BinaxNOW™ COVID-19 ANTIGEN TESTS AND EMERGING VARIANTS

No Predicted Impact of the Delta Variant on BinaxNOW™ COVID-19 Ag Card and the BinaxNOW™ COVID-19 Antigen Self Test

Abbott is continuously monitoring the global SARS-CoV-2 situation through complex processes overseen by the Abbott Pandemic Defense Coalition.[1,2] As emerging variants are identified, sequence and in silico analyses are conducted to evaluate potential impact of these mutations to our tests.

THERE IS NO PREDICTED IMPACTED ON BinaxNOW™ COVID-19 ANTIGEN TESTS PERFORMANCE BY ANY OF THESE VARIANTS ANALYZED AS OF JUNE 28, 2021, INCLUDING THE DELTA VARIANT:

COUNTRY FIRST DETECTED	LINEAGE	WHO NOMENCLATURE	ADDITIONAL NOMENCLATURE
BRAZIL	P.2	ZETA	VUI-202101/01, VUI-21JAN-01, 20J
CALIFORNIA, USA	B.1.427	EPSILON	20C/S:452R; CLADE GH/452R.V1; CAL.20C/L452R
CALIFORNIA, USA	B.1.429	EPSILON	20C/S:452R; CLADE GH/452R.V1; CAL.20C/L452R
COLOMBIA	B.1.621	NOT DESIGNATED	NONE TO DATE
ENGLAND, UK	A.23.1+E484K	NOT DESIGNATED	VUI-21FEB-01, VUI-202102/01
ENGLAND, UK	AV.1	NOT DESIGNATED	VUI-21MAY-01
ENGLAND, UK	B.1.1.7	ALPHA	VOC-202012/01, VOC-20DEC-01, VUI-202012/01; VUI-202012/01; CLADE GR; 20I/501Y.V1
ENGLAND, UK	B.1.1.7 WITH E484K	NOT DESIGNATED	VOC-21FEB-02; VOC-202102/02
ENGLAND, UK	B.1.1.318	NOT DESIGNATED	VUI-21FEB-04, VUI-202102/04
ENGLAND, UK, NIGERIA	B.1.525	ETA	VUI-21FEB-03, VUI-202102/03; 20A/S:484K; CLADE G/484K.V3
FRANCE	B.1.616	NOT DESIGNATED	20C; CLADE GH
INDIA	B.1.617.1	KAPPA	VUI-21APR-01; 20A/S:154K
INDIA	B.1.617.2	DELTA	VOC-21APR-02; 20A/S:478K
INDIA	B.1.617.3	NOT DESIGNATED	VUI-21APR-03; 20A
INDIA	B.1.618	NOT DESIGNATED	NONE TO DATE
JAPAN AND USA	R.1	NOT DESIGNATED	NONE TO DATE
JAPAN EX MANAUS, BRAZIL	P.1	GAMMA	B1.1.28.1, VOC-202101/02, VOC-21JAN-02, 20J/501Y.V3
MEXICO	B.1.1.519	NOT DESIGNATED	NONE TO DATE
NEW YORK, USA	B.1.526	IOTA	20C/S:484K; CLADE GH
NEW YORK, USA	B.1.526.1	NOT DESIGNATED	20C
NEW YORK, USA	B.1.526.2	NOT DESIGNATED	NONE TO DATE
PERU	C.37	LAMBDA	20D, GR/452Q.V1
PHILLIPPINES	P.3	THETA	VUI-21MAR-02
RUSSIA	AT.1	NOT DESIGNATED	VUI-21MAY-01
SOUTH AFRICA	B.1.351	BETA	VOC-202012/02, VOC-20DEC-02, 20H/501Y.V2, 501Y.V2, CLADE GH/501Y.V1
NOT CONFIRMED	AY.1	NOT DESIGNATED	DELTA PLUS
NOT CONFIRMED	A.27,B.1.429.1, B.1.620, C.36.3, P.1.1, P.1.2	NOT DESIGNATED	NONE TO DATE

Abbott will continue to publish evaluations as emerging variants continue to arise.

The BinaxNOW COVID-19 Rapid Antigen Tests are only available in the US.

1. https://abbott.mediaroom.com/2021-03-11-Abbott-Announces-its-Pandemic-Defense-Coalition-A-Global-Network-of-Expert-Collaborators-Designed-To-Help-Prevent-Future-Pandemics-Currently-Searching-for-COVID-19-Variants
2. https://www.abbott.com/corpnewsroom/products-and-innovation/how-we-track-covid-19-variants.html

The BinaxNOW™ COVID-19 Antigen Self Test and the BinaxNOW™ COVID-19 Ag Card have not been FDA cleared or approved. They have been authorized by the FDA under an emergency use authorization. They have been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and is 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 soon. The BinaxNOW COVID-19 Antigen Self-Test should be performed twice in 3 days, at least 36 hours apart.

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