“It is correct to test – as long as you test for the right things”

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Corona Virus

- We have known different types of Corona virus causing respiratory infections for a long time. Since 2003 three additional and important strains have been identified.
- A Corona virus related to bats was discovered in China in 2003 which resulted in severe lung infections. This virus was named Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) and it spread to Europe and America before the epidemic died out.
- In 2012 another Corona virus – called Middle East Respiratory Syndrome (MERS-CoV), with dromedaries acting as the host resulted in serious lung infections in humans particularly in the Arabian Peninsula.
- In December 2019 a new strain of Corona virus was discovered in China which also resulted in severe lung infections. It has been shown that this new virus SARA-CoV-2 is 80% identical to SARS CoV. It is this virus that results in the disease COVID-19 which has spread across the globe.
- SARS-CoV-2 is the official name for this new Corona virus and COVID-19 is the resulting disease that it causes.

The infectious pathway and contagion

- COVID-19 spreads primarily via droplets from sneezing and coughing and inhaling these droplets can infect others directly.
- Droplets can also be spread indirectly via surfaces and items that have been touched by infected individuals. It has been shown that individuals may infect others up to 6 days before they experience symptoms related to COVID-19 themselves.

Incubation Time

- Our current knowledge is that 2-12 days may pass before the first symptoms of COVID-19 are experienced, and that the majority of individuals may not experience any symptoms at all.

Symptoms

- COVID-19 has a varied symptom picture – from a common cold like symptoms to serious life-threatening respiratory infections and other complications.
- Initial symptoms include fever, coughing, swallowing, muscle, stomach pain, diarrhoea, as well as symptoms resembling a common cold and severe headache. The cough is typically “dry” in that patients do not typically produce a lot of sputum or phlegm. Additionally, many individuals lose their ability to taste and smell. Later on in the course of the disease breathing difficulties and reduced heart and kidney function can be observed in the more serious cases.

Diagnosis COVID-19

Currently, a diagnosis of SARS-CoV-2 can be demonstrated in 3 ways.

1. A clinical diagnosis pointing to COVID-19.
2. Detection of SARS-CoV-2 antibodies in the respiratory system (swabs) and/or
3. The presence of antibodies against SARS-CoV-2 in the blood.

Ad 1:

- If a patient has symptoms reminiscent of COVID-19 during an epidemic, it is not difficult to make a diagnosis of COVID-19 – a so-called **clinical diagnosis**.
- However, a patient may well be infected with SARS-CoV-2 without experiencing symptoms thereof - a subclinical infection, and there is ample evidence of this phenomenon which results in a large percentage of the population that are contagious without knowing that they themselves are infected.

Ad 2:

- In many European countries tests relating to COVID-19 are carried out with swab tests from the back of the throat to gather secretions.
- Theses secretions are tested in laboratories in order to determine if the individual has been infected with SARS-CoV-2.
- Studies have demonstrated that throat swab tests are only valid in 1/3 of individuals resulting in 2/3ds not being properly diagnosed (= false negatives).
- This means that an individual may have COVID-19 or not experiencing symptoms and still be contagious in up to 2/3ds of individuals tested by this method. Swab tests must therefore be classified as an ineffective method to determine whether individuals are infected with SARS-CoV-2.
- It is known that secretions examined from deep down in the airways due to a suspicion of COVID-19 increase the likelihood of demonstrating SARS-CoV2 to approximately 90%. This procedure requires hospital facilities and competent personnel.

Ad 3:

- As soon as the first symptoms of COVID-19 appear the body's immune system has already begun fighting the infection and fever and muscular pain are reflective of this.
- This process facilitates the activation of the immune defence system in which cells that "remember" the infection are particularly important. "Memory cells" include both cells that react to other cells that have been infected and others that produce antibodies, substances that can bind to the viral cells are render them harmless. Therefore, knowledge of an individual's antibodies demonstrates whether they have had the infection, is susceptible to becoming infected or be contagious.
- Typically, immunoglobulin M (=IgM) and immunoglobulin G (=IgG) are studied. IgM can often be found a few days after the disease has begun but they do not bind effectively to the viral cells while IgG binds far more strongly and can be found from several days to several months after the onset of the disease.
- The presence of IgG is therefore very reliable as it both protects against re-infection indicates whether an individual may infect others.

- Antibody test used for SARS-CoV-2 measure the body's response to COVID-19 and are found in two types – popularly called "conventional antibody tests" and "finger prick tests".
- Both of these test types are qualitative tests, but it should be noted that there is currently no data that correlates the amount of antibodies found with the degree of immunity.

Conventional Antibody Testing:

1. This can only be carried out after a blood sample has been taken i.e., it requires a trained phlebotomist and a needle and syringe.
2. The blood must be prepared before it is evaluated.
3. Requires stable and advanced laboratory facilities.
4. Requires well qualified personnel.
5. Requires up to several days before results are available.
6. Expensive.

Finger Prick Testing:

1. Only requires a droplet of blood from a finger prick test.
2. Does not require preparation of the blood before further examination.
3. Does not require a laboratory with skilled personnel.
4. Can be carried out anywhere.
5. Results are available after 10 minutes.

- The finger prick test that Apodan A/S provides is produced in France by Biosynex SA and is called BIOSYNEX COVID-19 BSS IgG/IgM.
- The test has – at a minimum – the same sensitivity as conventional antibody tests, but is easier to carry out and provides a quick "on site" result as to whether an individual has IgM and/or IgG antibodies.
- It tests for IgM and IgG separately
- The test is unique in that it is able to expose antibodies after 1 day's infection and 100% of the infection can be measured 15 days after symptom debut. Furthermore, its efficiency has been tested on more than 1000 patients.
- BIOSYNEX COVID-19 BSS IgG/IgM has been quality tested at the renowned Pasteur Institute – a leading National Centre of Reference for Viral Infections which found the test extremely reliable (internal publication: "RAPPORT D'EVALUATION DE LA PERFORMANCE POUR LA DETECTION DES ANTICORPS ANTI SARS-COV-2. Nom du Kit: BIOSYNEX COVID-19 BSS (IgG/IgM)").
- Furthermore, the serum from positive tests has been shown to combat COVID-19, i.e., to confer immunity.
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Conclusions

- Demonstrating SARS-CoV-2 in the respiratory system with swab tests is an uncertain method to determine whether an individual has been infected with COVID-19.
- A negative swab test cannot determine whether an individual is contagious even though their test may be negative.
- It is necessary to carry out an antibody test for SARS-CoV-2 in order to determine whether an individual or segments of the general population have been infected and are potentially immune from further infection by COVID-19 for months to years.
- This finger prick test can safely be used to provide instant and reliable results.
- This provides significant advantages for community, organisation and corporate testing strategies in that it is far less expensive, easy to carry out, provides immediate data and has an equally strong reliability compared to conventional hospital antibody testing.
- It safely places the technology in the public's hands allowing individuals and their families to test themselves.