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

TECHNICAL BRIEF
November 26th, 2021

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] 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

**N – Nucleocapsid; **RdRp – RNA dependent RNA polymerase*

Table 2: Summary of Variants Analyzed to Date:[2-4,6,7,8, 9]

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
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.27	Not confirmed
Delta*	AY.30	Not confirmed
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
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.1.1.519	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.1.429.1	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. * Includes all AY lineages, which as noted by the WHO, is an alias for B.1.617.2 in Pango nomenclature.[9,10]

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

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[1] www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html (Accessed 11/26/2021)
[2] https://www.gov.uk/government/publications/covid-19-variants-genomically-confirmed-case-numbers/variants-distribution-of-cases-data (Accessed 11/26/2021)
[3] https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html (Accessed 11/26/2021)
[4] https://www.ecdc.europa.eu/en/covid-19/variants-concern (Accessed 11/26/2021)
[5] https://www.abbott.com/corpnewsroom/products-and-innovation/how-we-track-covid-19-variants.html (Accessed 11/26/2021)
[6] https://doi.org/10.1101/2021.04.24.21256045 (Accessed 11/26/2021)
[7] Abbott data on file
[8] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports (Accessed 11/26/2021)
[9] https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (Accessed 11/26/2021)
[10] http://pango.network/new-ay-lineages/ (Accessed 11/26/2021)

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, and Panbio™ COVID-19 Antigen Self-Test are not available for sale in 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:

- 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;
- 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.