Predicted Impact of Variants on Abbott SARS-CoV-2/COVID-19 Diagnostic Tests

Technical Brief
April 29th, 2022

Purpose: This Technical Brief is an up-to-date overview on the predicted impact, if any, to the performance of Abbott SARS-CoV-2/COVID-19 diagnostic tests in the detection of SARS-CoV-2 viral variants, as determined through ongoing analysis by the Abbott Pandemic Defense Coalition. This document is provided as assurance to customers that Abbott is conducting continuous and thorough analysis of emerging SARS-CoV-2 variants.

Background: Emerging variants of the SARS-CoV-2 virus have been identified across the globe with concerning pathogenic properties.[1,2] Assessing the risk emerging variants may pose to public health relies on continued identification and characterization.[3] Concerns have been raised as some variants have been reported to have increased viral transmission and disease severity.[4] As these variants are identified, it is imperative that efforts are taken to monitor any potential impact the genomic mutations have on viral detection by Abbott diagnostic tests.

Abbott Monitoring: Abbott is continuously monitoring the global SARS-CoV-2 situation through complex processes overseen by the Abbott Pandemic Defense Coalition.[5,6,7] As emerging variants are identified, sequence and *in silico* analyses are conducted to evaluate potential impact of these mutations to our tests. This proactive monitoring scheme enables Abbott to communicate the most up to date information specific to our tests. While the detailed evidence is proprietary, Abbott recognizes the need to provide customer assurance on our test performance. In addition to this document, the Abbott Pandemic Defense Coalition has published a study evaluating the Abbott molecular, antigen, and serologic assays with several SARS-CoV-2 viral variants and will continue to publish as evaluations of emerging variants continue to arise.[6]

Predicted Impact of Variants on Abbott SARS-CoV-2/COVID-19 Diagnostic Tests:
The following table lists the Abbott SARS-CoV-2/COVID-19 diagnostic tests, the target(s) detected, and any predicted impact on assay performance based on data analyses to date (see **Table 2, Summary of Variants Analyzed to Date**).

Table 1: Predicted Impact of Variants on Abbott SARS-CoV-2/COVID-19 Diagnostic Tests:

Abbott SARS-CoV-2/COVID-19 Test	Detected Target(s)	Test Performance
Panbio™ COVID-19 Ag Rapid Test Device	N* protein	No Predicted Impact
Panbio™ COVID-19 Antigen Self-Test	N protein	No Predicted Impact
Panbio™ COVID-19 IgG/IgM Rapid Test Device	N protein	No Predicted Impact
BinaxNOW™ COVID-19 Ag Card	N protein	No Predicted Impact
BinaxNOW™ COVID-19 Antigen Self Test	N protein	No Predicted Impact
ID NOW™ COVID-19 Test	RdRp** gene	No Predicted Impact
Alinity m SARS-CoV-2	RdRp and N genes	No Predicted Impact
Alinity m Resp-4-Plex	RdRp and N genes	No Predicted Impact
RealTi*m*e SARS-CoV-2	RdRp and N genes	No Predicted Impact
Alinity i SARS-CoV-2 IgG	N protein	No Predicted Impact
ARCHITECT SARS-CoV-2 IgG	N protein	No Predicted Impact
Alinity i SARS-CoV-2 IgM	S*** protein	No Predicted Impact
ARCHITECT SARS-CoV-2 IgM	S protein	No Predicted Impact
AdviseDx SARS-CoV-2 IgM (Alinity i)	S protein	No Predicted Impact
AdviseDx SARS-CoV-2 IgM (ARCHITECT)	S protein	No Predicted Impact
Alinity i SARS-CoV-2 IgG II Quant	S protein	No Predicted Impact
ARCHITECT SARS-CoV-2 IgG II Quant	S protein	No Predicted Impact
AdviseDx SARS-CoV-2 IgG II (Alinity i)	S protein	No Predicted Impact
AdviseDx SARS-CoV-2 IgG II (ARCHITECT)	S protein	No Predicted Impact

N – Nucleocapsid; **RdRp – RNA dependent RNA polymerase; * S - Spike*

Table 2: Summary of Variants Analyzed to Date:[2-4,6,8,9,10]

WHO Nomenclature	Lineage	Country First Detected
Alpha#	B.1.1.7	England, UK
Alpha#	Q.5	Not confirmed
Alpha#	Q.6	Not confirmed
Alpha#	Q.7	Not confirmed
Beta	B.1.351	South Africa
Beta	B.1.351.2	South Africa
Beta	B.1.351.3	South Africa
Beta	B.1.351.5	Not confirmed
Gamma	P.1	Japan ex Manaus, Brazil
Gamma	P.1.1	Brazil

Gamma	P.1.2	Brazil
Delta*	B.1.617.2	India
Delta*	AY.1	India
Delta*	AY.2	India
Delta*	AY.3	India
Delta*	AY.3.1	USA
Delta*	AY.4	Not confirmed
Delta*	AY.4.2	England, UK
Delta*	AY.5	Not confirmed
Delta*	AY.5.1	Not confirmed
Delta*	AY.5.2	Not confirmed
Delta*	AY.6	Thailand
Delta*	AY.7	India
Delta*	AY.8	Not confirmed
Delta*	AY.9	India
Delta*	AY.10	Not confirmed
Delta*	AY.11	Not confirmed
Delta*	AY.12	Not confirmed
Delta*	AY.25	Not confirmed
Delta*	AY.27	Not confirmed
Delta*	AY.30	Not confirmed
Delta*	AY.31	Not confirmed
Delta*	AY.70	Not confirmed
Delta*	AY.74	Not confirmed
Delta*	AY.88	Not confirmed
Delta*	AY.97	Not confirmed
Delta*	AY.107	Not confirmed

Delta*/Omicron^&	XD@	England, UK
Delta*/Omicron^&	XF	England, UK
Epsilon	B.1.427	California, USA
Epsilon	B.1.429	California, USA
Zeta	P.2	Brazil
Eta	B.1.525	England, UK, Nigeria
Theta	P.3	Philippines
Iota	B.1.526	New York, USA
Kappa	B.1.617.1	India
Lambda	C.37	Peru
Mu	B.1.621	Colombia
Mu	B.1.621.1	Not confirmed
Omicron^	B.1.1.529	Multiple Countries
Omicron^	BA.1	Multiple Countries
Omicron^	BA.1.1	Not confirmed
Omicron^	BA.2	Multiple Countries
Omicron^	BA.2.2	Multiple Countries
Omicron^	BA.2.12	Multiple Countries
Omicron^	BA.2.12.1	Multiple Countries
Omicron^	BA.3	Not confirmed
Omicron^	BA.4	South Africa
Omicron^	BA.5	South Africa
Omicron^%	XE	England, UK
Not designated	A.23.1+E484K	England, UK
Not designated	A.27	Not confirmed
Not designated	AT.1	Russia
Not designated	AV.1	England, UK

Not designated	B.1.1.318	England, UK
Not designated	B.1.1.451	Not confirmed
Not designated	B.1.1.519	Mexico
Not designated	B.1.1.523	Not confirmed
Not designated	B.1.1.7 with E484K	England, UK
Not designated	B.1.214.2	Not confirmed
Not designated	B.1.36.26	Not confirmed
Not designated	B.1.429.1	Not confirmed
Not designated	B.1.466.2	Indonesia
Not designated	B.1.526.1	New York, USA
Not designated	B.1.526.2	New York, USA
Not designated	B.1.616	France
Not designated	B.1.617.3	India
Not designated	B.1.618	India
Not designated	B.1.619	Not confirmed
Not designated	B.1.620	Not confirmed
Not designated	B.1.628	Not confirmed
Not designated	C.1.2	South Africa
Not designated	C.36.3	Not confirmed
Not designated	C.36.3.1	Not confirmed
Not designated	R.1	Japan and USA
Not designated	P.4	Not confirmed

Includes all Q lineages, which as noted by the WHO, is an alias for B.1.1.7 in Pango nomenclature. [9,10]

* Includes all AY lineages, which as noted by the WHO, is an alias for B.1.617.2 in Pango nomenclature. [11]

^ Includes all BA lineages, which is an alias for B.1.1.529 in Pango nomenclature. [12, 13]

& XD and XF are recombinant variants of Delta and Omicron BA.1. [14]

%XE is a recombinant variant of Omicron BA.1 and BA.2. [14]

@ *In silico* analysis of the XD variant identified the presence of a mutation in one of the Abbott test targets. This mutation is found in the N gene of the Delta variant and was shown to have no impact. [8]

Technical Support:

If you have any questions on the provided information or are able to provide access to emerging variant samples, please contact Technical Support.

ID NOW™ COVID-19 test^: https://www.globalpointofcare.abbott/en/product-details/id-now-covid-19.html

BinaxNOW™ COVID-19 Ag Card^:

Professional: https://www.globalpointofcare.abbott/en/product-details/navica-binaxnow-covid-19-us.html

Proctored: https://www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-home-test-us.html

BinaxNOW™ COVID-19 Self Test:

https://www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-antigen-self-test-us.html

Panbio™ COVID-19 Ag Rapid Test Device#:

https://www.globalpointofcare.abbott/en/product-details/panbio-covid-19-ag-antigen-test.html

Panbio™ COVID-19 IgG/IgM Rapid Test Device#:

https://www.globalpointofcare.abbott/en/product-details/panbio-covid-19-igg-igm-antibody-test.html

Panbio™ COVID-19 Antigen Self-Test#:

https://www.globalpointofcare.abbott/en/product-details/panbio-covid-19-antigen-self-test.html

Abbott Alinity m SARS-CoV-2^, Alinity m Resp-4-Plex^, RealTime SARS-CoV-2^:

Global: https://www.molecular.abbott/int/en/contact-technical-support

US: https://www.molecular.abbott/us/en/knowledge-center/support

Abbott SARS-CoV-2 IgM, SARS-CoV-2 IgG, SARS-CoV-2 IgG II Quant, AdviseDx SARS-CoV-2 IgM, and AdviseDx SARS-CoV-2 IgG II Assays for the Use with ARCHITECT and Alinity i#^:

https://www.corelaboratory.abbott/int/en/about-us/customer-service-support

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[1] CDC. What You Need to Know About Variants. Updated April 26, 2022. Accessed May 3, 2022. www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html

[2] UK Health Security Agency. Research and analysis. Variants: distribution of cases data, 20 May 2021. Updated April 29, 2022. Accessed May 3, 2022. https://www.gov.uk/government/publications/covid-19-variants-genomically-confirmed-case-numbers/variants-distribution-of-cases-data

[3] CDC. SARS-CoV-2 Variant Classifications and Definitions. Updated April 26, 2022. Accessed May 3, 2022. https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html

[4] ECDC. SARS-CoV-2 variants of concern as of 28 April 2022. Updated April 28, 2022. Accessed May 3, 2022. https://www.ecdc.europa.eu/en/covid-19/variants-concern

[5] Abbott Newsroom. How We're Tracking COVID-19 Variants. Updated February 23, 2021. Accessed May 3, 2022. https://www.abbott.com/corpnewsroom/products-and-innovation/how-we-track-covid-19-variants.html

[6] Rodgers MA, Olivo A, Harris BJ, *et al.* Detection of SARS-CoV-2 variants by Abbott molecular, antigen, and serological tests. *J Clin Virol.* 2022;147:105080. https://doi.org/10.1016/j.jcv.2022.105080

[7] Averhoff F, Berg M, Rodgers M, *et al.* The Abbott Pandemic Defense Coalition: a unique multisector approach adds to global pandemic preparedness efforts [published online ahead of print, 2022 Feb 5]. *Int J Infect Dis.* 2022;117:356-360. doi: https://doi.org/10.1016/j.ijid.2022.02.001

[8] Abbott data on file

[9] WHO. Coronavirus disease (COVID-19) Weekly Epidemiological Update and Weekly Operational Update. Accessed May 3, 2022. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

[10] WHO. Tracking SARS-CoV-2 Variants. Updated May 3, 2022. Accessed May 3, 2022. https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/

[11] Pango Network. New AY Lineages. Updated August 13, 2021. Accessed May 3, 2022. http://pango.network/new-ay-lineages/

[12] Pango Network. Updates to Omicron Lineage B.1.1.529. Updated December 9, 2021. Accessed May 3, 2022. https://www.pango.network/updates-to-omicron-lineage-b-1-1-529/

[13] WHO. Statement on Omicron sublineage BA.2. Updated February 22, 2022. Access May 3, 2022. https://www.who.int/news/item/22-02-2022-statement-on-omicron-sublineage-ba.2

[14] UK Security Agency. SARS-CoV-2 variants of concern and variants under investigation in England. Updated March 25, 2022. Access May 3, 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063424/Tech-Briefing-39-25March2022_FINAL.pdf

FOR EXTERNAL USE

Products not available in all countries. Available to consumers in select markets.

#The Panbio™ COVID-19 Ag Rapid Test Device, Panbio™ COVID-19 IgG/IgM Rapid Test Device, Panbio™ COVID-19 Antigen Self-Test, and SARS-CoV-2 IgM and SARS-CoV-2 IgG II Quant Assays for the Use with ARCHITECT and Alinity i are not available for sale in the US.

^ Emergency Use Authorization (EUA) Conditions for BinaxNOW™ COVID-19 Ag Card, BinaxNOW™ COVID-19 Antigen Self Test, ID NOW™ COVID-19, Alinity m SARS-CoV-2, Alinity m Resp-4-Plex and Realti*m*e SARS-CoV-2 assay, SARS-CoV-2 IgG, AdviseDx SARS-CoV-2 IgM, and AdviseDx SARS-CoV-2 IgG II assays for the use with ARCHITECT and Alinity i:

- BinaxNOW™ COVID-19 Ag Card has not been FDA cleared or approved, but have been authorized for emergency use by FDA under an EUA. It has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens;
- The BinaxNOW™ COVID-19 Antigen Self Test has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization. It has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. BinaxNOW™ COVID-19 Antigen Self Test should be performed twice in 3 days, at least 24 hours apart (and no more than 48 hours) apart;
- ID NOW™ COVID-19 has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories or patient care settings;
- Alinity m SARS-CoV-2, Alinity m Resp-4-Plex and Realti*m*e SARS-CoV-2 assays have not been FDA cleared or approved, but have been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- Alinity m SARS-CoV-2 and Alinity m Resp-4-Plex assays have been authorized by the FDA under an EUA for use by laboratories certified under CLIA, to perform moderate or high complexity tests;
- ID NOW™ COVID-19, Alinity m SARS-CoV-2 assay and RealTi*m*e SARS-CoV-2 assay have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;
- Alinity m Resp-4-Plex has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B, and/or Respiratory Syncytial Virus, not for any other viruses or pathogens;
- SARS-CoV-2 IgG, AdviseDx SARS-CoV-2 IgM, and AdviseDx SARS-CoV-2 IgG II Assays for the Use with ARCHITECT and Alinity i have not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. These products have been authorized only for detecting the presence of IgM or IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. Prescription Use Only.
- The emergency use of the products are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.