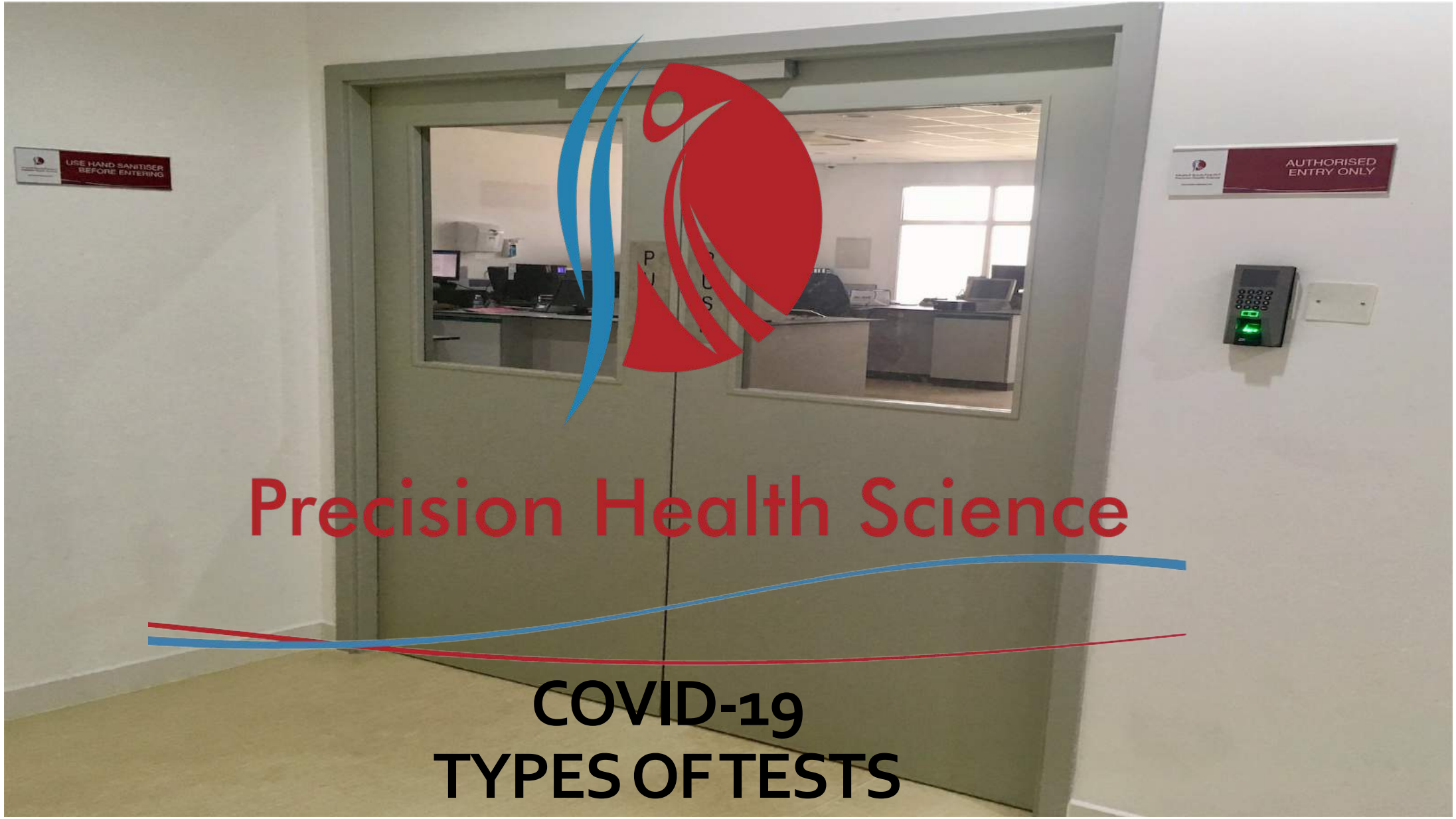

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COVID-19
TYPES OF TESTS

The virus and the disease

Virus

- Severe acute respiratory syndrome coronavirus 2
- SARS-CoV-2

Disease

- Coronavirus disease 2019
- Covid-19

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There are 2 types of tests for Covid-19

Testing for the virus

- Look for the virus in the body
- Specifically looks for the genetic information of the virus (RNA)
- Respiratory virus
- Samples from the back of the throat (Oropharyngeal) and the upper nose (Nasopharyngeal)
- Could also be sputum brought up through a rasping throat clearance or cough (only for certain tests)

Detects if you HAVE the virus

Testing for the body's reaction to the virus

- The immune system fights infections by producing certain proteins
- These proteins are called Immunoglobulins (Ig) or Antibodies (Ab)
- These Antibodies are secreted by cells into the blood
- Blood samples, ie Serological test

Detects if you HAVE or HAD the virus

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Testing for the virus

Serological Antigen test

- Looks for the virus in the blood
- Tests are in early developmental stages
- Standard lab analyser test and rapid test
- Currently not reliable

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Testing for the virus

Real Time RT-qPCR (short form: PCR)

- PCR = Polymerase Chain Reaction
- q = Quantitative
- RT = Reverse Transcription

What does it all mean?

- Reverse Transcription: conversion of the virus' RNA into DNA
- Quantitative: volume of virus (instead of a Qualitative +ve or –ve)
- PCR: exponential amplification (Chain Reaction) of DNA through adding an enzyme (Polymerase)
- Real Time: detection during the reaction (rather than at end point)

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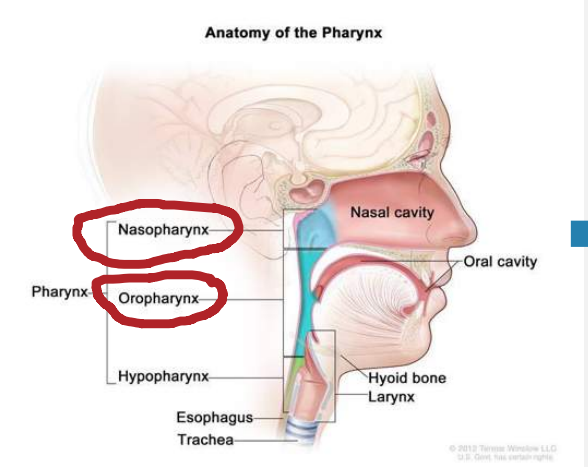
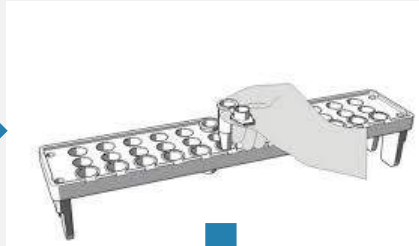
The PCR testing process





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PCR instruments: 2 types

Standard laboratory PCR instrument

- Global gold standard
- Done in batches of 24, 48, 96 etc tests
- 3-4 hours test; 50-250 tests/hour
- Total time to deliver reports 1-5 days
- Expensive instruments
- Main test used worldwide

Rapid/POC PCR instrument

- Some very compact and quick test instruments 15-60 minutes
- Bosch Germany point-of-care(POC) test 2.5 hours: Only 10 tests/day
- Highest cost/test
- Limited use

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PCR Pros and Cons

Pros

- Global gold standard for detecting current infection
- False positives very low (very high specificity)

Cons

- Cumbersome and labour intensive sample taking
- Improper sample taking: undetectable amount of viral RNA
- Several stages at which errors may occur
- High proportion of false negatives (some reports up to 30%)
- Expensive
- Global shortage of swabs, reagents

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Serological Antibody tests: 3 types

Standard laboratory Antibody test

- Global gold standard for serological detection of antibodies
- Renowned manufacturers such as Roche, Abbott Laboratories
- 30-minute test; same day reporting
- Venous blood

Enzyme Linked Immunosorbent Assay (ELISA) test

- 2to4-hour test
- Done on a plate for 96 samples; manually or on instruments
- Venous blood

Rapid Antibody test

- Very quick within 10-15 minutes
- Single test can be done in lab or point-of-care (POC)
- Finger prick or venous blood

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Standard laboratory Antibody test

- Conducted on large analysers (eg our Roche E411 in photo)
- Well established sophisticated instruments and methods
- High volume: about 80-300 tests/hour
- Quantitative: measures the volume of antibodies
- Cold chain 2-8C required for reagents
- Cost effective only if done in batches

- Tests only now coming to market, so use is still very limited

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ELISA test

- Test kit for lab use
- Manual: Ideal for labs without expensive analysers
- Cold chain 2-8C for reagents
- About 2-4 hours
- 96 test samples at a time
- Larger machines can analyse multiple plates, up to 300 tests/hour
- Qualitative
- Accuracy not as good as analyser test but better than rapid test

- Few manufacturers, so use is not widespread

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Rapid Antibody Test

- Lateral flow immunoassay
- Quickest of all tests
- Room temperature
- Qualitative
- Sensitivity (correctly identifying infected patients): 85-95%
- Specificity (correctly identifying healthy patients): 90-100%

- Used extensively across Europe, the USA, South Korea, China, Singapore, Australia etc.

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What do Serological Antibody tests measure

- Measure 2 types of antibodies: IgM & IgG
- IgM: Appear about 3-7 days after infection
- IgG: Appear a further week later
- IgM antibodies disappear within about 2 weeks
- IgG antibodies persist for at least a month and well after the infection is over
- Some tests measure each IgM and IgG separately
- Some tests measure both together: "Total Antibodies"

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Variation of virus levels after infection

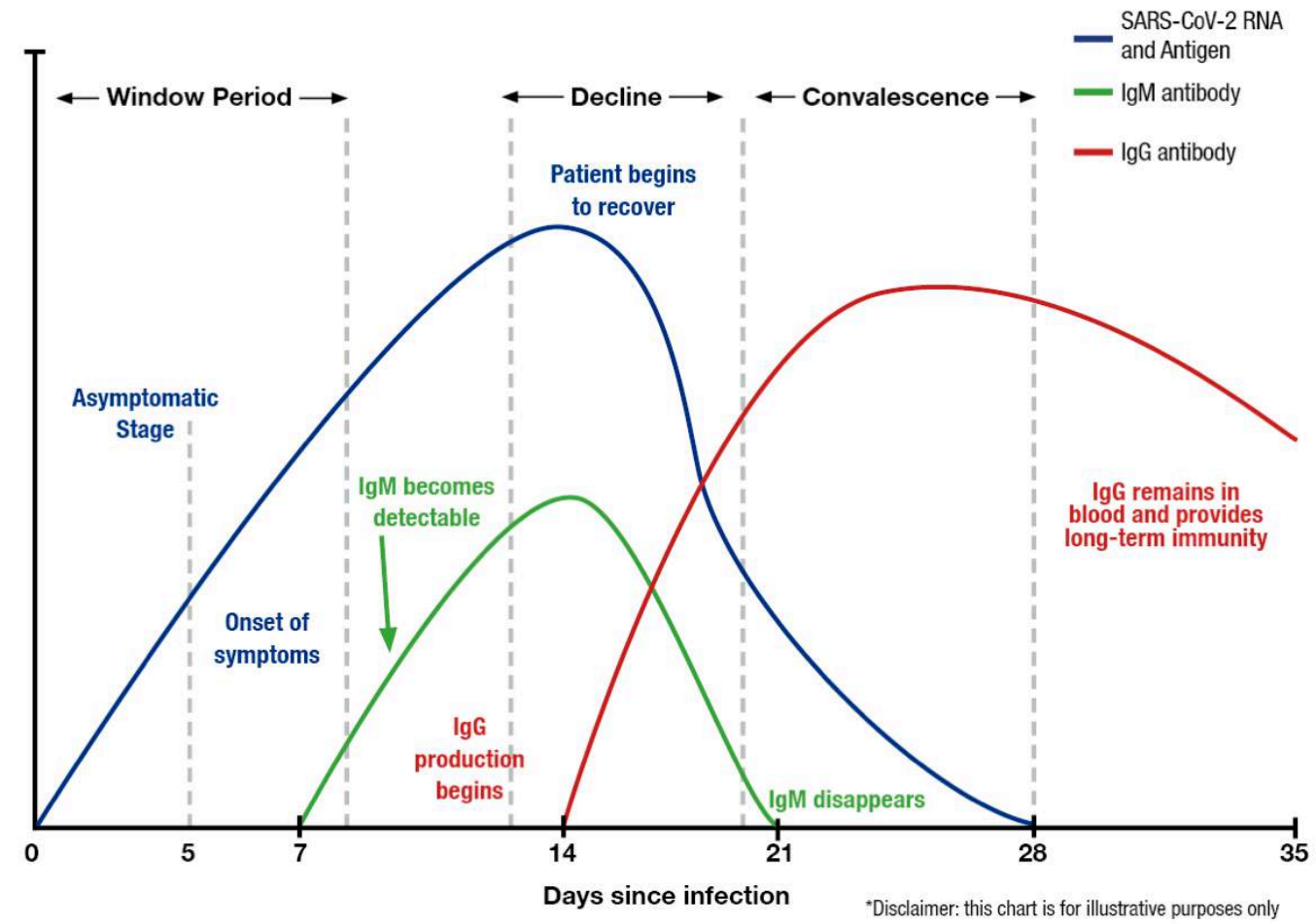

Figure 1: Variation of the Levels of SARS-CoV-2 RNA and Antigen, IgM and IgG after infection.

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Clinical significance of a serological Antibody test result

Test results			Clinical Significance
RT-qPCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patients is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. RT-qPCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative.

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Rapid Antibody test Pros and Cons

Pros

- Quickest test
- Very easy to administer; no additional equipment
- Can detect past infections
- Can be easily scaled up for mass screening
- Most cost-effective test

Cons

- Antibodies not detectable in early stages of infection
- False positives; antibodies of other viruses detected
- False negatives; antibodies in early infection stage undetected

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Summary

- PCR: main test conducted globally
- PCR remains the best test for infected patients
- Rapid Antibody test: being increasingly used outside Oman
- As the disease progresses through the population only the Antibody test will tell who has HAD the virus
- PCR: cost of equipment and reagents and shortage of supplies will limit its spread in developing nations

TESTING IS ART AS WELL AS SCIENCE
THERE IS NO 100% PERFECT TEST

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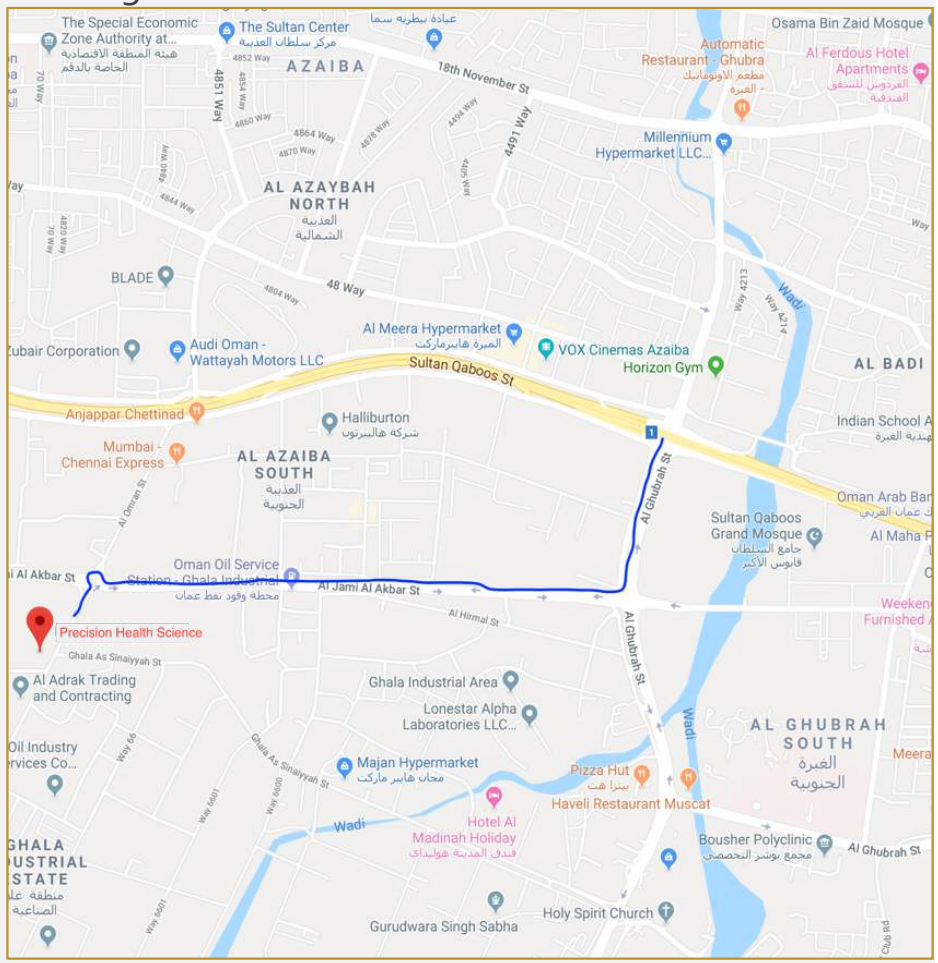
Please visit us

Ground Floor of National Engineering Office building, Ghala Heights



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