Important New Requirement for Genetic Testing

Effective for dates of service May 1, 2017 and forward, all genetic testing (e.g., Cystic fibrosis, BRCA, colon and lung cancer genomics, etc.) must be performed by The Henry Ford Health System Center for Precision Diagnostics. This affects all HAP members in all products where genetic testing is a covered benefit.

Prior authorization must be obtained

Henry Ford Health System will not process genetic testing without an approved authorization. Authorizations can be submitted via CareAffiliate*, HAP's online authorization application. These are the steps:

1. Log in at **hap.org**.
2. To ensure the genetic test is covered, go to Procedure Reference Lists and review *Services that Require Prior Authorization*.
3. If it is covered, you may submit the request. Click on *Authorizations.*
4. Use one of the appropriate genetic testing requests types:
   - BRCA: BRCA1 and BRCA2
   - Cologenetic: genetic testing for colorectal cancer
   - Gengentic: general genetic testing
5. Complete the request with all pertinent clinical information.

*For all other members, refer to the back of their ID card for authorization instructions.

All the information you need in one location

Visit **henryford.com/hfcpd for:**

- Information on sample types
- Collection and transport requirements
- Printable testing request forms
- Frequently asked questions
- Other tools

Henry Ford's Integrated Specimen Receipt Area accepts all types of specimen 24/7 year-round. Results are reported via:

- Epic in-basket or Epic Autofax for physicians with Henry Ford Epic EMR access
- Fax for clients without access to Henry Ford Epic EMR
- Atlas Outreach portal for providers who elect to be set up for electronic reporting

If you have questions, call (313) 916-4362 to speak with a laboratory customer service representative. They're available Monday through Friday from 8 a.m. to 9 p.m.

Professional staff are available for consultation the same day or within one business day. You can speak directly with a board-certified molecular scientist for:

- Ordering advice for test indications and appropriateness
- Professional interpretation and advice regarding test results
- Specimen submission requirements

For your convenience, FAQs from the Henry Ford Center for Precision Diagnostics website are enclosed.

Frequently Asked Questions

Q: How do I get more information?

- Visit **henryford.com/hcp/academic/pathology/precision-diagnostics**
  Call Laboratory Customer Service at **(313) 916-4362**. Client services phone hours are: Monday through Friday, from 8 a.m. to 5 p.m. Professional staff are available for consultation the same day or within one business day. Speak directly with a board certified molecular pathologist for:
  - Ordering advice for test indications and appropriateness
  - Professional interpretation and advice regarding test results

Q: Where do I find information on how to obtain a specimen?

A: Our website includes information about sample types, collection and transport requirements, and printable test requisitions to accompany samples. We provide wide access to HFHS patient service blood draw centers for all patients. Blood may be drawn at a Henry Ford Lab Patient Service Centers conveniently located throughout southeast Michigan (map, addresses and hours of operation accessible via **henryford.com/services/lab**). Blood tube samples drawn in your own clinic may be couriered or mailed to (see instructions on website).

Q: How do I place an order for a test or tests?

A: We offer high tech and low tech options customized to meet your needs. We provide a Laboratory Users Guide accessible via the internet for all orderable testing that clearly defines the order process, consent and/or preauthorization as applicable and specimen requirements.

- Place an order in Henry Ford Epic EMR - for clients with access to Henry Ford Epic EMR, place an Epic order and print an Epic requisition to accompany the sample.
- Place an order in our Lab Outreach Portal (Atlas), for Henry Ford Medical Lab Outreach clients. Print a requisition from our website. For any client, access test requisitions on our website, and print to accompany the sample

Q: How do I submit specimens for testing?

A: Our Integrated Specimen Receipt Area is prepared to receive any type of specimen 24 hours a day, seven days a week, 365 days a year. Specimen(s) should be sent to:

Henry Ford Hospital
Center for Precision Diagnostics
Core Lab | Clinic Building | K6, Rm. E-655
2799 W. Grand Boulevard
Detroit, MI 48202

Our website includes information about sample types, collection and transport requirements, and printable test requisitions. Blood tube samples may be mailed to us (see instructions on website). Processed tissue or bone marrow blocks may be mailed to us (see instructions on website).

Q: Where are specimens received?

A: Samples collected at HFHS draw sites will be transported to Henry Ford Hospital. Samples drawn elsewhere can be dropped off at one of our specimen collection sites, or samples should be delivered to Henry Ford Hospital Core Laboratory, open 24 hours a day, seven days a week, 365 days a year.

Henry Ford Hospital
Center for Precision Diagnostics
Core/STAT Lab | Clinic Building | K6, Rm E-655
2799 West Grand Blvd
Detroit, MI 48202

Q: How are results reported?

A: For physicians with Henry Ford Epic EMR access, results will be reported electronically to the Epic EMR by preferred choice of Epic in-basket or Epic Autofax.

For clients without access to Henry Ford Epic EMR, standard reporting of results will be to the clinician fax number on the requisition.

Some clients may elect to be set up for electronic reporting through our Atlas Outreach portal with online inquiry or printed reports.

Q: How is the appropriateness of test requests managed?

A: Testing requests that pass insurance medical review/preauthorization will be reviewed by our molecular pathologists and cytogeneticists for appropriateness before initiating testing. Germline (inherited) test requests require appropriate informed consent (applicable tests defined in our online Lab Users Guide) that should be indicated on the test requisition form.

Q: What is Precision Genomics?

A: Precision Genomics is the scientific basis of Precision Medicine enabling your doctor to offer personalized or individualized treatments by analyzing the specific genetic makeup of your DNA in health and disease. Our Center for Precision Diagnostics specializes in analyzing your specific condition at the genetic (DNA and RNA) level to test for abnormalities or mutations in your genes.

Q: What is a genetic variant or mutation?

A: A genetic mutation (also known as a variant) is a change in the DNA as compared to the usual human genome. All people have variants in their genes, and it's part of what makes us unique individuals. Variants can be either benign (harmless), pathogenic (disease-causing) or unknown. Variants not clearly benign or pathogenic are called VUS, or Variant of Unknown Significance.

Q: What is a VUS?

A: A VUS is a change in the DNA not seen before, or has not been seen often. Genetic professionals aren't sure if the variant is benign or pathogenic because there isn't yet enough data on that specific variant. Testing a large number of genes increases the chance a VUS will be identified.

Q: What is an actionable gene?

A: An actionable gene has specific recommendations for health care management for individuals with a pathogenic variant. Not all genes have management guidelines. Changes to your health care management may include specific targeted drug therapies, or increased cancer screenings or referral to specialists.

Q: What is the report turnaround time for genomic testing?

A: Once the sample is received in our lab, the average turnaround time is less than five days for most tests. Testing multiple genes in a large panel or reflex testing may take longer.

Q: Will the patient's insurance cover the cost of genetic testing?

A: Yes, most major insurance carriers will cover this testing if medically indicated by your doctor. Some insurance carriers require prior authorization. Please contact your insurance company or work with your clinician. In cases where insurance coverage is denied, you may pay for this testing out of pocket. Please contact our Lab Customer Service for pricing.

Q: How does your facility bill?

A: We'll bill the patient's insurance carrier for medically indicated covered benefits. Payment for testing not covered by insurance is the patient's responsibility. We'll accept a major credit card for payment.

When applicable, please provide personal payment information on the test requisition. For Medicare patients, an Advance Beneficiary Notice defining patient responsibility in event of non-coverage may be printed from this website and shared with the patient in advance of specimen submission.

Q: What if I don't live near the Henry Ford Center for Precision Diagnostics?

A: We serve any eligible patient regardless of where they live. We work directly with your doctor who must order the test. We currently serve many clinicians, surgeons and oncologists throughout the United States. After the test data is compiled, reviewed and interpreted by our board certified molecular pathologists, a detailed report is sent directly to your ordering physician. The report will indicate any known pathologic variants and treatment options.

Q: Why do I need to be informed and to give medical consent for genetic testing?

A: Informed consent is required for medical procedures associated with risk. A positive result can help your medical professional design a custom program to treat your condition with precision, yet may limit access to life and rarely health insurance in the future. Genetic testing may identify changes that are uncertain, neither clearly benign nor clearly pathogenic, or may detect unexpected results outside the scope of testing. Your health care professional will discuss these risks prior to testing. Genetic counseling may be indicated.

Q: What does genetic or hereditary cancer risk mean?

A: Mutations in genes passed from parent to child can drastically increase the risk of disease, including many types of cancer. A positive test does not mean you have cancer, only that you carry the gene mutation that can increase your risk of developing certain types of cancer. Knowing this can help you and your health care team determine steps to lower your risk or even possibly prevent the development of certain cancers.