UK Health Security Agency

Laboratory Action Required

Omicron enhanced surveillance for testing laboratories

The UK Health Security Agency, in partnership with scientific bodies across the globe, is constantly monitoring the status of SARS-CoV-2 variants as they emerge and develop worldwide. A new variant, Omicron (B.1.1.529) was first identified in Hong Kong, from a case of someone travelling from South Africa. It has since been detected in several countries including the UK. The UKHSA designated the variant B.1.1.529 as a Variant of Concern (VoC) on Saturday 27th November.

Some of the Omicron mutations are common to those seen in other variants and as such, we are able to use our existing tests to identify possible cases and confirm by sequencing. Pillar 1 NHS and UKSHA testing laboratories are providing valuable assistance in the early identification of cases for follow-up. The full details are provided in the latest technical briefing published on gov.uk, Investigation of SARS-CoV-2 variants: technical briefings - GOV.UK (www.gov.uk)

Of relevance to in-use primary Molecular and reflex genotyping assays;

-Omicron contains the S gene deletion at position 69-70. This can be identified through target failure in the thermofisher Taqpath assay and other S gene assays that target this region

-Omicron contains the K417N mutation and does not contain the P681R mutation. This profile is the same seen for Mu and Beta variants both of which are absent or in low circulation in the UK at the current time and therefore this profile can be used as an indicator for a probable Omicron

Laboratories are asked to perform primary SARS-CoV-2 testing and onwards genotyping and sequencing samples according to their current arrangements **as promptly as possible**. In addition, any observations of laboratory results with the profiles stated in table 1 should be highlighted to the sequencing laboratory and reported to the UKHSA virology cell WNCoV.virology@phe.gov.uk for follow-up. **All cases must be notified to the local health protection team (HPT)**

Table 1. Profile for possible Omicron samples (to be confirmed by sequencing)

Target observation	**Action required by testing laboratory**
S gene target failure (SGTF) in primary assay **AND** remaining targets are CT<30	Refer via existing pathways for sequencing and genotyping. **Sequencing has priority** where sample volume is insufficient for both. Alert WNCoV.virology@phe.gov.uk
P681R wildtype (negative), K417N mutant (detected)	Refer via existing pathways for sequencing. Alert WNCoV.virology@phe.gov.uk

Table 2. Referral details for suspected Omicron variants

Name of sending laboratory	
Laboratory sample number	
Date of sample collection	
Date referred for sequencing	
Name of referral UKHSA sequencing laboratory	
S gene status by PCR	
CT values for remaining targets(state gene target and CT)	
P681R status by genotyping	
K417N status by genotyping	

1. Sending laboratories should copy the table above and send the completed details to WNCoV.virology@phe.gov.uk

2. If the samples are identified prior to shipping for sequencing, please mark the outside of the package as **URGENT** highlight and if using the E53 form clearly write **"?OMICRON"** on the form and send to your usual sequencing or genotyping provider. Please send both the extract and original sample where possible.

3. Laboratories must alert the local health protection team (HPT)

Thank you to all testing laboratories for providing this enhanced surveillance action that will contribute to the monitoring and control of Omicron in England