

AAV NEUTRALIZING ANTIBODIES FREQUENTLY ASKED QUESTIONS



PATIENT FAQ SHEET - PLEASE READ

1. How long will it take to get results?

a. It takes about 4-6 weeks to get the results from the time the blood is drawn. Once results are available, CRD staff will reach out to you to schedule time to discuss these results and answer any questions you may have.

2. Can I discuss these results with my doctor?

a. You may. It's critical to note though that this is a research test so results cannot go into the patient medical record and they also cannot be used to make medical decisions about a clinical trial to participate in or other medical action to take. They are purely informational in nature.

3. Can the results change?

a. Yes. This is a measurement at a single time point. Neutralizing antibody levels can, and likely will, change over time.

4. Where can I find out more information on neutralizing antibodies?

a. More information can be found on CRD's website where we have links to prominent publications on neutralizing antibodies. You can also ask your specialist about neutralizing antibodies.

5. Are all neutralizing antibodies bad?

a. No. Neutralizing antibodies are protective measures produced by your body to guard against foreign antigens. Since AAV is a virus (adeno-associated virus), the body can have specific pre-existing antibodies to this AAV which creates challenges when AAV is used as a therapeutic. Your body has other neutralizing antibodies present which target other antigens and which are important for preventing sickness.

6. I'm considering enrolling in a gene therapy study - do these results impact that?

a. No. This is a research test and cannot be used to make medical decisions. Moreover, the decision to enroll into a clinical trial is incredibly personal. The sponsor (drug company) responsible for a clinical trial will repeat these results using their own tests. If the patient is currently involved in an ongoing clinical trial he or she is not eligible to participate in the Cure Rare Disease NAb testing program.

7. Are all neutralizing antibody tests the same?

a. No. As of Fall 2020, there is no standardized neutralizing antibody test for AAV (regardless of AAV type - known as serotype). Thus, results can, and likely will, vary based on the neutralizing antibody test conducted.

8. What if I am positive for AAV NABs?

a. You should repeat the test and consult your clinician regarding any further action.

Please email research@cureRD.org with any questions or concerns regarding sample collection, processing, post-processing, shipping or general questions.