Jan 2020

COVID-19 Antigen Rapid Test

Nasopharyngeal Swab (NP)

International | BIOMERICA

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

MAYO CLINIC Mayo Medical Laboratories

CVS/pharmacy Expect something extra

Winn-Dixie

Quest Diagnostics

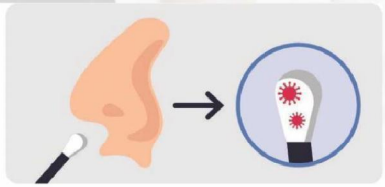
Walgreens

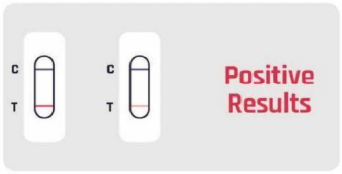
McKESSON Empowering Healthcare

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

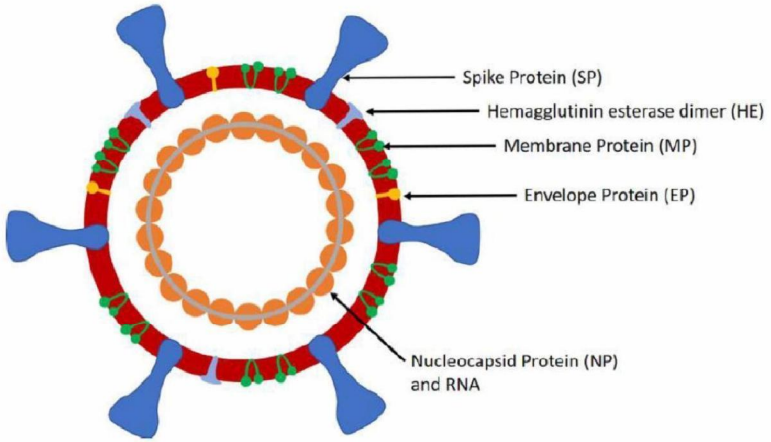
Quick, simple to use
Convenient. Read by eye. 15 minutes to result

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[1].



SARS-CoV-2 schematic[1]

References: [1] Vashist, S.K. In Vitro Diagnostic Assays for COVID-19: Recent Advances and Emerging Trends. *Diagnostics* 2020, *10*, 202 [3] Ria Lassaunière1, Anders Frische1, Zitta B. Harboe2,3, Alex C.Y. Nielsen4, Anders Fomsgaard1, Karen A. Krogfelt1,5, Charlotte S. Jørgensen1*

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[1]
- 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

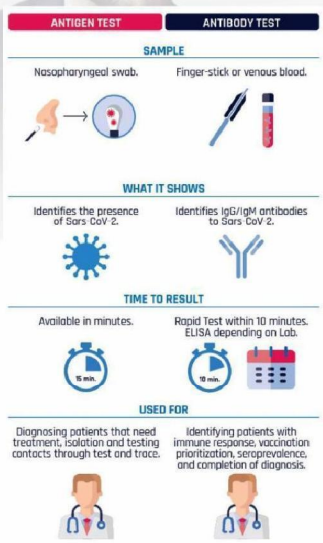
› Testing for COVID-19 is broadly split into Tests for Viral RNA, Antigen, and Serology.

Testing Technology	RNA	Antigen	Antibody
Pros	– Higher accuracy and lower error margin in results – Confirmative or repeat testing not required	– Less expensive – Faster results than RNA and antibody tests – Can be used as an alternative to RNA tests for mass testing purpose	– Lower cost – Quicker results than RNA tests – Helps assess infection rate – Also assists in development of therapies for treatment (e.g., plasma transfer)
Cons	– Most expensive among the COVID-19 testing technologies – Longer duration to receive results, sometimes up to a week – Not preferred for mass testing of large populations	– Low accuracy – Samples prepared for testing are less sensitive – High accuracy of positive results, but negative results may need to be confirmed with an RNA test	– Detects infection only after 5–14 days of onset of disease – Low accuracy and sometimes a second antibody test is needed to get accurate results – Diagnostic usage currently limited

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…



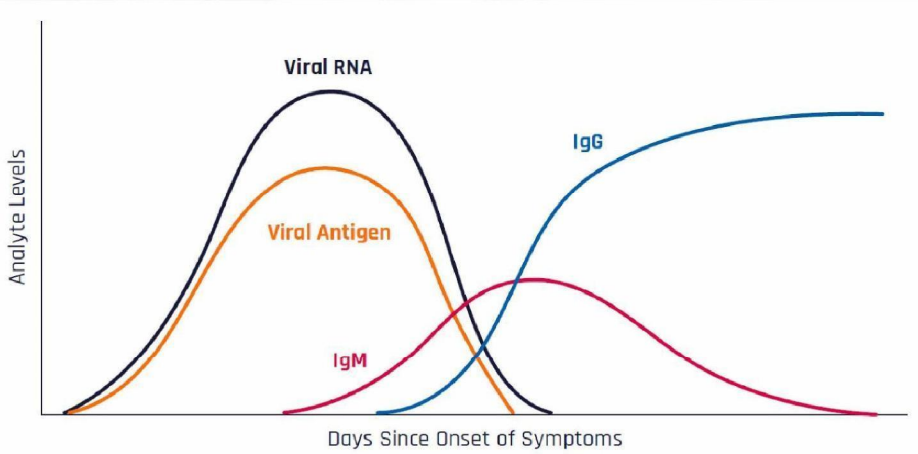
COVID-19 Antigen Rapid Test (NP): Market Overview

	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)
Test type	Antigen	Antibody	Antibody	Viral RNA	Viral RNA
Intended use	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.
POC Setting	Yes	Yes	No	Yes	No
Training	Moderate	Minimal	Lab Staff	Moderate	Lab staff
Sample type	Nasopharyngeal swab	Whole blood, serum and plasma	Serum and plasma	Nasal, nasopharyngeal or throat swabs	Nasal, nasopharyngeal or throat swabs
Sample Volume	n/a	10-20 µl	10-20 µl	n/a	n/a
Sample preparation	Yes	No for whole blood	Yes	Yes	Yes
Test time	Minutes	Minutes	Hours	Minutes	Hours
Turnaround time	Minutes	Minutes	Next day	Minutes	Next day
Transport	No	No	Yes	No	Yes
Calibration / Control	No	No	Yes	Yes	Yes
Instrument cost	n/a	n/a	Moderate	High	Very High

POC = 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)[2,3]

References: [1] https://www.nature.com/articles/d41586-020-02661-2. Accessed: 30th 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

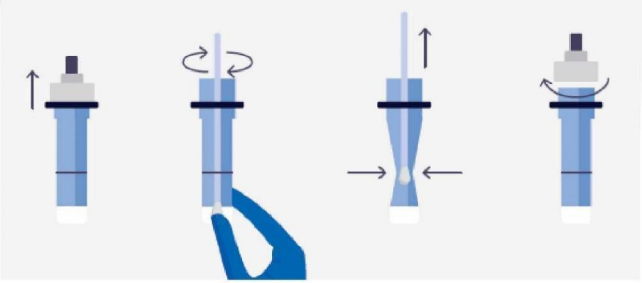
- It is proposed that there is a place for viral RNA testing and antigen and antibody detection when accessible (Figure 4).
- In some countries and settings this may not be possible and antigen and antibody detection may offer the best a cost-effective option for identifying COVID-19 patients.

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 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; Amoore, 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

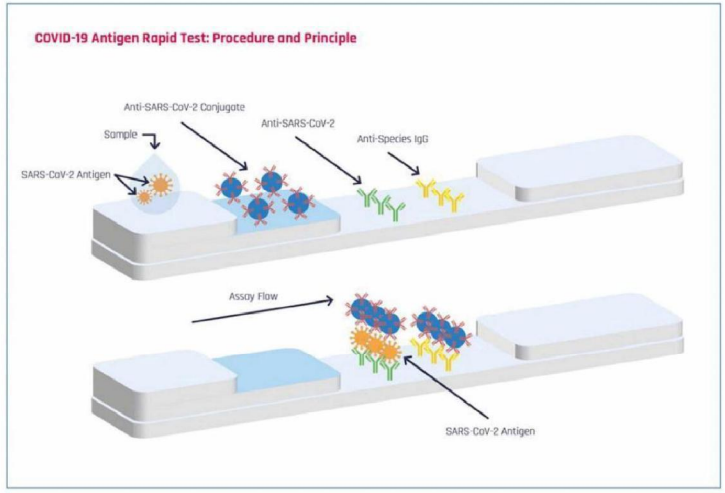
COVID-19 Antigen Rapid Test (NP): Procedure and Principle

› Integrated Extraction Tube



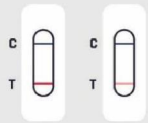
› Remove test device from foil pouch.
› Place test device on a level surface.
› Set timer for 15 minutes.
› Add 3 drops of extracted specimen.
› Read result and control line after 15 minutes.

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



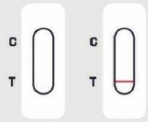
COVID-19 Antigen Rapid Test (NP): Results

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
COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)	Results	Positive	Negative	
	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