World Health Organization
REGIONAL OFFICE FOR Africa

COVID-19 RESPONSE

WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR AFRICA SUPPORTS THE COVID-19 RESPONSE

TECHNICAL NOTE USING PCR SCREENING FOR OMICRON VARIANT

On 26 November 2021, WHO on the advice of the Technical Advisory Group on SARS-CoV-2 Virus Evolution (TAG-VE) designated a new Variant of Concern (VOC), Omicron. The variant has the Pango lineage B.1.1.529 and was first reported by South Africa from a specimen collected in early November, however recent data suggests that this variant may have been circulating in Europe earlier than this time. Since its initial detection Omicron has been identified in countries in four of the six WHO Regions. As with the identification of the Alpha variant in the UK, the lab team in South Africa detected an increasing number of specimens with an S gene target dropout using the Thermo Fisher TaqPath COVID-19 Combo Kit as their diagnostic assay. Sequencing of these specimens identified the new variant of SARS CoV-2 B.1.1.529, now called Omicron which has over 30 mutations in the S gene. The relative prevalence of each mutation in Omicron sequences in not yet known as the sequencing data at the present time is limited.

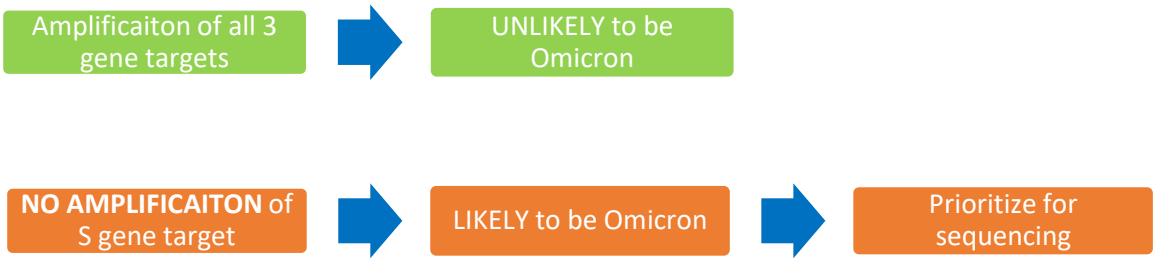
This technical note aims to provide information to member states for using PCR Assays as a screening tool for Omicron variant. PCR screening can support the selection of specimens for sequencing which will provide definitive identification of Omicron. PCR screening assays specifically for this variant are rapidly being produced by manufacturers.

For the most part Delta VOC has been identified as circulating broadly in African countries. **As a first step** it is suggested to review VOCs identified in the past 4-8 weeks in your country if this information is available, to identify the prevalent circulating VOC. **Secondly,** identify which diagnostic assays are being used to detect SARS CoV-2 and which VOC PCR Screening reagents you have.

Screening for the suggested presence of Omicron VOC can be performed by identifying S gene target failure (SGTF) or by using assays that target specific mutations.

SCREENING USING S GENE TARGET FAILURE (SGTF)

If you are using the Thermo Fisher TaqPath COVID-19 Combo Kit (3 target PCR assay) as your diagnostic reagent, consider the results below as an indication of a sample which might be Omicron variant.



Please Note: i) to be able to use this assay you must be using an ABI Thermocycler e.g. ABI7500, QuantStudio 5 or others. Additionally, these machines need to be calibrated for the two fluorophores that are propriety to ThermoFisher; and
ii) not all Omicron viruses have the DEL69/70 mutation. At 2/12/2021, 5% of Omicron sequences in GISAID **DID NOT** have DEL69/70 mutation) therefore it is important to monitor the epidemiological evolution of the deletion if used as a screening method.

PCR SCREENING TO EXCLUDE DELTA

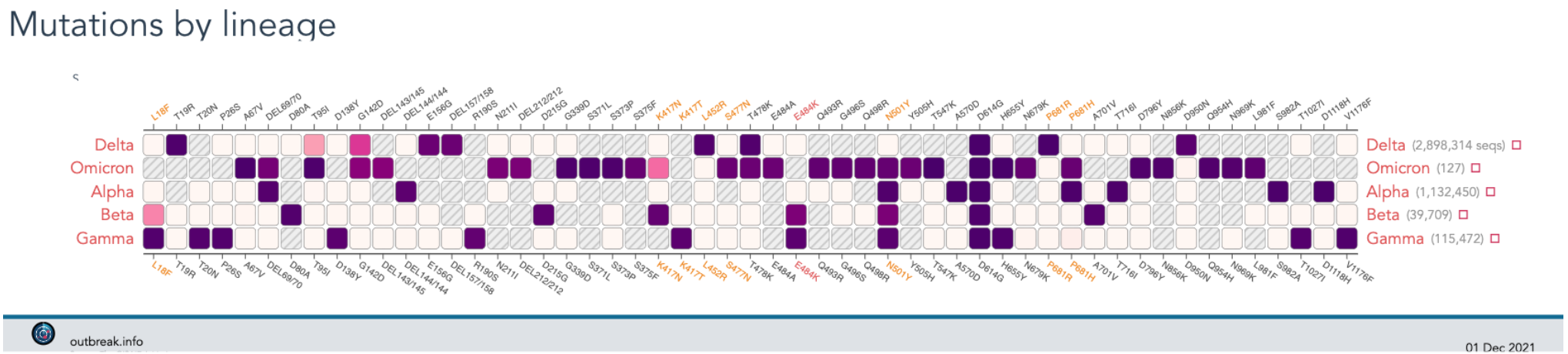
If Delta is/was the predominant variant circulating in your country use a PCR screening assay (e.g. EscapePlex or L452R single mutation assay) that has the capacity to identify Delta variant.
Consider the results from your assay and the interpretations below:

- **POSITIVE** result will **identify Delta** variant
- **NEGATIVE** result will exclude Delta but may indicate the presence of Omicron or another variant. This specimen should be **prioritized for sequencing.**

Targeted sequencing of the S gene, using either NGS or Sanger sequencing, or whole genome sequencing using NGS will provide positive identification of Omicron.

For any technical assistance please contact the AFRO Lab Team afrgocovidlab@who.int

Mutation Profile of VOC (from Outbreak.info, 1 December, 2021)



Lineage Comparison. Alaa Abdel Latif, Julia L. Mullen, Manar Alkuzweny, Ginger Tsueng, Marco Cano, Emily Haag, Jerry Zhou, Mark Zeller, Emory Hufbauer, Nate Matteson, Chunlei Wu, Kristian G. Andersen, Andrew I. Su, Karthik Gangavarapu, Laura D. Hughes, and the Center for Viral Systems Biology. outbreak.info, (available at https://outbreak.info/compare-lineages). Accessed 1 December 2021.