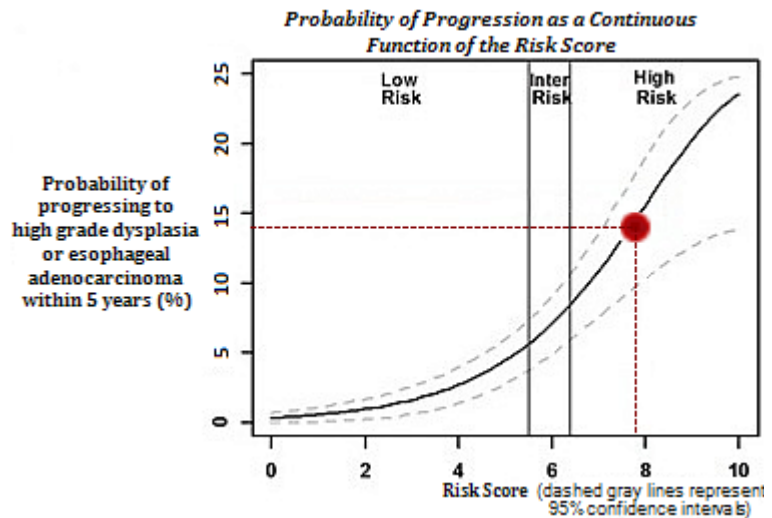
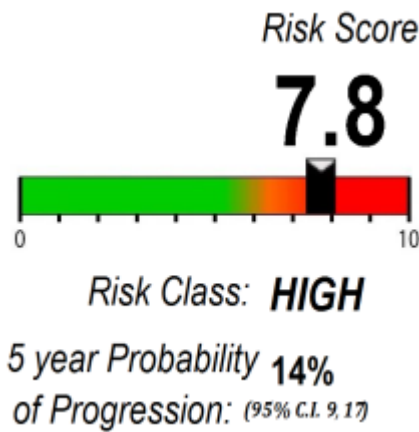


**BARRETT'S ESOPHAGUS PATIENT REPORT**

Patient Name:	John, Doe	Date Biopsy Collected:	9/9/2018
Medical Record #:	D123456789	Date Received:	9/12/2018
Cernostics ID:	20180912001A	Ordering Institution:	Clinic A
Date of Birth:	7/27/1955	Ordering Physician:	Dr. John Brown
Sex:	Male	Submitting Pathologist:	Dr. Sarah Smith
Specimen #:	S12-33456	Number of Levels/Blocks Submitted:	1
Specimen Type:	Esophageal Pinch Biopsy (Part C)	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 7.8 had a 14% (95% C.I. 9, 17) risk of progression\* to high grade dysplasia or esophageal adenocarcinoma within 5 years.

\*Estimates of 5 year probability of progression were adjusted for prevalence due to the nested case-control design of the cited study.

**Qualitative Biomarker Assessment:**

Biomarker Panel	Biomarker(s) & Fluorescence Channels(s)	Qualitative Expression Score(s)
2	p16	Loss in majority of columnar epithelial cells
2	AMACR	Low/normal in columnar epithelial cells
2	p53	Diffuse overexpression in columnar epithelial cells
3	COX-2	Moderate in columnar epithelial cells
3	CD68   COX-2	Moderate density in lamina propria with low COX-2 expression
4	HIF1A	High density in lamina propria
4	CD45RO	Moderate density in lamina propria
5	HER2   CK-20	Moderate in CK-20+ columnar epithelial cells, and moderate in CK-20- columnar epithelial cells

Patient: Doe, John

Date of Birth: 7/27/1955

Specimen ID: S12-33456

Laboratory Director: Marvin Lessig, D.O.

Email: customer.service@cernostics.com

CLIA#: 39D2110302  
Form#: TCBEAv4-0218

**Comments:**

N/A

**TISSUECYPHER® BARRETT'S ESOPHAGUS ASSAY DESCRIPTION**

The TissueCypher® Barrett's Esophagus Assay comprises immunostaining for p16, p53, alpha-methylacyl-CoA racemase (AMACR), HER2/neu, Cytokeratin-20 (K20), Cyclooxygenase-2 (COX-2), CD68, Hypoxia-inducible factor 1-a (HIF1A), and CD45RO, with Hoechst 33342 counterstaining of nuclei. The relevance of the biomarkers in risk assessment in Barrett's esophagus is summarized in the literature (1). The TissueCypher® Image Analysis Platform (2) is used to measure the 9 biomarkers and nuclear morphology in whole slide images. 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 (1, 3). 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 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:**

X

**Patient: Doe, John**

**Date of Birth: 7/27/1955**

**Specimen ID: S12-33456**

**Laboratory Director: Marvin Lessig, D.O.**

**Email: customer.service@cernostics.com**

**CLIA#: 39D2110302  
Form#: TCBEAv4-0218**