EZH2now℠
Testing Program

EZH2Now℠ Testing Program to determine the *EZH2* mutation status of your adult patients with relapsed or refractory (R/R) follicular lymphoma (FL)

About the EZH2Now Testing Program

Epizyme is proud to offer no-cost access to the EZH2Now Testing Program, a single gene EZH2 test for your R/R FL patients. Launched in partnership with Quest Diagnostics, this program offers a comprehensive experience for you, your staff, and your patients.

About the test

The test employs the **cobas®** EZH2 Mutation Test. It is an FDA-approved, real-time, allele-specific polymerase chain reaction (PCR) test that detects single nucleotide mutations of the *EZH2* gene.[1] The *EZH2* gene plays an important role in follicular lymphoma, regardless of mutation status.[2]

A comprehensive experience

Launched in partnership with Quest Diagnostics, a leading provider of diagnostic information services, the EZH2Now Testing Program promises a seamless, comprehensive experience to streamline the testing process for you and your staff. The program provides a hassle-free process which will be managed entirely by Quest Diagnostics, from gathering and shipping the tissue sample to sending you a report with the results.

EZH2=enhancer of zeste homologue 2.

Procedure for Initiating the Test

Your medical office needs to simply

Provide the pathology report and access to the tissue sample.

Submit a completed Test Requisition Form (TRF) together with the patient's pathology report and be sure to fill in the information on where to retrieve the tissue block to start the process.

- **The TRF and pathology report are both required** for the test to be processed.

Test Requisition Forms can be obtained through your Epizyme Oncology Account Manager, or you can download them at: **EZH2NOW.com**.*

Quest Diagnostics will

Request the paraffin block from your pathology lab per block retrieval Standard Operating Procedure.

Expedite prepaid shipping of the tissue sample to the Quest Lab.

Share the test results with you via fax within 7 days after receipt of the block at the Quest Central Lab.

A Quest Program Manager is available to answer any questions about the testing procedure. They can be reached via EZH2Now-E@questdiagnostics.com or 1-866-226-8046.

*The patient ID is the identification number **used by your office** to identify the patients and will **only** be shared with Quest Diagnostics. When calling regarding a request form, your office may refer to this number with Quest.

Frequently Asked Questions

Q: What is the EZH2Now Testing Program?

A: The EZH2Now Testing Program is a collaboration between Epizyme and Quest Diagnostics. The program provides a single gene test for the *EZH2* mutation status of your R/R FL patients. The EZH2Now Program is part of the EpizymeNOW Support Program.

Q: How do you participate in the EZH2Now Testing Program?

A: You will need to complete and send the following items to Quest Diagnostics: the EZH2 Test Request Form, the patient's pathology report, and the patient's tissue sample.

Q: Do I need to be an existing Quest Diagnostics customer in order to use the EZH2Now Testing Program?

A: No, all physicians may participate in the EZH2Now Testing Program as long as their patient fits the eligibility requirements (see "Patient eligibility" for details).

Q: What are the requirements for the patient's pathology sample?

A: A deparaffinized 5-µm section of a formalin-fixed paraffin embedded tissue (FFPET) specimen.[3] Please contact Quest Diagnostics for further specifications.

Q: Which tool does Quest Diagnostics use to conduct the EZH2 test?

A: Quest Diagnostics uses the Roche **cobas**® EZH2 PCR test.

Patient eligibility

Q: Who is eligible for the EZH2Now Testing Program?

A: This program is for adult patients with R/R FL.

Q: Are newly diagnosed FL patients eligible for the program?

A: No, newly diagnosed patients are not currently eligible. Check with your pathology department or commercial lab partner for EZH2 testing options for newly diagnosed patients.

Insurance coverage and cost

Q: Are patients who are covered by federal, state, or local government insurance programs or uninsured able to participate in the program?

A: Yes, all R/R FL patients are eligible to participate regardless of insurance coverage status.

Q: Is there a cost associated with the EZH2Now Testing Program?

A: There is no cost associated with the EZH2Now Testing Program. Epizyme will cover the costs of testing for all eligible R/R FL patients. Neither you nor your patients will receive a bill.

Q: Should I seek reimbursement for the test?

A: No, reimbursement for the EZH2Now Testing Program cannot be sought from any insurance plans.

Q: Will Epizyme cover the cost if the EZH2 test is negative?

A: Yes, Epizyme will cover the cost of the test, regardless of *EZH2* mutation status.

Q: If I need to acquire a new tissue sample for the program, is that expense covered by the EZH2Now Testing Program?

A: No, the EZH2Now Testing Program only covers the cost of the **cobas**® EZH2 PCR test.

Patient data

Q: Who will have access to the patient's data?

A: Only Quest Diagnostics will receive protected health information to complete the EZH2 test. Quest Diagnostics does not share personally identifiable information with Epizyme.

Receiving test results

Q: Who will receive the test report?

A: The test report will be sent directly to the requesting healthcare provider via secure fax only. Epizyme will not receive a copy of the report.

Q: How soon will I receive the test results?

A: Once the tissue block arrives at the lab, you will receive the results within 7 days after receipt of the block at Quest's Central Lab.

Q: How will I receive the test results?

A: You will receive the test results via secure fax only.

References: 1. F. Hoffmann-La Roche Ltd. cobas® EZH2 mutation test. Accessed April 21, 2021. https://diagnostics.roche.com/global/en/products/params/cobas-ezh2-mutation-test.html. **2.** Béguelin W, Popovic R, Teater M, et al. EZH2 is required for germinal center formation and somatic *EZH2* mutations promote lymphoid transformation. *Cancer Cell.* 2013;23:677-692. **3.** Roche Molecular Systems, Inc. cobas® *EZH2* mutation test for in vitro diagnostic use. Accessed April 21, 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200014C.pdf.

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