Barrett's Esophagus FISH Assay
Stratify patients' grade of dysplasia and risk of progression to esophageal adenocarcinoma

Benefits of FISH technology

- Molecular DNA diagnostic test for detection of low grade and high grade dysplasia/adenocarcinoma
- Simple and quick cytology brushing technique
- Detects genetic changes when biopsies are negative
- Enhances “gold standard” of 4-quadrant biopsies
- Helps to stratify patient risk for development of dysplasia/adenocarcinoma

The American College of Gastroenterology recommends that Barrett’s esophagus patients undergo regular four-quadrant biopsies to monitor the development of dysplasia and esophageal adenocarcinoma (EAC). However, this “gold standard” of esophageal monitoring has some limitations, including false negatives due to sampling error, lengthy procedure time, and variable diagnoses from one pathologist to another.

Broward Medical Laboratory (BML) is proud to offer the Barrett’s Esophagus fluorescence in situ hybridization (FISH) assay, a molecular test that looks at increased DNA instability, an event that precedes histological changes. This assay not only helps in differentiating between low-grade and high-grade dysplasia based on underlying molecular changes, but also stratifies patient risk for progression to EAC. By utilizing cytological brushings in addition to biopsies, a more complete tissue sampling is obtained, improving surveillance and reducing variability in diagnosis.

Broward Medical Laboratory is a full service pathology laboratory specializing in urology, gastroenterology and dermatology since 1980. BML is considered an expert at FISH technology, with veteran specialty pathologists reading every FISH case. Chief pathologist Dr. Donald J. Zeller has extensive training and experience analyzing FISH results, along with 37 years of anatomic and clinical pathology experience.

References:

For more information about the Barrett’s esophagus FISH assay, please contact your BML sales representative or call Client Services at 877-561-8616.
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CLIA ID # 10D 284578

Case Details for VE12-0031

Name: GEORGE SMITH  Sample type: Esophageal Brushing
Analyzer by:  Male
Collection Date: 2/2/2013  Date of Birth: 2/7/1958
Indication: 530.85  Received date: 2/3/2013
Physician name: Daryl Bell, MD  I.D.: 12-31G

Test Result

POSITIVE FISH TEST. POLYSOMY CELLS PRESENT. THESE GENETIC ALTERATIONS HAVE BEEN CORRELATED MOSTLY WITH HIGH GRADE DYSPLASIA/ESOPHAGEAL ADENOCARCINOMA AND ARE ALSO PRESENT IN SOME LOW GRADE DYSPLASIAS AND INTESTINAL METAPLASIAS.

DONALD ZELLER, MD
PATHOLOGIST

REFERENCE RANGE

POSITIVE

>4 cells showing gains for 2 or more loci (17q12, 8p24, and 20q13.2)

ABNORMAL:

≥5% cells showing gains for a single locus (17q12, 8p24, and 20q13.2); or ≥6% cells with homozygous loss of the 9p21 locus, or ≥1% cells with any combination of homozygous and heterozygous 9p21 loss

INTENDED USE:

BML Barrett’s Esophagus FISH Test is a fluorescence in situ hybridization (FISH) assay that was developed to detect cytogenetic evidence of Barrett’s associated neoplasia in esophageal brushing specimens collected from patients undergoing endoscopy for the surveillance of Barrett’s esophagus. The test consists of a mixture of fluorescently labeled Abbot DNA probes. The probes are Locus Specific Indicator (LSI) ENBOD SpectrumGreen DNA probe, LSI p16 SpectrumRed DNA Probe, LSI MYC SpectrumAqua DNA probe, and LSI ZNF217 SpectrumGold Probe. These probes hybridize to human chromosomes 17q12, 8p21, 8q24 and 20q13.2, respectively.

Results of this assay are restricted by many variables, which may limit its accuracy and should be interpreted in association with other cytology and pathology data and the overall clinical picture. This test greatly aids the clinical evaluation but in light of clinical suspicion it is not meant to replace the tissue biopsy, which still remains the cornerstone for a definitive diagnosis. Like other methods, FISH does not detect all neoplasms at every application.

Chromosome and genetic instability are common features of cancers in Barrett’s esophagus. Changes in chromosome numbers are associated with Barrett’s Adenocarcinoma occurrence and progression. This assay uses the Abbott probe set mixture to assess chromosomal abnormalities associated with malignancy. This test was developed and its performance characteristics determined by Broward Medical Lab. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity testing.

The technical component of this assay was performed at Broward Medical Lab 181 West Prospect Road, Oakland Park, Florida. CLIA# 10D 284578.

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