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## Why serologic testing ?

- ✓ Is to identify individuals who have previously been infected with SARS-CoV-:
- ✓ Determine exposure to SARS-CoV-2 : **Sero prevalence studies**
- ✓ Immunity and "**Back to Work**"



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## IgG antibodies and immune status

- ✓ The detection of IgG antibodies after 3-4 weeks of onset can be a sign of previous exposure and immunity.
- ✓ Presence of IgG antibodies with negative RT-PCR is suggestive of non-contagious person with immunity.



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## Specimen Type

- Serum, Plasma
- Finger stick/venous whole blood (LFAs)



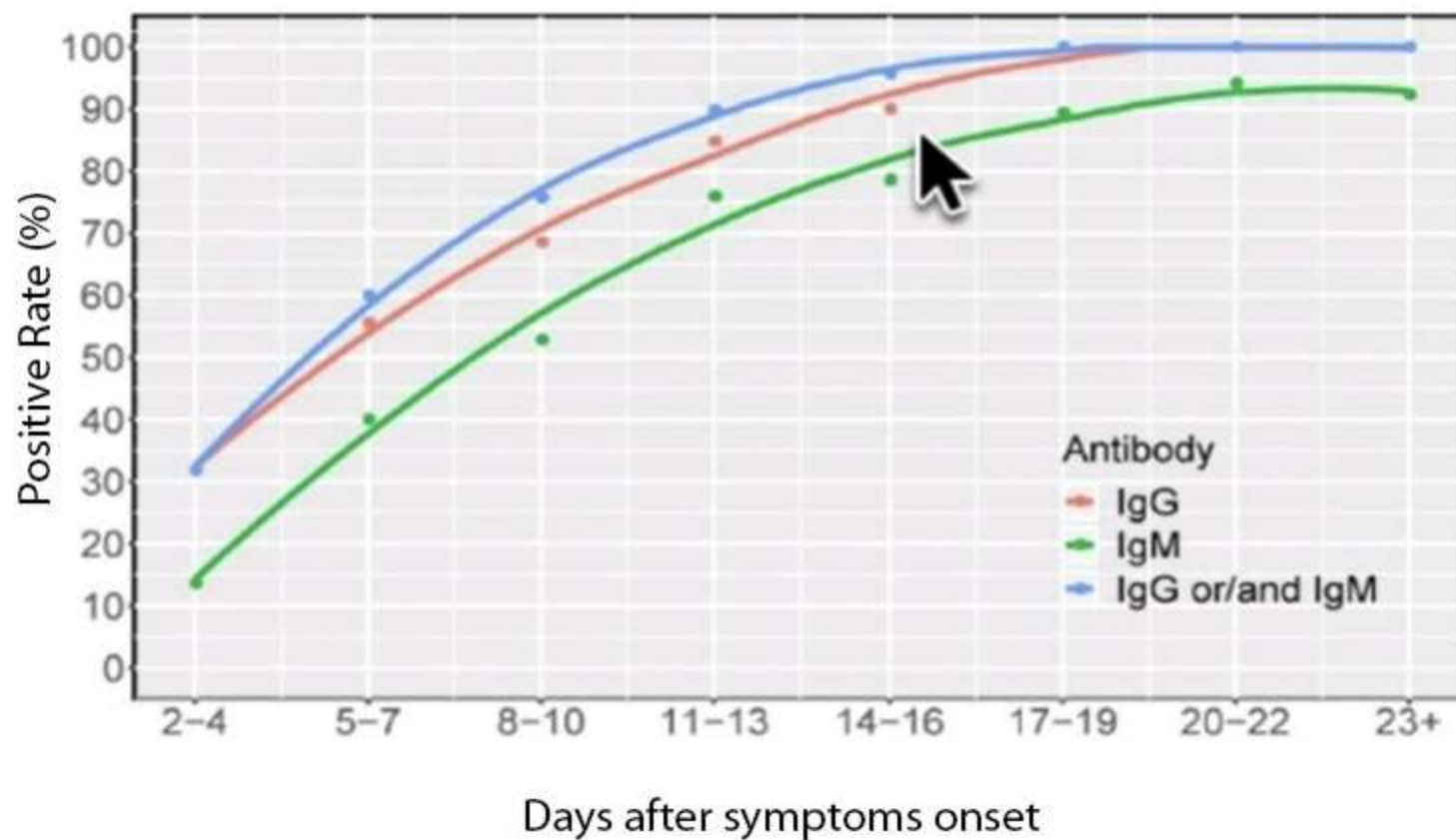
## Specimen, Storage and Stability

Specimen	Type	Stability		
		20°C to 25°C (Hours)	2°C to 8°C (Hours)	-20°C or colder (Days)
Serum	Serum Serum separator tube	8	48	30
Plasma	Heparin, EDTA, and Citrate	8	48	30

Thaw samples only once.

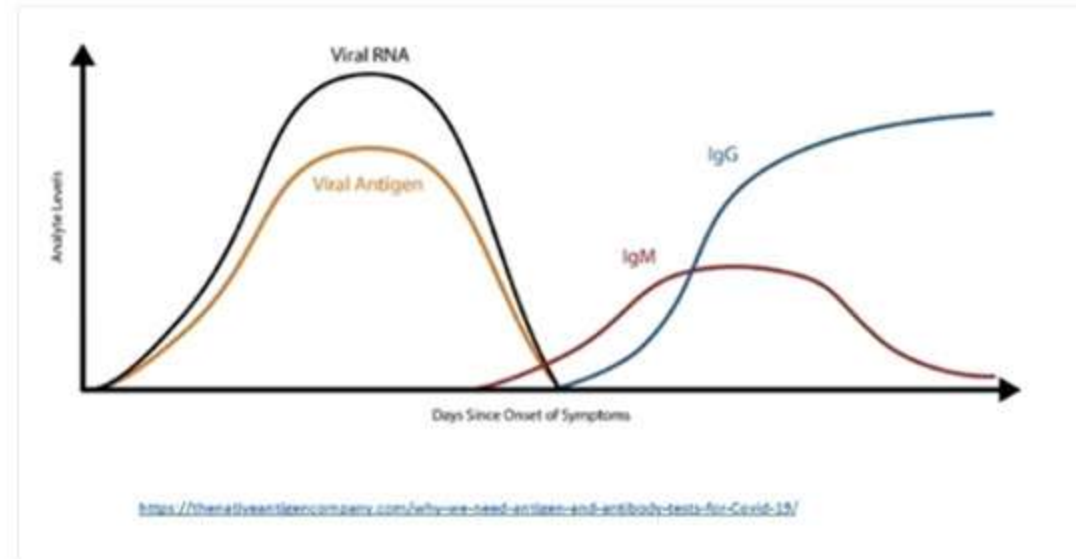


## Antibody response by days after onset (Long et al )



## COVID-19 Viral and Antibody Response : IgG vs IgM

- ✓ IgM as the first immunoglobulin class to rise as early as 4 days indicating acute infection
- ✓ As IgM plateaus, IgG begins to rise as early as 7-10 days which indicates an infected person has generated an immune response
- ✓ IgG is generally an indication of longer-term immunity (months to years)
- ✓ In COVID 19 however 3 types of seroconversion are seen :
  - Synchronous seroconversion of IgG and IgM
  - IgM seroconversion earlier than IgG
  - IgM seroconversion later than IgG
- ✓ The IgG-positive rate is consistently higher than the IgM-positive rate
- ✓ Since IgM antibodies may appear with IgG antibodies or even after them therefore detection of both IgG and IgM is required for diagnosis.

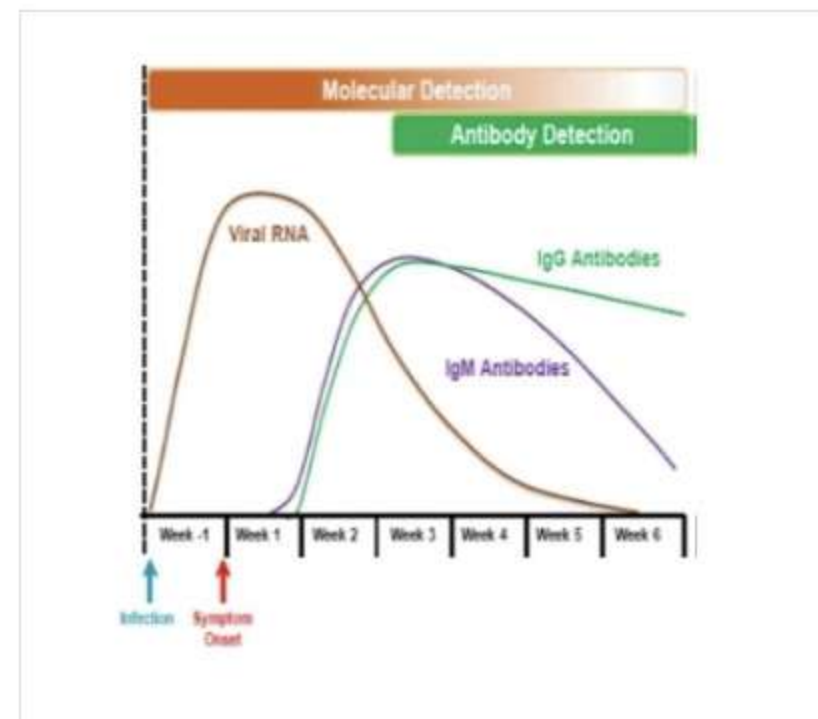




## Cross-Reactivity Concerns

### Timing of Antibody Response to SARS-CoV-2

- ✓ New virus = no pre-existing antibodies or immunity
- ✓ We are still learning about our immune response to SARS-CoV-2
- ✓ Most pts develop Antibodies 1-2 weeks after symptom onset
- ✓ Due to delay in seroconversion, Antibodies not play a routine role in diagnosis
- ✓ >95% of patients are Antibodies positive after 2 weeks
- ✓ Some patients may not seroconvert







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## Antibody positivity at different days post onset of symptoms

No of days post onset	IgG Positivity (%)	IgM Positivity (%)	IgM and/or IgG Positivity(%)
2-4	31.8	13.6	31.8
5-7	55.5	40	60
8-10	68.5	52.8	75.7
11-13	84.8	75.9	89.8
14-16	90	78.5	95.7
17-19	100	89.4	100
20-22	100	94.1	100
23+	100	92.3	100



## Sero-surveillance

- ✓ **Sero surveillance** i.e. continued surveillance of **seroprevalence** through serial antibody testing would help to determine herd immunity
- ✓ **Healthcare Industry**
- ✓ Potential Utility In Screening healthcare workers
- ✓ Screening Patients prior to surgery to define the right protocol for their in-hospital management
- ✓ **Security Personnel , Paramilitary Force and Police and Prisoners**
- ✓ **Hospitality Sector**



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## Possible Groups for Sero-Surveillance



1<sup>st</sup> Responders &  
Immunocompromised  
Patients



Police & Paramilitary  
Forces Security  
Personnel



Press CORP



Industrial Workers &  
Labor Force



Bankers, Post Office  
& Courier & Telecom  
Offices



1<sup>st</sup> Responders &  
Immunocompromised  
Patients



Air Travel Related  
Staff



Staff in Municipal  
Office & Sanitization



## Summary of Testing for COVID 19

Test	Ideal time to test from onset of illness	Clinical Utility	Benefits	Limitations
RT-PCR	0-14 Days	Confirmatory Diagnostic Test for COVID- 19 Infection	High sensitivity, Best Suited for testing symptomatic patients	High TaT~2.5-3 hours for testing 1 patients, High Cost of infrastructure and complex Sample Collection & handling
Rapid AG	0-14 Days	Aid in Acute & Early infection Diagnosis	Can be used for mass/Community Screening, Faster Results, Accelerate Speed of testing. Cost Effective	Relatively Low Sensitivity compared to RT-PCR Complex Sample Collection & handling
SARS-CoV-2-IgM	4-21 Days	Aid in Community Screening for detecting Active and Early Infections	Shorter Turn Around Time, High Throughput Analyzers present Across the country, Easy Sample Collection & Transport. Cost Effective	Limited evidence on clinical efficacy of Serology based Ab tests at this stage, can't be used in detecting early infections esp. 0-4 days
SARS-CoV-2-IgG	7 Days and beyond	Assess Immunity, Screen potential Plasma Donors, Assess Recovery & Past Exposure to Virus, Return to Work		



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## Protocol for allowing the workers to resume work

- ✓ Rapid antibody(AB)testing - collection of blood
- ✓ [Employer and Lab partner NM Medical -decides location ,time and number of employees for testing]
- ✓ Results are available on same day
- ✓ Negative results - repeat after one week , if again negative ,allowed to resume the duty
- ✓ If Positive , do RT PCR
- ✓ If Negative - allowed to resume
- ✓ If Positive - needs isolation and treatment



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### Employee

Employer & Lab Partner Agree on date, Location & # Employees for Screening in Advance



### Sample Collection

Sample is Collected at the Collection Centre and Sent to the Lab



### Result 1

#### Negative



Negative Result-Repeat after one week, if again negative.

Allowed to go work

#### Positive



If Positive, do RT PCR

Hospital If PCR is Positive

If Negative

Allowed to go work

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