

AffiDX[®] SARS-CoV-2 Antigen Lateral Flow Test



Accurate detection, comfortable sample collection,
and interpretation of results in just 20 minutes.



The AffiDX[®] SARS-CoV-2 Antigen Lateral Flow Test is an ideal solution for point-of-care and decentralised testing to identify individuals with higher viral loads of SARS-CoV-2 that increase the likelihood of transmitting the infection to others. Wholly developed and manufactured in the UK utilising accurate, flexible Affimer[®] technology, and validated against emerging variants of SARS-CoV-2.

Intended Use









The Avacta[®] AffiDX[®] SARS-CoV-2 antigen lateral flow test is a qualitative *in vitro* diagnostic (IVD) test to detect SARS-CoV-2 antigen in human anterior nasal swab samples.

Assay validation and clinical evaluations of the test were conducted in the UK and EU using routine prospective samples in general population and healthcare settings.

Kit Contents


- 25 lateral flow devices
- 25 buffer capsules
- 25 sterile swabs
- 25 swab extraction tubes
- 1 Instructions For Use

Features and Benefits


- | | |
|--|---|
|  <p>Patient-Friendly
Anterior nares (nasal) swab samples for more comfortable collection</p> |  <p>Accessible
Suitable for Point of Care settings and allows for decentralised testing</p> |
|  <p>Reliable Results
Accurate for identifying individuals likely to be infectious: 98% sensitivity and 99% specificity</p> |  <p>Rapid & Simple
Easy to use, simple workflow, results in only 20 minutes</p> |
|  <p>Monitored Against Variants
Routine monitoring of emerging variants to ensure continued diagnostic accuracy</p> |  <p>Convenient
Contains everything needed to run a test with no additional equipment required</p> |
|  <p>U.K Made
Developed and manufactured in the United Kingdom</p> |  <p>Practical
Room temperature storage, transportation and testing</p> |

Test Procedure

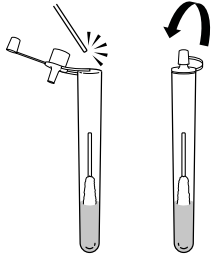
1. Insert the swab tip in to one nostril to a depth of around 1-2cm and hold against the inner wall of the nostril. Move the swab around the nostril wall, whilst rotating the swab between the fingertips. Continue this process for a minimum of 10 seconds.



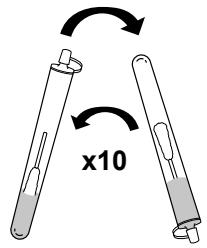
2. Repeat with the other nostril using the same swab.



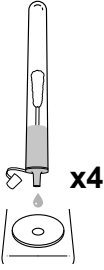
3. Place the swab (tip end first) in the swab extraction tube and snap the tip of the swab off at the breakpoint, leaving the tip in the tube. Close the lid of the tube and put the cap on the nozzle.




4. Mix by rapid inversion of the tube 10 times.



5. Remove the nozzle cap of the swab extraction tube and holding the tube vertically carefully dispense 4 drops into the sample well of the lateral flow test device.



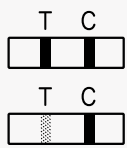
6. Using a timer, leave the device on a flat surface for 20 minutes. A test identification label (not provided) can be affixed to the device.



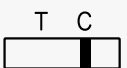
7. Read test results after 20 minutes. Test results **MUST NOT** be interpreted after 30 minutes.

Results Interpretation

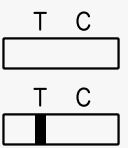
Positive



Negative



Invalid



For full swab sample collection, test procedure and results interpretation, please refer to Instructions For Use

Clinical Evaluation

PCR Result (Ct Range)	Number of Samples Tested in Ct Range	Avacta® AffiDX® Result		Cumulative Clinical Sensitivity by Ct Range		
		Positive	Negative	Ct Range	% Sensitivity	95% CI
< 27	52	52	0	0 - 27	100.0 %	(93.1 - 100.0 %)
27 - 28	7	6	1	0 - 28	98.3 %	(91.0 - 99.7 %)
28 - 29	18	18	0	0 - 29	98.7 %	(93.0 - 99.8 %)
29 - 30	19	19	0	0 - 30	99.0 %	(94.3 - 99.8 %)
> 30	2	1	1	All	98.0 %	(92.9 - 99.4 %)
TOTAL	98	96	2		98.0 %	(92.9 - 99.4 %)

PCR Result	Number of Negative Samples Tested	Avacta® AffiDX® Result		Clinical Specificity	
		Positive	Negative	% Specificity	95% CI
Negative	102	1	101	99.0%	(94.7 - 99.8%)

Order Information

Product code	AVA62001
Product name	AffiDX® SARS-CoV-2 Antigen Lateral Flow Test
Pack size	1 carton containing x 25 tests



For further information, please contact your local Avacta® distributor or email diagnostics@avacta.com