

Detection of Emerging SARS-CoV-2 Variants with Hologic SARS-CoV-2 Assays

Worldwide IVD Distribution

Purpose

The purpose of this Customer Technical Bulletin (CTB) is to inform Hologic, Inc. (Hologic) customers using the Panther Fusion® SARS-CoV-2* and/or the Aptima® SARS-CoV-2* assay(s) that, based on *in silico* analysis, we do not expect any of the emerging SARS-CoV-2 variants identified as of April 28, 2021 will impact the performance of our assays.

Scope

This CTB refers to the Panther Fusion SARS-CoV-2 and Aptima SARS-CoV-2 assays. This CTB is intended for site administrators and operators and is effective upon receipt.

What is Affected

As part of post-launch surveillance activities, Hologic routinely monitors available target sequences to ensure that our product performance is not impacted by the emergence of SARS-CoV-2 variants.

Recently, several new SARS-CoV-2 variants have been identified. Revision 005 of this CTB includes updates to Table 1, noted by **bold** font.

Hologic performed *in silico* analysis by reviewing available sequences from all variants in Table 1 below and did not find any mutations at a reported frequency that would be expected to impact assay performance.

The names of the variants and their aliases are tabulated below:

TABLE 1:

SARS-CoV-2 Variant	Aliases
UK Variant	20I/501Y.V1 VOC 202012/01 B.1.1.7 lineage
South Africa variant	20H/501Y.V2 B.1.351 lineage VOC-202012/02
Mink variant	NA (includes Spike Y453F mutation)

SARS-CoV-2 Variant	Aliases
Brazilian (Manaus) variant	484K.V2 (includes P.1 and P.2 lineages) P.1 lineage B.1.1.28.1 20J/501Y.V3 VOC-202101/02
California variant	CAL.20C B.1.429 and B.1.427 lineages Includes Spike L452R mutation
Ohio variants	COH.20G/501Y and COH.20G/677H
Nigerian Variant	B.1.1.207 Includes Spike P681H mutation
VOC-202102/02	Sub-population of lineage B.1.1.7 that has the E484K mutation
VUI-202102/01	Sub-population of lineage A.23.1 that has the E484K mutation
VUI-202102/03	Lineage B.1.525
New York Variant	Lineage B.1.526
VUI-202102/04	Lineage B.1.1.318
VUI-202103/01	Lineage B.1.324.1 with E484K
Breton variant	French VUI derived from Clade 20C
VUI-21MAR02	Lineage P.3 (aka B.1.1.28.3) from the Philippines
B.1.617	VUI-21APR-01 Indian “double mutant”
C.37 lineage	Lineage B.1.1.1.37 from Peru and Chile

What is Required

If there are any questions or concerns regarding this communication, please contact your local Hologic support representative. Alternatively, country-specific telephone and email contact information for Technical Support can be found at www.hologic.com/support.

*Based on local regulatory authorization and/or inventory availability in the customer's geography. Contact your local Hologic representative for more information about product availability.

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