Creating the WHO Antibody Reference Panel

Mark Page, NIBSC

Coronavirus Standards Working Group
What should a Coronavirus Standards Working Group do?

Assure development and availability of standards, controls, interlab testing, knowledge to support successful rollout & scaling of 2019-nCoV testing.

Identify and develop critical infrastructure to support...
- confidence in test results
- interoperability
- scale-up
- long-term capacity

Identify best practices that should be institutionalized

Learn what we need to do next time we have a global network in place ready to make standards.
Agenda

Updates

Creating the WHO Antibody Reference Panel

Mark Page
Updates

Viral RNA Standards Harmonization Study
- Panels Shipped!
- Details following

Serology Standards Harmonization Study
- May Chu and team at Colorado School of Public Health Anschutz Medical Center leading development
- Requests being sent out to develop panel of materials
- Design and planning underway
Viral RNA Harmonization Study

Samples received at 12/14 labs as of 11 March

• One package mis-shipped
• One package in transit
Zeptometrix sample not included in panel
Imperial College samples packaging failure

- Rescued and shipped in outer "Falcon" tube
- Might consider as provisional results; samples can be excluded at lab discretion
Results reporting template distributed

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CSWG Shipping Manifest

Supplied Reagents: Each lab will receive 4 vials of each of the following:

**Instand**
Catalogue no. 340069. Store at 4°C. (more info)
Physical description: Screw top tubes in freezer box containing lyophilized powder.

**Microbiolitics**
Catalogue no. HE0065N. Store at 4°C
Helix Elite Inactivated SARS-CoV-2 Whole Virus (Pellet); (more info)
Physical description: Clear plastic bag containing 4 mylar bags.

**Thermofisher**
AccroMetrix SARS-CoV-2 Control; Catalogue no. 954517. Store at -20°C. (more info)
Physical description: Screw top tubes in freezer box.

**LGC SeraCare**
AccuFlex™ SARS-CoV-2; Catalogue no. 0505-0168. Store at 4°C. (more info)
Physical description: Screw top tubes in freezer box.

**NIBSC**
SARS-CoV-2 RNA; Catalogue no. 20/138. Store at -20°C. (more info)
Physical description: Glass vials bubble wrapped in clear bag in second freezer box.

**Asuragen**
Armored RNA Quant SARS-CoV-2 Control; Catalogue no. 52036. Store at -20°C. (more info)
Physical description: Screw top tubes in freezer box. Next to TSM III dilution buffer.

**Imperial College**
MS2-SARS-CoV-2 nucleocapsid gene Virus-like Particles; non-commercial. Store at -20°C. (more info)
Physical description: 2 mL snap cap tube containing frozen liquid. Located either in freezer box or in 50 mL conical tube inside of a clear plastic bag. This sample should be considered optional at the lab’s discretion due to packaging failure.

**WHO International Standard (NIBSC)**
NIBSC code: 20/146. Store at -20°C. (more info)
Physical description: Glass vials bubble wrapped in clear bag in second freezer box.

Note – The original study design included a sample from Zeptometrix, which is NOT included in the study.
SOP Updated to reflect changes

- Updated Google Doc
  - Concentration number line
- Design
- Tables
- Refinements
Coordination of tests

• “Which test do you want us to use?”
  • whichever you have best confidence in!
  • you can note your top 2 choices and we’ll try to best cover the landscape
Timeline for results
Creating the WHO antibody reference panel

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva, 9 - 10 December 2020

Establishment of the WHO International Standard and Reference Panel for anti-SARS-CoV-2 antibody

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Discussion