Q&A | The PhenoSense® Anti-SARS-CoV-2 Neutralizing Antibody Assay

1. What is the PhenoSense Anti-SARS-CoV-2 Neutralizing Antibody Assay?

A: The PhenoSense Anti-SARS-CoV-2 Neutralizing Antibody Assay is a cell-based assay for use in determining if detectable antibodies in a patient sample have the capacity to inhibit SARS-CoV-2 infectivity in the laboratory.

2. What is the intended use of this assay?

A: The PhenoSense Anti-SARS-CoV-2 Neutralizing Antibody Assay has been developed to enable semi-quantitative measurements of neutralizing antibody (nAb) activity directed against the SARS CoV-2 S (spike) envelope protein in response to natural infection and vaccination. This assay is intended for the evaluation of convalescent plasma for prophylactic and therapeutic use, and for vaccine development. This assay is intended for use in vaccine development, as an aid in surveillance studies to characterize nAb prevalence, and as an assay to further define the correlates of protection.

3. Does this test replace other SARS-CoV-2 serology (antibody) tests?

A: No. This assay is an addition to the existing serology tests which are used to determine if an antibody is present. The PhenoSense Anti-SARS-CoV-2 Neutralizing Antibody Assay evaluates whether antibodies that are present in patient samples are capable of neutralizing virus infectivity in the laboratory.

4. What are the acceptable sample types for this assay?

A: Serum is preferred, but plasma is acceptable. Collect specimen in SST gel barrier tube, red-top tube, EDTA lavender-top or ACD yellow top tube. Transfer the serum or plasma to one polypropylene screw-capped tube(s) (not “pop-top” or “snap-cap”), and freeze. Ship specimen frozen. **Note**: Internal thread tubes are not recommended for submission.

5. What are the volume requirements for sample submission?

A: The volume requirement is 1.0 mL, which may allow for repeat testing.

6. What is the expected turnaround time on this assay?

A: The expected turnaround time is 10 days or less from receipt of the specimen in the Monogram Biosciences laboratory. The turnaround time may vary depending upon the volume of samples received.

7. How was this assay developed?

A: The PhenoSense Anti-SARS-CoV-2 Neutralizing Antibody Assay is based on the proprietary PhenoSense® Assay platform that was developed to evaluate antiretroviral drug susceptibility (Petropoulos et al., AAC 2000) and later adapted to evaluate entry inhibitors, nAb activity (Richman et al., PNAS 2003) and co-receptor tropism (Whitcomb et al., 2007). Over time, the PhenoSense assay platform has been successfully adapted to evaluate vaccines and entry inhibitors that target a variety of enveloped viruses, including orthomyxovirus (influenza), paramyxovirus (para-influenza), filovirus (Ebola), and most recently coronavirus (SARS CoV-2, SARS CoV).

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8. How does the assay work?

A: The measurement of nAb activity is performed by generating replication-defective HIV-1 pseudovirions that express the SARS CoV-2 spike protein. nAb activity is measured by assessing the inhibition of luciferase activity in target cells following pre-incubation of the pseudovirions with serial dilutions of the patient sample.

9. How are the assay results reported?

A: We report a positive and a negative result. The limit of detection is a nAb titer value less than 40, representing a negative result. Semi-quantitative nAb titers greater than 40 are considered positive, (aligned with a specificity control). The nAb titer is defined as the specimen dilution that produces a 50% reduction in virus infectivity (50% inhibitory dilution, ID50). PhenoSense SARS-CoV-2 titers are reported as the reciprocal of the specimen dilution, e.g. a dilution of 1:160 is reported as 160.

10. Who do we contact if we get questions about this assay?

A: Please call Monogram Biosciences' Customer Service at 800-777-0177.

References

1. Petropoulos CJ, et.al. A Novel Phenotypic Drug Susceptibility Assay for Human Immunodeficiency Virus Type 1. Antimicrobial Agents and Chemotherapy Apr 2000, 44 (4) 920-928.
2. Richman DD, Wrin T, Little SJ, Petropoulos CJ. Rapid evolution of the neutralizing antibody response to HIV type 1 infection. Proc Natl Acad Sci USA. 2003 Apr 1;100(7):4144-4149.
3. Whitcomb JM, et.al. Development and Characterization of a Novel Single-Cycle Recombinant-Virus Assay To Determine Human Immunodeficiency Virus Type 1 Coreceptor Tropism. Antimicrobial Agents and Chemotherapy Jan 2007, 51 (2) 566-575.

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