

# GUIDANCE FOR DETECTION OF OMICRON THROUGH REAL-TIME PCR

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## 1 Background

The B.1.1.529 variant of SARS-CoV-2 was first detected in South Africa on November 11, 2021. The World Health Organization has designated B.1.1.529 as Variant of Concern (VOC), with the name 'Omicron' on November 26, 2021. This variant has large number of mutations in the spike protein, several of them are novel. This level of variation has led to concerns regarding its transmissibility, immune system evasion, and vaccine resistance. Initial reports are suggesting that variant is highly transmissible, and it has spread to more than 80 countries with 20,356 confirmed cases as of December 22, 2021, where two cases of the variant have been reported from Pakistan. The detection of Omicron in Pakistan highlights the need for enhanced genomic surveillance and sharing of data with health authorities including the National Institute of Health.

The whole genome sequencing of SARS-CoV-2 is a sensitive method for lineage confirmation. However, it cannot be performed by every laboratory due to limitations of turn-around time, expertise, and resources. Alternatively, PCR genotyping methods for detection of specific mutations serve as a good tool for timely detection of Omicron. The widely used test for Omicron i.e., SGTF (Thermo fisher RT-PCR TaqPath™ Kit) can be used as marker for variant detection. However, in case of Pakistan it is not that specific due to reports of lineage A cases having SGTF. So, additional testing of mutations specific for Omicron are recommended for lineage confirmation. In this regard, the National Institute of Health, Islamabad has prepared a revised version of protocol for the PCR based detection of Omicron variant.

## 2 Case Definitions

The definition of confirmed and suspected case of Omicron is as follows:

**Confirmed Case:** Omicron (B.1.1.529) by sequencing or genotyping;

1. 69-70del (spike gene target failure) + K417N
2. 69-70del (spike gene target failure) + N501Y
3. 69-70del (spike gene target failure) + K471N + N501Y
4. K417N + P681R failure
5. Other relevant genotyping results

**Suspected case:** The COVID-19 positive sample from November 1, 2021, with spike gene target failure (69-70del).

### 3 PCR-based Testing Algorithm for Omicron detection

