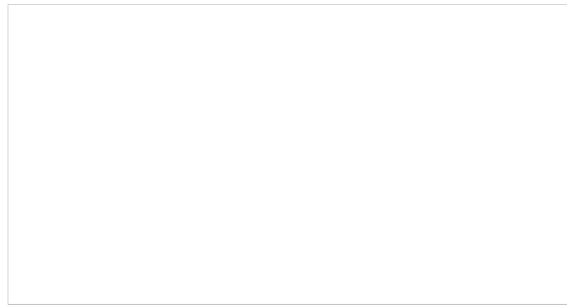
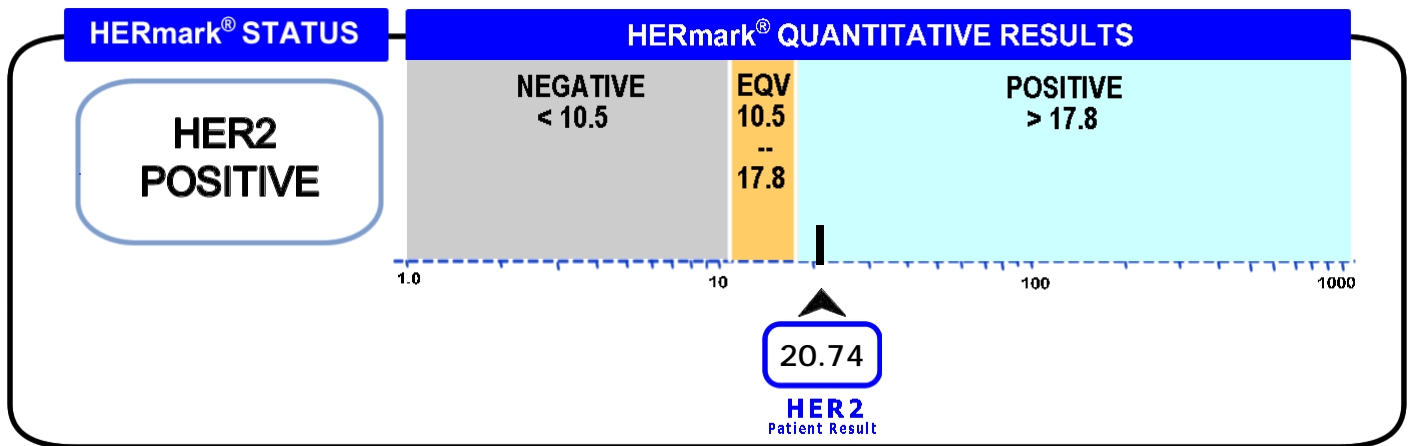




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Patient Name:	DOB	Patient ID/Medical Record #	Gender	Monogram Accession #
Date of Surgery	Date Sample Received	Date Reported	Mode	Report Status
Submitting Pathologist			Reference Lab ID/Order #/Case #	
Additional Physician - 1		Additional Physician - 2		
Comments			Specimen Tissue ID	



### HERmark® Interpretation

- To determine the HERmark® Patient HER2 Status, HERmark® Assay Results were compared to reference methods in 1090 breast cancer tissue specimens from the Hershey Medical Center/Medical University of Vienna cohort, The Mayo Clinic cohort and the FinHer Adjuvant Breast Cancer Study. Reference methods were immunohistochemistry (IHC) and/or in-situ hybridization (FISH or CISH) performed by independent central laboratories.
- HERmark HER2 Positive is defined as > 95th percentile of samples classified as HER2-negative by reference methods; HERmark HER2 Negative is defined as <5th percentile of samples classified as HER2-positive by reference methods; and HERmark HER2 Equivocal is the overlap of HER2-positive and HER2-negative distributions.

### HERmark® Methodology

- HERmark® Breast Cancer Assay is a CLIA-validated\*, quantitative assay, based on VeraTag® technology, that measures HER2 total protein levels. It is intended for use with formalin-fixed paraffin-embedded (FFPE) tumor specimens.
- HERmark® Assay provides a continuum of HER2 protein expression values over a 3-log dynamic range.
- HERmark® Assay reproducibly measures HER2 levels from approximately 2,500 to >1 million receptors per cell.
- HERmark® HER2 protein levels are reported using a relative scale that is calibrated within each assay using well-characterized breast cancer cell line controls with a range of HER2 expression levels.

For more information on interpreting the HERmark report, please visit [www.hermarkassay.com](http://www.hermarkassay.com) or call Monogram Customer Service at 800-777-0177 between the hours of 6:30am to 5:00pm PT Monday through Friday.

\*The HERmark® Breast Cancer Assay meets the United States standards for performance characteristics and all other quality control and assurance requirements established by the Clinical Laboratory Improvement Amendments (CLIA). HERmark® Breast Cancer Assay is a proprietary, proximity-based immunoassay with quantification by capillary electrophoresis. HERmark® and VeraTag® are registered trademarks of Laboratory Corporation of America Holdings. This test was developed and its performance characteristics determined by Monogram Biosciences. It has not been cleared or approved by the Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Integrated Oncology is a business unit of Esoterix Genetic Laboratories, LLC, a wholly owned subsidiary of Laboratory Corporation of America Holdings.