



Jan 2020

**COVID-19 Antigen  
Rapid Test  
Nasopharyngeal Swab (NP)**

**International**



# Company Background

## Who We Are



We are an experienced manufacturer of FDA cleared products

World Class Scientific Advisory Board – Members of the ROME Foundation

We contract manufacturer for 2 multinational pharma companies, Bio-Rad and other leading organizations

Device manufacturing experience with over 20 products

Two FDA registered manufacturing facilities

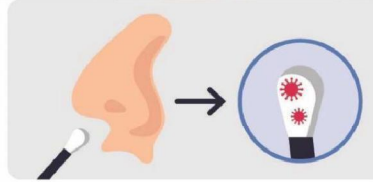
Major customers



## COVID-19 Antigen Rapid Test (NP): Introduction






- > The Biomerica COVID-19 Antigen Rapid Test (NP) is a lateral flow chromatographic immunoassay for rapid, qualitative detection of antigens specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in nasopharyngeal swab specimens collected by a health professional.

Line appearing in the test area represents the presence of SARS-CoV-2 in specimens.



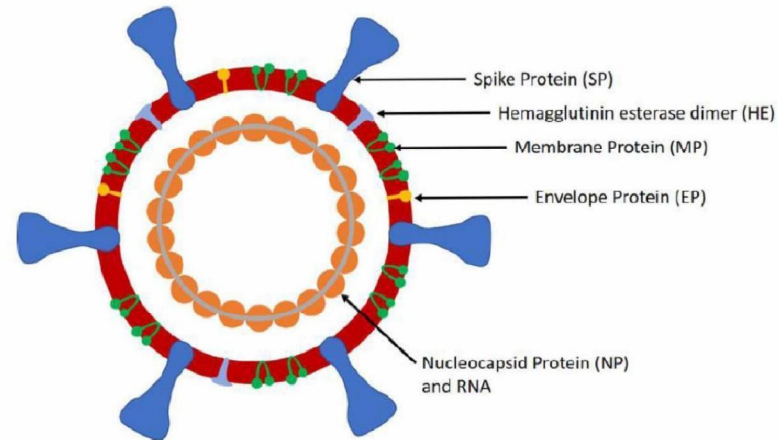


## COVID-19 Antigen Rapid Test (NP): Benefits

-  **Patient management**  
Fast decision-making
-  **Does not require lab processing**  
No equipment required
-  **Quick, simple to use**  
Convenient. Read by eye. 15 minutes to result
-  **Reliable and accurate**  
CE Mark. Sensitivity: 93.8%. Specificity: 100%
-  **Inexpensive compared to lab tests**

## COVID-19 Antigen Rapid Test (NP): SARS-CoV-2

- › SARS-CoV-2 is a large positive-sense single-stranded ribonucleic acid (RNA) virus that comprises of four structural proteins; nucleocapsid protein (NP) that holds the viral RNA, spike protein (SP), envelope protein (EP), and membrane protein (MP), that create the viral envelope<sup>[1]</sup>.



SARS-CoV-2 schematic<sup>[1]</sup>

References: [1] Vashist, S.K. In Vitro Diagnostic Assays for COVID-19: Recent Advances and Emerging Trends. *Diagnostics* 2020, 10, 202 [3] Ria Lassaunière<sup>1</sup>, Anders Frische<sup>1</sup>, Zitta B. Harboe<sup>2,3</sup>, Alex C.Y. Nielsen<sup>4</sup>, Anders Fomsgaard<sup>1</sup>, Karen A. Krogfelt<sup>1,5</sup>, Charlotte S. Jørgensen<sup>1\*</sup>



## COVID-19 Antigen Rapid Test (NP): COVID-19

- › The World Health Organization (WHO) termed the disease, coronavirus disease 2019 (COVID-19), and the causative virus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- › Most common symptoms:
  - › Fever.
  - › Dry cough.
  - › Tiredness
- › Less common symptoms:
  - › Aches and pains
  - › Diarrhea
  - › Loss of taste and smell

References: World Health Organisation. Questions and Answers on coronaviruses (COVID-19), M 2020, viewed 04 May 2020, <<https://www.who.int/news-room/q-a-detail/q-a-coronaviruses>>



## COVID-19 Antigen Rapid Test (NP): Why Test?



### To identify people who are at the peak of infection<sup>[1]</sup>

- Who should be isolated
- Contact tracing
- Clinical management



### To determine who has been infected

- Who can return to work – healthcare workers, emergency services, public health stakeholders
- Surveillance
- Who can visit other people, family and friends.



### Public Health

- Social distancing strategy
- Prevention of spreading e.g. in hospitals and care homes

References: [1] Giorgia Guglielmi, Fast coronavirus tests: what they can and can't do, Nature 585, 496–498 (2020), DOI: <https://doi.org/10.1038/d41586-020-02661-2>, accessed Nov. 16, 2020

## COVID-19 Antigen Rapid Test (NP): Test Types

> Testing for COVID-19 is broadly split into Tests for Viral RNA, Antigen, and Serology.

Testing Technology	RNA	Antigen	Antibody
<i>Pros</i>	<ul style="list-style-type: none"> <li>- Higher accuracy and lower error margin in results</li> <li>- Confirmative or repeat testing not required</li> </ul>	<ul style="list-style-type: none"> <li>- Less expensive</li> <li>- Faster results than RNA and antibody tests</li> <li>- Can be used as an alternative to RNA tests for mass testing purpose</li> </ul>	<ul style="list-style-type: none"> <li>- Lower cost</li> <li>- Quicker results than RNA tests</li> <li>- Helps assess infection rate</li> <li>- Also assists in development of therapies for treatment (e.g., plasma transfer)</li> </ul>
<i>Cons</i>	<ul style="list-style-type: none"> <li>- Most expensive among the COVID-19 testing technologies</li> <li>- Longer duration to receive results, sometimes up to a week</li> <li>- Not preferred for mass testing of large populations</li> </ul>	<ul style="list-style-type: none"> <li>- Low accuracy</li> <li>- Samples prepared for testing are less sensitive</li> <li>- High accuracy of positive results, but negative results may need to be confirmed with an RNA test</li> </ul>	<ul style="list-style-type: none"> <li>- Detects infection only after 5–14 days of onset of disease</li> <li>- Low accuracy and sometimes a second antibody test is needed to get accurate results</li> <li>- Diagnostic usage currently limited</li> </ul>









Source: WHO, FINDDX, CDC USA, Pitt Street Research

Table: Pitt Street Research. What are the types of COVID-19 tests being used currently?. <https://www.pittstreetresearch.com/s/Achiko-initiating-report-1-October-2020.pdf>. Accessed 16NOV20





# COVID-19 Antigen Rapid Test (NP): When to use...

ANTIGEN TEST	ANTIBODY TEST
<b>SAMPLE</b>	
Nasopharyngeal swab. 	Finger-stick or venous blood. 
<b>WHAT IT SHOWS</b>	
Identifies the presence of Sars-Cov-2. 	Identifies IgG/IgM antibodies to Sars-Cov-2. 
<b>TIME TO RESULT</b>	
Available in minutes. 	Rapid Test within 10 minutes. ELISA depending on Lab. 
<b>USED FOR</b>	
Diagnosing patients that need treatment, isolation and testing contacts through test and trace. 	Identifying patients with immune response, vaccination prioritization, seroprevalence, and completion of diagnosis. 

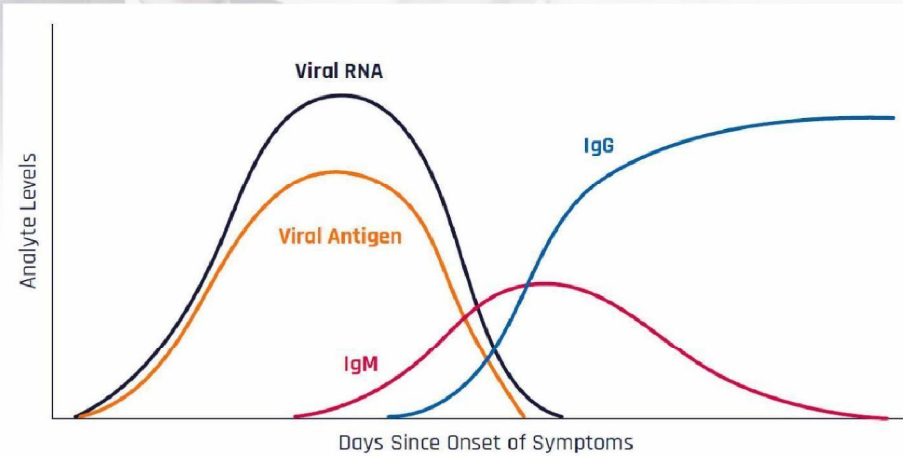
## COVID-19 Antigen Rapid Test (NP): Market Overview

	BIOMERICA COVID Antigen Rapid Test	BIOMERICA COVID IgG/IgM Rapid Test	IgG/IgM Lab Tests (e.g. Abbott Architect)	PCR Point-of-care (e.g. Abbott, ID NOW COVID)	PCR Lab Test (e.g. TF, Taqpath)
<b>Test type</b>	Antigen	Antibody	Antibody	Viral RNA	Viral RNA
<b>Intended use</b>	Immunoassay test kit for the qualitative detection of antigens specific to SARS-CoV-2 in nasopharyngeal swab specimens.	Immunoassay test kit for the qualitative detection of IgG and IgM antibodies specific to SARS-CoV-2 in human capillary whole blood, serum, or plasma specimens.	Chemiluminescent microparticle immunoassay (CMIA) intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum.	Rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA.	Real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens.
<b>PQC Setting</b>	Yes	Yes	No	Yes	No
<b>Training</b>	Moderate	Minimal	Lab Staff	Moderate	Lab staff
<b>Sample type</b>	Nasopharyngeal swab	Whole blood, serum and plasma	Serum and plasma	Nasal, nasopharyngeal or throat swabs	Nasal, nasopharyngeal or throat swabs
<b>Sample Volume</b>	n/a	10-20 µl	10-20 µl	n/a	n/a
<b>Sample preparation</b>	Yes	No for whole blood	Yes	Yes	Yes
<b>Test time</b>	Minutes	Minutes	Hours	Minutes	Hours
<b>Turnaround time</b>	Minutes	Minutes	Next day	Minutes	Next day
<b>Transport</b>	No	No	Yes	No	Yes
<b>Calibration / Control</b>	No	No	Yes	Yes	Yes
<b>Instrument cost</b>	n/a	n/a	Moderate	High	Very High

PQC = Point-of-care / Near patient

## COVID-19 Antigen Rapid Test (NP): Presence of Antigen in Course of Disease

- › Rapid antigen tests detect the presence of viral proteins and can return positive results when a person is most infectious [1].



- › For illustrative purposes only. Data from Liu et al. (2020) and Li et al. (2020)<sup>[2,3]</sup>

References: [1] <https://www.nature.com/articles/d41586-020-02661-2>, Accessed: 30<sup>th</sup> Oct 2020. [2] Li, Z, Yi, Y, Luo, X, et al. Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis. *J Med Virol.* 2020; 1– 7. <https://doi.org/10.1002/jmv.25727>. [3] Liu L, Liu W, Zheng Y, et al. A preliminary study on serological assay for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in 238 admitted hospital patients [published online ahead of print, 2020 May 18]. *Microbes Infect.* 2020;10.1016/j.micinf.2020.05.008. doi:10.1016/j.micinf.2020.05.008

## COVID-19 Antigen Rapid Test (NP): Clinical Significance

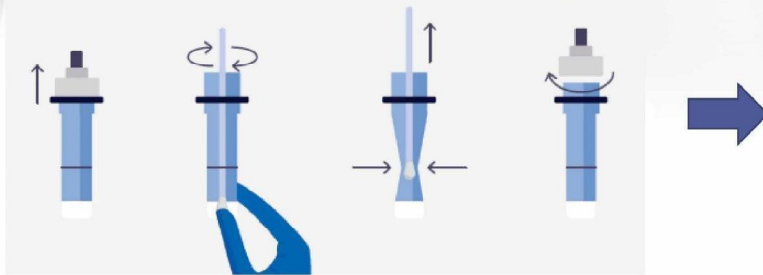
- It is proposed that there is a place for viral RNA testing and antigen and antibody detection when accessible (Figure 4).
- In some countries and settings this may not be possible and antigen and antibody detection may offer the best a cost-effective option for identifying COVID-19 patients.

Test Results				Clinical Significance
ANTIGEN	PCR	IgM	IgG	
+	+	-	-	Patient may be in the window period of infection.
+	+	+	-	Patient may be in the early stage of infection.
+	+	+	+	Patient may be in the active phase of infection.
+	+	-	+	Patient may be in the late or recurrent stage of infection.
-	-	+	-	Patient may be in the early stage of infection. Antigen or PCR result may be false-negative. Antibody test could be false-positive.
-	-	-	+	Patient may have had a past infection, and has recovered or antibody test could be false-positive.
-	-	+	+	Patient may be in the recovery stage of an infection, or the Antigen or PCR result may be false-negative. Antibody test could also be false-positive.

References: Prestidge, Marelize, Amore, Zara. 2020. Purpose and Options for Testing for SARS-Cov2 (the COVID-19 Virus) - Considerations for World Bank Task Teams Managing COVID-19 Fast Track Facility Operations (English). Washington, D.C. : World Bank Group. <http://documents.worldbank.org/curated/en/145161586536712080/Purpose-and-Options-for-Testing-for-SARS-Cov2-the-COVID-19-Virus-Considerations-for-World-Bank-Task-Teams-Managing-COVID-19-Fast-Track-Facility-Operations>

## COVID-19 Antigen Rapid Test (NP): Procedure and Principle

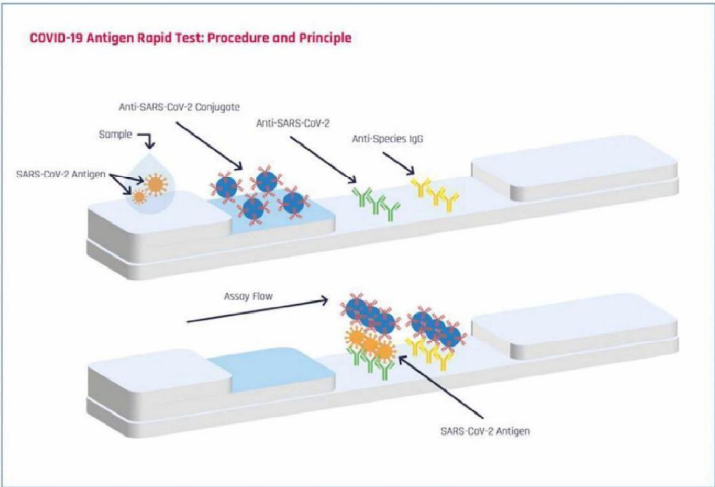
### > Integrated Extraction Tube



- > Remove test device from foil pouch.
- > Place test device on a level surface.
- > Set timer for 15 minutes.
- > Add 3 drops of extracted specimen.
- > Read result and control line after 15 minutes.



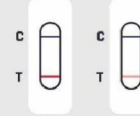
# COVID-19 Antigen Rapid Test (NP): Procedure and Principle



## COVID-19 Antigen Rapid Test (NP): Results

### POSITIVE:

If the sample contains SARS-CoV-2 antigens, a pink/red-colored band next to the "T" in the test window will appear. **NOTE:** Any shade of pink/red color next to the "T" should be considered positive.



### NEGATIVE:

A single colored band appears next to the "C". No pink/red-colored band appears next to the "T".



### INVALID:

An absence of a colored band next to the "C" regardless of the appearance of a colored band next to "T". **NOTE:** Insufficient sample volume, most common reasons for invalid results. The sample should be retested using a new test device.



## COVID-19 Antigen Rapid Test (NP): Sensitivity and Specificity

- › The sensitivity and specificity of the BIOMERICA COVID-19 Antigen Rapid Test (NP) were calculated in comparison with a commercial PCR (BGI) (Novel Coronavirus 2019-nCov PCR Kit)
- › **Sensitivity** of the BIOMERICA COVID-19 Antigen Rapid Test (NP) is the percentage of patients correctly identified as having a positive response when compared to a positive PCR result.
- › **Specificity** of the BIOMERICA COVID-19 Antigen Rapid Test (NP) is the percentage of patients correctly identified as having a negative response when compared to a negative PCR result.

Method:	RT - PCR		Total Results	
	Results	Positive		Negative
COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)	Positive	30	0	30
	Negative	2	140	142
Total Results		32	140	172

**Relative Sensitivity:** 93.8% (95%CI\*: 79.2% - 99.2%)

**Relative Specificity:** 100.0% (95%CI\*: 97.9% - 100.0%)

**Accuracy:** 98.8% (95%CI\*: 95.9% - 99.9%)

\*Confidence Intervals