Avacta® DIAGNOSTICS

Application note

Validation of the Avacta® AffiDX® SARS-CoV-2 Antigen Lateral Flow Test for Detection of the SARS-CoV-2 Delta Variant of Concern

Application benefits

- Conclusive evidence that the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test can accurately detect the SARS-CoV-2 Delta Variant of Concern (VOC)
- Validation conducted independently within a European healthcare facility
- Study performed using real clinical samples and not limited to *in-silico* analysis
- Less invasive and patient-friendly anterior nasal swab sample collection method was used throughout the study
- Further evidence of clinical utility of Affimer® technology in rapid antigen diagnostic applications

Introduction

The emergence and rapid spread of COVID-19 represents a major health threat to countries and populations around the world. Due to regular mutations, there has been continuous emergence of SARS-CoV-2 variants around the globe. SARS-CoV-2 Variants of Concern (VOC) are routinely monitored and reported by national and international organisations such as Public Health England (PHE), World Health Organisation (WHO) and European Centre for Disease Prevention and Control (ECDC) [1,2]. There is clear evidence that the Delta variant (B.1.617.2) of SARS-CoV-2 causes more infections and spreads faster than earlier variants [3,4,5,6]. This variant has caused a surge in the number of COVID-19 cases in many countries across the world. The emergence of such new variants highlights the need for rapid tests for population screening and to limit transmission of SARS-CoV-2. Therefore, given the crucial part of *in-vitro* diagnostics (IVD) in the management of the global pandemic, it is important that manufacturers of IVD devices monitor and validate their devices routinely to ensure continued diagnostic accuracy with newly emerging Variants of Concern.

Objectives

Avacta Diagnostics actively monitors the performance of the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test against the emergence of new SARS-CoV-2 Variants of Concern. When a variant is designated as a VOC, Avacta obtains the irradiated virus and tests it on the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test.

In this case, an independent validation study was conducted at an additional external site to verify that the device can detect the virus in samples of patients that had been confirmed as carrying the Delta variant of the virus.

Materials and methods

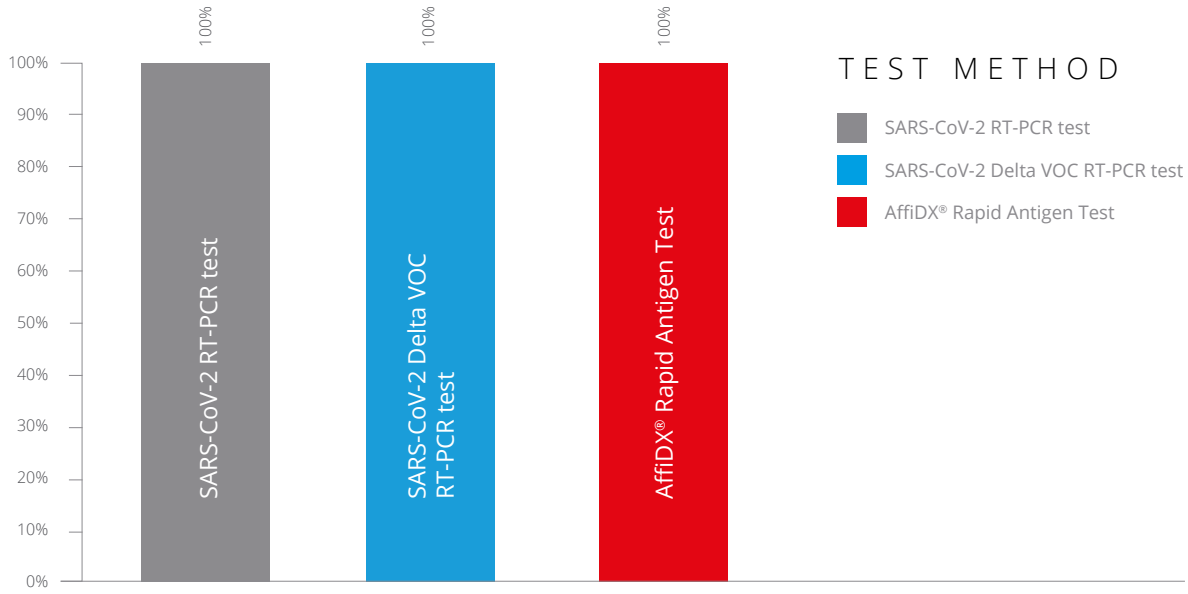
Validation study conducted at Hospital Carlos III, Madrid, Spain between June-August 2021. Samples (N=11) were taken from both symptomatic and asymptomatic individuals at various hospital and non-hospital settings. The samples were first analysed by RT-PCR using the methods described in the table below to verify positivity and characterise the samples as being consistent with the Delta Variant of Concern.

All samples were confirmed as carrying mutations consistent with the Delta variant and were then assayed on the Avacta AffiDX® SARS-CoV-2 Antigen Lateral Flow Test in duplicate. Positive results were recorded when positive visual signal appeared at both the Test and Control lines of the lateral flow device. The results are summarized in the next section.

Sample number	Clinical information	RT-PCR result	Mutations detected	Consistent with Delta VOC (Y/N)	AffiDX® result 1	AffiDX® result 2	Delta VOC detected with AffiDX® (Y/N)
1	M48* †	POSITIVE	L452R / P681R	YES	POSITIVE	POSITIVE	YES
2	M72 * †	POSITIVE	E484Q	YES	POSITIVE	POSITIVE	YES
3	F37 * †	POSITIVE	L452R	YES	POSITIVE	POSITIVE	YES
4	M39 * †	POSITIVE	E484Q	YES	POSITIVE	POSITIVE	YES
5	F69 * †	POSITIVE	L452R	YES	POSITIVE	POSITIVE	YES
6	Subject 6 * †	POSITIVE	E484Q	YES	POSITIVE	POSITIVE	YES
7	Subject 7* †	POSITIVE	E484Q	YES	POSITIVE	POSITIVE	YES
8	Subject 8* †	POSITIVE	L452R	YES	POSITIVE	POSITIVE	YES
9	Subject 9* †	POSITIVE	L452R	YES	POSITIVE	POSITIVE	YES
10	Subject 10* †	POSITIVE	E484Q	YES	POSITIVE	POSITIVE	YES
11	Subject 11* †	POSITIVE	P681R	YES	POSITIVE	POSITIVE	YES

Table 1: *Testing of COVID-19 positive samples using AffiDX® SARS-CoV-2 Antigen Lateral Flow Test.*
** Refers to positive signal using MIRNAX SARS-CoV-2 RTqPCR Diagnostic Test for the diagnosis of COVID-19 in saliva and respiratory samples.*
† Refers to confirmation using the TaqMan SARS-CoV-2 Mutation Panel with the TaqPath™ 1-Step RT-qPCR Master Mix.

DETECTION OF SARS-COV-2 DELTA VARIANT OF CONCERN
USING THE AFFIDX® SARS-COV-2 ANTIGEN LATERAL FLOW TEST



Conclusion

Based on the results of the analysis above, this study showed conclusively that the Avacta AffiDX® SARS-CoV-2 Antigen Lateral Flow Test device is confirmed as being able to detect the SARS-CoV-2 Delta Variant of Concern in routine samples.

The SARS-CoV-2 Delta variant has a higher transmission rate and is prevalent in many countries. Rapid lateral flow COVID-19 tests are commonly used across the world for mass screening; hence it is important that these rapid antigen tests are accurately evaluated against the Delta variant. Very few SARS-CoV-2 rapid antigen tests that are currently available in the market have been clinically evaluated against the Delta variant and these studies are usually conducted based on *in-silico* laboratory approach instead of using real-life patient samples. In this study, the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test was independently validated against Delta Variant of Concern using routine, prospective clinical samples.
The AffiDX® SARS-CoV-2 Antigen Lateral Flow Test uses novel Affimer® technology which is highly sensitive and specific for the detection of SARS-CoV-2 antigens in human anterior nasal swab samples.

This study provides further evidence that Affimer® technology can be successfully applied to rapid antigen diagnostic platforms.

References

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