NIBSC

Reference materials for analysis of vaccine serology response to VOCs

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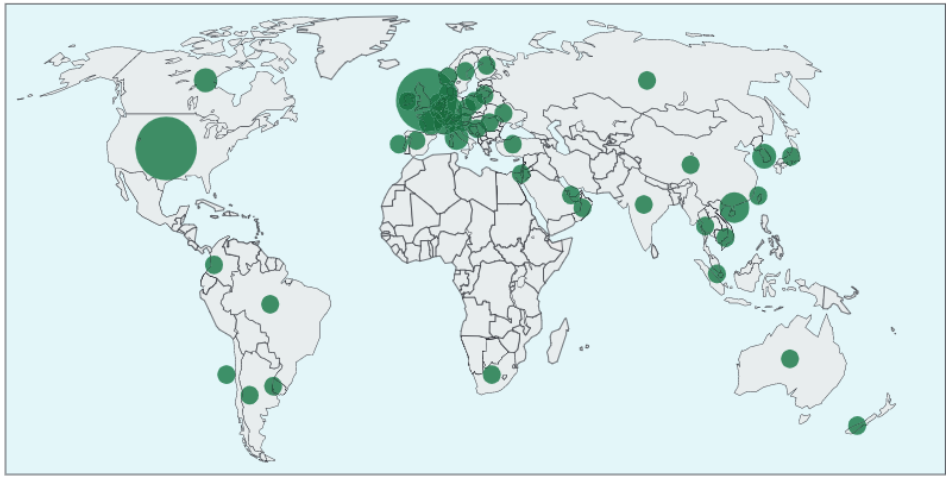
Establishment of First WHO IS for anti-SARS-CoV-2 immunoglobulin

- Pool of convalescent plasma from 11 COVID-19 recovered individuals from UK
- Characterised by 44 laboratories from 15 countries worldwide, using 125 methods
- WHO IS established by WHO ECBS on 10th December 2020;
- Available in NIBSC catalogue on 18th December 2020

- Allows comparison of data by different assays
- Reduces interlab variation (harmonisation) using a common arbitrary unit value

Uptake of the WHO IS 20/136

Over 2400 units 20/136 were shipped to 581 individual customers



Knezevic et al. *Lancet Microbe* 2021

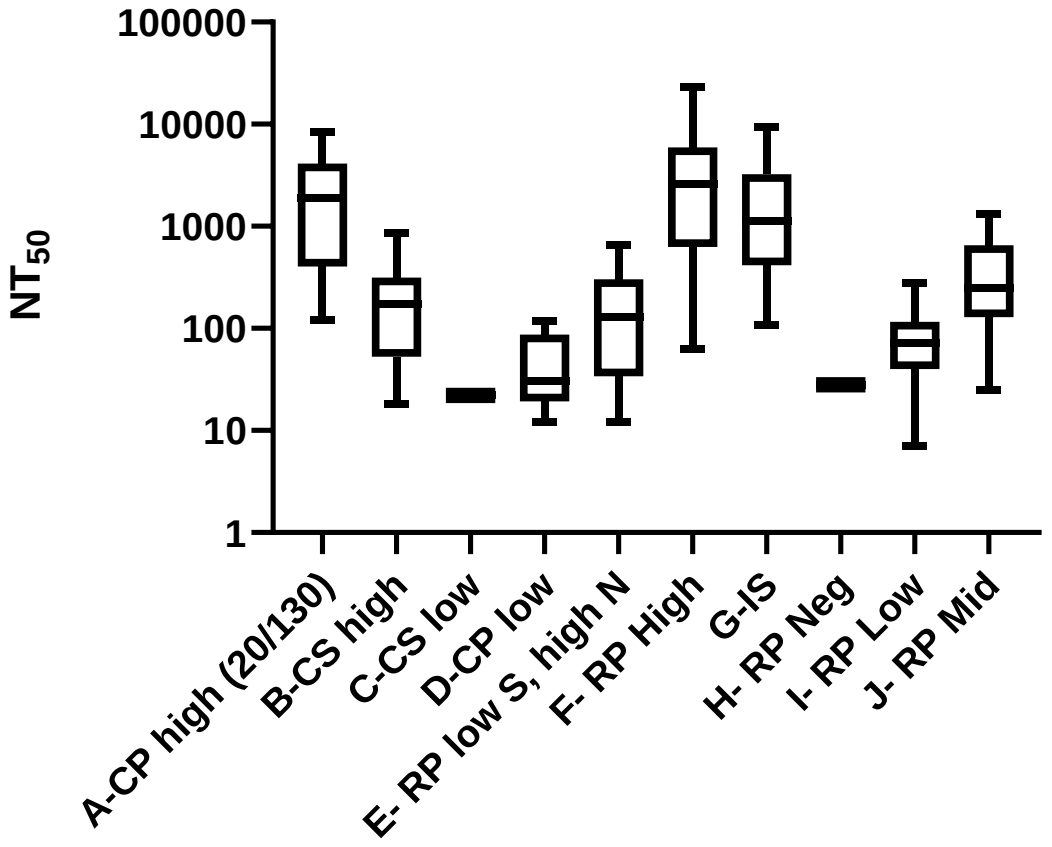
Kit manufacturers have adopted the WHO IS units

Correlate of protection studies are reporting values using the WHO IS units
Khoury et al, Nat Med, 2021
Feng et al, Nat Med, 2021
Gilbert at al, medRxiv, 2021
Goldbaltt et al, research square, 2021

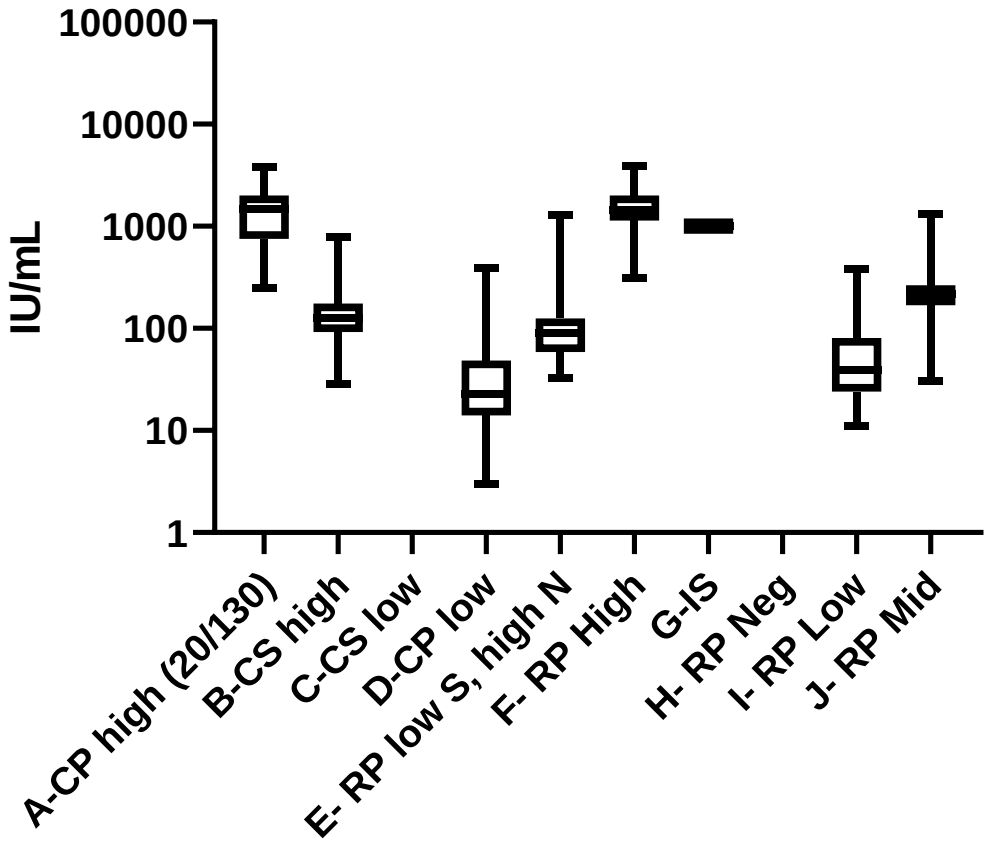
Other immunogenicity studies have been reported in WHO IS units.

Role of the WHO IS for anti-SARS-CoV-2 immunoglobulin

RAW data



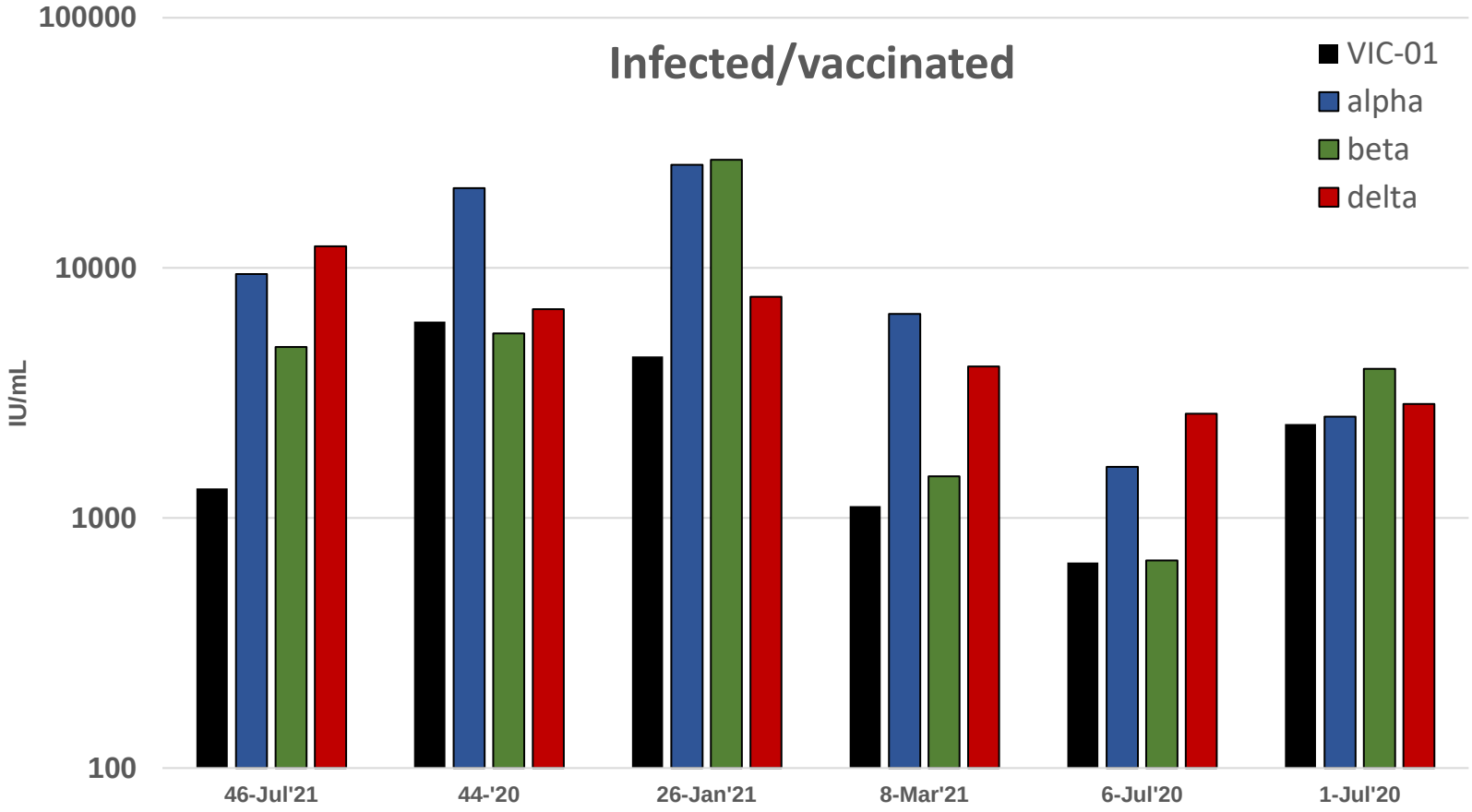
Relative to candidate IS sample G



Replacement IS timelines

- collaborative study mid-Jan 2022 → 50 labs recruited
- Results returned within 6 weeks (end Feb 2022)
- preliminary analysis to ECBS –Apr 2022
- Establishment in October 2022

Utility of vaccinate/infected serum/plasma as a secondary standard for VOC?



Convalescent plasma/serum from infected and vaccinated individuals has

- Higher titres
- Broader responses
- Including omicron?

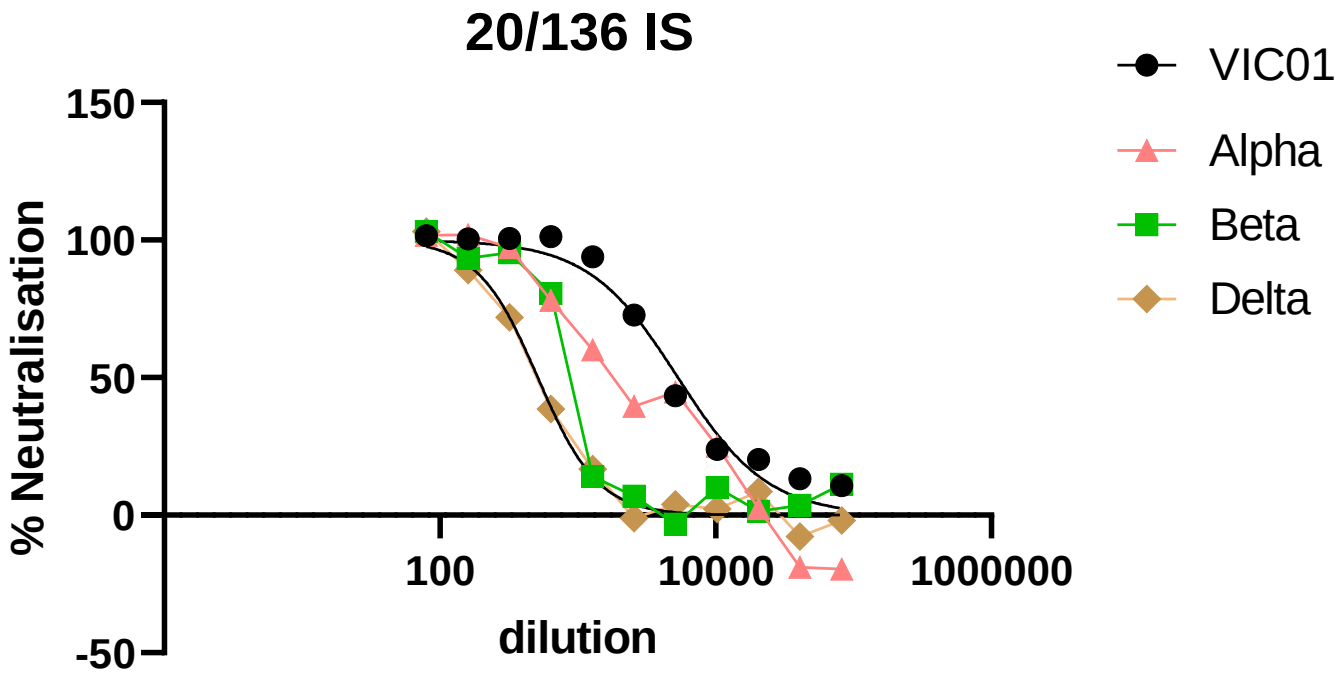
WHO Reference Panel for VOC

VOC	source	sequenced	status
Wuhan-like	USA-2020	no	filled
Alpha	UK- Jan 2021	no	filled
Beta	UK	yes	too little
Gamma	Brazil- Jan 2021	no	collected
Delta	Kenya-2021	yes	filling

Plan to add VOC plasma to this panel dynamically
Panel members will have a unit value calibrated to the IS in the upcoming collaborative study
Omicron serum/plasma needed
Please contact Giada.Mattiuzzo@nibsc.org if you have access to large volumes that are sequence confirmed.

Use of First WHO IS for VOC

- The International unit is an arbitrary value, it does not equal to a physical measurement, therefore cannot be “calculated” per variant
- In this cases, the potency of the IS should be reported specific per isolate used



As long as the IS produces a titration curve for a given variant a calibration can be performed and a unit value derived.

Other reagents

NIBSC working reagent 21/234 1473 IU/mL (vs Wuhan isolate)

- High neutralising titre conducive to broader response
- Pool of plasma samples giving a wide antibody repertoire
- likely neutralises omicron?
- Other NIBSC reagents in catalogue
  - See https://nibsc.org/science_and_research/idd/cfar/covid-19_reagents.aspx

NCI FNL secondary standard

- https://frederick.cancer.gov/seronet/serologystandard Serological Sciences Network (SeroNet)

See also

- https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/coronavirus-disease-(covid-19)

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