Detection of SARS-CoV-2 Genomic Variants by Abbott Diagnostic Tests

TECHNICAL BRIEF
May 28th, 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]

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

Country of Origin	Lineage	Additional Nomenclature
Brazil	P.2	VUI-202101/01, VUI-21JAN-01, 20J, Zeta
California, USA	B.1.427	20C/S:452R; Clade GH/452R.V1; CAL.20C/L452R, Epsilon
California, USA	B.1.429	20C/S:452R; Clade GH/452R.V1; CAL.20C/L452R, Epsilon

England, UK	B.1.1.7	VOC-202012/01, VOC-20DEC-01, VUI-202012/01; VUI-202012/01; Clade GR; 20I/501Y.V1, Alpha
England, UK	B.1.1.7 with E484K	VOC-21FEB-02; VOC-202102/02
England, UK, Nigeria	B.1.525	VUI-21FEB-03, VUI-202102/03; 20A/S:484K; Clade G/484K.V3, Eta
France	B.1.616	20C; Clade GH
India	B.1.617.1	VUI-21APR-01; 20A/S:154K, Kappa
India	B.1.617.2	VOC-21APR-02; 20A/S:478K, Delta
India	B.1.617.3	VUI-21APR-03; 20A
India	B.1.618	None to date
Japan and USA	R.1	None to date
Japan ex Manaus, Brazil	P.1	B1.1.28.1, VOC-202101/02, VOC-21JAN-02, 20J/501Y.V3, Gamma
New York, USA	B.1.526	20C/s:484k; Clade GH, Iota
New York, USA	B.1.526.1	20C
New York, USA	B.1.526.2	None to date
South Africa	B.1.351	VOC-202012/02, VOC-20DEC-02, 20H/501Y.V2, 501Y.V2, Clade GH/501Y.V1, Beta

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 previous table, **Summary of Variants Analyzed to Date**).

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 IgG/IgM Rapid Test Device	N protein	No Predicted Impact
Panbio™ COVID-19 Antigen Self-Test	N protein	No Predicted Impact
BinaxNOW™ COVID-19 Ag Card	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 Respiratory-4-Plex	RdRp and N genes	No Predicted Impact
RealTi*m*e SARS-CoV-2	RdRp and N genes	No Predicted Impact

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

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

Over the Counter: 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 Respiratory-4-Plex^, RealTi*m*e 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 06/04/2021)
[2] https://www.gov.uk/government/publications/covid-19-variants-genomically-confirmed-case-numbers/variants-distribution-of-cases-data (Accessed 06/04/2021)
[3] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance.html (Accessed 06/04/2021)
[4] https://www.ecdc.europa.eu/en/covid-19/variants-concern (Accessed 06/04/2021)
[5] https://www.abbott.com/corpnewsroom/products-and-innovation/how-we-track-covid-19-variants.html (Accessed 05/28/2021)
[6] https://doi.org/10.1101/2021.04.24.21256045 (Accessed 05/21/2021)
[7] Abbott data on file
[8] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports (Accessed 05/28/2021)
[9] https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (Accessed 06/07/2021)

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, 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 and EUA. It has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens;
- ID NOW™ COVID-19 has not been FDA cleared or approved, but has been authorized for emergency use by FDA under and 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 and EUA for use by authorized laboratories;
- 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.