LIAISON® controls should be run in singlicate to monitor the assay performance. Quality control must be performed by running LIAISON® SARS-CoV-2 IgM controls
(a) at least once per day of use, before running the test,
(b) whenever the kit is calibrated,
(c) whenever a new lot of Starter Reagents is used, or in agreement with guidelines or requirements of local regulations or accredited organizations.

Control values must lie within the expected ranges: whenever one or both controls lie outside the expected ranges, calibration should be repeated and controls retested. If the control values obtained after successful calibration lie repeatedly outside the predefined ranges, the test should be repeated using an unopened control vial. If control values lie outside the expected ranges, patient results must not be reported.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate value ranges should then be established for quality control materials used.

13. INTERPRETATION OF RESULTS

The analyzer automatically calculates SARS-CoV-2 IgM antibodies concentrations expressed as an Index value and grades the results. Do not dilute specimens before testing. For details, refer to the analyzer operator's manual.

Sample results should be interpreted as follows:

LIAISON® SARS-CoV-2 IgM assay		
Index	**Results**	**Rules and interpretation**
< 1.10	Negative	A result below the 1.10 Index may indicate the absence or level of IgM antibodies to SARS-CoV-2 below the threshold. The test could score negative in patients during the incubation period and in the early stages of infection.
≥ 1.10	Positive	A result above or equal to the 1.10 Index generally indicates exposure of the subject to SARS-CoV-2.

14. LIMITATIONS OF THE PROCEDURE

Assay performance characteristics have not been established when any LIAISON® SARS-CoV-2 IgM test is used in conjunction with other manufacturers' assays for the detection of specific SARS-CoV-2 serological markers. Under these conditions, users are responsible for establishing their own performance characteristics.

A skillful technique and strict adherence to the instructions are necessary to obtain reliable results. Bacterial contamination or heat inactivation of the specimens may affect the test results.

The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.

Performance has not been established for the use of cadaveric specimens or the use of bodily fluids other than human.

The combination of LIAISON® IgM and IgG test and clinical data is recommended when the diagnosis of COVID-19 is based on a single specimen. A single result may not be sufficient for diagnosis.

15. SPECIFIC PERFORMANCE CHARACTERISTICS

15.1. Analytical specificity

Analytical specificity may be defined as the ability of the assay to accurately detect specific analyte in the presence of potentially interfering factors in the sample matrix (e.g., anticoagulants, haemolysis, effects of sample treatment), or cross-reactive antibodies.

Interference.
Controlled studies of potentially interfering substances show ed no interference to each substance listed below in the LIAISON® SARS-CoV-2 IgM assay, at the indicated concentration.

Substances	Tested concentrations
Biotin	3500 ng/mL
Triglycerides	3000 mg/dL
Hemoglobin	1000 mg/dL
Unconjugated bilirubin	40 mg/dL
Conjugated bilirubin	40 mg/dL
Cholesterol total	500 mg/dL
Paracetamol	500 mg/L
Ibuprofen	500 mg/L
Total Protein (high)	≥ 120 g/L
Total Protein (low)	≤ 60 g/L
Total IgM	5.5 mg/dL

Cross-reactions.
The cross-reactivity study for the LIAISON® SARS-CoV-2 IgM assay was designed to evaluate potential interference from antibodies to other viruses that may cause symptoms similar to SARS-CoV-2 infection, other organisms that may cause infectious diseases, as well as from other conditions that may result from atypical immune system activity. Samples for the evaluation were collected before October 2019, prior to the SARS-CoV-2 pandemic. 3 specimens out of 180 assessed specimens resulted Positive with the LIAISON® SARS-CoV-2 IgM assay. The observed specificity for potentially cross-reactive specimens is comparable to that of open populations.

Condition	Number of tested samples	LIAISON® XL Positive results
Anti-nuclear auto-antibodies (ANA)	10	0
Anti-HBV	10	0
Anti-HCV	10	0
Anti-Influenza A	10	0
Anti-Influenza B	10	0
Anti-respiratory syncytial virus	10	0
Anti-Mycoplasma pneumoniae	10	1
HAMA	10	1
Anti-Chlamydia pneumoniae	10	0
Mycobacterium tuberculosis	10	0
Anti-Borrelia Burgdorferi	10	0
Anti-CMV	10	0
Anti-EBV	10	0
Anti-HSV 1/2	10	1
Anti-Parvovirus B19	10	0
Rheumatoid factor	10	0
Anti-Rubella Virus	10	0
Anti-VZV	10	0
Total	180	3

15.2. Precision

A five-day precision study was performed by using a coded panel of 6 samples prepared by either spiking or diluting samples as necessary to obtain negative, low positive and moderate positive samples. Kit Controls sets were also included in the study. The panel samples and kit controls were tested with the LIAISON® SARS-CoV-2 IgM assay in 6 replicates per run, 3 runs per day for 5 operating days on one LIAISON® XL Analyzer, on 1 kit lot. The CLSI document EP5-A3 was consulted in the preparation of the testing protocol.

Data	N	Mean (Index)	Within run		Between run		Between day		Overall	
			SD	CV %	SD	CV %	SD	CV %	SD	CV %
CONTROL Neg	90	0.057	0.004	6.8	0.002	4.3	0.002	4.2	0.005	9.0
CONTROL Pos	90	3.05	0.070	2.3	0.084	2.7	0.119	3.9	0.161	5.3
CONTROL Pos	90	2.75	0.063	2.3	0.047	1.7	0.116	4.2	0.141	5.1
COVM-1-U1	90	0.861	0.038	4.4	0.039	4.5	0.041	4.8	0.068	7.9
COVM-1-U2	90	0.869	0.042	4.8	0.040	4.6	0.024	2.8	0.062	7.2
COVM-1-U3	90	1.71	0.073	4.3	0.040	2.3	0.063	3.7	0.105	6.1
COVM-1-U4	90	1.99	0.069	3.5	0.033	1.6	0.061	3.1	0.098	4.9
COVM-1-U5	90	4.12	0.154	3.7	0.162	3.9	0.125	3.0	0.256	6.2
COVM-1-U6	90	4.7	0.117	2.5	0.130	2.8	0.143	3.0	0.226	4.8

The results refer to the groups of samples investigated and are not guaranteed specifications, as differences may exist between laboratories and locations.

16. SUMMARY OF CLINICAL PERFORMANCE

The results refer to the groups of samples investigated and are not guaranteed specifications, as differences may exist between laboratories and locations.

16.1. Diagnostic sensitivity

The sensitivity was determined by investigating 268 samples collected over the course of time from 223 European patients. Infection with SARS-CoV-2 was confirmed by RT-PCR test at the time of the diagnosis.

The LIAISON® SARS-CoV-2 S1/S2 IgG and LIAISON® SARS-CoV-2 IgM tests were performed on samples collected at the time of admission and thereafter up to 30 days. The group included patients hospitalized with moderate symptoms, patients admitted to the ICU with severe symptoms and patients not hospitalized without or with mild symptoms.

The following table describes LIAISON® SARS-CoV-2 IgM diagnostic sensitivity in three groups, i. e. the early samples (≤ 7 days after diagnosis), the samples between 8 and 14 days after diagnosis, and the later samples (15 – 30 days after diagnosis).

	LIAISON® SARS-CoV-2 IgM		Total	Sensitivity (Wilson 95% CI)
	< 1.10 Index	≥ 1.10 Index		
≤ 7 days	37	68	105	64.8% (55.3% - 73.2%)
8-14 days	4	43	47	91.5% (80.1% - 96.6%)
15-30 days	7	109	116	94.0% (88.1% - 97.1%)

The percentage of positive findings between 30 and 81 days was determined by investigating 180 samples collected from 121 European patients resulting in 72.8% (95% CI: 65.9% - 78.8%).

Combined sensitivity performance of LIAISON® SARS-CoV-2 S1/S2 IgG and LIAISON® SARS-CoV-2 IgM assays is shown in the following table.

	Number of LIAISON® IgG and/or IgM Positive results	Sensitivity (Wilson 95% CI)
≤ 7 days	73 / 105	69.5% (60.2% - 77.5%)
8-14 days	43 / 47	91.5% (80.1% - 96.6%)
15-30 days	114 / 116	98.3% (93.9% - 99.5%)

16.2. Diagnostic specificity

2473 presumed SARS-CoV-2 negative samples collected before the COVID19 outbreak from a European laboratory routine (n=1072), a US laboratory routine (n=400) and European blood donors (n= 1001) were tested with LIAISON® SARS-CoV-2 IgM assay resulting in 99.3% clinical specificity (2455 / 2473, 95% CI: 98.9% – 99.5%).

The following table shows the results with LIAISON® SARS-CoV-2 IgM assay:

	LIAISON® SARS-CoV-2 IgM		Total	Specificity (Wilson 95% CI)
	< 1.10 Index	≥ 1.10 Index		
US Laboratory routine	398	2	400	99.5% (98.2% - 99.9%)
European Laboratory routine	1063	9	1072	99.2% (98.4% - 99.6%)
Blood donors	994	7	1001	99.3% (98.6% - 99.7%)

A total of 500 presumed SARS-CoV-2 negative samples were tested with LIAISON® SARS-CoV-2 S1/S2 IgG and LIAISON® SARS-CoV-2 IgM assays resulting in 99.2% combined clinical specificity (496 / 500, 95% CI: 98.0% – 99.7%).

16.3. SARS-CoV-2 variants detection

A panel of twenty-two (22) serum/plasma specimens from UK, collected from nineteen (19) patients diagnosed for COVID-19 by RT-PCR, and infected by virus variants (as demonstrated by sequencing) was tested with the LIAISON® SARS-CoV-2 IgM to assess the performance of the assay. Serum/plasma specimens were collected between 15 and 34 days from the date of onset of symptoms. All 22 specimens were successfully detected with LIAISON® SARS-CoV-2 IgM assay.

Lineage	**Number of specimens**	**Positive result by LIAISON® SARS-CoV-2 IgM**	**Diagnostic Sensitivity and Wilson 95% CI**
B.1.1.7	22	22	100% (95% CI: 85.1 – 100%)

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200/008-030, 05 - 2022-07