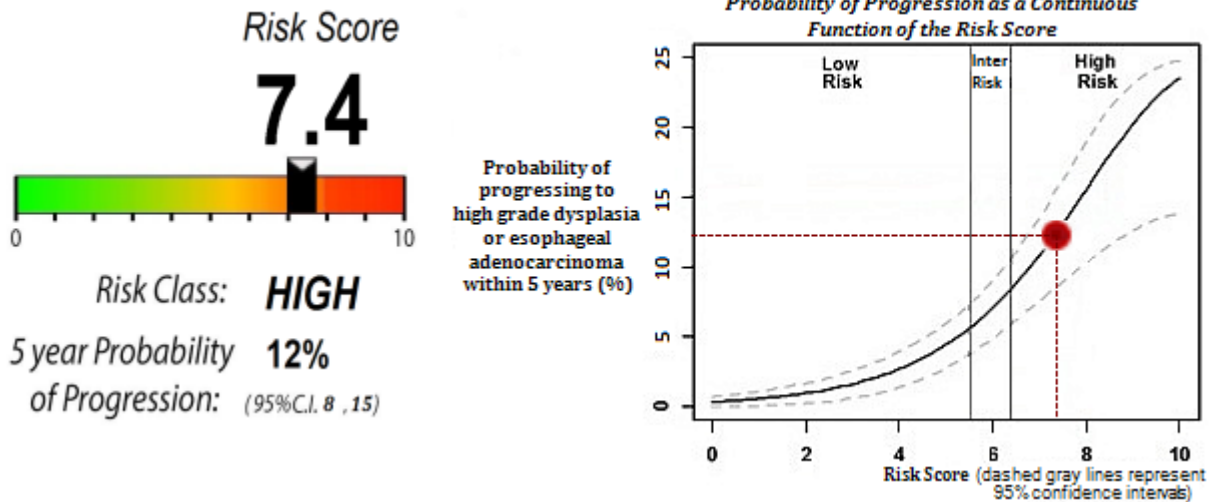


BARRETT'S ESOPHAGUS PATIENT REPORT

Patient Name:	Doe, James	Date Biopsy Collected:	8/16/2020
Medical Record #:	909993	Date Received:	8/17/2020
Cernostics ID:	20200817003A	Ordering Institution:	CRN
Date of Birth:	5/20/1970	Ordering Physician:	Dr. Edward Smith
Sex:	Male	Submitting Pathologist:	Dr. Evelyn Johnson
Specimen #:	S20-90993	Number of Levels/Blocks Submitted:	1
Specimen Type:	Esophageal Pinch Biopsy (Part A)	Number of Levels/Blocks Tested:	1
Other Comments/Reason for Ordering Test:	NA		

PATIENT RESULTS: TISSUECYPHER® RISK SCORE AND RISK CLASS



Clinical Experience in Barrett's Esophagus:

In a multi-institutional nested case-control validation study involving 366 patients with Barrett's esophagus from four institutions (1), patients with a risk score of 7.4 had a 12% (95% C.I. 8, 15) risk of progression to high grade dysplasia or esophageal adenocarcinoma within 5 years.

Comments:

N/A

TISSUECYPHER® BARRETT'S ESOPHAGUS ASSAY DESCRIPTION

The TissueCypher® Barrett's Esophagus Assay uses quantitative image analysis to measure the expression of 9 biomarkers and tissue morphology in whole slide digital images of labeled Barrett's esophagus biopsies. A risk score for progression to high grade dysplasia or esophageal adenocarcinoma is generated from the image analysis results. The risk score ranges from 0-10, with 0 indicating lowest risk and 10 indicating highest risk. The risk score is independent of clinical variables, including pathologic diagnosis.

The TissueCypher® Barrett's Esophagus Assay was developed and its performance characteristics determined by Cernostics, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes and should not be regarded as investigational or for research. This test has not been reviewed by the Food

Patient: Doe, James	Date of Birth: 5/20/1970	Specimen ID: S20-90993
Laboratory Director: Marvin A. Lessig, D.O., FCAP	Email: customer.service@cernostics.com	CLIA#: 39D2110302
		Form#: TCBEAv5-0720

and Drug Administration (FDA). The results provided here are adjunctive to the ordering physician's workup for patients with Barrett's esophagus. The reported 5 year probability of progression was adjusted based on estimated prevalence as described in the cited study (1), however, the prevalence of progression of Barrett's Esophagus may vary between clinical institutions.

References

1. Critchley-Thorne et al. A Tissue Systems Pathology Assay for High-Risk Barrett's Esophagus. *Cancer Epidemiol Biomarkers Prev* 2016;25(6):958-68.
2. Prichard et al. TissueCypher™: A systems biology approach to anatomic pathology. *J Pathol Inform.* 2015; 31;6:48.
3. Critchley-Thorne et al. A Tissue Systems Pathology Test Detects Abnormalities Associated with Prevalent High-Grade Dysplasia and Esophageal Cancer in Barrett's Esophagus. *Cancer Epidemiol Biomarkers Prev.* 2017;26(2):240-248.

Based on my review, the TissueCypher® Barrett's Esophagus Assay batch controls passed quality assessment and the observed biomarker expression patterns are consistent with the results described herein.

Reviewer:

Date Reported:

9/1/2020

X Marvin Lessig, DO, FCAP

Patient: Doe, James

Date of Birth: 5/20/1970

Specimen ID: S20-90993

Laboratory Director: Marvin A. Lessig, D.O., FCAP **Email:** customer.service@cernostics.com

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