Employer Testing Playbook

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The 5 Roles of Testing in the COVID Era

- Preventing the spread
  - Identifying infected and contagious members of the workforce as early as possible to quarantine them and to potentially perform contact tracing.
- Mitigating risk of complications and hospitalization for infected people
  - Implementing telehealth support services to minimize unnecessary use of the ER, risks of hospitalization, and further complications.
- Safely returning to work
  - Ensuring that infected members of the workforce are no longer contagious prior to their return.
- Workforce deployment
  - Identifying those members of the workforce who are susceptible as well as those who have already developed antibodies and presumed immunity for a period of time to maximize their utility within the workforce.
- Workforce and public confidence
  - Establishing a sense of confidence in the company's approach to COVID risk mitigation both within the workforce and for members of the public with whom the company interacts.

Employer and/or Departmental Risk Assessment

- Does the organization provide healthcare services directly to patients?
- Does the organization directly interact with high-risk members of the population (i.e. the elderly)?
- Are certain members of the organization at a particularly high risk of exposure (i.e. due to travel, frequent public interaction, etc.)
- Do members of the workforce work in close proximity to one another or in settings in which COVID-19 would easily spread?
- Have there already been known or suspected COVID-19 cases within the health plan (employees or dependents)?
- Is the organization mandated or advised to demonstrate a defined COVID-19 risk mitigation strategy?

Why Testing & Health Surveillance for COVID-19 is Unusually Important

- The need for testing, in the context of any disease, seems to be common sense. However, with respect to COVID-19, the critical role of testing is more pronounced – and also more nuanced.
- Infected, contagious, and symptom-free
  - The time from exposure to COVID-19 to development of symptoms ranges from 2-21 days.
  - >90% of infected people who develop symptoms do so within 14 days, however as many as 10% may take longer to develop symptoms.
  - Many people never develop symptoms but are still contagious.
- Given these facts, employers must apply well-designed testing strategies that are calibrated to their need to control COVID risk within their populations.
  - i.e. Nursing homes require a different level of vigilance than law firms.

Timing and Testing for COVID-19

- COVID-19 is diagnosed through the detection of viral RNA shedding through the respiratory system.
  - Samples may be acquired from the nose, throat, saliva, or sputum.
  - Testing evaluates viral RNA, not shedding of intact virus (i.e., infectivity).
- Viral RNA shedding can begin 3-21 days after exposure (preceding symptoms).
- While viral RNA shedding can occur in nasopharynx, oropharynx, saliva, and sputum for up to 21 days **after** symptom resolution. It appears that intact viral shedding (infectivity) is complete 14 days after symptoms begin.

False Negatives

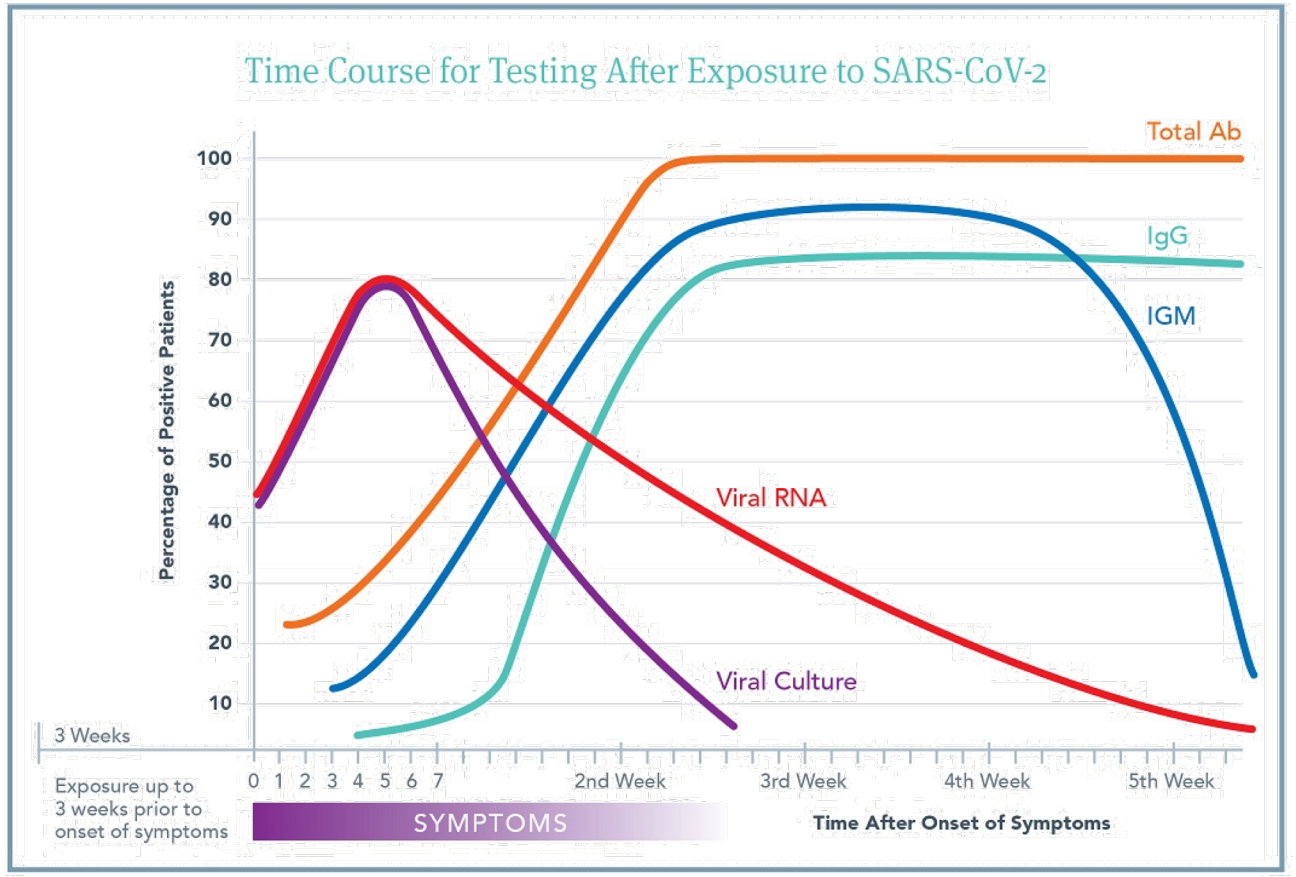
- RT-PCR is estimated to have up to a 30% false negative rate for identifying viral RNA in an infected person.
  - The majority of this is the result of collection procedures that use inappropriate sites or collect inadequate amounts of material.
  - Collection outside the diagnostic window (3-21 days after exposure) can also increase the false negative rate.
  - Handling, transport, and storage of swabs as well as the presence of interfering substances or contamination also play a role in the false negative rate.

The Timing of Antibodies

- Antibody production begins soon after symptoms (5-14 days).
  - Timing of antibody development (IgM, IgA, and IgG) varies across individuals.
  - Median antibody production is at 15 days after exposure.
  - IgM antibodies tend to be the body's more general and immediate response.
  - The IgG antibodies that follow typically confer long-term immunity.
- Antibody testing should be performed no earlier than 7 days following symptom onset.

Understanding Testing & Timing

- This graphic is an aggregate view based on a number of published studies.
- It illustrates the likelihood that an individual will have a positive test result at a specific time after symptom onset (day 0).
- It also illustrates he importance of understanding timing and the specific target of a test.



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Immunity

- While it appears that close to 100% of individuals who are infected (PCR positive) go on to develop some type of antibody response to the virus, there is tremendous individual variability in the time course of antibody production, the amount of antibody produced, and the specificity of the antibodies, i.e., which viral proteins are recognized.
  - Antibody levels also appear to correlate with severity of disease and presence of comorbidities. More severe disease results in higher viral load and also higher antibody titers.
  - An individual's underlying immune competence will also affect whether they are capable of mounting an efficient immune response that results in positive antibody titers.
- Many people never develop symptoms but may still develop antibody responses.
  - The timing and level of antibody responses in asymptomatic people is presently unknown.

The Importance of Test Selection

- All antibody tests are NOT the same.
  - The purpose of antibody testing is to determine the presence of specific antibodies to different protein components of COVID-19 called “viral antigens.”
  - It is important to understand the viral antigens that are used by a particular lab because, among other reasons, other coronaviruses (i.e. the common cold) have similar proteins, and a person’s immune response to a previous coronavirus may result in a false positive test for COVID-19 antibodies.
  - FDA EUA (emergency use authorization) does not provide the level of rigor required under ordinary circumstance for FDA approval. So, it is also important to understand the lab’s process of validation.
  - CLIA certification is also important and ensures that a test meets analytical validity.

Individual Symptom-based Scenarios

- A known exposure but asymptomatic:
  - Quarantine for two weeks, then test for Abs and viral RNA two weeks post-exposure.
  - Implement prevention supplement and lifestyle protocol.
- Mild or non-classic symptoms:
  - Perform viral RNA test to confirm infection.
  - If viral RNA is negative, then perform Ab test seven days after symptoms resolve. If negative, consider confirmatory Ab test in one to two weeks.
  - If viral RNA is positive, perform Ab test three to seven days after symptoms resolve, with confirmatory Ab test in one to two weeks.
  - It is prudent to confirm a second negative RNA test prior to considering return to work.
  - Implement active treatment supplement and lifestyle protocol.

Individual Symptom-based Scenarios

- Classic symptoms:
  - Perform viral RNA test to confirm infection.
  - If viral RNA negative, perform Ab test three to seven days after symptoms resolve. If negative, consider confirmatory Ab test in one to two weeks.
  - If viral RNA positive, then viral RNA and Ab test seven days after symptoms resolve. If negative, consider confirmatory Ab test in one to two weeks.
  - It is prudent to confirm a second negative RNA test prior to considering return to work.
  - Implement active treatment supplement and lifestyle protocol.

Individual Testing Scenarios

- This table provides a guide for interpreting and acting upon the variety of possible individual testing scenarios.

Symptomatic	Viral RNA shedding (RNA)	Production of antibodies (Ab)	Interpretation	Action
-	-	-	Susceptible	Social isolation to prevent contracting virus; risk stratification to determine return to work (based upon public policy).
-	+	-	Infected	Quarantine, retest RNA and Ab in two weeks.
-	-	+	Past exposure, immunity likely, evaluate for return to work	If an individual had symptoms, then RNA and Ab test seven days after resolution of symptoms. Return to work if RNA negative and Ab positive. If individual never had symptoms, repeat RNA test and Ab test and consider return to work if RNA negative and Ab positive.
-	+	+	Infected with developing immunity	Quarantine, retest RNA and Ab in seven days, return to work if RNA negative and Ab positive (consider additional RNA negative test if exposure to high risk populations).
+	-	-	Assume infected	Quarantine, consider second RNA test to confirm.
+	+	-	Infected	Quarantine, retest RNA and Ab in two weeks.
+	-	+	Infected with developing immunity	Quarantine, consider second RNA test to confirm.
+	+	+	Infected, with developing immunity	Quarantine, retest RNA and Ab in two weeks.

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Screening Precautions for Employers

- Ensure that unless otherwise requested, COVID-19 screening tests do not include expanded panels (including flu, bronchitis, or other viruses) that enable the plan to be billed for full respiratory panels at double the cost.
- Understand the time required for the lab to produce results. Every day that passes without results, the value of the screening goes down as infected people may not have been identified and quarantined.

Recommendations: COVID-19 Testing

- Partner with a local medical practice (for localized populations) or group that meets the following criteria:
  - Has identified and continues to track labs that:
    - Meet the quality standards defined here for COVID-19 testing
    - Can ensure a results turn-around time of not more than three days
    - Can ensure the plan is not over-billed for other testing
  - Can safely implement or facilitate on-site and/or home-based screening
  - Offers a virtual support service for high-risk members and for infected members to minimize their risk of requiring hospitalization
  - Can offer the company informed guidance on calibrating its investment and approach to testing to the company's level of risk tolerance

Recommendations: COVID-19 Testing

- Will bill the organization transparently for the following program components in exchange for guaranteed volume minimums:
  - A flat fee per-sample collected
  - A fee per testing cycle for program implementation, reporting, and maintenance of the company's antibody registry (to avoid re-testing antibody positive plan members for 12 months or in accordance with best practices)
  - A fixed, bundled fee for supporting infected

Antibody Testing Precautions for Employers

- There is an enormous amount of confusion and misunderstanding of the correct application of antibody testing – even among benefits brokers.
- The most common mistake is the use of a rapid test using finger stick as a substitute for COVID-19 diagnostic testing.
  - Some tests claim the ability to produce a “near exact timeline for when the virus was contracted based on the body’s antibody response.” This is simply a false claim.
- Rapid panel tests are flooding the market with widely varying prices and levels of quality.
  - Kits are prone to false positives from cross-reaction with other coronaviruses

Screening Scenarios: Back to Work

- **Step 1.** Antibody testing for the entire (asymptomatic) workforce
  - Symptomatic employees remain quarantined and receive PCR testing.
- **Step 2.** Employees with negative antibody results (i.e. still susceptible) may either return to work or, if dictated by the organization risk profile, receive confirmatory RNA testing prior to returning to work.
- **Step 3.** Positive antibody results are followed by an RNA test to confirm no infectivity prior to returning to work.
- **Step 4.** Antibody positive employees may be logged in a registry, and unless otherwise dictated by the organization risk profile or emerging evidence, they may be excused from screenings for the next 12 months.

Other Screening Scenarios

- Early identification of infection
  - Individual or group testing in response to symptoms or exposure
  - Total staff or department/shift level viral RNA screenings on a proactive basis
- Previous exposure and immunity assessment
  - Total staff, random selection, or department/ shift level antibody testing to determine:
    - The organization's previous rate of exposure to COVID-19
    - Which employees may have immunity, and which remain susceptible
    - Potential to detect asymptomatic, infected people
  - Employees testing positive for antibodies who are not already in the company registry of antibody positive employees receive RNA test to confirm no infectivity.

COVID-19 Telehealth Support Programs

- Rationale:
  - Average cost per admission: $72,000 (source: Covered California)
    - Average hospital stay: 12 days
  - Average COVID-19 related outpatient visit: $600

Population Prevention Initiatives

- Population-wide vitamin D optimization
  - Vitamin D testing
  - Members with vitamin D levels lower than 60 receive supplementation
- Targeted measures for higher risk plan members and/ or executives:
  - Home testing for genetic and lifestyle related Immune risk factors that increase severity of disease
    - Lifestyle Risk Check (finger stick blood panel testing Vitamin D, glucose, HbA1c, and hsCRP)
    - Respiratory Resilience Panel (saliva-based genetic panel testing for known nutritional and systems related genetic risk factors)
  - Full nutraceutical support
    - Immune Defense Kit