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).

2. What tests are available through this program?

A: In Canada, the Anti-AAVRh74var HB-FE Assay to determine eligibility for treatment with BEQVEZ™ (fidanacogene elaparvovec), test 007213, is available through this program.

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 hemophilia B to determine eligibility for treatment with the Pfizer® hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec). Testing should only be ordered for patients who conform to the Health Canada Product Monograph and for whom a healthcare provider (HCP) intends to treat with BEQVEZ™ (fidanacogene elaparvovec).

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, healthcare programs, or beneficiary shall **not** be billed for the nAbCyte Assay testing conducted pursuant to this 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 web page at www.nAbCyteHemB.com. Before testing can be ordered, HCPs must first register for the program. A program-specific Labcorp account will be created and a welcome package with detailed ordering instructions will be delivered via email approximately 7-10 business days after enrollment.

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

A: Labcorp accepts 1 mL frozen serum (minimum 0.2 mL) collected in a red top tube (glass or plastic clot activator, silicone-coated plastic red-top tube). Do not use gel barrier tubes. 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. Ship the sample frozen on dry ice which will be provided by Marken, the courier service. Please refer to Labcorp's web page at www.nAbCyteHemB.com for further detailed instructions.

4. What are the causes for rejection of specimens?

A: Testing may not be performed if the specimen quantity is not sufficient. Samples that are received unfrozen or hemolyzed cannot be tested.

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5. Can I submit the order via an electronic medical record or other electronic ordering system?

A: No. Testing must be ordered under the program-specific Labcorp account using the dedicated test request form provided in the welcome package.

Test Results / Clinical Questions

1. How quickly will I receive my results?

A: The turnaround time is approximately 7-10 calendar days (based on the date that a specimen has been received at the Labcorp-Monogram Biosciences lab). Please allow up to two business days for shipment to be received.

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

A: Results will be delivered to you based on the preference selected during account creation. Results may be delivered either via fax or Labcorp's online results portal, Labcorp Link™.

3. What will the results look like?

A: This is a qualitative assay and results will be reported as a positive or negative results. Patients who test negative for antibodies are eligible for treatment with BEQVEZ™ (fidanacogene elaparvovec). Patients who test positive for antibodies are not eligible for treatment with BEQVEZ™ (fidanacogene elaparvovec).

4. 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

The nAbCyte Anti-AAVRh74var HB-FE Assay for BEQVEZ™ (fidanacogene elaparvovec)

US FDA Approved Indications for Use

Eligibility in moderate to severe hemophilia B, or nAbCyte Anti-AAVRh74var HB-FE 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).

The nAbCyte Anti-AAVRh74var HB-FE Assay 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.

Methodology

Cell-based luciferase reporter adeno-associated virus (AAV) neutralizing antibody assay.

The nAbCyte™ AAVRh74var HB-FE assay has been approved by the U.S. Food and Drug Administration 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.