QUESTIONS & ANSWERS

nAbCyte™ Hemophilia B Testing Program

Program Overview

1. What is the purpose of the nAbCyte Hemophilia B Testing Program?

A: The nAbCyte™ Anti-AAVRh74var HB-FE Assay (nAbCyte Assay) helps to determine eligibility for treatment with the Pfizer® hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec-dzkt).

2. What tests are available through this program?

A: 007150 – nAbCyte Anti-AAVRh74var HB-FE Assay

3. Which laboratory performs the nAbCyte Assay?

A: These tests will be performed by Labcorp's Monogram Biosciences, Inc. laboratory in South San Francisco, CA.

4. Is the nAbCyte Hemophilia B Testing Program part of a clinical trial?

A: No. This program is conducted independently of any clinical trials.

5. Who is eligible for the nAbCyte Hemophilia B Testing Program?

A: The nAbCyte Assay is indicated for patients previously diagnosed with moderate to severe hemophilia B to determine eligibility for treatment with the Pfizer® hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec-dzkt). Testing should only be ordered on patients who conform to the drug label and for whom a healthcare provider (HCP) intends to treat with BEQVEZ™ (fidanacogene elaparvovec-dzkt).

Ordering Instructions & Logistics

1. Is the cost of the nAbCyte Assay testing covered through the nAbCyte Hemophilia B Testing Program?

A: Yes. Pfizer® will cover the cost of testing for eligible patients prescribed the diagnostic test by their HCP, to include shipping, specimen processing, and reporting of results through the nAbCyte Hemophilia B testing program. Patients and health care providers must **not** submit any claims to any insurance provider or government health care program for reimbursement for costs through the program.

2. How do I order the nAbCyte Assay through the nAbCyte Hemophilia B Testing Program?

A: Detailed ordering instructions can be found by visiting Labcorp's webpage at nAbCyteHemB.com.

3. What are the specimen requirements for the nAbCyte Assay?

Labcorp accepts 1 mL frozen serum collected in a red-top tube (glass or plastic clot activator, silicone-coated plastic red-top tube).

After mixing, allow the whole blood to clot for 30 minutes with the tube standing upright before centrifugation. Centrifuge the tube at 1,500-2,000 g for 15 minutes to separate the clot from serum.

Please refer to Labcorp's webpage at https://www.nAbCyteHem.com for further detailed instructions.

4. Causes for Rejection of Specimens

A: Quantity not sufficient; unfrozen specimen; hemolysis.

5. Can I submit the order via an electronic ordering method?

A: Electronic ordering is allowed. Please note that test #007150 and your program-specific account number would need to be added to your electronic ordering platform. To add the test to Labcorp Link™, please contact your Labcorp sales representative or email nAbCyteHemB@Labcorp.com. To add the test to your EMR, please follow your standard process for test additions.

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6. How do I arrange shipping of the specimen to the lab?

A: Once the sample is collected, please call 855-Labcorp to schedule a routine Labcorp courier pickup.

Test Results / Clinical Questions

1. How quickly will I receive my results?

A: The turnaround time is approximately 7-10 calendar days from the time the sample is received at the lab.

2. How will I receive my patient's test results?

A: Reports will be delivered via the report receipt method selected during registration. Results may be delivered via fax or Labcorp's online results portal Labcorp Link™.

3. Is confirmatory testing allowed?

A: HCPs should use their discretion in requesting an additional blood sample and testing to re-evaluate the patient for neutralizing antibodies. A redraw and second test is not recommended as a standard practice.

Test Details

1. nAbCyte Assay Indications for Use:

A: The nAbCyte Assay is indicated as a cell-based qualitative *in vitro* companion diagnostic device intended for the detection of neutralizing antibodies to the AAVRh74var capsid in serum specimens from adult patients previously diagnosed with moderate to severe hemophilia B to determine eligibility for treatment with the Pfizer® hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec-dzkt).

This diagnostic device is a single-site assay for professional use only and is to be performed only at Labcorp-Monogram Biosciences by trained and qualified laboratory personnel.

2. What is the Methodology?

A: Cell-based luciferase reporter virus (AAV) neutralizing antibody assay.

3. What is a Humanitarian Use Device (HUD)?

A: Humanitarian Use Device (HUD): a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year (Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255).

The nAbCyte Assay is classified as a Humanitarian Use Device (HUD) by the FDA. This test is authorized by federal law for use as a companion diagnostic in the selection of patients to receive the Pfizer® hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec-dzkt). The effectiveness of this device for this use has not been demonstrated.

4. What is a Humanitarian Device Exemption (HDE)?

A: Humanitarian Device Exemption (HDE): a marketing application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

5. What do I need to do differently to order the nAbCyte Assay since it is a HUD approved under an HDE?

A: To order testing, the HCP must complete a one-time enrollment in the program which includes registration with Labcorp's Institutional Review Board (IRB) or appropriate local committee. Once registered, the nAbCyte Assay can be ordered like any other diagnostic test from Labcorp. To use the nAbCyte Assay as an HUD, the laboratory (Labcorp's Monogram Biosciences, Inc.) must also have institutional review board (IRB) or appropriate local committee approval.

If you have any further questions or require assistance regarding the nAbCyte HemB Testing Program, please visit nAbCyteHemB.com or contact our dedicated team at nAbCyteHemB@labcorp.com or 844-294-7361.

The nAbCyte™ AAVRh74var HB-FE assay is FDA approved as a Humanitarian Use Device for use as a companion diagnostic in the selection of patients to receive the Pfizer hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec-dzkt). The effectiveness of this device for this use has not been demonstrated.

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