VITASSAY

SARS-CoV-2

Rapid test for the qualitative detection of nucleoprotein antigen of SARS-CoV-2 from nasopharyngeal and nasal swabs.

IUE-7355052 Ed04-1 January 2022

CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

The test should be used by professional trained in IVD devices.

INTENDED USE

Vitassay SARS-CoV-2 is a rapid, immunochromatographic, one step assay for the qualitative detection of nucleoprotein antigen of SARS-CoV-2 from nasopharyngeal swabs or nasal swabs samples from patients suspected of COVID-19 infection.

Simple and highly sensitivity immunoassay to make a presumptive diagnosis of SARS-CoV-2 respiratory infection.

INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) appeared in China the first time and subsequently has spread to over 200 countries of the world with thousands of health's workers infected.

The SARS-CoV-2 an agent causing a disease called COVID-19, is a new species of coronaviruses. The world Health Organization (WHO) characterized COVID-19 as a pandemic in March 2020. International guidelines and general and local recommendations focus on the importance of hygiene measurements and rapid identification and isolation of COVID-19 positive patients for preventing infection spread.

Coronavirus belongs to the order of Nidovirales, identified by its envelope characteristics and positive-sense RNA as genetic material. The length of the coronavirus genome is about 26,4-31,7 kb. Coronavidae and Ronividae family are the largest RNA virus among other viruses. The SARS-CoV-2 genome is 29.9 kb.

SARS-CoV-2 infection can be affected individuals of any age, severe illness is uncommon in children. Clinically, patients with SARS-CoV-2 infection tend to suffer from mile symptoms such as fever, dry cough, anosmia, fatigue, dyspnea, headache, diarrhea, and sore throat followed by vascular and systemic complications such as leukocyte infiltration of the lungs, pneumonia, severe pneumonia, severe acute respiratory diseases syndrome (ARDS), sepsis and septic shock. Recent studies in COVID-19 patients commonly manifest olfactory and gustatory dysfunction even in the absence of rhinorrhea or nasal obstruction.

Truly asymptomatic infections were not frequent and did not appear to be a major driver of transmission. However, some recent papers propose transmission from pre-symptomatic or asymptomatic cases. Although the pre-symptomatic infectious period is not well defined, some preliminary data suggest that it might be around 2 days before the onset symptoms.

The current COVID-19 pandemic caused by SARS-CoV-2 virus demands the development of strategies not only to detect or inactivated the virus, but to treat it. COVID-19 is not only a critical threat for the population with risk factors, but also generates a dramatic economic impact in terms of morbidity and the overall interruption of economic activities.

PRINCIPLE

Vitassay SARS-CoV-2 is a qualitative immunochromatographic assay for the detection nucleoprotein antigen of SARS-CoV-2 from nasopharyngeal or nasal swab samples from patients suspected of COVID-19 infection.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against SARS-CoV-2.

During the process, the sample reacts with the antibodies against SARS-CoV-2, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears.

The presence of this green line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- **For professional *in vitro* use only.**
- Do not use after expiration date.
- Do not use the test if its pouch is damaged.
- Clean up spills thoroughly using an appropriate disinfectant.
- Specimens should be considered as potentially hazardous (especially samples from patients suspected of SARS-CoV infection) and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device. Dangerous samples, handle with caution.
- Tests (swabs, testing tubes, pipettes, positive control swabs and devices) should be discarded in a proper biohazard container after testing. These containers should be discarded in accordance with local or national laws or regulations.
- Sterile swabs provided in the kits should be only used for taking the nasopharyngeal or nasal sample collection. They cannot be reuse.
- Do not touch the head of the sterile swab provided when opening their primary packaging to avoid contamination.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.

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- Components provided in the kit are approved for use with the **Vitassay SARS-CoV-2**. Do not use any other commercial kit component.
- Use proper infection control practices when collecting and handling specimens. These practices should include, but are not limited to, personal protective equipment (PPE), such as laboratory coat, surgical or appropriate mask, or face shield, disposable gloves, and eye protection. Follow local or national regulations regarding collecting and handling specimens.
- The presence of yellow lines in the result window (control line zone and test line zone), before using the test, is completely normal and does not imply failure of the test functionality.
- All positive results should be processed following local laws and regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF) on the sealed pouch.

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use. Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ **25** tests/kit **Vitassay SARS-CoV-2.** ▪ 25 Swabs. ▪ 25 Sample extraction vials (double cap: blue and white-translucent) with diluent (sample and control diluent). ▪ **Vitassay SARS-CoV-2 Positive Control swab.** ▪ Instructions for use.	▪ Disposable gloves (other personal protective equipment that will be considered necessary). ▪ Timer. ▪ Vortex (optional).

SPECIMEN COLLECTION

Samples should be process as soon as possible after collection. Follow proper infection control practices. If this is not possible, the samples can be store in the refrigerator (2-8ºC/35.6-46.4ºF) for 8 hours prior testing. If the samples (only for nasopharyngeal samples) are preserved in validated transport media (VTM, UTM o Saline Buffer) could be preserved on it until 6 hours at room temperature or in the refrigerator (2-8ºC).

Samples must be brought to room temperature before testing.

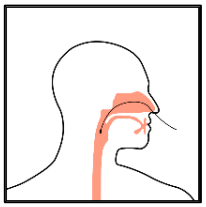
Homogenize the samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

- **Nasopharyngeal swab:**

1. Remove the swab from its packing.
2. Use the sterile swab to collect the sample from the nostril. Insert the swab, rotating against the nasapharyngeal wall (to ensure swab contains cells as well as mucus).Remove the swab from the nostril carefully.
3. Consider repeating procedure using other nostril only if the protocol of the professional taking the sample required do it.
4. Process the swab as soon as possible after collecting the specimen.

Follow the test procedure (samples).



- **Nasopharyngeal samples previously extracted by transport media:**

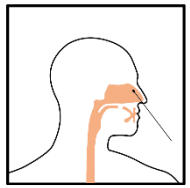
Even while using direct nasopharyngeal swab is the preferred protocol, the device can be also used with samples from nasopharyngeal swabs previously diluted in transport media such as: VTM, UTM or Saline Buffer.

1. Use the minimun volume of transport media in order to avoid loss in sensitivity of the system.
2. Dilute the extract sample 1:1 in Reagent (sample diluent) provided.

Follow immediately with the point 3 of the test procedure (samples).

-Nasal swab method:

1. Remove the sterile swab from its packing.
2. Use the sterile swab to collect the specimen from the nostril. Recommended blow your nose once using a tissue before collection of the specimen.
   Insert the swab, rotating against the nasal wall (to ensure swab contains cells as well as mucus). Remove the swab from the nostril carefully and repeat the procedure with the other nostril.
3. Process the swab (sample) as soon as possible after collecting the specimen.



Follow the test procedure (samples).

PROCEDURE (SAMPLES)

Follow proper infection control practices. Allow the test, samples and reagents to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until the performance of the assay.

1. Put the sample extraction vials in the laboratory rack (identify properly samples from the different patients). Open the blue cap and immediately put the swab into the sample extraction vial.
2. Mix and homogenize the solution by rotating the swab forcefully against the side of the sample extraction vial to allow the solution to mix for 15 seconds (figure 2). Best results are obtained when it is mixed to extract as much liquid as possible from the swab avoiding splashes an aerosols. Rotate the swab against the side of the sample extraction vial as the swab is withdrawn to extract as much liquid as possible. Discard the swab. Close the extraction vial with his blue cap, please be sure that both caps (blue and white-translucent caps) are properly closed. The sample can be shake using a vortex (this is optional).
3. Remove the **Vitassay SARS-CoV-2** from its sealed bag just before using it.
4. Use a separate sample extraction vial and test for each sample. Open the white-translucent cap of the sample extraction vial (figure 3) and dispense 3 drops (approx. 100-120µL) from the sample extraction vial into the circular window marked with the letter S (figure 4). After adding the drops into the sample window close the white-translucent cap (figure 5).
5. Read the results at **10 minutes**. Do not read the test results later than 10 minutes.

1

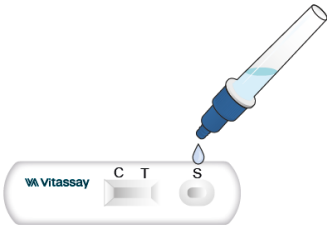
2

Put the swab into the tube, rotating 15 seconds and extract the liquid. Close the vial with the blue cap.
If you desire the sample can be shake (vortex).

3

Open the white-translucent cap.

4



Dispense 3 drops in the circular window marked with the letter S.

5

Close the white-translucent cap.

If the test does not run (it means that liquid -sample+ diluent- does not rise through the strip -reaction zone or result window- due to the type of sample), mix the liquid added in the sample window (S) with the pipette. If it does not work (test does not run), dispense a drop of Reagent (sample diluent) until seeing the liquid running through the reaction zone.

The Reagent (sample diluent) has SARS-CoV-2 inactivation capability: 99.68% after 1 minute and 99.98% after 10 minutes.

INTERPRETATION OF THE RESULTS

C T	**NEGATIVE** Only one green line in the control zone (**C**)	There is no SARS-CoV-2 presence.
C T	**POSITIVE** In addition to the green line (**control line C**), a red line appears, (**test line T**)	There is SARS-CoV-2 presence.
ANY OTHER RESULTS		Invalid result, we recommend repeating the assay using the sample with another test. **Note:** Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor.

Notes: The intensity of the red coloured test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value nor the rate of increase in antigen can be determined by this qualitative test.

QUALITY CONTROL

The Vitassay SARS-CoV-2 presents two controls:

Internal control: Internal procedural control is included in **Vitassay SARS-CoV-2**. A Green line appearing in the control line (C) in the result window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

External control: Positive control swab.

EXTERNAL CONTROL

Vitassay SARS-CoV-2 Positive Control is an external quality control for Vitassay SARS-CoV-2 test. Use this control swab to check that the extraction reagents and the test are working properly.

Store as packaged in the sealed pouch 2-30ºC. The positive control swab is stable through the expiration date printed on the sealed pouch. The positive control swab must remain in the sealed pouch until use. Do not freeze.

POSITIVE CONTROL PROCEDURE

Allow test and positive control swabs to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the package until the performance of the assay.

1. Open the blue cap of the extraction vial and immediately introduce the positive control swab.
2. Mix the solution by rotating the positive control swab forcefully against the side of the sample extraction vial at least 15 seconds. Extract as much liquid as possible from the swab

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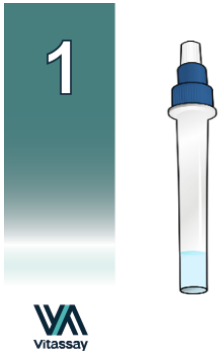
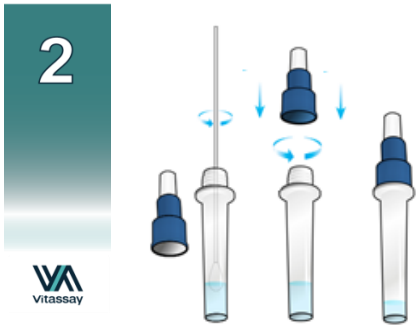
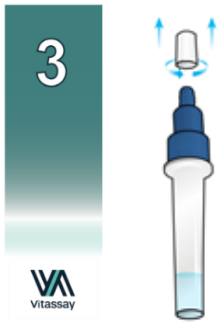
rotating the swab focefully against the side of the of the sample extraction vial as the swab is withdrawn (figure 2). Discard the swab.

3. Remove the **Vitassay SARS-CoV-2** test from its sealed bag just before using it.
4. Use a sample extraction vial and test for each control. Open the white-translucent cap of the sample extraction vial (3) and dispense 3 drops (approx. 100-120µL) from the sample extraction vial into the circular window marked with the letter S (4). After adding the drops into the sample window close the white-translucent cap (5).
5. Read the result at **10 minutes**. Do not read the test result after 10 minutes.

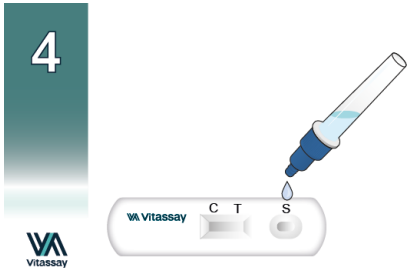




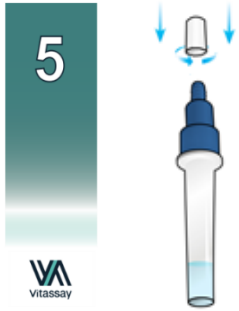
Put the swab into the tube, rotating 15 seconds and extract the liquid. Close the vial with the blue cap.
If you desire the sample can be shake (vortex).



Open the white-translucent cap.



Dispense 3 drops in the circular window marked with the letter S.



Close the white-translucent cap.

Positive controls could be tested once for each new test kit opened and as otherwise required by your laboratory´s standard quality control procedures.

INTERPRETATION OF THE POSITIVE CONTROL RESULTS

	**POSITIVE** In addition to the green line (**control line C**), a red line appears, (**test line T**)	**Control + SARS-CoV-2 POSITIVE**: A green line (control line (C)) and a red line (test line (T)) appear across the results window during the test performance due the presence of SARS-CoV-2 antigens in the positive control swab.
ANY OTHER RESULTS		Invalid result: Total absence of the control-coloured line (green, regardless the appearance or not of the test line (red), or only the control (C) coloured line (green). Incorrect procedural techniques or deterioration of the reagents are mostly the main reason for control line failure. Review the procedure and repeat the control with a new test and a new positive swab.

RECOMMENDATIONS

Recommendations World Health Organization: Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays- 11 September 2020.

1. To optomize performance, testing should be conducted by trained operators in strict accoordance with the test procedure and within the first 5-7 days following the onset of symptoms.
2. Where possible, all positive samples giving positive results should be transported to laboratories with NAAT (Nucleid Acid Amplification Test) capability for confirmatory testing.
3. This test could be used to screen at risk individuals and rapidly isolate positive cases in NAAT- confirmed COVID-19 outbreaks.
4. To monitor trends in disease incidence in communities.
5. For early detection and isolation of positive cases in health facilities, where there is widespread community transmission.
6. A negative result cannot competely exclude an active COVID-19 infection, repeat testing or preferably confirmatory testing should be performed (NAAT) whenever possible, paticulary in symtomatic patients.
7. Even Vitassay SARS-CoV-2 test was not validated using samples form asymtomatic contacts of cases, asymptomatic cases have been demostrated to have viral loads similar to symtomatic cases, so Vitassay SARS-CoV-2 could detect as positive.

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LIMITATIONS

- **Vitassay SARS-CoV-2** must be carried out within 2 hours of opening the sealed bag.
- It should only be used with nasopharyngeal or nasal swabs. The use of other samples has not been established.
- The quality of **Vitassay SARS-CoV-2** depends on the quality of the sample; Proper nasopharyngeal or nasal specimens must be obtained.
- The intensity of test line may vary from very strong (high antigens concentration) to faint (antigens concentration is close to the detection limit).
- Positive results determine the presence of SARS-CoV-2 antigens. A positive result should be followed up by a physician and must be based in the correlation of the results with further clinical observations.
- Positive results do not rule out co-infections with other pathogens.
- Only VTM, UTM and Saline Buffer has been validated with **Vitassay SARS-CoV-2**. When using transport media, the sensitivity of the device can be reduced due to excessive dilution of sample. It is not recommended for nasal samples.
- Negative results should not be considered as conclusive; it is possible that the antigens concentration in nasopharyngeal or nasal samples is lower than the detection limit value. If symptoms or situation persist, it is recommended that all negative results undergo confirmatory testing using other method and/or virus identification by cell culture, PCR or other technique.
- To obtain accurate results, do not use bloody nasopharyngeal or nasal samples.
- Very viscous nasopharyngeal or nasal samples may cause non-specific reaction in the test.

EXPECTED VALUES

Until 17 November 2021, the pandemic has caused around five million deaths worldwide. Spain is one of the countries in the European region most affected by the infection, accounting for 5.067.712 cases and 87.775 deaths as of that date.

In general, most patients only develop mild (40%) or moderate (40%) disease, 15 % develop in the severe condition that requires oxygen support, and 5% have a critical disease with complications such as respiratory distress syndrome (ARDS), sepsis and septic shock, thromboembolism, and/or multiorgan failure, including acute kidney injury and cardiac injury.

Hospitalization rates were estimated at 20.7%-31.4% in United States, and 23% in Iran. In our area this figure is 42% of reported cases. Then 60%-70% COVID-19 patients remain at home.

Transmission risk factors were age, presence of only two household members, and index case age. Age affectation in household contacts has little difference, suggesting that children may have an important role in the transmission.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity (detection limit)

Detection limit value (typical value) of **Vitassay SARS-CoV-2** is $1.25x10^2$ PFU/mL ncoV-2019 D614G(S).

Clinical sensitivity and specificity

An evaluation, with 556 nasopharyngeal samples from people suspected of infection by SARS-CoV-2 virus, was performed comparing the results obtained by **Vitassay SARS-CoV-2** vs PCR tecnique.

Results were as follows:

		qPCR technique		
		Positive	Negative	Total
Vitassay SARS-CoV-2	Positive	93	1	94
	Negative	7	455	462
	Total	100	456	556

Vitassay SARS-CoV-2 vs qPCR technique		
	Mean value	95% (Confidence Interval)
Sensitivity (*)	93.0%	86.1-97.1%
Specificity	99.8%	98.8-100.0%
PPV	98.9%	94.2-100.0%
NPV	98.5%	96.9-99.4%

This multi-center evaluation (nasopharyngeal samples) with positive samples with Ct< 28 (*) showed the following results: sensitivity 95.1% (95% confidence interval: 88.0-98.7%) and specificity: 99.8% (95% confidence interval: 98.8-100.0%).

(*) Taking into account the recommendations for *Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (11 September 2020)* from WHO, the sensitivity of the test was calculated with nasopharyngeal samples with high viral load (high viral load is expected in early symptomatic phases of the illness (with the first 5-7 days of illness) in the range of Ag-RDT test detection.

The results showed that **Vitassay SARS-CoV-2** has a high sensitivity and specificity to detect SARS-CoV-2.

An evaluation, with 990 nasal samples from people suspected of infection by SARS-CoV-2 virus, was performed comparing the results obtained by **Vitassay SARS-CoV-2** vs PCR tecnique (nasopharyngeal samples).

Results were as follows:

		qPCR technique		
		Positive	Negative	Total
Vitassay SARS-CoV-2	Positive	129	7	136
	Negative	27	827	854
	Total	156	834	990

Vitassay SARS-CoV-2 vs qPCR technique		
	Mean value	95% (Confidence Interval)
Sensitivity (*)	82.7%	75.8-88.3%
Specificity	99.2%	98.3-99.7%
PPV	94.9%	89.7-97.9%
NPV	96.8%	95.4-97.9%

This evaluation (nasal samples for the evaluation with the rapid test) with positive samples with Ct< 28 showed the following results: sensitivity 96.9% (95% confidence interval: 91.2-99.4%) and specificity: 99.2% (95% confidence interval: 98.3-99.7%).

The results showed that **Vitassay SARS-CoV-2** has a high sensitivity and specificity to detect SARS-CoV-2.

Hook effect

Vitassay SARS-CoV-2 does not show inhibitory hook effect at the concentration of SARS-CoV-2 protein tested (202500.0 ng/mL).

Cross reactivity

No cross reactivity was detected against organisms that cause other infections:

Adenovirus	*Cryptosporidium*	*RSV*	*Salmonella enteritidis/typhi/ typhimurium/ paratyphi*
Astrovirus	*Escherichia coli O:157*	*Legionella pneumophila*	*Parainfluenza virus*
Bocavirus	*Enterovirus*	*Metapneumovirus human (hMPV)*	*Haemophilus influenzae*
Bordetella pertussis	*Mycobacterium tuberculosis*	*Chlamydia pneumoniae*	*Mycoplasma tuberculosis/pneumoniae*
Campylobacter jejuni	*Entamoeba histolytica*	*Listeria monocytogenes*	*Shigella flexneri/boydii/ Sonnei/dysenteriae*
C. difficile antigen GDH	*Giardia lamblia*	*Norovirus GI/Norovirus GII*	*Streptococcus pneumococcal/ pyogenes/pneumonia e*
C. difficile Toxin A/ *C. difficile* Toxin B	*Helicobacter pylori*	*Staphylococcus aureus/epidermis*	*Yersinia O3/ Yersinia O9*
Coronavirus (strain 229E,	*Pneumocystis jirovecii*	*Rotavirus*	*Influenza A/ Influenza B*

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NL63, OC43, HKUI)			
Haemoglobin pig/bovine	*Pooled human nasal wash-representative of normal respiratory microbial flora*	*Rhinovirus*	

Vitassay SARS-CoV-2 showed some cross reaction with SARS and with MERS.

Interferences

It was performed an evaluation to determine the possible interferences of **Vitassay SARS-CoV-2**, no interferences against the substances tested were detected:

Metronidazole	*Loratadine*	*Loperamide hydrochloride (Fortasec)*	*Phenoxymethylpenicillin potassium*
Ampicillin	*Dexchloropheniramine (Polaramine)*	*Heparin (Hibor)*	*Ambroxol hydrochloride (Mucosan)*
Oseltamivir	*Ebastine (Ebastel)*	*Almagato (Almax)*	*Macrogol 3350 (Movicol)*
Amantadine	*Acetyl Salicylic (Adiro)*	*Fosfamycin (Monurol)*	*Lysine Carbocysteinate (Pectox)*
Ribavirin	*Ibuprofen (Espidifen)*	*Acetylcysteine (Fluimucil)*	*Hydroxyzine dihydrochloride*
Codeine (Toseina)	*Paracetamol (Dolocatil)*	*Dexketoprofen trometamol (Enantyum)*	*Lorazepam*
Benzocaine (Angileptol)	*Metamizole (Nolotil)*	*Levofloxacin*	*Amoxicillin*
Cloperastine (Flutox)	*Prednisone*	*Ciprofloxacin*	*Mercaptopurine*
Carbocisteine (Iniston mucolítico)	*Omeprazole*	*Rifampicin (Rifaldin)*	*Biotine*
Naso GEL	*CVS Nasal Spray (Cromolyn)*	*Afrin (Oxymetazoline)*	*CVS Nasal Drops (Phenylephrine)*
Sore Throat Phenol spray	*Tobramycin*	*Mupirocin*	*Fluticasone Propionate*
ZICAM	*Homeopathic*	*HAMAs (Human anti-mouse antibodies*	*Chloraseptic (Menthol/Benzocaine)*
Human Haemoglobin	*HumanTransferrin*	*Human Calprotectin*	*Human Lactoferrinn*
Mucin	*STREP A*	*Adeno*	*RSV*
Influenza A/ Influenza B			

REFERENCES

1. TSIVGOULIS, G; FRAGKOU, P; DELIDES, A; KAROFYLAKIS. E; DIMOPOULOU, D; SFIKAKIS, P; TSIODRAS, S. Quantitative evaluation of olfactory dysfunction in hospitalized patients with Coronavirus [2] (COVID-19) Journal of Neurology. https://doi.org/10.1007/s00315-020-09935-9.

2. RINCÓN, A; MORESO, F; LÓPEZ-HERRADÓN, A; FERNÁNDEZ-ROBRES, M.A; CIDRAQUE, I; NIN, J; MÉNDEZ, O; LÓPEZ, M; PÁJARO, C; SATORRA, Á; STUARD, S; AND RAMOS, R: The keys to control a coronavirus disease 2019 outbreak in a haemodialysis unit. Clinical Kidney Journal, 2020, 1-8. Doi: 10.1093/ckj/sfaa119.

3. ROCA-GINÉS, J, TORRES-NAVARRO, J; SÁNCHEZ-ARRÁEZ, J; ABRIL-PÉREZ, C; SABALZA-BAZTÁN, O; PARDO-GRANELL, S; MARTÍNEZ, V; BOTELLA- ESTRADA, R; ÉVOLE-BUSELLI, M. Assessment of acute acral lesions in a case series of children an and adolescents during the covid-19 pandemic .Jama Dermatology. Doi: /jamadermatol.2020.2340

4. RAMDANI MOEIS, M; PUJI RAHAYU, A; IHSANI, N; PERTIWI, W. Coronavirus-SARS-CoV-2: Biology and Problems in rRT-PCR Detection. Borneo Journal of Pharmacy. Vol 3 Special Issue 1 June 2020 Page 136-145.

5. ABIODUN, B; OLALEKAN, A; ADENIPEKUN, E; SENAPON, O; MUTIU, B; ORIJA, O; ADEGBOLA, R; SALOKO, B; AKINLOYE, O Improving the understanding of immunopathogenesis of lymphopenia as a correlate of SARS-COV-2 infection risk and disease progression in African Patients: UGLY SARS-CoV-2 Study Protocol.. JMIR Preprints 09/06/2020:21242) DOI: https://doi.org/10.2196/preprints.21242.

6. ARNEDO-PENA, A; SABATER-VIDAL, S; MESEGUER-FERRER, N, PAC-SA, Mª R, MAÑES-FLOR, P; GASCÓ-LABORDA, C;; LARREA, R; ET. AL. COVID-19 secondary attack rate and risk factors in household contacts in Castellon (Spain): Preliminary report. Rev Enf Emerg 2020, 29 (2); 64-70.

7. PÉREZ-GARCÍA, F; PÉREZ-TANOIRA, R; ROMANYK, J; ARROYO, T; GÓMEZ-HERRUZ, P; CUADROS-GONZÁLEZ, J. *Alltest* rapid Flow immunoassays is reliable in diagnosing SARS-CoV-2 infection from 14 days after symptom onset: A prospective single-center study. Journal of Clinicals Virology 129 (2020) 104473. https://do.org/10.1016/j.jvc.2020. 104473.

8. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020. World Health Organization.

9. Centro de Coordinación de Alertas y Emergencias Sanitarias. Secretaria General de Sanidad. Actualización no505. Enfermedad por el coronavirus (COVID-19).17.11.2021. Minist Sanid - Gob España 2021;1–2. Available from: https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/Actualizacion_44_COVID_1200.pdf

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number
CE	CE marking	Control +	Positive Control
STERILE EO	Sterilized using ethylene oxide		Do not re-sterilize
	Do not use if package is damaged		Only one use