Bioanalytical solutions in support of the COVID-19 pandemic

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on behalf of EBF

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2020 the year that changed the world

- Late December 2019 a novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first reported in Wuhan, China
- Classified as an epidemic and subsequently a pandemic by the WHO
- Currently affecting 216 countries and territories around the world and 2 international conveyances
- Scientific communities mobilised swiftly
- Urgent need for tests, effective drugs and vaccines

https://www.worldometers.info/coronavirus/
Structure of SARS-CoV-2 and Spike Protein Trimer


Detection of SARS-CoV-2 virus and antibody responses

**CATCHING COVID-19**

Different types of COVID-19 test can detect the presence of the SARS-CoV-2 virus or the body’s response to infection. The probability of a positive result varies with each test before and after symptoms appear.

- **PCR-based tests** can detect small amounts of viral genetic material, so a test can be positive long after a person stops being infectious.
- **Rapid antigen tests** detect the presence of viral proteins and can return positive results when a person is most infectious.
- **Antibody tests** detect the body’s immune response to the virus and are not effective at the earliest phase of infection.

Exposure to virus ➔ Symptom onset ➔ Probabilty of detection ➔ Time from symptom onset (weeks)

- IgG antibody
- IgM antibody

PCR Positive ➔ PCR Negative ➔ Antibody Positive ➔ Antibody Negative
Virus detection

**PCR methods**

- Sampling
- Inactivation
- RNA extraction
- Transfer to plate
- RNA → cDNA → Amplification and detection
- OR
- Barcoding and Sequencing

**Rapid Antigen Tests (Point of Care Tests)**

- Performed alongside the patient
- Results within 15-30 minutes
- Usually less sensitive than PCR
- Good for high viral loads
- Useful if no access to PCR methods

**Results take a few hours**

**Reporting make take a few days**

**Result is only as good as the day that the test is taken**

*Nature Communications* volume 11, Article number: 4812 (2020)
Antibody responses (serology)

Lateral flow assay (Point of Care Test)

Other methods:

- Immunoassay methods
  - May differ in the antigen used or the assay format (ELISA, ECL etc.)

- Flow based methods
  - Immunoglobulins
  - T cell responses
  - B cell responses

Still much to learn about immunity

- Which antigen is the best for neutralising responses?
- Will a vaccine confer long-term immunity?
- Will COVID passports become reality?

Such assays are diagnostic tests

- Diagnostic tests and therefore validation looks different from typical BMV
  - For serology assays assay thresholds are not set in the same way as immunogenicity cut points
- Sensitivity (% true positives) and specificity (% true negatives) using blinded sample sets
- Serology:
  - ≥98% sensitivity ≥20 days post symptoms
  - ≥98% specificity >6 months before the pandemic
- Concordance of data between testing labs
PHE evaluation of serological assays show potential of false positives/cross reactivity

Looking to the future ....

- Better access to testing
  - Such tools may be useful to allow “COVID secure” workplaces when combined with measures such as regular hand washing, physical distancing, wearing of masks and temperature monitoring
- Better understanding of immune responses
- Assessment of mutations in the virus and infectivity
- Repurposing and novel drugs to improve clinical outcomes
- The availability of one or even multiple vaccines
  - Logistical issues in vaccination of 8 billion people
  - Willingness of the population to be vaccinated
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