



HDPCR™ SARS CoV-2 Assay Inclusivity Analysis

Last updated: May 27, 2021

ChromaCode diligently performs inclusivity analysis of its HDPCR SARS-CoV-2 Assay, considering new and emerging SARS-CoV-2 sequences as they become available on the GISAID database. The HDPCR SARS-CoV-2 Assay includes the same N1 and N2 oligonucleotide primer and probe sequences for the detection of the SARS-CoV-2 viral RNA and the human RNase P gene used in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel for Emergency Use Only, effective 03/15/2020. The ChromaCode team does extensive *in silico* analysis against all United States sequences deposited into the GISAID on a monthly cadence.

Specifically, in light of recent strain variants highlighted in the media, we can confirm that the ChromaCode HDPCR SARS-CoV-2 Assay is inclusive of the following:

- The United Kingdom Variant, known as 20I/501.V1, VOC 202012/01, or B.1.1.7
- The South African Variant, known as 20H/501Y.V2 or B.1.351
- The Brazil/Japan Variant, known as 20J/501Y.V3 or P.1
- The US-California Variant, known as 20C/S:452R or B.1.427
- The US-California Variant, known as 20C/S:452R or B.1.429
- The United Kingdom/Nigeria Variant, known as 20A/S:484K or B.1.525
- The United States (New York) Variant, known as 20C/S:484K or B.1.526
- The United States (New York) Variant, known as 20C or B.1.526.1
- The India Variant, known as 20A or B.1.617
- The India Variant, known as 20A/S:154K or B.1.617.1
- The India Variant, known as 20A/S:478K or B.1.617.2
- The India Variant, known as 20A or B.1.617.3
- The Brazil Variant, known as 20J or P.2

For a full list of updated *in silico* inclusivity study results, please see the most updated version of the HDPCR SARS-CoV-2 Assay Instructions for Use available at www.chromacode.com, through your instance of ChromaCode Cloud, or on www.fda.gov.

Support

For any questions or clarifications regarding this update, please contact ChromaCode Technical Support.
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