

Hughes Healthcare

Covid-19 Testing Protocol

Rapid Antigen Test



The Hughes Group originally started in 2001 as a private family office. Healthcare operations began in 2015 in neurology and in 2018 expanded into drug development and medical devices. These included robotic medical devices for drug infusion in neuro oncology, modifying existing large molecule drugs into water soluble versions for infusion via catheters into the brainstem and diagnostic assays for viral antibodies and antigens.

We have engineered a mass human dual testing protocol to control and eradicate Covid-19. We supply the point of care test kits (both rapid antigen lateral flow and RT LAMP), qualified training for staff and crew (which isn't complex but is helpful) and any other aspects of consultancy. Our protocol has received support, agreement and purchasing agreements from governments in the EU and elsewhere.



Timeline

▶ The first case of COVID-19 was reported in China in December 2019.

12.2019

▶ The World Health Organization declared COVID-19 as a pandemic on 11 March 2020. The first UK lockdown was ordered on 16 March.

03.2020

▶ In April 2020, a global travel ban was implemented to slow the spread of the virus.

04.2020

▶ By the end of July 2020, the epidemic had spread worldwide with over 17 million confirmed cases.

07.2020

▶ Over 60m cases and 1.4m deaths worldwide by November 2020. Mass testing rolled out as best way to combat virus.

11.2020

Rapid Antigen Tests



Components

Hughes Healthcare's Coronavirus (SARS-CoV-2) Antigen Rapid Test Cassette (using a swab administration) is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present along the mucosa wall on the inside of the nostril..



Components	Amount
Test Cassette	25 pcs
Buffer Solution	25 pcs
Cotton Swab	25 pcs
Specifications	1 pcs

Test Process



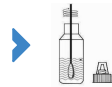
Step 1

A nasal swab sample is collected from the test subject.



Step 3

The swab should be stirred well and the test cassette removed from the foil packaging.



Step 2

The swab is then inserted into a bottle that contains 2 ml of Lysis Solution. The swab containing cell samples should be stirred well and pressed to the bottom of the bottle.



Step 4

3-4 drops of sample are dripped onto the test card. The result will be shown within 15 minutes.

Results Interpretation

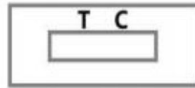
The entire test time is a maximum of **15 minutes**; the test results are interpreted as shown below.



Negative



Positive



Invalid



- If the Quality Control Line (C-Line) shows a red line, but there is no red line on the Test Line (T-Line), this result is **NEGATIVE**.
- If both the C-Line and the T-Line shows a red line (even if it is faint), this result is **POSITIVE**.
- If there is no red line on the C-Line, regardless of whether there is a line on the T-Line, this result is **INVALID** and another test has to be taken.

Clinical Test Results

A study using a total 605 nasal swab samples was conducted. Test results of the Hughes Healthcare rapid antigen test were compared with a nucleic acid detection test. The diagnostic sensitivity and specificity of the test results are given as below:

Sars-CoV-2 Rapid Antigen Test		PCR			Clinical Performance
		Positive	Negative	Total	
	Positive	165	2	167	Sensitivity 97.1%
	Negative	5	433	438	Specificity 99.5%
	Total	170	435	605	Consistency 98.8%