COVID-19 ANTIBODY TESTING

Policy Number: 15GS

Effective Date: 6/01/2020

Revised Date: 11/09/2020

Scope

The policy on COVID-19 Antibody Testing applies to directors, officers, and members of the nonprofit organizations within the Stowers Group of Companies ("SGC" and "SGC Organizations"), including Stowers Institute for Medical Research ("SIMR") and Stowers Resource Management Inc. ("SRM"), and to individuals who make substantial use of a SGC Organization's facilities, such as post-doctoral research associates, pre-doctoral researchers and approved visitors (collectively, "Covered Individuals").

Purpose

This policy describes Covered Individuals participation in the SGC's COVID-19 antibody testing program.

The COVID-19 antibody testing program is governed by the following principles.

Testing for the COVID-19 antibody may indicate that an individual is less likely to be contagious or susceptible to COVID-19.

Evidence is still emerging on the strength of the link between the presence of COVID-19 antibody and the degree of susceptibility and infectivity.

SIMR will make COVID-19 antibody testing available to individuals to use at their discretion and adjust its policy on antibody testing as evidence emerges.

The Graduate School of the Stowers Institute for Medical Research ("The School") is included in the Stowers Group of Companies ("SGC") Organizations and has adopted the following policy as its own.

Policy

Availability of COVID-19 antibody testing. Covered Individuals and their household members may choose whether or not to use COVID-19 antibody tests provided by SIMR.

Agreement to share test results. Covered Individuals using the COVID-19 antibody tests provided by SIMR must agree to share the results with SIMR's Office of Infection Control.

Guidelines and procedures. Participation in the Institute's COVID-19 antibody testing is voluntary. Covered Individuals who wish to participate in the COVID-19 antibody testing program must follow the guidelines.

Consequences of non-compliance. Participation in COVID-19 antibody testing is voluntary and will not have any impact on a Covered Individuals' employment status or other association with the SGC. However, Covered Individuals participating in COVID-19 antibody testing must conform with the requirements of the testing program.

This policy was approved by the GSSIMR Board of Directors on June 18, 2020. This policy was last updated by the GSSIMR Board of Directors on November 09, 2020. This policy will be reviewed by the GSSIMR Board of Directors in 2022.

Policy 15GS COVID-19 Antibody Testing Guidelines

1. Overview

| A. | What policy do these guidelines | | Policy | Number 15C "COVID-19 Antibody Testing" | |
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| | reference? | | | | |
| В. | What do these guidelines cover? | | Expec | tations for participation in the COVID-19 antibody testing program | |
| C. | Who must comply with these | | "Cove | red Individuals," defined as directors, officers, and members of the SGC or individuals | |
| | guidelines? | | who n | nake substantial use of an SGC Organization's facilities. | |
| D. | What are | the | general | i. | Covered Individuals may choose whether or not to use the COVID-19 antibody tests |
| | requirements | for | Covered | | provided by SIMR |
| | Individuals? | | | ii. | Covered Individuals opting to use the COVID-19 antibody tests must agree to share |
| | | | | | their test results with SIMR's Office of Infection Control |

2. Description of the COVID-19 antibody test

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| A. | What is the COVID-19 antibody test? | The COVID-19 antibody test detects the presence of antibodies that the body's immune system produces to fight COVID-19 infection. A positive result with the antibody test suggests that the person has had an infection in the past and may be less likely to spread or contract the virus. |
| В. | How does the COVID-19 antibody test work? | For the COVID-19 tests used by SIMR, you will provide a blood sample by pricking your finger. Unlike other tests, the current tests used by SIMR do not require a phlebotomist to collect a tube of blood via venipuncture. The sample is then analyzed to determine whether your body is producing antibodies against proteins from SARS-CoV-2, the virus that causes COVID-19. |
| C. | What does a positive result from the COVID-19 antibody test mean? | A positive test result suggests that you have been exposed to SARS-CoV-2 or a similar coronavirus. The presence of these antibodies suggest that you may be less susceptible to COVID-19 infection and less likely to transmit COVID-19 to others. Evidence is still emerging about the degree of protection that these antibodies provide and how long the protection lasts. |
| D. | What does a negative result from the COVID-19 antibody test mean? | A negative test result indicates the absence of detectable antibodies against SARS-CoV-2 or a similar coronavirus. The absence of these antibodies suggest that you are likely to be susceptible to COVID-19 infection. |
| E. | How confident should one be in positive or negative test results? | Like any diagnostic test, the test results must be interpreted carefully and often must be repeated for confirmation. The level and type of antibodies change during the course of |

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| | | infection by the virus. The stage of infection, errors in sample collection, differences |
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| | | between individuals and other factors can all influence the results. |
| F. | How does the COVID-19 virus test | The COVID-19 virus test detects the presence of viral RNA. A positive result with the virus |
| | differ from a COVID-19 antibody | test suggests the presence of active infection. In contrast, the COVID-19 antibody test |
| | test? | detects the presence of antibodies that the body's immune system produces to fight COVID- |
| | | 19 infection. A positive result with the antibody test suggests that the person has had an |
| | | infection in the past and may be less likely to spread or contract the virus. The virus test |
| | | uses a saliva sample while the antibody test uses a blood sample. |

3. Voluntary testing

| A. Is the COVID-19 antibody test voluntary? How do I provide a specimen for the COVID-19 antibody test? Blood self-collection devices will be distributed before the scheduled test. Covered individuals will receive training as needed in the use of the collection device. Covered individuals will bring specimens to the designated drop off site and follow the instructions for logging and depositing the sample. C. How often will the COVID-19 antibody test be available? The current plan is to make the test available once a month for all Covered Individuals and their household members. The frequency and availability of testing is likely to change during the course of the pandemic. D. What happens if a COVID-19 antibody test is missed? E. If I agree to take the test, how are the results reported? F. If I use the Institute's COVID-19 antibody test, do I need to have the tests results reported to the Institute. Covered Individuals' test results will be reported to the SIMR, you may choose to keep the results private. The use of COVID-19 antibody test not provided by SIMR may not be covered Individual decides not to take a voluntary COVID-19 antibody test? There are no consequences if a Covered Individual decides not to take a voluntary COVID-19 antibody test. | | , , | |
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| | | a COVID-19 antibody test? | antibody test. |

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4. Possibility of mandatory testing

| A. | Will COVID-19 antibody testing become mandatory in the future? | Possibly. The SGC may decide to make COVID-19 antibody testing and reporting mandatory depending upon the course of the pandemic and available information about the predictive value of antibody test results. |
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| В. | | SIMR will assess the course of infection within the SIMR and the strength of evidence on the health implications of the presence of COVID-19 antibodies. |
| C. | How will I know if SIMR decides to make COVID-19 antibody testing mandatory? | SIMR will amend and redistribute this policy. |

5. Use of results

| A. | Who will have access to my | You and the Office of Infection Control will have access to your antibody test results. The |
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| | COVID-19 antibody test results? | Office of Infection Control is staffed by licensed professionals, who are trained to maintain |
| | | the privacy of healthcare information in compliance with the Health Insurance Portability and |
| | | Accountability Act of 1996 (HIPAA). |
| В. | How should the COVID-19 | Individuals should not make healthcare decisions or change their behavior based on the |
| | antibody test results be used by | result of antibody-testing. While the presence of antibody is suggestive of lower susceptibility |
| | individuals? | to COVID-19 infection, evidence is still emerging about the strength of this link. |
| C. | Will a positive COVID-19 antibody | Not at this time. The Institute will consider modifying the virus testing requirement for |
| | test exempt me from further | antibody-positive individuals as evidence emerges about the link between a positive antibody |
| | COVID-19 virus testing? | test and immunity. |
| D. | Should I relax social distancing | Not at this time. The evidence for a link between a positive antibody test and immunity is |
| | and the use of PPE if I test positive | still emerging. Individuals are encouraged to be conservative until evidence is stronger. |
| | for COVID-19 antibodies? | |
| E. | How will COVID-19 antibody test | SIMR will use the information to assess the potential emergence of "herd immunity" among |
| | results be used by SIMR? | theSGC's population. |
| F. | How will confidentiality be | Your test results will be kept in a HIPAA-compliant file with access limited to the Office of |
| | maintained? | Infection Control. Identified, individual test results will not be placed in your personnel file or |
| | | any other file outside of the Office of Infection Control. De-identified or aggregated test |

| | results may be used for infection control, reporting, research or other purposes. For some |
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| | commercial tests, the test results will be managed using the provider's secure portal. For |
| | other tests, the test results may be coded with only you and the Office of Infection Control |
| | knowing the code that has been assigned to you. |

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