VERMONT
DEPARTMENT OF HEALTH

The Public Health Role of COVID-19 Serologic (Antibody) Assays in the State of Vermont

Final Recommendations of the Serology Working Group

April 16, 2020

Background

There has been broad interest in the use of COVID-19 serologic (antibody) tests to learn if individuals have been infected with SARS-CoV-2 (the causal agent of COVID-19) and, more broadly, what percentage of the population of Vermont has already been infected with the virus. Some have advocated using the test results to determine proof of immunity and to use this data to help re-open businesses and in return-to-work decisions.

Serologic testing relies on the detection of antibodies to SARS-CoV-2. Antibodies are proteins produced by the host immune system after infection that help clear the infection and prevent future infections with the same organism. Depending on the type of serologic test, the assay may detect IgM antibodies (seen early after infection), IgG antibodies, or both. The Food and Drug Administration (FDA) developed policies aimed to accelerate development of SARS-CoV-2 antibody tests by allowing private companies to market the serology tests without FDA approval. The companies or labs cannot claim that the FDA authorized the tests and must include disclaimers noting that such tests might falsely conclude whether a person had a prior infection. While many serologic assays are in development and in use, only three have emergency authorization use by the FDA. More recently, the FDA said it will (through the National Cancer Institute) start evaluating COVID-19 antibody tests amid concerns about their accuracy.

A working group of content experts from the fields of laboratory medicine, public health, infectious diseases, and ethics from the **Vermont Department of Health, Larner College of Medicine at the University of Vermont, and the University of Vermont Medical Center** met to review the current data on the use of serologic testing in individuals and populations.

Key Findings

The working group bases their recommendations on the following findings:

1. Currently available serologic tests lack sufficient evidence of high-level sensitivity and specificity.
2. Current serologic tests may not be specific for SARS-CoV-2 and a positive result could instead reflect infection with other similar viruses (cross-reactivity).
3. While there is an expectation that a positive antibody test to SARS-CoV-2 suggests some immunity to future infection by the virus, we do not yet know how protective that immune response is and how durable it will be. Early data suggests that measurable antibody responses and the effectiveness of these antibodies may be dependent on the age of the patient, their baseline health, and severity of their past COVID-related illness.
4. There are risks of using serologic test results to inform decisions for a single individual, including the concern that test results could “immune-privilege” certain populations. One such risk is the discrimination of employees and their ability to work based on “immune” status. If/when serology is used for individuals, strategies to minimize this risk will be required.
5. The governor’s policies including “Stay Home, Stay Safe” appear to have been very effective in limiting community transmission of SARS-CoV-2 in Vermont. Based on current data, it is possible that a low number of Vermont residents would have a positive serologic test for SARS-CoV-2. Therefore, given the current status of serologic tests, policies aimed to re-open Vermont businesses and communities should depend on other pragmatic public health criteria and continuously updated information regarding the epidemic curve of COVID-19 in Vermont.
6. Serology may be useful for future decisions and periodic reevaluation will be required as data evolve.
7. Despite high enthusiasm for COVID-19 vaccine development, it is far too early to suggest the use of any single candidate vaccine.

Recommendations

1. The currently available serologic tests lack sufficient accuracy and reliability for making decisions or recommendations to change individual or population-level behaviors.
2. Specifically, at the present time, serologic testing in Vermont should not be used to make decisions about individuals, e.g. used to establish proof of immunity.
3. As more data emerge, periodic review of this issue, including future improvements in the serologic tests themselves and the interpretation of results, will be necessary. Recommendations may change based on new data.
4. The Vermont Department of Health should consider conducting seroprevalence studies in Vermont to establish what percentage of the general population has been infected with SARS-CoV-2. An additional survey of high-risk individuals or settings may also be desired. Ideally, serologic surveys would be repeated periodically to assess changes in population exposure. Collaboration with The University of Vermont, The University of Vermont Medical Center and other entities in Vermont may be helpful in this effort.
5. Criteria used to reopen businesses and for return-to-work decisions should be made on established public health practices and clinical data including the health risk of the individual, the work/home exposures of the individual, and the density and face-face exposures likely in community and business contacts.
6. No data exist to make any recommendations yet regarding vaccination strategies in Vermont.
7. The above-mentioned group of content experts will reconvene in one month to reassess available data.

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