Patient ID	Patient Name		Birth Date	Gender	Age
SA00118651	TESTINGHERGM, JESSICA		1981-12-26	F	37
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00118651	SA00118651	CLIENT, CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		07 Mar 2019 14:51			

HER2, Gastroesophageal FISH, Tissue

Result Summary
MCR

Negative

Interpretation
MCR

There is no evidence of HER2 (ERBB2) gene amplification in this tumor specimen.

According to CAP/ASCP/ASCO guidelines for HER2 testing in gastroesophageal adenocarcinoma, dual-probe in situ hybridization (ISH) results indicating a HER2/centromere ratio less than 2.0 and an average HER2 copy number less than 4.0 signals per cell are interpreted as ISH negative (1).

Reference:
1. Bartley et al., Am J Clin Pathol, 146(6);647–669, 2016.

Result
MCR

nuc ish(D17Z1,HER2)x2

HER2/D17Z1 ratio: 1.00
Average HER2 signals per cell: 2.0
Average D17Z1 signals per cell: 2.0

Reason for Referral
MCR

r/o HER2/neu gene amplification

Specimen
MCR

Tissue, Paraffin

Source
MCR

Esophagus

Tissue ID
MCR

CR-19–95

Fixative
MCR

Formalin

Method
MCR

FISH using probes for HER2 (17q12) and a chromosome 17 centromere (D17Z1) control probe (PathVysion, Abbott Molecular, Inc). Two technologists score signals in 60 total nuclei from invasive or metastatic tumor after confirmation of probe performance by concurrent controls.

Disclaimer
MCR

Laboratory Developed Test (LDT). This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It is intended as an adjunct to existing prognostic clinical and pathologic information for gastroesophageal cancer patients. This test is not intended to diagnose or screen for gastroesophageal cancer. Since only a portion of the tumor was tested, it is possible that this result may not represent the entire tumor population. Per ASCO/CAP guidelines, HER2 FISH test results are valid for non-decalcified paraffin embedded specimens fixed in 10% neutral buffered formalin between 6 and 72 hours. Results from specimens fixed outside these parameters should be interpreted accordingly.

Released By
MCR

RICHARD WANG

Received: 07 Mar 2019 15:27 **Reported:** 08 Mar 2019 07:42

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292

Patient ID	Patient Name		Birth Date	Gender	Age
SA00118651	TESTINGHERGM, JESSICA		1981-12-26	F	37
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00118651	SA00118651	CLIENT, CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		07 Mar 2019 14:51			

HER Gastric/Esoph IHC + Reflex

Case Number CR-19-95

Interpretation

MCR

Distal Esophagus, original accession: SA-19–230, block: SA19–230

SPECIAL PROCEDURE REPORT

Biomarker(s) for:
Stomach/gastroesophageal junction adenocarcinoma

Result(s):

HER2 by Immunohistochemistry (IHC)
Equivocal (Score 2+)

Fluorescence in situ hybridization (FISH) for HER2 amplification will be performed at Mayo Clinic Rochester by the Division of Laboratory Genetics.

METHOD AND SCORING

HER2 Stomach/gastroesophageal junction Manual Method: Testing is performed using FDA approved Ventana Pathway HER2 (4B5) rabbit monoclonal primary antibody and a proprietary detection system. Controls used have: no expression (HER2 score of 0), low expression (HER2 score of 1+) and high expression (HER2 score of 3+). All controls show appropriate reactivity.
Scoring: Scoring is performed according to the following article: Ruschoff J, Dietel M, Baretton G, et al. HER2 diagnostics in gastric cancer-guideline validation and development of standardized immunohistochemical testing. Virchows Arch. Sep; 457 (3):299–307.
Surgical resections: Score of 0 is no reactivity or membranous reactivity in <10% of invasive tumor cells. Score of 1+ is faint/barely perceptible membranous reactivity in ≥10% of tumor cells; cells are reactive only in part of their membrane. Score of 2+ is weak to moderate complete, basolateral or lateral membranous reactivity in ≥10% of tumor cells. Score of 3+ is strong complete, basolateral or lateral membranous reactivity in ≥10% of tumor cells.
Biopsy specimens: Score of 0 is no reactivity or no membranous reactivity in any invasive tumor cells. Score of 1+ is *tumor cell cluster(s) with a faint/barely perceptible membranous reactivity irrespective of percentage of invasive tumor cells stained. Score of 2+ is *tumor cell cluster(s) with a weak to moderate complete, basolateral or lateral membranous reactivity irrespective of percentage of invasive tumor cells stained. Score of 3+ is *tumor cell cluster(s) with a strong complete, basolateral or lateral membranous reactivity irrespective of percentage of invasive tumor cells stained. *Tumor cells cluster is defined as a cluster of 5 or more tumor cells by Ruschoff and colleagues. There is no percentage cutoff in biopsy specimens for upper GI tract HER2 scoring.

Material Received

MCR

A. SA-19–230: Distal Esophagus
1 block

Report electronically signed by

MCR

JESSICA PHILLIPS

Tumor classification

MCR

Primary G/E adenocarcinoma including intramucosal only

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292

MAYO CLINIC LABORATORIES

Patient ID	Patient Name		Birth Date	Gender	Age
SA00118651	TESTINGHERGM, JESSICA		1981-12-26	F	37
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00118651	SA00118651	CLIENT, CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		07 Mar 2019 14:51			

Received: 07 Mar 2019 13:58

Reported: 07 Mar 2019 14:20

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292