VITASSAY

SARS-CoV-2+Flu A+B+RSV+Adeno Resp.

Rapid test for the simultaneous qualitative detection of nucleoprotein antigen of SARS-CoV-2, Influenza type A, Influenza type B, RSV and Adenovirus from nasopharyngeal and nasal swabs.

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CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only. EN

INTENDED USE

Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp. is a rapid, immunochromatographic assay for the simultaneous qualitative detection of nucleoprotein antigen of SARS-CoV-2, Influenza type A, Influenza type B, RSV and Adenovirus from nasopharyngeal swabs or nasal swabs samples from patients suspected of COVID-19 infection and/or Influenza A and/or Influenza B and/or Respiratory Syncytial Virus (RSV) and/or Adenovirus infection.

Simple, non-invasive and highly sensitivity immunoassay to make a presumptive diagnosis of SARS-CoV-2, and/or Influenza type A, influenza type B, and/or RSV and/or Adenovirus infection.

INTRODUCTION

Acute Respiratory Diseases (ARD) are transmittable diseases, among which viruses are the leading cause (1). Among these, the most common ones are influenza, parainfluenza, rhinovirus and respiratory syncytial virus (2), and the family of SARS-CoV have recently become sheer relevant for the global population.

ARDs are the main causes of mortality worldwide, especially in children under five (3). The high morbidity, of which these infections are responsible, has a big socio-economic impact as well (4). Fast and accurate diagnosis is essential to select the appropriate treatment and diminish the impact on the population and health systems. Since all viruses already mentioned can cause upper and lower respiratory tract infections, and clinical manifestations can overlap, diagnoses need to be based on laboratory analysis.

SARS-CoV-2

In December 2019, a group of pneumonia cases was reported at a wholesale seafood market in Wuhan, Hubei province, which was found to be caused by previously unknown Coronaviruses (5). Airway epithelial cells from infected patients were used to isolate a novel coronavirus. The International Committee for the classification of viruses designated the name of this coronavirus as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The World Health Organization has named the disease caused by the SARS-CoV-2 as coronavirus disease 2019 (COVID-19) (6).

People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness, which include fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting and diarrhoea. Symptoms may appear 2-14 days after exposure to the virus (7). Elder people, and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness and infection may progress to pneumonia, acute respiratory distress syndrome and multi-organ failure (8).

The COVID-19 may be transmitted from person to person through several different routes. SARS-CoV-2 primarily spreads through droplets of saliva or discharge from the nose when an infected person coughs or sneezes, but also by contact with an infected subject either direct or indirectly contact (hand-mediated transfer of the virus from contaminated fomites to the mouth, nose, or eyes). Virus transmission occurs from person to person, even during the asymptomatic incubation period (9) (10).

Influenza virus

Influenza in humans is caused by influenza A and influenza B viruses, which presents a broad spectrum of clinical features: from mild respiratory symptoms like sore throat, runny nose, cough, fever, headache, myalgia and fatigue, to severe (and sometimes life threatening) pneumonia or non-respiratory complications (11). Both viruses are a significant cause of global morbidity and mortality, and it is especially important along elderly and immunocompromised population due to the high risk of presenting complications. Transmission is usually through droplets and aerosols or by direct or indirect contact with an infected person.

These enveloped negative-sense single-strand RNA viruses, belong to the family of Orthomyxoviridae. Influenza B usually cause localised outbreak, while influenza A produces epidemics and pandemics (12). The latter one can be classified into different subtypes depending on the glycoproteins located on its surface: hemagglutinin (HA) and neuraminidase (NA). Up to date, eighteen HA (H1-18) and eleven NA (N1-11) subtypes have been identified (13).

Regarding the diagnosis, viral culture is the gold standard for diagnosing influenza viral infections, however the technique is time consuming. Hence, other methods have been more commonly used in clinical practice, including real-time PCR and immunochromatographic rapid tests.

Respiratory Syncytial Virus

The human respiratory syncytial virus (RSV) is an enveloped, single stranded linear RNA genome virus. RSV, which belongs to the genus *Orthopneumovirus*, is divided into two major groups, A and B, based on antigenic and genomic differences. RSV infection most commonly causes a cold-like illness. But it can also cause bronchitis, croup, and lower respiratory infections like bronchiolitis and pneumonia. Of every 100 infants and young children with RSV infection, 25 to 40 (25% to 40%) will show signs of pneumonia or bronchiolitis (14).

RSV is transmitted via large nasopharyngeal secretion droplets coming from infected individuals. These droplets enter via the mucus membranes of the eyes, nose and mouth following close contact, or self-inoculation after touching contaminated surfaces (15).

Adenovirus

Adenoviruses are members of a non-enveloped and double-stranded DNA virus family: *Adenoviridae* family. This family contains more than 50 immunologically distinct human Adenovirus serotypes, which are classified in 6 species (A-F) (16). These species can cause different disorders in humans: Adenovirus -B and C are responsible for respiratory infections, Adenovirus -B and D cause conjunctivitis, and Adenovirus-F serotypes 40 and 41 produce gastroenteritis. In terms of respiratory infections, clinical manifestations are common cold, fever, pharyngitis, bronchitis, and pneumonia.

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Transmission can take place by air due to cough and sneezes, or close contact with an infected person. Interestingly, around 95% of 6 years-old children are seropositive for adenovirus and in up to 5% of overall respiratory infections and 4-10% of acquired pneumonia adenovirus infection is source (17) (18). Thus, Adenovirus plays an important role in paediatric respiratory tract infections.

PRINCIPLE

Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp. is a qualitative immunochromatographic assay for the simultaneous qualitative detection of nucleoprotein antigen of SARS-CoV-2, Influenza type A, Influenza type B, RSV and/or Adenovirus from nasopharyngeal swab or nasal swab samples from patients suspected of COVID-19 infection and/or Influenza A and/or Influenza B and/or Respiratory Syncytial Virus (RSV) and/or Adenovirus infection.

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

Strip B: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against Influenza type A.

Strip C: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against Influenza type B.

Strip D: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against RSV.

Strip E: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against Adenovirus.

During the process, the sample reacts with the antibodies against SARS-CoV-2 (strip A), and/or Influenza A (strip B) and/or Influenza B (strip C) and/or RSV (strip D), and/or Adenovirus (strip E) forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is SARS-CoV-2 positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in the strip A. If the sample is Influenza type A positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in the strip B. If the sample is Influenza type B positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip C. If the sample is RSV positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip D and if the sample is Adenovirus positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip E. Although the sample is positive or negative, the mixture continues to move across the membranes, and the green control line always appears (for all the strips).

The presence of these green lines (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* diagnostic use only.**
- Do not use after expiration date.
- Do not use the kit without having read and understood the information on procedures, precautions, and limitations provided in the instructions for use.
- Do not use the kit if the label sealing the outer carton is torn or damaged.
- Do not use the product if the outer carton or the aluminium pouches are open or damaged on arrival.
- Do not use the test (and positive/negative controls if applicable) if the desiccant material is missing or broken inside the aluminium pouch.
- Do not use the vial with sample diluent if it is opened or damaged upon arrival.
- It is recommended to protect the reagents from moisture.
- Components provided in the kit are approved for use with the **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** Do not mix components from different kits and/or lots. Do not use any other commercial kit component.
- Do not reuse. This is a single-use device.
- Sterile swabs provided in the kits should be only used for taking the nasopharyngeal or nasal sample collection. They cannot be reused.
- For the correct traceability of the sample, each vial with sample diluent and test used must be perfectly recognisable including patient identification.
- Specimens and material in contact with samples 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, in accordance with local/national safety regulations. Use appropriate infection control practices when collecting and handling samples.
- Do not touch the head of the sterile swab provided when opening their primary packaging to avoid contamination.
- A new test must be used for each sample to avoid contaminations errors.
- Follow Good Laboratory Practices. These practices should include, but are not limited to, personal protective equipment (PPE), such as lab coat, surgical or appropriate mask or face shield, disposable gloves, and eye protection. Take the necessary precautions during sample collection, transport, storage, handling, and disposal. Each sample must be correctly and unequivocally identified to ensure proper traceability of samples.
- Do not eat, drink, smoke or apply cosmetic products in the workplace. Once the test is completed wash your hands thoroughly.
- Avoid handling solvents near the kit to prevent possible deterioration to the labelling and pouch printing information.
- In case of spillage, clean thoroughly with a suitable disinfectant.
- The material of the kit used should be disposed of in an appropriate biohazard container after testing. These containers must be disposed of in accordance with local or national regulations.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. In accordance with Regulation (EC) No 1907/2006 (REACH), **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** do not contain substances and/or mixtures which meet the hazard classification criteria available in Regulation (EC) No 1272/2008 (CLP) or which are in concentrations higher than the value established in the mentioned regulation for their declaration.
- 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.
- The interpretation of the results is visual, using coloured lines. The interpretation of the results should be performed by a professional user without problems of visualisation and colour interpretation.
- Perform the interpretation of results in a well-lit place.
- All positive results should be processed following local laws and regulations.
- A statement declaring no requirement for Material Safety Data Sheet, and certificate of analysis, can be provided on request (not included).

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC). 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
▪ **10** Tests/kit **Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp.** ▪ 10 Vials with Reagent (sample diluent). ▪ 10 Swabs. ▪ Instructions for use.	▪ Specimen collection container ▪ Other personal protective equipment that will be considered necessary. ▪ Timer. ▪ Vortex (optional).

SPECIMEN COLLECTION

Samples should be collected in clean and dry containers, following proper infection control practices.

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Samples should be processed as soon as possible after collection. If this is not possible, the samples can be stored in the refrigerator (2-8ºC) for maximum 8 hours prior testing. If the samples (only for nasopharyngeal samples) are preserved in validated transport media (VTM, or Saline Buffer) could be preserved on it for 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 testing.

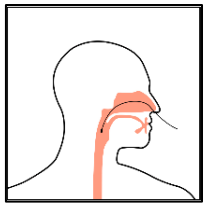
SPECIMEN PREPARATION

Use a sterile swab and a separate device for each sample. Please ensure that samples from different patients have been correctly identified.

Nasopharyngeal swab method:

1. Remove the sterile swab from its packing.
2. Use the sterile swab to collect the specimen from one nostril. Insert the swab into the nostril to the nasopharynx, rotating against the nasapharyngeal wall (4 times) to ensure that the swab contains cells as well as mucus.
3. Remove the swab from the nostril carefully and consider repeating procedure using the 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, or Saline Buffer.

1. Use the minimun volume of transport media in order to avoid loss in sensitivity. Example: 1.0 mL. The use of higher volumes affects the sensitivity of the system.
2. Dilute the extract sample 1:1 in Reagent (sample diluent 1,2mL/vial) provided. Take into account that the minimun volume to perform the test is 1,2mL. Do not use the swabs provided to dilute this type of sample in the sample diluent.

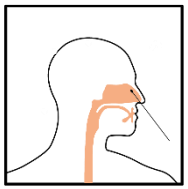
Follow immediately with point 3 of the test procedure (samples).

Nasal swab method:

Recommended blow your nose once using a tissue before collection of the specimen.

1. Remove the sterile swab from its packing.
2. Use the sterile swab to collect the specimen from one nostril. Insert the swab into the nostril (approx. 2 cm), rotate against the nasal wall several times (5 times) to ensure that the swab contains cells as well as mucus.
3. Remove the swab from the nostril carefully and repeat the procedure with the other nostril.
4. Process the swab as soon as possible after collecting the specimen.

Follow the test procedure (samples).

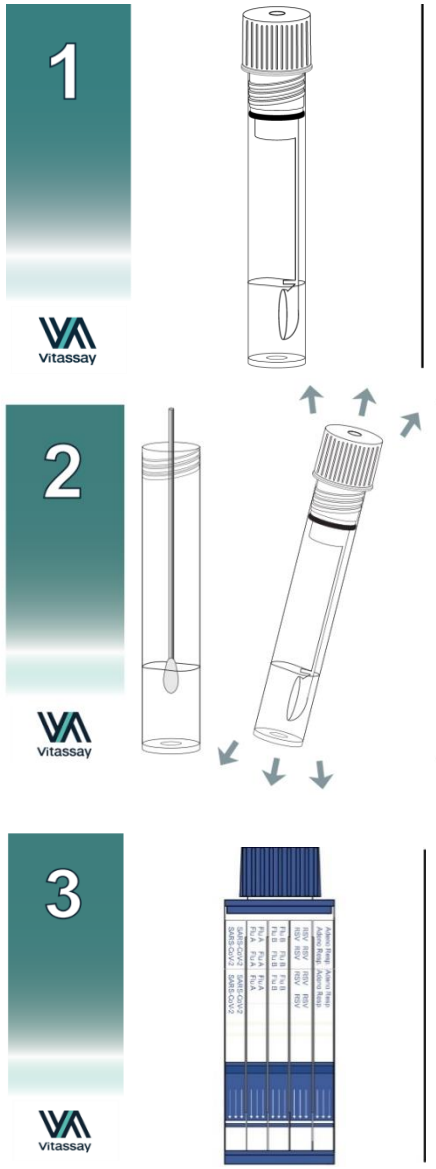


PROCEDURE (samples)

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

1. Open the cap of the vial for sample dilution with Reagent (figure 1).
2. Introduce the swab immediately into the vial for sample dilution (figure 2) and mix the solution by rotating the swab forcefully against the side of the tube at least 60 seconds. Best results are obtained when the specimen is vigorously extracted in the solution, avoiding splashes and aerosols. Extract as much liquid as possible from the swab, by squeezing the sides of the tube or rotating the swab against the side of the tube as the swab is withdrawn. Discard the swab.
3. Close the vial with sample and diluent. Shake the vial to assure a good sample dispersion, sake for 60 seconds (figure 2).
4. Remove **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp**. from its sealed bag just before using it (figure 3).
5. Take the vial for sample dilution containing the diluted sample (figure 4), place it inside the multitest tube (figure 5). Screw the cap of the multitest tube tightly (figure 6). The bottom of the vial for sample dilution will break and the diluent+sample solution reaches the sample zone of the strips (figure 7).
6. Place the multitest tube vertically on e flat surface and read the results **at 10 minutes**. Do not read the test result later than 10 minutes. Any result read after 10 minutes will be considered invalid.

If the test does not run due to solid particles (the sample is not homogenized), migration process can stop on one or more strips. In this case, tap the end of the multitest tube on hard surface to allow migration to start again.



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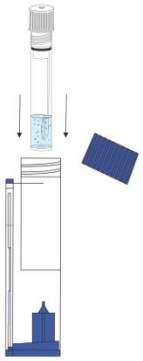
4

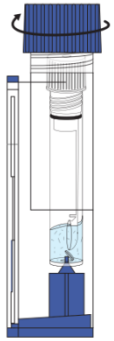
Vial with the diluted sample inside.

5



Introduce the vial with the diluted sample into the multitest.

6



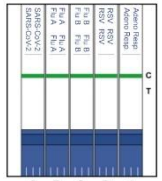
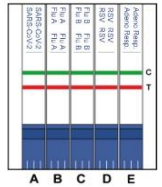
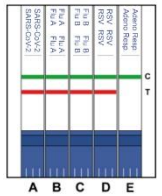
Close the cap and the bottom of the diluent vial will break.

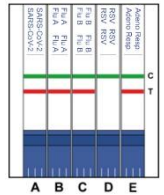
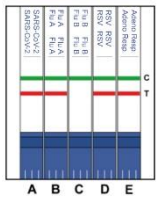
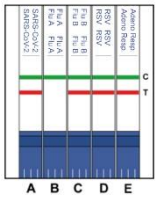
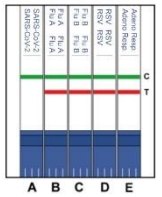
7

Reaction takes place. **Read results at 10 minutes.**

INTERPRETATION OF THE RESULTS

Strip A: SARS-CoV-2, Strip B: Influenza A, Strip C: Influenza B, Strip D: RSV and Strip E: Adenovirus Resp.

	**NEGATIVE** Only one green line in the control zone (C) in the five strips (A,B,C D and E)	There is no SARS-CoV-2, Influenza A, Influenza B, RSV and Adenovirus Resp. presence.
	**POSITIVE** In addition to the green line (control line C), a red line appears in each strip, test line (T).	There is SARS-CoV-2, Influenza A, Influenza B, RSV and Adenovirus Resp. presence.
	**NEGATIVE** Strip E (Adenovirus Resp)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip B (Influenza A)→ green/red lines Strip C (Influenza B)→ green/red lines Strip D (RSV)→ green/red lines	There is SARS-CoV-2, Influenza A, Influenza B and RSV presence.

	**NEGATIVE** Strip D (RSV)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip B (Influenza A)→ green/red lines Strip C (Influenza B)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is SARS-CoV-2, Influenza A, Influenza B and Adenovirus Resp presence.
	**NEGATIVE** Strip C (Influenza B)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip B (Influenza A)→ green/red lines Strip D (RSV)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is SARS-COV-2, Influenza A, RSV and Adenovirus Resp. presence.
	**NEGATIVE** Strip B (Influenza A)→ green line. **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip C (Influenza B)→ green/red lines Strip D (RSV)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is SARS-COV-2, Influenza B RSV and Adenovirus Resp. presence
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line **POSITIVE** Strip B (Influenza A)→ green/red lines Strip C (Influenza B)→ green/red lines Strip D (RSV)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is Influenza A, Influenza B, RSV and Adenovirus Resp presence.

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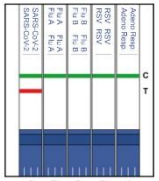
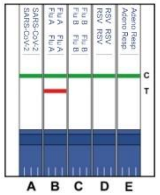
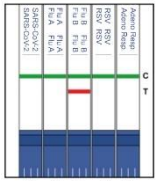
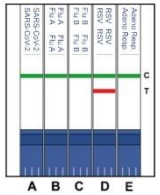
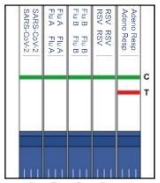
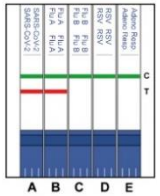
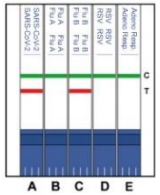
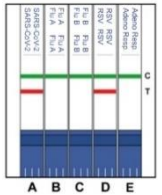
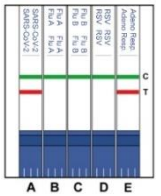
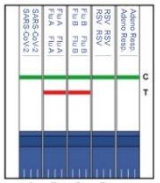
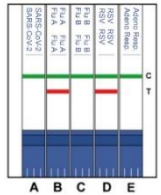
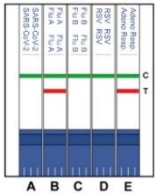
	**NEGATIVE** Strip B (Influenza A)→ green line Strip C (Influenza B)→ green line Strip D (RSV)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines	There is SARS-CoV-2 presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip C (Influenza B)→ green line Strip D (RSV)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip B (Influenza A)→ green/red lines	There is Influenza A presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip B (Influenza A)→ green line Strip D (RSV)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip C (Influenza B)→ green/red lines	There is Influenza B presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip B (Influenza A)→ green line Strip C (Influenza B)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip D (RSV)→ green/red lines	There is RSV presence.

	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip B (Influenza A)→ green line Strip C (Influenza B)→ green line Strip D (RSV)→ green line **POSITIVE** Strip E (Adenovirus Resp.)→ green/red lines	There is Adenovirus Resp presence.
	**NEGATIVE** Strip C (Influenza B)→ green line Strip D (RSV)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip B (Influenza A)→ green/red lines	There is SARS-CoV-2 and Influenza A presence.
	**NEGATIVE** Strip B (Influenza A)→ green line Strip D (RSV)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip C (Influenza B)→ green/red lines	There is SARS-CoV-2 and Influenza B presence.
	**NEGATIVE** Strip B (Influenza A)→ green line Strip C (Influenza B)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip A (SARS-COV-2)→ green/red lines Strip D (RSV)→ green/red lines	There is SARS-CoV-2 and RSV presence.

	**NEGATIVE** Strip B (Influenza A)→ green line Strip C (Influenza B)→ green line Strip D (RSV)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is SARS-CoV-2 and Adenovirus Resp presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip D (RSV)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip B (Influenza A)→ green/red lines Strip C (Influenza B)→ green/red lines	There is Influenza A and B presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip C (Influenza B)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip B (Influenza A)→ green/red lines Strip D (RSV)→ green/red lines	There is Influenza A and RSV presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip C (Influenza B)→ green line Strip D (RSV)→ green line **POSITIVE** Strip B (Influenza A)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is Influenza A and Adenovirus Resp. presence.

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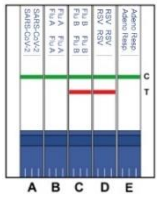
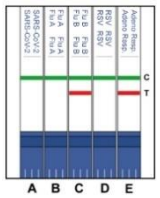
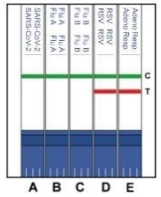
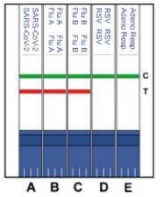
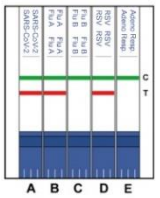
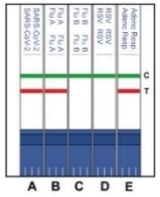
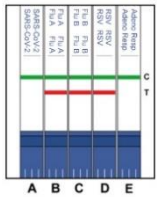
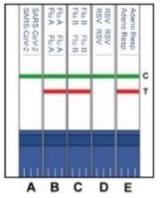
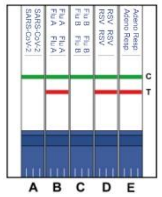
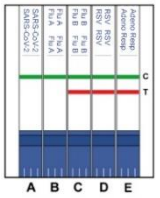
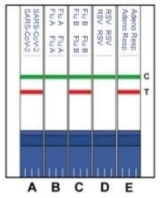
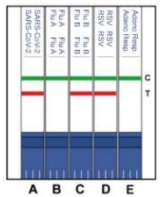
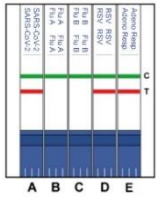
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip B (Influenza A)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip C (Influenza B)→ green/red lines Strip D (RSV)→ green/red lines	There is Influenza B and RSV presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip B (Influenza A)→ green line Strip D (RSV)→ green line **POSITIVE** Strip C (Influenza B)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is Influenza B and Adenovirus Resp. presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip B (Influenza A)→ green line Strip C (Influenza B)→ green line **POSITIVE** Strip D (RSV)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is RSV and Adenovirus Resp. presence.
	**NEGATIVE** Strip D (RSV)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip B (Influenza A)→ green/red lines Strip C (Influenza B)→ green/red lines	There is SARS-CoV-2, Influenza A and Influenza B presence.

	**NEGATIVE** Strip C (Influenza B)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip B (Influenza A)→ green/red lines Strip D (RSV)→ green/red lines	There is SARS-CoV-2, Influenza A and RSV presence.
	**NEGATIVE** Strip C (Influenza B)→ green line Strip D (RSV)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip B (Influenza A)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is SARS-CoV-2, Influenza A and Adenovirus Resp. presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip B (Influenza A)→ green/red lines Strip C (Influenza B)→ green/red lines Strip D (RSV)→ green/red lines	There is Influenza A, Influenza B and RSV presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip D (RSV)→ green line **POSITIVE** Strip B (Influenza A)→ green/red lines Strip C (Influenza B)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is Influenza A, Influenza B and Adenovirus Resp. presence.

	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip C (Influenza B)→ green line **POSITIVE** Strip B (Influenza A)→ green/red lines Strip D (RSV)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is Influenza A, RSV and Adenovirus Resp. presence.
	**NEGATIVE** Strip A (SARS-CoV-2)→ green line Strip B (Influenza A)→ green line **POSITIVE** Strip C (Influenza B)→ green/red lines Strip D (RSV)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is Influenza B, RSV and Adenovirus Resp. presence.
	**NEGATIVE** Strip B (Influenza A)→ green line Strip D (RSV)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip C (Influenza B)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is SARS-CoV-2, Influenza B and Adenovirus Resp. presence.
	**NEGATIVE** Strip B (Influenza A)→ green line Strip E (Adenovirus Resp.)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip C (Influenza B)→ green/red lines Strip D (RSV)→ green/red lines	There is SARS-CoV-2, Influenza B and RSV presence.

	**NEGATIVE** Strip B (Influenza A)→ green line Strip C (Influenza B)→ green line **POSITIVE** Strip A (SARS-CoV-2)→ green/red lines Strip D (RSV)→ green/red lines Strip E (Adenovirus Resp.)→ green/red lines	There is SARS-CoV-2, RSV and Adenovirus Resp presence.
Any other results	Invalid result either A, B, C, D and/or E. We recommend repeating the assay using the same sample with another test. Any result read after more than 10 minutes has elapsed will be considered invalid.	

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

NEGATIVE: The presence of only one green line (green control line) should be considered a negative result.

POSITIVE: The presence of both lines (green control line and red test line), regardless of the intensity of the red line, should be considered a positive result.

The results detailed in the above table should be followed up with additional confirmatory diagnostic procedures.

A single or double viral infection is more common than a triple, quadruple or quintuple infection.

Invalid results: Total absence of any control coloured lines (green) indicates an invalid result, regardless of the appearance or not of the test lines (red). Wrong procedural techniques, deterioration of the reagents or insufficient sample volume are mostly the main reasons for an invalid result. Review the procedure and repeat the assay with a new test. If the problem persists, discontinue using the kit and contact your local distributor.

QUALITY CONTROL

Internal procedural control is included in **Vitassay SARS-CoV-2 + Flu A + B + RSV + Adeno Resp.** Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

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.

LIMITATIONS

- **Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp.** must be carried out within 2 hours of opening the sealed bag.
- The intensity of the test lines may vary depending on the concentration of antigens.
- The use of the test on samples other than nasopharyngeal or nasal swabs has not been determined.
- The quality of the test depends on the quality of the sample. Samples must be obtained appropriately.
- Positive results determine the presence of SARS-CoV-2, Influenza type A, Influenza type B, RSV and/or Adenovirus respiratory antigens. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been evaluated 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.
- The sensitivity of the test may be reduced when transport media are used due to greater dilution of the sample. The use of transport media is not recommended.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigen in the sample is lower than the test detection limit value. If symptoms or situation still persist, it is recommended that all negative results undergo confirmatory testing using other methods, and/or virus identification by cell culture, PCR or another technique.
- To obtain accurate results, do not use bloody samples.
- Highly viscous samples may cause a non-specific reaction in the test.

EXPECTED VALUES

Influenza virus types A and B circulate and cause seasonal epidemics of the disease. Seasonal influenza is an acute respiratory infection common throughout the world. According to the WHO, there are approximately one billion cases of seasonal influenza each year; of these, between three and five million are severe.

Most people recover without treatment. However, the disease causes between 290,000 and 650,000 respiratory deaths each year. In industrialised countries, most influenza-related deaths occur in people aged 65 and older. 99% of deaths among children under five with influenza-related lower respiratory tract infections occur in developing countries. Vaccination is the best way to prevent the disease (19).

Each year, respiratory syncytial virus causes approximately 3.6 million hospitalisations and around 100,000 deaths among children under five worldwide. Most of these deaths (97%) occur in low- and middle-income countries, where access to supportive medical care is limited. In adults, it is estimated that in the United States alone, this virus causes up to 160,000 hospitalisations and 10,000 deaths among adults over 65 years of age. The hospitalisation rate for infected adults is higher among people with underlying conditions such as asthma, chronic obstructive pulmonary disease or congestive heart failure (20).

Adenoviruses account for at least 5–10% of respiratory tract infections (RTIs) in children and 1–7% in adults. In immunocompromised individuals, dissemination and/or severe respiratory failure develop in 10-30% of cases, and mortality rates from severe AdV pneumonia can exceed 50% (21).

WHO collects SARS-CoV-2 data from a global network of sentinel and systematic virologic surveillance sites. In the 28-day period from 21 July 2025 to 17 August 2025, the following data were obtained:

During this 28-day period, a total of 71,687 new cases were reported from 87 countries across five WHO regions, which is a decrease compared to the 92,519 new cases reported from 95 countries in the previous 28-day period. Overall, 35 countries from Africa, the Americas, Europe, and South-East Asia showed an increase in new cases of over 10%.

During this 28-day period, a total of 8,559 new COVID-19 hospitalizations were reported from 35 countries, and 247 new ICU admissions were reported from 32 countries across four WHO regions. Among these, 10 countries from the Americas and Europe showed an increasing trend in hospitalizations, and 6 countries from the Americas and Europe showed an increasing trend in ICU admissions.

During this 28-day period, a total of 969 new deaths were reported from 40 countries across four WHO regions, which is a decrease compared to the 1,022 new deaths reported from 43 countries in the previous 28-day period. Twelve countries from Europe and

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South-East Asia showed an increase in new deaths of over 10%. In July 2025, 87% of reported deaths with age information occurred in the population aged 65 and over (22).

PERFORMANCE CHARACTERISTICS

Analytical sensitivity (detection limit)

Detection limit value (typical value) of **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** (strip A: SARS-CoV-2) is $1.25x10^2$ PFU/mL ncoV-2019 D614G(S).

Detection limit value (typical value) of **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** (strip B: Influenza A) is 12.5 ng/mL of Influenza A recombinant nucleoprotein.

Detection limit value (typical value) of **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** (strip C: Influenza B) is 50.0 ng/mL of Influenza B recombinant nucleoprotein.

Detection limit value (typical value) of **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** (strip D: RSV) is 20.0 ng/mL of RSV recombinant nucleoprotein.

Detection limit value (typical value) of **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** (strip E: Adenovirus Resp.) 6.25 ng/mL Adenovirus Hexon recombinant protein.

Clinical sensitivity and specificity

Evaluations for SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (strip A: SARS-CoV-2)

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+ Flu A+B+RSV+Adeno Resp.** (strip A) vs PCR tecnique.

Results were as follows:

		qPCR technique		
		Positive	Negative	Total
Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (SARS-CoV-2)	Positive	93	1	94
	Negative	7	455	462
	Total	100	456	556

Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. 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-centre 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.

Evaluations for SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (strip A_ 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+ Flu A+B+RSV+Adeno Resp. (strip A) vs PCR technique (nasopharyngeal samples).

		Technique qPCR		
		Positive	Negative	Total
Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (SARS-CoV-2 strip A)	Positive	129	7	136
	Negative	27	827	854
	Total	156	834	990

Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. vs technique qPCR		
	Mean value	95% confidence interval
Sensitivity (*)	82.7%	75.8-88.3%
Specificity	99.2%	98.3-99.7%
VPP	94.9%	89.7-97.9%
VPN	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%).

Evaluations for SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (strip B and C: Influenza A and Infuenza B)

Respiratory samples were used in order to evaluate the results obtained by **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** (strip B and C) with other immunochromatographic tests ((BinaxNOW® Influenza A&B (Alere).

Results were as follows:

		BinaxNOW® Influenza A&B		
		Positive	Negative	Total
Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (Influenza A+B)	Positive	5	0	5
	Negative	0	6	6
	Total	5	6	11

Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. vs BinaxNOW® Influenza A&B			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

Evaluations for SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (strip D_ RSV)

Respiratory samples were used in order to evaluate the results obtained by **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** (strip D) with other immunochromatographic tests BinaxNOW® RSV (Alere).

Results were as follows:

		BinaxNOW® RSV		
		Positive	Negative	Total
Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (RSV)	Positive	18	0	5
	Negative	1	10	11
	Total	19	10	29

Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. vs BinaxNOW® RSV			
Sensitivity	Specificity	PPV	NPV
95%	>99%	>99%	91%

Evaluations for SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (strip E_ Adenovirus Resp.)

Respiratory samples were used in order to evaluate the results obtained by **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** (strip E) with other immunochromatographic tests, Adenovirus Respi, (CorisBioConcept) and a immunofluorescence test (PathoDx®Adenovirus, Remel).

Results were as follows:

		PathoDx®Adenovirus		
		Positive	Negative	Total
Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (Adenovirus)	Positive	20	0	20
	Negative	0	5	5
	Total	20	5	25

		Adenovirus Respi		
		Positive	Negative	Total
Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. (Adenovirus)	Positive	20	0	20
	Negative	0	5	5
	Total	20	5	25

Vitassay SARS-CoV-2+Flu A+B+RSV+Adeno Resp. vs PathoDx®Adenovirus Test and Adenovirus Respi Test			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

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The results showed that **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** has a high sensitivity and specificity to detect SARS-CoV-2, Influenza type A, Influenza type B, RSV and Adenovirus.

Hook effect

Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp. does not show hook effect at:

-The concentration of SARS-CoV-2 protein tested (202500.0 ng/mL).

-The concentration of Influenza A protein tested (200000.0 ng/mL).

-The concentration of Influenza B protein tested (200000.0 ng/mL).

-The concentration of RSV protein tested (395000.0 ng/mL).

-The concentration of Adenovirus Resp. protein tested (100000.0 ng/mL).

Cross reactivity

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

Strip A: SARS-CoV-2

Adenovirus	*Cryptosporidium*	*RSV*	*Salmonella enteritidis/typhi/ typhimurium/ paratyphi*
Astrovirus	*Escherichia coli O:157*	*Legionella pneumophila*	*Parainfluenza virus*
Bocavirus	*Enterovirus*	*Metapneumo virus human (hMPV)*	*Haemophilus influenzae*
Bordetella pertussis	*Mycobacterium tuberculosis/*	*Chlamydia pneumoniae*	*Mycoplasma tuberculosis*
Campylobacter jejuni	*Entamoeba histolytica*	*Listeria monocytogenes*	*Shigella flexneri/boydii/ Sonnei/dysenteriae*
C. difficile antigen GDH	*Giardia lamblia*	*Norovirus GI/Norovirus GII*	*Streptococcus pneumococcal/ pyogenes/ pneumoniae*
C. difficile Toxin *A/ C. difficile* Toxin B	*Helicobacter pylori*	*Staphylococcus aureus/epidermis*	*Yersinia O3/ Yersinia O9*
Coronavirus (strain 229E, NL63, OC43, HKU1)	*Pneumocystis jirovecii*	*Rotavirus*	*Influenza A/ Influenza B*
Pig/ bovine haemoglobin	*Pooled human nasal wash-representative of normal respiratory microbial flora*	*Rhinovirus*	

Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp. (SARS-CoV-2, strip A) showed some cross reaction with SARS and with MERS.

Strip B: Influenza A

Adenovirus	*SARS-CoV-2 (SARS-CoV-2)*	*Influenza B*	*RSV*
Astrovirus	*Coronavirus (strain 229, NL63, OC43)*	*Legionella pneumophila*	*Salmonella enteritidis/typhi/ typhimurium/ paratyphi*
Enterovirus	*Haemophilus Influenzae*	*Listeria monocytogenes*	*Shigella flexneri/boydii/ Sonnei/dysenteriae*
Campylobacter jejuni	*Escherichia coli 0:157/0:026/ 0:111*	*MERS*	*Streptococcus pneumococcal/pyogenes*
Norovirus GI/Norovirus GII	*Entamoebqa histolytica*	*Yersinia O3/ Yersinia O9*	*Pig/ bovine haemoglobin*
C. difficile antigen GDH	*Giardia lamblia*	*Rotavirus*	*Helicobacter pylori*
C. difficile Toxin *A/ C. difficile* Toxin B	*SARS-CoV-1 (SARS)*	*Cryptosporidium*	

Strip C: Influenza B

Adenovirus	*SARS-CoV-2 (SARS-CoV-2)*	*Influenza A*	*RSV*
Astrovirus	*Coronavirus (strain 229, NL63, OC43)*	*Legionella pneumophila*	*Salmonella enteritidis/typhi/ typhimurium/ paratyphi*
Enterovirus	*Haemophilus Influenzae*	*Listeria monocytogenes*	*Shigella flexneri/boydii/ Sonnei/dysenteriae*
Campylobacter jejuni	*Escherichia coli 0:157/0:026/ 0:111*	*MERS*	*Streptococcus pneumococcal/ pyogenes*
Norovirus GI/Norovirus GII	*Entamoebqa histolytica*	*Yersinia O3/ Yersinia O9*	*Pig/ bovine haemoglobin*
C. difficile antigen GDH	*Giardia lamblia*	*Rotavirus*	*Helicobacter pylori*
C. difficile Toxin *A/ C. difficile* Toxin B	*SARS-CoV-1 (SARS)*	*Cryptosporidium*	

Strip D: RSV

Adenovirus	*SARS-CoV-2 (SARS-CoV-2)*	*Influenza A/ Influenza B*	*Yersinia O3/ Yersinia O9*
Astrovirus	*Coronavirus (strain 229, NL63, OC43)*	*Legionella pneumophila*	*Salmonella enteritidis/typhi/ typhimurium/ paratyphi*
Enterovirus	*Haemophilus Influenzae*	*Listeria monocytogenes*	*Shigella flexneri/boydii/ Sonnei/dysenteriae*
Campylobacter jejuni	*Escherichia coli 0:157/0:026/ 0:111*	*MERS*	*Streptococcus pneumococcal/pyogenes*
C. difficile antigen GDH	*Entamoebqa histolytica*	*Cryptosporidium*	*Norovirus GI/Norovirus GII*
C. difficile Toxin *A/ C. difficile* Toxin B	*Giardia lamblia*	*SARS-CoV-1 (SARS)*	*Rotavirus*
Helicobacter pylori	*Pig/ bovine haemoglobin*		

Strip E: Adenovirus Resp.

Astrovirus	*Coronavirus (strain 229, NL63, OC43)*	*Influenza A/ Influenza B*	*Salmonella enteritidis/typhi/ typhimurium/ paratyphi*
Enterovirus	*Haemophilus Influenzae*	*Legionella pneumophila*	*Shigella flexneri/boydii/ Sonnei/dysenteriae*
Campylobacter jejuni	*Escherichia coli 0:157/0:026/ 0:111*	*Listeria monocytogenes*	*Streptococcus pneumococcal/pyogenes*
C. difficile antigen GDH	*Entamoebqa histolytica*	*MERS*	*Norovirus GI/Norovirus GII*
C. difficile Toxin *A/ C. difficile* Toxin B	*Giardia lamblia*	*Yersinia O3/ Yersinia O9*	*Rotavirus*
SARS-CoV-1 (SARS)	*Helicobacter pylori*	*Cryptosporidium*	*Pig/ bovine haemoglobin*
SARS-CoV-2 (SARS-CoV-2)			

Interference

An evaluation was performed to determine the possible interferences of **Vitassay SARS-CoV-2+ Flu A+B+RSV+Adeno Resp.** 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 (Oxymetazoli*	*CVS Nasal Drops*

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		ne)	*(Phenylephrine)*
Sore Throat Phenol spray	*Tobramycin*	*Mupirocin*	*Fluticasone Propionate*
ZICAM	*Homeopathic*	*HAMAs (Human anti-mouse antibodies*	*Chloraseptic (Menthol/Benzo caine)*
Human haemoglobin	*Human transferrin*	*Human calprotectin*	*Human Lactoferrinn*
Mucine	*Human blood*		

SARS-CoV-2 strip:

STREP A	*ADENO*	*RSV*	*Influenza A*
Influenza B			

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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		

Changes control		
Nº Version	**Changes**	**Date**
IUE-7715053 Ed00 September 2020	Original version	09/2020
IUE-7715053 Ed01 October 2020	-	10/2020
IUE-7715053 Ed02 November 2021	-	11/2021
IUE-7715053 Ed03 June 2025	Updated format. Correction of typographical errors in sections "PROCEDURE (samples)", "RECOMMENDATIONS" and "INTERPRETATION OF THE RESULTS"	11/06/2025
IUE-7715053 Ed04 September 2025	Updated introduction, addition of precautions and limitations, correction of material not provided, improved wording on specimen collection, specimen preparation and procedure more detailed, limitation on the use of VTM or saline buffer, addition of clarifications on interpretation of results, updated expected values and bibliography.	09/09/2025

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