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

Technical Brief
June 28, 2024

Purpose: This Technical Brief is an up-to-date overview on the predicted impact, if any, to the performance of Abbott's 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 SARS-CoV-2 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's diagnostic tests.

Abbott's 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 Abbott's 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's SARS-CoV-2/COVID-19 Diagnostic Tests: The following table (Table 1) lists the Abbott's 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**).

ADD-136869-GBL-EN 6/24
AMD.15594 6/24
COL-04232-25 6/24

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

Abbott's SARS-CoV-2/COVID-19 Test	SARS-CoV-2 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/Flu A&B Rapid Panel	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 2.0 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 (sorted by lineage in alphabetical order):[2-4, 6, 8, 9, 10,15]

Lineage	WHO Nomenclature
A.23.1+E484K	Not designated
A.27	Not designated
AT.1	Not designated
AV.1	Not designated
AY.1	Delta*
AY.10	Delta*
AY.107	Delta*
AY.11	Delta*
AY.12	Delta*

Lineage	WHO Nomenclature
AY.2	Delta*
AY.25	Delta*
AY.27	Delta*
AY.3	Delta*
AY.3.1	Delta*
AY.30	Delta*
AY.31	Delta*
AY.4	Delta*
AY.4.2	Delta*

Lineage	WHO Nomenclature
AY.5	Delta*
AY.5.1	Delta*
AY.5.2	Delta*
AY.6	Delta*
AY.7	Delta*
AY.70	Delta*
AY.74	Delta*
AY.8	Delta*
AY.88	Delta*
AY.9	Delta*
AY.97	Delta*
B.1.1.318	Not designated
B.1.1.451	Not designated
B.1.1.519	Not designated
B.1.1.523	Not designated
B.1.1.529	Omicron^
B.1.1.7	Alpha#
B.1.1.7 with E484K	Not designated
B.1.214.2	Not designated
B.1.351	Beta
B.1.351.2	Beta
B.1.351.3	Beta
B.1.351.5	Beta
B.1.36.26	Not designated
B.1.427	Epsilon
B.1.429	Epsilon

Lineage	WHO Nomenclature
B.1.429.1	Not designated
B.1.466.2	Not designated
B.1.525	Eta
B.1.526	Iota
B.1.526.1	Not designated
B.1.526.2	Not designated
B.1.616	Not designated
B.1.617.1	Kappa
B.1.617.2	Delta*
B.1.617.3	Not designated
B.1.618	Not designated
B.1.619	Not designated
B.1.620	Not designated
B.1.621	Mu
B.1.621.1	Mu
B.1.628	Not designated
BA.1	Omicron^
BA.1.1	Omicron^
BA.1.15	Omicron^
BA.2	Omicron^
BA.2.10	Omicron^
BA.2.12	Omicron^
BA.2.12.1	Omicron^
BA.2.16	Omicron^
BA.2.2	Omicron^
BA.2.86	Omicron^

Lineage	WHO Nomenclature
BA.2.86.1	Omicron^
BA.2.3	Omicron^
BA.2.3.20	Omicron^
BA.2.38	Omicron^
BA.2.38.1	Omicron^
BA.2.75	Omicron^
BA.2.75.2	Omicron^
BA.2.76	Omicron^
BA.2.86.1	Omicron^
BA.2.87.1	Omicron^
BA.2.9	Omicron^
BA.2.9.1	Omicron^
BA.3	Omicron^
BA.4	Omicron^
BA.4.1	Omicron^
BA.4.6	Omicron^
BA.4.7	Omicron^
BA.5	Omicron^
BA.5.1	Omicron^
BA.5.1.12	Omicron^
BA.5.1.25	Omicron^
BA.5.2	Omicron^
BA.5.2.1	Omicron^
BA.5.2.48	Not designated
BA.5.3	Omicron^
BA.5.3.1	Omicron^

Lineage	WHO Nomenclature
BA.5.3.5	Omicron^
BA.5.5	Omicron^
BA.5.6	Omicron^
BE.1	Omicron^
BE.1.1	Omicron^
BF.5	Omicron^
BF.7	Omicron^
BF.7.14	Not designated
BF.7.4	Omicron^
BN.1	Omicron^
BN.1.3	Not designated
BQ.1	Omicron^~
BQ.1.1	Omicron^~
BQ.1.1.13	Omicron^~
BQ.1.1.18	Omicron^~
BQ.1.1.20	Omicron^~
BQ.1.1.22	Omicron^~
BQ.1.8	Omicron^~
BR.2.1	Not designated
BW.1	Omicron^
C.1.2	Not designated
C.36.3	Not designated
C.36.3.1	Not designated
C.37	Lambda
CH.1.1	Omicron^
CH.1.1.1	Not designated

Lineage	WHO Nomenclature
CH.1.1.3	Not designated
CK.2.1.1	Omicron^
DV.7.1	Omicron^
EG.1	Omicron^~
EG.5	Omicron^
EG.5.1	Omicron^~
EG.5.1.1	Omicron^~
EG.5.1.3	Omicron^~
EG.5.1.6	Omicron^~
EG.5.1.8	Omicron^~
EG.5.2	Omicron^~
EU.1.1	Omicron^
FD.2	Omicron^~
FE.1	Omicron^~
FE.1.1	Omicron^
FE.1.2	Omicron^
FK.1	Omicron^
FK.1.1	Omicron^
FL.1.5.1	Omicron^
FL.2	Omicron^
FL.4	Omicron^
FL.15.1.1	Omicron^
FU.1	Omicron^
FU.2	Omicron^
FY.4	Omicron^
GK.1	Omicron^

Lineage	WHO Nomenclature
GK.1.1	Omicron^
GN.1.1	Omicron^~
GS.4.1	Omicron^
HK.1	Omicron^
HK.3	Omicron^
HK.3.2	Omicron^
HV.1	Omicron^
JD.1.1	Omicron^~
JE.1.1	Omicron^~
JG.3	Omicron^~
JN.1	Omicron^
JN.1.1	Omicron^
JN.1.4	Omicron^
JN.1.4.5	Omicron^
JN.1.5	Omicron^
JN.1.7	Omicron^
JN.1.7.2	Omicron^
JN.1.13	Omicron^
JN.1.13.1	Omicron^
JN.1.16	Omicron^
JN.1.16.1	Omicron^
JN.1.18	Omicron^
JN.1.21	Omicron^
JN.1.32	Omicron^
JN.1.42	Omicron^
JN.2.5	Omicron^

Lineage	WHO Nomenclature
KP.1.1	Omicron^
KP.1.1.1	Omicron^
KP.2	Omicron^
KP.3	Omicron^
KP.3.1	Omicron^
KP.3.2	Omicron^
KW.1	Omicron^
LB.1	Omicron^
P.1	Gamma
P.1.1	Gamma
P.1.2	Gamma
P.2	Zeta
P.3	Theta
P.4	Not designated
Q.5	Alpha#
Q.6	Alpha#
Q.7	Alpha#
R.1	Not designated
XBB	Omicron^~
XBB.1	Omicron^~
XBB.1.5	Omicron^~

Lineage	WHO Nomenclature
XBB.1.5.1	Omicron^~
XBB.1.5.13	Omicron^~
XBB.1.5.55	Omicron^~
XBB.1.9	Omicron^~
XBB.1.9.1	Omicron^~
XBB.1.9.2	Omicron^~
XBB.1.16	Omicron^~
XBB.1.16.1	Omicron^~
XBB.1.16.6	Omicron^~
XBB.1.41.1	Omicron^~
XBB.2	Omicron^~
XBB.2.3	Omicron^~
XBB.2.3.11	Omicron^~
XBC.1	Omicron^~
XBC.1.3	Omicron^~
XBC.1.6	Omicron^~
XBF	Not designated
XD@	Delta*/Omicron^&
XE	Omicron^%
XF	Delta*/Omicron^&

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.

^ Includes all BA and BE lineages, which is an alias for B.1.1.529 in Pango nomenclature.[11,13]

& XD and XF are recombinant variants of Delta and Omicron BA.1.[12]

% XE is a recombinant variant of Omicron BA.1 and BA.2.[12]

@ *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]

~WHO's Technical Advisory group on SARS-CoV-2 Virus Evolution (TAG-VE) has decided that sublineages XBB and BQ.1 remain a part of the Omicron variant.[14]

Newly added variants are in bold.

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 2.0 test:
https://www.globalpointofcare.abbott/ww/en/product-details/id-now-covid-19-ww.html

BinaxNOW™ COVID-19 Ag Card^:
Professional: https://www.globalpointofcare.abbott/us/en/product-details/binaxnow-covid-19.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/ww/en/product-details/panbio-covid-19-ag-antigen-test-ww.html

Panbio™ COVID-19 Antigen Self-Test#:
https://www.globalpointofcare.abbott/ww/en/product-details/panbio-covid-19-antigen-self-test-global.html

Panbio™ COVID-19/Flu A&B Rapid Panel#:
https://www.globalpointofcare.abbott/ww/en/product-details/panbio-covid-19-flu-ab-rapid-panel.html

Alinity m SARS-CoV-2^, Alinity m Resp-4-Plex^, Abbott 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's 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

---

[1] CDC. Variants of the Virus. Updated Feb. 6, 2023. Accessed July 11, 2024. https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html
[2] UK Health Security Agency. Research and analysis. Variants: distribution of cases data, 20 May 2021. Updated July 11, 2022. Accessed April 4, 2024. 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 September 1, 2023. Accessed July 11, 2024. https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-classifications.html
[4] ECDC. SARS-CoV-2 variants of concern as of 28 June 2024. Updated July 1, 2024. Accessed July 11, 2024. https://www.ecdc.europa.eu/en/covid-19/variants-concern
[5] Abbott Newsroom. How We're Tracking COVID-19 Variants. Updated Feb. 23, 2021. Accessed July 11, 2024. 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) Epidemiological Update and Monthly Operational Update. Accessed July 11, 2024. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports
[10] WHO. Tracking SARS-CoV-2 Variants. Updated June 28, 2024. Accessed July 11, 2024. https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/
[11] WHO. Statement on Omicron sublineage BA.2. Updated Feb. 22, 2022. Accessed July 11, 2024. https://www.who.int/news/item/22-02-2022-statement-on-omicron-sublineage-ba.2
[12] UK Security Agency. SARS-CoV-2 variants of concern and variants under investigation in England. Technical briefing 39. Mar. 25, 2022. Accessed July 11, 2024. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063424/Tech-Briefing-39-25March2022_FINAL.pdf
[13] Cov-Lineages. Lineage List. Accessed July 11, 2024. https://cov-lineages.org/lineage_list.html
[14] CDC. TAG-VE statement on Omicron sublineages BQ.1 and XBB. Oct. 27, 2022. Accessed July 11, 2024. https://www.who.int/news/item/27-10-2022-tag-ve-statement-on-omicron-sublineages-bq.1-and-xbb
[15] WHO. Statement on the update of WHO's working definitions and tracking system for SARS-CoV-2 variants of concern and variants of interest. Updated Mar. 16, 2023. Accessed July 11, 2024. https://www.who.int/news/item/16-03-2023-statement-on-the-update-of-who-s-working-definitions-and-tracking-system-for-sars-cov-2-variants-of-concern-and-variants-of-interest

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 Antigen Self-Test, Panbio™ COVID-19/Flu A&B Rapid Panel, 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, 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;
- 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;
- 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.