



# PHLN

Public Health Laboratory Network

## Revision history

| Version | Date published   | Revision note                                |
|---------|------------------|--|
| 1.1     | 11 November 2021 | Updated terminology and sequencing strategy. |
| 1.0     | 6 April 2021     | Initial document                             |

## PHLN STATEMENT ON REPORTING OF SARS-CoV-2 VARIANTS OF CONCERN AND INTEREST

All viruses, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, change over time. These changes may not give the virus any advantage. However, when there are many infections in a population, it's likely changed viruses will emerge and be described as:

- Variant of Concern (VOC),
- Variant of Interest (VOI), or,
- Variant Under Monitoring (VUM).

Several SARS-CoV-2 VOC have emerged because of the current high rate of infection internationally. These have the potential to:

- increase the transmission and severity of clinical disease, and
- reduce the effectiveness of countermeasures such as vaccines, treatments and diagnostics.

As the pandemic evolves, it's important to stay up to date on how to detect, define and report on SARS-CoV-2 VOC, VOI and VUM.

The Public Health Laboratory Network (PHLN) notes that for several months there has been uncertainty, both nationally and internationally about how to define a VOC, VOI or VUM. Lack of a consistent definition has the potential to lead to conflicting health advice and response measures to potential or emerging SARS-CoV-2 outbreaks.

To ensure Australia has access to the most up-to-date information and advice, the PHLN recommends the standardised reporting of VOC, VOI, VUM and associated terms. This will facilitate:

- a uniform approach to SARS-CoV-2 VOC, VUI and VUM detection,
- a nationally consistent case definition and acceptance criteria for VOC, VOI and VUM, and
- consistency in public health advice and action across all Australian jurisdictions.

### Communicable Diseases Genomics Network

To achieve this, the Communicable Diseases Genomics Network (CDGN) established a multi-disciplinary working group. The CDGN is an expert reference panel of PHLN. The goal of the CDGN working group is to advance Australia's national detection of, and response to, SARS-CoV-2 VOC, VOI and VUM. The working group has laboratory and government representatives with expertise in:

- genomic sequencing,
- bioinformatics,

- genomics epidemiology,
- medical microbiology,
- viral evolution, and
- phylodynamics.

The main responsibilities include:

- (1) providing near real-time national surveillance and reporting on SARS-CoV-2 VOC, VOI, VUM and mutations interest,
- (2) updating surveillance capacity in Australia's national SARS-CoV-2 genomics surveillance platform, and
- (3) responding to requests for information on VOC, VOI and VUM.

#### Process of VOC, VOI and VUM designation

The use of consistent definitions is paramount to this process. The CDGN working group will give regular reports to approved networks based on these PHLN endorsed definitions of SARS-CoV-2 VoC, VuI, VOI and associated terms. These terms align with up-to-date international definitions and classifications<sup>1</sup>:

- **Variants of Concern (VOC)** may be designated locally or by international bodies if there is evidence of epidemiological, pathological or immunological features of concern.
- **Variant of Interest (VOI)** is where there is possible evidence for epidemiological, pathological or immunological features of concern.
- **Variant Under Monitoring (VUM)** has potential significance, but little to no evidence of current concern.
- **Mutation of Interest (MOI)** has significant biological impacts (for example, increased binding to host cells, reduced neutralisation), and may be a signature mutation in current VOC/VOI or arise independently in other lineages.
- **Laboratory Case Definition (LCD) for VOC** is where a sequence either meets the definitive criteria<sup>2</sup> (confirmed VOC), or suggestive criteria<sup>3</sup> (probable VOC).

#### **Laboratory detection of VOC, VOI and VUM**

Whole genome sequencing (WGS) of the SARS-CoV-2 genome is the preferred way to determine the variant and mutation patterns of the SARS-CoV-2 virus. There are emerging SARS-CoV-2 PCR tests designed to detect specific VOC. The performance of these tests is still being established, and they will not identify variants that they have not been designed for. These may be suited for use in diagnostic laboratories without sequencing capability. Guidance on sequencing of SARS-CoV-2 samples is available at [PHLN guidance on laboratory testing for SARS-CoV-2 \(the virus that causes COVID-19\)](#).

To date, Australia has employed a comprehensive sequencing strategy facilitated by low SARS-CoV-2 prevalence. [The National Plan to transition Australia's National COVID-19 Response](#) has highlighted the expected increase of case numbers across the country in the short-to-medium term. In turn, this requires a change in approach for genomic surveillance from comprehensive sequencing to selective and targeted sequencing, balancing the utility and cost of real-time SARS-CoV-2 genomic surveillance in the environment of the rapid spread of a dominant strain of the virus, and ability of the genomic data to show variations within clusters given the relative stability of the SARS-CoV-2 genome. The potential for new importations with greater genomic diversity will increase once international travel recommences.

<sup>1</sup> Public Health England. Investigation of novel SARS-CoV-2 variant, Variant of Concern 202012/01 Technical briefing 2-28 December 2020. PHE: London;2020.

<sup>2</sup> Genomic sequencing of a patient's sample has identified a pangolin lineage consistent with known VoC.

<sup>3</sup> Phylogenetically placed with other confirmed VoC, but does not meet *Definitive Criteria*, OR meets minimum required mutations to be assigned to VoC lineages.

To support the collection of timely and accurate information from SARS-CoV-2 genomic surveillance, Australia's CDGN has developed the [Sampling strategy guidance for SARS-CoV-2 genomic surveillance](#).

***Reporting of VOC, VOI and VUM***

Virus lineages that are designated as a VOC, VOI or VUM may change at any time. The biological significance of many of the variants and mutations under investigation or of interest are not well described in peer-reviewed literature. These should be reported on with caution, following consultation with an appropriately qualified pathologist.

CDGN has developed a *CDGN Laboratory Case Definition for Variants of Concern*. This provides a high-level summary of VoCs detected in Australia. It's available at: <https://www.cdgn.org.au/>.

The CDGN Working Group activities provide a systematic approach to national surveillance and monitoring of VOC, VUI and VUM. It ensures Australia is prepared to enact public health actions in response to the evolution of SARS-CoV-2 in a timely and consistent manner.

PHLN recommends that all authorities responsible for communication on SARS-CoV-2 VOC, VOI or VUM, refer to the definitions described in this advice. Authorities should seek further information if needed. This will ensure reporting accurately reflects the significance of the virus lineage being described, as supported by evidence.