

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 June 15, 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 006 of this CTB includes updates to Table 1, including the new WHO nomenclature for the variants.

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:

WHO nomenclature	Pangolin lineage	PHE Designation	First detected in seq from	Other names by which it may be known
Alpha	B.1.1.7	VOC-20DEC01	UK (Kent)	20I/501Y.V1 (formerly 20B/501Y.V1)
Beta	B.1.351	VOC-20DEC02	South Africa	20H/501Y.V2 (formerly 20C/501Y.V2)
Gamma	P.1	VOC-21JAN02	Japan ex Brazil (Manaus)	20J/501Y.V3
Delta	B.1.617.2	VOC-21APR02	India	20A/S:478K
Epsilon	B.1.427/B.1.429	N/A	USA (CA)	CAL.20C or 20C/S:452R

WHO nomenclature	Pangolin lineage	PHE Designation	First detected in seq from	Other names by which it may be known
Zeta	P.2	VUI-21JAN01	Brazil	-
Eta	B.1.525	VUI-21FEB03	UK & Nigeria	20A:/S:484K
Theta	P.3	VUI-21MAR02	Philippines	-
Iota	B.1.526	N/A	USA (NY)	20C/S:484K
Kappa	B.1.617.1	VUI-21APR01	India	20A/S:154K
N/A	B.1.1.7 with E484K	VOC-21FEB02	UK	-
N/A	A.23.1 with E484K	VUI-21FEB01	UK	-
N/A	B.1.1.318	VUI-21FEB04	UK	-
N/A	B.1.617.3	VUI-21APR03	India	-
N/A	N/A	N/A	Denmark	Danish mink variant or Y453F variant
N/A	B.1.616	N/A	France (Bretagne)	Breton or Brittany variant
N/A	N/A	N/A	USA (OH)	Ohio variants COH.20G/501Y and COH.20G/677H)
N/A	B.1.1.207 with P681H	N/A	Nigeria	-
N/A	B.1.324.1 with E484K	VUI-21MAR01	UK	-
Lambda	C.37	VUI-21JUN-01	Peru	-
N/A	AV.1	VUI-21MAY01	UK	-
N/A	C.36.3	VUI-21MAY02	Thailand ex Egypt	-