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Changes: §1, §5, §12, §13, §15;
Deletions: -

LIAISON® SARS-CoV-2 Ag ([REF] 311500)
For Emergency Use Authorization Only.
This product has not been FDA cleared or approved.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner.
For *in vitro* diagnostic use.

1. INTENDED USE

The LIAISON® SARS-CoV-2 Ag assay uses chemiluminescence immunoassay (CLIA) technology intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in nasopharyngeal swab (NPS) when collected by a healthcare provider in COPAN Universal Transport Media (UTM) and direct anterior nasal swab specimens (NS) without transport media, in symptomatic individuals suspected to have COVID-19 by their healthcare provider within the first ten days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests.

LIAISON® SARS-CoV-2 Ag assay does not differentiate between SARS-CoV, SARS-CoV-2, or MERS-CoV.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal swabs and nasopharyngeal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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

The LIAISON® SARS-CoV-2 Ag is intended for use by trained clinical laboratory personnel specifically instructed and trained in *in vitro* diagnostic procedures and proper infection control procedures. In the United States, The LIAISON® SARS-CoV-2 Ag is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

2. SUMMARY AND EXPLANATION OF THE TEST

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus.

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.

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[(1)].

This test identifies the presence of the SARS-CoV-2 in the specimen through the detection of nucleocapsid protein antigen. This antigen is generally detectable in anterior nasal swabs and nasopharyngeal swabs during the acute phase of infection.

3. PRINCIPLE OF THE PROCEDURE

The method for qualitative determination of SARS-CoV-2 Ag in specimens collected and processed through the indicated pre-analytical procedure, is a direct two-step sandwich chemiluminescence immunoassay (CLIA). Specific rabbit polyclonal antibodies to nucleocapsid antigen are used for coating magnetic particles (solid phase) and linked to an isoluminol derivative (isoluminol-antibody conjugate). During the first incubation, SARS-CoV-2 viral antigen present in calibrators, samples or controls binds to the conjugate. During the second incubation, the solid phase reacts with the SARS-CoV-2 viral antigen already bound to the conjugate. After the second 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 in relative light units (RLU) and indicates the presence or absence of the SARS-CoV-2 Ag in calibrators, samples or controls.

4. MATERIALS PROVIDED

Reagent integral

Magnetic particles (2.5 mL)	[SORB]	Magnetic particles coated with rabbit polyclonal to SARS-CoV-2 nucleocapsid antigen, BSA, phosphate buffer, < 0.1% sodium azide.
Calibrator 1 (1.8 mL)	[CAL|1]	Antiseptic agent, Recombinant nucleoprotein (from *E.coli*), BSA, detergents.
Calibrator 2 (1.8 mL)	[CAL|2]	Antiseptic agent, Recombinant nucleoprotein (from *E.coli*), BSA, detergents, an inert blue dye.
Specimen Diluent (19 mL)	[DIL|SPE]	BSA, phosphate buffer, detergents, ProClin® 300, preservatives, an inert yellow dye.
Conjugate (13 mL)	[CONJ]	Rabbit polyclonal to SARS-CoV-2 nucleocapsid antigen conjugated to an isoluminol derivative, human serum, BSA, phosphate buffer, detergents, ProClin® 300, preservatives.
Number of tests		100

All reagents are supplied ready to use. The order of reagents reflects the layout of containers in the Reagent Integral.
ProClin® is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

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).

Additional required materials:

LIAISON® Control SARS-CoV-2 Ag ([REF] 311501).
LIAISON® SARS-CoV-2 Sample Inactivation Buffer ([REF] 311502)

5. WARNINGS AND PRECAUTIONS

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
  For *in vitro* diagnostic use. For prescription use only.
- For professional use only.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.
- This product has been authorized only for the detection of proteins from 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. § 360bbb3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**.
- This test is more likely to give you a false negative result when you have COVID-19 than a laboratory-based molecular test.
- All human serum and plasma units used to produce the components provided in this kit have been tested for the presence of HBsAg, anti-HCV, anti-HIV-1, anti-HIV-2, and found to be non-reactive. However, as no test method can offer absolute assurance that pathogens are absent, all specimens of human origin should be considered potentially infectious and handled with care.
- Use appropriate precautions in the collection, handling and storage of patient samples. Refer to CDC Interim Guidelines for Collection, Handling and Transportation of clinical specimens from persons with Coronavirus Disease 2019 (COVID-19) at https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html, and to WHO's Interim guidance for Laboratory testing for coronavirus disease (COVID -19) in suspected human cases at http://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117, as amended and supplemented. Refer to the WHO website for additional publications.
- Used swabs must be treated as infectious waste.
- All samples, **even after the pre-analytical inactivation procedure**, and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents; accordingly samples, reagents and the waste must be handled with utmost care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country.
- Do not use the kit contents beyond the expiration date.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
- For sample handling please refer to Section 8 - Specimen Collection and Preparation
- Observe the normal precautions required for handling all laboratory reagents.
- Do not eat, drink, smoke or apply cosmetics during the assay.
- Do not pipette by mouth.
- Strict adherence to the LIAISON® SARS-CoV-2 Ag assay instructions is necessary to obtain accurate results.
- Avoid direct contact with potentially infectious substances by wearing appropriate personal protective equipment such as laboratory

coats, goggles, and disposable gloves. Wash hands thoroughly after removal of gloves.

- Avoid splashing or aerosolization of samples or reagents as droplets are a means of transmission of SARS-CoV-2 virus. All drops and spills must be wiped up with an appropriate disinfectant such as a sodium hypochlorite solution with 0.5% active chlorine, and all soiled materials must be disposed of as infectious waste.
- Visually inspect the integral vials for leaks at the membrane seals or elsewhere. If the vials are found to be leaking, discard them and the local customer service should be notified immediately.
- All waste associated with biological samples, biological reagents and disposable materials used for the assay must be considered potentially infectious and therefore should be disposed of in accordance with the national, state or local regulations and guidelines of the agencies holding jurisdiction over the laboratory.
- The LIAISON® XL Analyzer should be cleaned and decontaminated on a routine basis. See the LIAISON® XL Analyzer Operator's Manual for the cleaning and decontamination procedures.
- Previously frozen test samples, once thawed, must be thoroughly mixed prior to testing.
- Do not pool the contents of different vials of the same reagent (even if the reagents are from the same lot). Calibrators are also lot-specific and cannot be shared between kits.
- Do not use kits or components beyond the expiration date indicated on the label.

Chemical Hazard and Safety Information
Reagents in this kit are classified in accordance with the US OSHA Hazard Communication Standard; individual US State Right-to-Know laws; Canadian Centre for Occupational Health and Safety Controlled Products Regulations; and European Union EC Regulation 1272/2008 (CLP) (for additional information see Safety Data Sheet available on www.diasorin.com).

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

REAGENTS:	[DIL|SPE], [CONJ]
CLASSIFICATION:	Skin sens. 1 H317 Aquatic chronic 3 H412
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 GHS07 Exclamation mark
HAZARD STATEMENTS:	H317 May cause an allergic skin reaction. H412 Harmful to aquatic life with long lasting effects.
PRECAUTIONARY STATEMENTS:	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P273 Avoid release to the environment; P362 Take off contaminated clothing and wash 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).

Reagent containing sodium azide (Magnetic Particles [SORB])

Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Immediately after disposal,flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts", in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control and Preventions, Atlanta, GA, 1976.

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.

6. REAGENT PREPARATION

REAGENT INTEGRAL

Please note the following important reagent handling precautions:

Resuspension of magnetic particles

Magnetic particles must be completely resuspended before the Reagent Integral is placed on the LIAISON® XL Analyzer. Follow the steps below to ensure complete resuspension:

– Before the seal is removed, rotate the small wheel at the magnetic particle vial compartment until the color of the suspension has changed to brown.
– Gentle and careful side-to-side mixing may assist in the resuspension of the magnetic particles (avoid foam formation).
– Visually check the bottom of the magnetic particle vial to confirm that all settled magnetic particles have been resuspended.
– Carefully wipe the surface of each septum to remove residual liquid.
– Repeat all steps as necessary until the magnetic particles are completely resuspended.

Foaming of Reagents

In order to ensure optimal performance of the Reagent Integral, foaming of all reagents should be avoided. Follow the steps below to prevent foaming of reagents:

– Visually inspect the reagents, calibrators in particular (located in position two and three following the magnetic particle vial), to ensure there is no foaming present before using the Reagent Integral.
– If foam is present after resuspension of the magnetic particles, place the integral on the LIAISON® XL Analyzer and allow

the foam to dissipate.
– The Reagent Integral is ready for use once the foam of all reagents has dissipated and the integral is positioned onboard the LIAISON® XL Analyzer and mixing.

CONTROLS

Refer to the LIAISON® Control SARS-CoV-2 Ag Instructions for Use section for proper preparation and handling instructions.

7. 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 analyzer for the upright storage of the Reagent Integral.
– Do not freeze.
– Keep upright for storage to facilitate later proper resuspension of the magnetic particles.
– Keep away from direct light.

8. SPECIMEN COLLECTION AND PREPARATION

Acceptable specimen types include:

– Dry Nasal swab (NS) without transport media processed following the below indicated pre-analytical procedure.

– Nasopharyngeal Swab (NPS) transported in Copan Universal Transport Media (UTM), then processed following the pre-analytical procedure indicated below.

WARNING: for the collection and handling of swab specimens from the upper and lower respiratory tract, refer to the CDC Interim Guidelines for Collection, Handling and Transportation of clinical specimens from persons with Coronavirus Disease 2019 (COVID-19), and to the WHO's Interim guidance for Laboratory testing for coronavirus disease (COVID-19) in suspected human cases at http://www.who.int/publications-detail/laboratory-testing-for-2019- novel-coronavirus-in-suspected-human-cases-20200117, as amended and supplemented. Refer to the WHO website for additional publications.

PRE-ANALYTICAL PROCEDURE WORKFLOW FOR DRY ANTERIOR NASAL SWAB

1. Collect the sample by anterior nasal swab and place it dry into its container.
2. Dry swab placed into the container can be stored for up to 3 hours at room temperature (15-25°C) or 6 hours at 2°-8°C, prior to transferring the sample into the inactivation buffer.
3. All the following pre-analytical steps should be performed at room temperature (15°-25°C) using the universal precautions for handling potentially infectious specimens.
4. All clinical samples and reagents must be at room temperature (15°-25°C) before beginning the next step of the procedure.
5. Place and soak the swab in the pre-filled tube containing the LIAISON® SARS-CoV-2 Sample Inactivation Buffer ([REF] 311502).
6. Roll the swab at least 5 times while pressing the head against the bottom and side of the tube.
7. Leave the swab in the tube with the Sample Inactivation Buffer for at least 1 minute.
8. Roll the head of the swab at least 5 times against the inside wall of the tube and remove it.
9. Dispose of the used swab in the biohazardous waste collection.
10. Cap the tube and incubate for at least 120 minutes before handling it.
    Warning: Ensuring that the incubation time lasts at least 120 minutes is essential to properly manage the virus inactivation process and reduce the risk of potential infection. The Laboratory is responsible for the proper recording of this inactivation timing for each of the specimens. Samples that have undergone the pre-analytical inactivation process should be handled and disposed of as though they were potentially infectious.
11. Remove the cap and place the tube on board the instrument for testing. Samples should be tested as soon as possible after the completion of the pre-analytical procedure. If immediate testing is not possible, inactivated samples can be stored at 2°-8°C for up to 6 days, or at -20°C or colder for up to 1 month prior to testing. If samples are stored frozen, mix thawed samples well before testing. Frozen samples can undergo up to three freeze/thaw cycles without experiencing any change in performance. Samples after thawing may require centrifugation (i.e. 3,000g x 10') before testing.

PRE-ANALYTICAL PROCEDURE WORKFLOW FOR NASOPHARYNGEAL SWAB IN UNIVERSAL TRANSPORT MEDIUM (UTM)

1. Collect the sample by nasopharyngeal swab (not provided in the kit) transported in UTM.
2. Nasopharyngeal swab in UTM can be stored for up to 3 hours at room temperature (15-25°C) or 12 hours at 2°-8°C, prior to transferring the sample into the inactivation buffer.
3. All the clinical samples and reagents must be at room temperature (15°-25°C) before beginning the next step of the procedure.

4. All following pre-analytical steps should be performed at room temperature (15°-25°C) using universal precautions for handling potentially infectious specimens.

5. Add 1 mL of the specimen eluted in UTM into the tube containing the Sample Inactivation Buffer ([REF] 311502).

6. Cap the tube and mix the specimen by vortex for 5 - 10 sec.

7. Incubate the tube at RT for at least 120 minutes before handling it.
Warning: Ensuring that the incubation time lasts at least 120 minutes is essential to properly manage the virus inactivation process and reduce the risk of potential infection. The Laboratory is responsible for the proper recording of this inactivation timing for each of the specimens . Samples that have undergone the pre-analytical inactivation process should be handled and disposed of as though they were potentially infectious.

8. Remove the cap and place the tube on board the instrument for testing. Samples should be tested as soon as possible after the completion of the pre-analytical procedure. If immediate testing is not possible, inactivated samples can be stored at 2°-8°C for up to 5 days or at -20°C or colder for up to 1 month prior to testing. If samples are stored frozen, mix thawed samples well before testing. Frozen samples can undergo up to one freeze/thaw cycles without experiencing any change in performance. Freshly collected specimens or samples after thawing, may require centrifugation (i.e. 3,000g x 10') before testing.

Inadequate sample collection, handling, storage or transport may yield erroneous results.

For both procedures, the minimum volume required for a single determination is 400 µL of the inactivated specimen (100 µL inactivated specimen + 300 µL dead volume).

9. CALIBRATION

By testing the assay specific calibrator, the detected relative light unit (RLU) values can adjust the assigned master curve.

Each calibration solution is sufficient for performing four (4) calibrations.

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.

LIAISON® XL Analyzer: Calibrator values are stored in the Reagent Integral Radio Frequency IDentification transponder (RFID Tag).

10. 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 the specimens (calibrator or control) and conjugate into the reaction cuvettes
2. Incubate
3. Dispense the Specimen Diluent and magnetic particles into the reaction cuvettes
4. Incubate and wash
5. Add the Starter Reagents and measure the light emitted.

11. QUALITY CONTROL

The LIAISON® Control SARS-CoV-2 Ag ([REF] 311501) is recommended for the determination of quality control requirements for this assay and should be run in singlicate to monitor the assay performance.

Quality control is recommended once per day of use, or in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control procedures. It is recommended the user refer to CLSI document C24-A3 and 42 CFR 493.1256(c) for guidance on appropriate quality control practices [7].

The range of concentrations of each control is reported on the certificate of analysis and indicates the limits established by DiaSorin for control values that can be obtained in reliable assay runs.

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

Quality control could be performed by running the LIAISON® Control SARS-CoV-2 Ag:
– at least once per day of use,
– whenever the kit is calibrated,
– whenever a new lot of Starter Reagents is used.

Control values must lie within the expected ranges: whenever one of the controls lies outside the expected ranges, calibration should be repeated and the controls retested. If control values obtained after successful calibration repeatedly lie 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.

12. INTERPRETATION OF RESULTS

The analyzer automatically calculates results expressed as arbitrary units (AU) up to 10^5 AU and grades the results as negative

or positive. For details, refer to the analyzer operator's manual.
Numerical results should not be reported to health care providers.

Sample results should be interpreted as follows:

LIAISON® SARS-CoV-2 Ag assay		
AU	**Result**	**Rules and interpretation**
< 200.00	Negative	A result below 200 AU may indicate the absence of SARS-CoV-2 antigen in the specimen or the detection of antigen concentration below the established limit of detection.
≥ 200.00	Positive	A result above or equal to 200 AU generally indicates presence of the SARS-CoV-2 antigen in the specimen.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Interpretation
With Symptoms	Positive	N/A	Positive for COVID-19
	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Negative Results:

To increase the chance that the negative result for COVID-19 is accurate, you should:
· Test again in 48 hours if the individual has symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Positive Results:
Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the LIAISON® SARS-CoV-2 Ag test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

A failure to follow the indicated pre-analytical procedures may adversely affect the test performance.

13. LIMITATIONS

1. The performance of this device has not been assessed in a population vaccinated against COVID-19.
2. This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
3. Performance has not been established for use with specimens other than direct nasal swabs or NP swabs stored in COPAN UTM. Other specimen types have not been evaluated and should not be used with this assay.
4. For NP swabs stored in COPAN UTM, performance was established using a limited number of UTM lots and may differ due to lot-to-lot variability.
5. Only qualitative results should be reported. Semi-quantitative numerical results have not been clinically or analytically validated and may not correlate with patient disease status, duration of illness or severity of illness. Semi-quantitative results have not been demonstrated to correlate with the success or failure of any therapeutic interventions and should not be used

to guide clinical management.

6. Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
7. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2021 and June 2021. 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.
8. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
9. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
10. A false negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
11. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
12. If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
13. Incorrect test results may occur if a specimen is incorrectly collected or handled.
14. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
15. A skillful technique and strict adherence to the instructions are necessary to obtain reliable results.
16. Bacterial contamination or heat inactivation of the specimens may affect the test results.
17. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. In this case, direct testing for the SARS-CoV-2 virus (e.g. PCR testing) should be considered.
18. Positive results do not rule out co-infections with other pathogens.
19. Positive test results do not differentiate between SARS-CoV-2, SARS-CoV, or MERS-CoV.

Conditions of Authorization for the Laboratory
The LIAISON® SARS-CoV-2 Ag Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labelling 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 or at www.diasorin.com.

Authorized laboratories using the LIAISON® SARS-CoV-2 Ag ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

A. 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.
B. Authorized laboratories using your product must use your product as outlined in the Instructions for Use. 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 your product are not permitted.
C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to runyour product prior to initiating testing.
D. 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.
E. Authorized laboratories must 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 DiaSorin Inc. (via DiaSorin Italia S.p.A. or DiaSorin Inc. at www.diasorin.com) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of your product of which they become aware.
F. 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.
G. DiaSorin 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 FDAfor 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."

14. SPECIFIC PERFORMANCE CHARACTERISTICS

14.1. 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- reactants.

Endogenous and Exogenous substances Interference

Interfering substance	Active Ingredient	Concentration
Whole Blood	Blood	4%
Mucin	Mucin Protein	0.5%
Sore Throat Spray	Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Nasal Gel	Naso GEL (NeilMed)	5% v/v
Nasal Spray 1	CVS Nasal Drops (Phenylephrine)	15% v/v
Nasal Spray 2	Afrin (Oxymetazoline)	15% v/v
Nasal Spray 3	CVS Nasal Spray (Cromolyn)	15% v/v
Homeopathic Cold Remedy	Zicam	5% v/v
Nasal wash	Homeopathic (Alkalol)	1:10 dilution
Anti-Bacterial system	Tobramycin	4 µg/mL
Antibacterial	Mupirocin	7.5 mg/mL
Nasal Spray 4	Fluticasone Propionate	5% v/v
Anti viral drug	Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Sore Throat Phenol Spray	Chloraseptic (Phenol)	15% v/v

Cross-reactivity and Interference by microorganisms and viruses

A cross-reactivity and potential interference study for the LIAISON® SARS-CoV-2 Ag assay was evaluated by testing various microorganisms and viruses with the LIAISON® SARS-CoV-2 Ag assay. Each organism and virus was tested in triplicate in the absence or presence of inactivated SARS-CoV-2. The tested concentration of the microorganisms and viruses are documented in the Table below.

Virus / Micro-organism	Concentration tested	Cross-reactive result (Contains Virus/Micro-organism under evaluation)	Interference result (Contains Virus/Micro-Organism under evaluation and inactivated SARS-CoV-2)
Adenovirus	10^5 PFU/Ml	Negative	Positive
Coronavirus 229E	10^5 PFU/mL	Negative	Positive
Coronavirus NL63	10^4 PFU/mL	Negative	Positive
Coronavirus OC43	10^4 PFU/mL	Negative	Positive
Enterovirus 68	10^5 PFU/mL	Negative	Positive
hMPV	10^5 PFU/mL	Negative	Positive
Influenza A H1N1	10^5 PFU/mL	Negative	Positive
Influenza A H3N2	10^5 PFU/mL	Negative	Positive
Influenza B	10^4 PFU/mL	Negative	Positive
MERS Coronavirus*	0,0595 mg/mL	Positive	Positive
Parainfluenza Virus Type 1	10^5 PFU/mL	Negative	Positive
Parainfluenza Virus Type 2	10^5 PFU/mL	Negative	Positive
Parainfluenza Virus Type 3	10^5 PFU/mL	Negative	Positive
Parainfluenza Virus Type 4b	10^4 PFU/mL	Negative	Positive
Respiratory Syncytial Virus	10^5 PFU/mL	Negative	Positive
Rhinovirus	10^5 PFU/mL	Negative	Positive
SARS Coronavirus**	N/A**	Negative	Positive
Bordetella pertussis	10^6 CFU/mL	Negative	Positive
Candida albicans	10^6 CFU/mL	Negative	Positive
Chlamydia pneumoniae	10^6 CFU/mL	Negative	Positive
Haemophilus influenzae	N/A**	Negative	Positive
Legionella pneumophila	10^6 CFU/mL	Negative	Positive
Mycobacterium tuberculosis	10^4 CFU/mL	Negative	Positive
Mycoplasma pneumoniae	10^5 CFU/mL	Negative	Positive
Pneumocystis Carinii	5x 10^6 nuclei/mL	Negative	Positive
Staphylococcus aureus	10^6 CFU/mL	Negative	Positive
Staphylococcus epidermidis	10^6 CFU/mL	Negative	Positive
Streptococcus pneumoniae	10^4 CFU/mL	Negative	Positive
Streptococcus pyogenes	10^4 CFU/mL	Negative	Positive
Staphylococcus epidermidis	10^6 CFU/mL	Negative	Positive
Pooled Human Nasal Wash	N /A*	Negative	Positive

* Material was not quantified; therefore no tested concentration can be reported. The material was tested at a dilution of 1:20.Positive results do not differentiate between SARS-CoV-2 and MERS-CoV.

** The concentration of SARS-CoV tested is unknown. However, the in silico comparison between SARS-CoV-2 nucleocapsid protein and SARS-CoV shows high degree of homology and suggests cross-reactivity.

In silico analysis using the Basic Local Alignment Search Tool (BLAST) was carried out to assess the protein sequence homology and to estimate the likelihood of cross-reactivity with SARS-CoV-2 virus with organisms that were not available for wet testing. No protein sequence homology was found between *Pneumocystis jirovecii* or HCov-HKU1, however cross-reactivity cannot be ruled out.

14.3 Hook effect

The LIAISON® SARS-CoV-2 Ag assay was tested with a high concentration inactivated clinical sample (>10^5 $TCID_{50}$/mL) and no high-dose hook effect was observed across the assay range.

14.4. Limit of Detection (LoD)

The LoD was determined by evaluating different dilutions of heat inactivated SARS-CoV-2 virus added to pooled nasal wash.

Nasal swabs

50 µL of the viral particle solution was added to dry swabs and the swabs were then placed into 1 mL of inactivation buffer. The inactivation buffer with eluted viral particles was tested repeatedly using the LIAISON SARS-CoV-2 Ag test (n=20).

Nasopharyngeal swab

50 µL of the viral particle solution was added to dry swab and the swab was then placed into 3 mL of the transport media (UTM). The transport media with eluted viral particles was then diluted 1:1 with inactivation buffer and tested repeatedly using the LIAISON® SARS-CoV-2 Ag test (n=20).

Limit of Detection (LoD) is defined as the lowest virus concentration at which a minimum of 19 replicates out of 20 generate a Positive result. Results are reported in the following table.

Swab type	LoD ($TCID_{50}$/mL)	LoD ($TCID_{50}$/Swab)
Dry Nasal swab collected using CLASSIQswab™	300	15
Dry Nasal swab collected using FLOQswab™	300	15
Nasopharyngeal Swab collected using FLOQswab™ minitip	575	29

15. SUMMARY OF CLINICAL PERFORMANCE

Patient Demographics

Patient demographics (by age and gender) are available for the samples used in the studies.
The patient positivity breakdown based on age of the patient:

	LIAISON® SARS-CoV-2 Ag Anterior Nasal swabs (n= 399)			LIAISON® SARS-CoV-2 Ag Nasopharyngeal swabs (n= 373)		
Age	Total #	Total Positive	Prevalence	Total #	Total Positive	Prevalence
≤ 5 years	2	0	N/A	0	0	N/A
6 to 21 years	55	1	1.8%	37	0	0.0%
22 to 59 years	238	20	8.4%	206	15	7.3%
≥ 60 years	81	8	9.9%	69	2	2.9%
unknown	23	0	0.0%	61	12	19.7%

Anterior Nasal swabs

The clinical performance of the LIAISON® SARS-CoV-2 Ag test was evaluated with a total of 399 anterior nasal swab samples collected between April 2021 and June 2021 from individual subjects during the COVID-19 pandemic. Specimens were collected from 2 different vendors (in the US) and 2 clinical centers (in Europe) from symptomatic patients suspected of COVID-19. Nasal swabs were collected and eluted in Sample Inactivation Buffer ([REF] 311502) and tested fresh. Samples were tested with LIAISON® SARS-CoV-2 Ag accordingly to the assay procedure. All subjects were confirmed as positive (≤10 days from onset of symptoms) or negative by a reference high sensitivity extracted EUA RT-PCR method, used as comparator method for the study. All testing was conducted by operators blinded to the reference RT-PCR result, which was conducted on NP swabs collected as part of the standard of care testing.

		Reference extracted RT-PCR assay		
		POS	NEG	Total
LIAISON® SARS-CoV-2 Ag on nasal swabs	POS	27	2	29
	NEG	5	365	370
	Total	32	367	399

Positive Percentage Agreement (Sensitivity): 27/32 (84.4%, Wilson 95% CI: 68.2 – 93.1%).
Negative Percentage Agreement (Specificity): 365/367 (99.5%, Wilson 95% CI: 98.0 – 99.9%).

Positive results broken down by days since symptom onset.

Days Since Onset of Symptoms	Cumulative RT-PCR Positive (+)	Cumulative LIAISON® Positive (+)	PPA
0	2	2	100%
1	4	4	100%
2	4	4	100%
3	7	7	100%
4	10	10	100%
5	14	14	100%
6	22	20	90.9%
7	29	24	82.8%
8	30	25	83.3%
9	31	26	83.9%
10	32	27	84.4%

An additional clinical study conducted between September 2020 and October 2020 with frozen anterior nasal samples calculated the PPA to be 97.0% (32/33, Wilson 95% CI: 84.7 – 99.5%) and the NPA to be 100% (108/108, Wilson 95% CI: 96.6– 100%). In this study, specimens were collected from 2 different vendors (in the US) and 1 clinical center (in Europe) from symptomatic patients suspected of COVID-19. Nasal swabs were collected and eluted in Sample Inactivation Buffer ([REF] 311502) and stored frozen until tested. Samples were thawed and tested with LIAISON® SARS-CoV-2 Ag, in accordance to the assay procedure. All subjects were confirmed as positive (≤10 days from onset of symptoms) or negative by a reference high sensitivity extracted EUA RT-PCR method, used as comparator method for the study. All testing was conducted by operators blinded to the reference RT-PCR result, which was conducted on NP swabs collected as part of the standard of care testing.

Nasopharyngeal swabs

The clinical performance of the LIAISON® SARS-CoV-2 Ag test was evaluated with a total of 373 nasopharyngeal swab collected between February 2021 and June 2021 from individual subjects during the COVID-19 pandemic. Specimens were collected from 2 different vendors (in the US) and 2 clinical centers (in Europe) from symptomatic patients suspected of COVI D-19. Nasopharyngeal swabs were collected in transport media, eluted in Sample Inactivation Buffer ([REF] 311502), and testedfresh. Samples were tested with LIAISON® SARS-CoV-2 Ag accordingly to the assay procedure. All subjects were confirmed as positive (≤10 days from onset of symptoms) or negative by a reference high sensitivity extracted EUA RT -PCR method, used as comparator method for the study. All testing was conducted by operators blinded to the reference RT -PCR result, which was conducted on NP swabs collected as part of the standard of care testing.

		Reference extracted RT-PCR assay		
		POS	NEG	Total
LIAISON® SARS-CoV-2 Ag on nasopharyngeal swabs	POS	29	0	29
	NEG	7	337	344
	Total	36	337	373

Positive Percentage Agreement (Sensitivity): 29/36 (80.6%, Wilson 95% CI: 65.0 – 90.2%).
Negative Percentage Agreement (Specificity): 337/337 (100%, Wilson 95% CI: 98.9 – 100%).

Positive results broken down by days since symptom onset

Days Since Onset of Symptoms	Cumulative RT-PCR Positive (+)	Cumulative LIAISON® Positive (+)	PPA
0	2	2	100%
1	3	3	100%
2	3	3	100%
3	4	4	100%
4	5	5	100%
5	12	11	91,7%
6	17	14	82,4%
7	29	22	75,9%
8	32	25	78,1%
9	33	26	78,8%
10	36	29	80,6%

An additional clinical study conducted between September 2020 and October 2020 with frozen nasopharyngeal samples calculated the PPA to be 96.1% (49/51, Wilson 95% CI: 86.8 – 98.9%) and the NPA to be 99.3% (133/134, Wilson 95% CI: 95.9 – 99.9%). In this study, specimens were collected from 3 different vendors (2 in the US, 1 in Europe) and 1 clinical center (inEurope) from symptomatic patients suspected of COVID-19. Nasopharyngeal swabs were collected in transport media, stored frozen, thawed and eluted in Sample Inactivation Buffer ([REF] 311502), and tested with LIAISON® SARS-CoV-2 Ag, in accordance to the assay procedure. All subjects were confirmed as positive (≤10 days from onset of symptoms) or negative by a reference high sensitivity extracted EUA RT-PCR method, used as comparator method for the study. All testing was conducted by operators blinded to the reference RT-PCR result, which was conducted on NP swabs collected as part of the standard of care testing.

Prospective Clinical Study

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.
At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.
Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.
Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection.

Performance of the antigen test with serial testing in individuals is described in the following Table:
Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)		
	1 Test	2 Test	3 Test
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.55%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	
1 Test=one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.			

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test

REFERENCES

1. Lauer SA, Grantz KH, Bi Q, et al. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Ann Intern Med. 2020;172(9):577-582. doi:10.7326/M20-0504.

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Changes: Update of Legal Manufacturer name
; Deletions: -

LIAISON® Control SARS-CoV-2 Ag ([REF] 311501)

1. INTENDED USE

The LIAISON® SARS-CoV-2 Ag controls (negative and positive) are intended for use as assayed quality control samples to monitor the performance and reliability of the LIAISON® SARS-CoV-2 Ag assay. The performance characteristics of the LIAISON® SARS-CoV-2 Ag controls have not been established for any assays or instrument platforms other than LIAISON® XL.

The certificate of analysis barcodes give specific information on the lot of controls and should be read by the hand-held barcode scanner of the LIAISON® XL Analyzer prior to loading the control vials on board. For details, refer to the analyzer operator's manual.

For Emergency Use Authorization Only.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner. For *in vitro* diagnostic use only.

2. MATERIALS PROVIDED

Negative control (2 x 2.7 mL)	[CONTROL|-]	Two (2) vials. Antiseptic agent, BSA, detergents.
Positive control (2 x 2.7 mL)	[CONTROL|+]	Two (2) vials. Antiseptic agent, recombinant nucleoprotein (from E.coli), BSA, detergents.

All reagents are supplied ready to use. The range of values of each control is reported on the certificate of analysis and indicates the limits established by DiaSorin for control values that can be obtained in reliable assay runs. If external control results are not within the ranges listed on the certificate of analysis, users should contact Diasorin Customer Care at 1-800-328-1482 for further instruction.

3. WARNINGS AND PRECAUTIONS

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- For prescription use only
- For use under an Emergency Use Authorization Only
- For *in vitro* diagnostic use.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.
- This product has been authorized only for the presence of SARS-CoV-2 Antigen 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 the authorization is revoked sooner.
- Controls are not kit lot specific and may be safely interchanged even with different Reagent Integral lots.
- Observe the normal precautions required for handling all laboratory reagents.
- Dispose of all waste material in accordance with local guidelines.

4.SAFETY PRECAUTIONS

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

Avoid direct contact with potentially infectious 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 infectious 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 stated on the label.

5.STORAGE AND STABILITY

Upon receipt, the controls must be stored at 2-8°C in an upright position to prevent adherence of the solution to the vial cap. Do not freeze.

When the controls are stored sealed, and kept upright, they remain stable at 2-8°C until the expiry date.

Once opened, the controls are stable for up to 4 weeks when properly stored at 2 - 8° C between two successive uses. Avoid bacterial contamination of the controls.

The controls should not be used past the expiry date indicated on the vial labels

.6. PREPARATION OF REAGENTS

– Place the control vials in type C racks on the analyzer. Each control vial is sufficient for performing at least 20 tests.
– The dead volume is 400 µL.
– At the time of use, equilibrate the controls to room temperature (20-25°C) before opening the vials and keep them on board the instrument only for the amount of time required for quality control testing.
– After use, stopper the vials promptly and store them at 2-8°C in an upright position.
– During handling, use appropriate precautions to avoid bacterial contamination of the controls.

7. LIMITATIONS

Control values for assays other than the LIAISON® SARS-CoV-2 Ag assay have not been established.

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

If the control values obtained after successful calibration repeatedly lie outside the expect ranges, the test should be repeated using an unopened control vial.

8. HANDLING

For proper handling please refer to the analyzer operator's manual.

9. ASSIGNED VALUES

The ranges of SARS-CoV-2 Ag concentration in the controls are printed on the certificate of analysis. They have been established after taking into account run variability, in order to guarantee the accuracy of analytical results and to obtain indications on stability or deterioration of reagents.

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Changes: Update of Legal Manufacturer name;
Deletions: -

LIAISON® SARS-CoV-2 Sample Inactivation Buffer ([REF] 311502)

1. INTENDED USE

Sample Inactivation Buffer is used during the pre-analytical procedure in association with nasopharyngeal swab (NPS) collected in COPAN Universal Transport Media (UTM) and with direct anterior nasal swab (NS), when testing the samples with the LIAISON® SARS-CoV-2 Ag assay.

The performance characteristics of LIAISON® SARS-CoV-2 Sample Inactivation Buffer have not been established for any assays or instrument platforms other than LIAISON® XL.

For Emergency Use Authorization Only.
Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner.
For *in vitro* diagnostic use only.

2. MATERIALS PROVIDED

Sample Inactivation Buffer (100 x 1.0 mL)	[BUF]	Antiseptic agent, detergents and inert blue dyes.

Supplied ready to use.

3. WARNINGS AND PRECAUTIONS

– Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
– For prescription use only
– For use under an Emergency Use Authorization Only
– For *in vitro* diagnostic use.
– In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.
– This product has been authorized only for the presence of SARS-CoV-2 Antigen 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. § 360bbb3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.
– Sample shall be collected following the manufacturer's instructions for use and the COVID-19 standard of care.
– Observe the normal precautions required for handling all laboratory reagents.
– Dispose of all waste material in accordance with local guidelines.

4. SAFETY PRECAUTIONS

Do not eat, drink, smoke or apply cosmetics in the assay laboratory.
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 infectious waste.
All samples and reagents containing the 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 reagents beyond the expiration date stated on the label.

5. STORAGE AND STABILITY

Keep away from sunlight.
Upon receipt, the vials must be stored at 2-8°C in an upright position to prevent adherence of the solution to the vial cap.
Do not freeze.
When the vials are stored sealed and kept upright, they remain stable at 2°-8°C until the expiry date.
Unopened vials can be stored for up to eight (8) weeks at 15-25°C.
Avoid bacterial contamination.
The reagent should not be used past the expiry date indicated on the vial labels.

6. LIMITATIONS

- Do not use to inactivate any viruses other than SARS-CoV-2.
- Ali samples, **even after the pre-analytical inactivation procedure,** and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents; accordingly samples, reagents and the waste must be handled with utmost care and disposed of in compliance with the laboratoryguidelines 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.
- Ali waste associated with biologica! samples, biologica! reagents and disposable materials used for the assay must be considered potentially infectious and therefore should be disposed of in accordance with the national, state or local regulations and guidelines of the agencies holding jurisdiction over the laboratory.

7. HANDLING

For proper handling please refer lo the LIAISON SARS-CoV-2 Ag Instructions for Use.