

# Pathology and Laboratory Medicine New Test Announcement

PRC-PALM-5.17 polpro 1-frm1: New Test Announcement Form

### **Test Name:**

## Molecular Diagnostic Decision Support (MDDS)

Test Change Effective Date: 11/14/2018 Memo Release Date: 11/13/2018

#### **Test Background:**

Molecular Diagnostic Decision Support (MDDS) for Precision Medicine is a post-analytic analysis of Next Generation Sequencing (NGS) of a patient's tumor based on individualized mutation data generated by Henry Ford Laboratories at Henry Ford Center for Precision Diagnostics. This in-depth crowd-sourced clinical guidance provides interpretation of patient-specific biomarkers that are of biological and clinical relevance to inform medical judgment related to selection of mutation-specific relevant therapies and biomarker matched clinical trials. Variants of strong clinical significance (Tier 1), variants of potential clinical significance (Tier 2) and variants of uncertain clinical significance (Tier 3) are evaluated. Results available in 2-3 days.

#### Link(s) To Medical Literature:

https://jmd.amjpathol.org/article/S1525-1578(16)30223-9/fulltext - Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer. A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists (January 2017. Volume 19, Issue 1, Pages 4–23)

#### **Report Content:**

Tier 1,2 and 3 variants, clinical relevance and clinical trial information for each variant.

#### **Locating Testing Results In Epic:**

Summary Report: Chart Review: Path Tab and Results Review: Pathology/Molecular Specimen.

Full Report: Emailed upon request - Instructions on requesting full version included in Summary Report.

#### For Non-Epic Users, You May Access Your Report:

**Summary Report:** Sent to the provider's office.

Full Report: Emailed upon request - Instructions on requesting full version included in Summary Report.

#### **Result Interpretation:**

MDDS information is specific and based on each patient's individual NGS data generated by Henry Ford Laboratories. Results available in 2-3 days.

#### **Epic/Atlas Order code:**

Epic Oder: LAB137080/Atlas Order: Molecular Diagnostic Decision Support

#### CPT Code:

80502

#### **Insurance Prior-Authorization:**

Not required for most insurance companies. Patient insurance benefit packages vary.

#### **Acceptable Specimen Source(S):**

Must have previous NGS analysis performed at Henry Ford Laboratories prior to ordering MDDS.

#### **Causes For Rejection:**

NGS analysis not performed at Henry Ford Center for Precision Diagnostics.

#### For More Information:

For Questions About This Specific New Test Contact: HF Center for Precision Diagnostics (313) 916-4362

http://pathology.hfhs.org/lug Search our Electronic Lab Users Guide Test Catalog

313.916. LABS (5527) for Lab Customer Service or to speak with a Pathologist

313.916.4DNA (4362) Molecular Genomic Subject Matter Expert