MAYO CLINIC LABORATORIES

Test Definition: FBILM

Biliary Tract Malignancy-Cytology, FISH, Varies

Overview

Useful For

Assessing bile duct brushing or hepatobiliary brushing specimens for bile tract malignancy

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
BILMB	Biliary Tract Malignancy, FISH	No	No
BILMC	Biliary Tract Malignancy, FISH	No	No
BILMD	Biliary Tract Malignancy, FISH	No	No
BILME	Biliary Tract Malignancy, FISH	No	No
BILMF	Biliary Tract Malignancy, FISH	No	No

Additional Tests

Test Id	Reporting Name	Available Separately	Always Performed
BILMA	Biliary Tract Malignancy, FISH	No	Yes

Testing Algorithm

When this test is ordered, fluorescence in situ hybridization testing will be performed. When additional specimens are received, the laboratory will add BILMA to the first specimen, BILMB to the second specimen, BILMC to the third specimen, and so on.

Method Name

Cytology Light Microscopy and Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Varies

Specimen Required

Supplies:
PreservCyt Vial (T536)
CytoLyt Solution (T564)
Specimen Type: Bile duct brushing, bile duct aspirate, hepatobiliary brushing, or hepatobiliary aspirate
Container/Tube: Separate ThinPrep vial containing 20 mL PreservCyt or CytoLyt solution for each specimen
Specimen Volume: Entire collection
Collection Instructions: Label with site specimen was collected from (eg, right hepatic duct or common bile duct).

Specimen Minimum Volume

See Specimen Required

Reject Due To

Pancreatic mass Pancreatic cyst Pancreatic fine-needle aspiration (FNA)	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)		
	Ambient		

Clinical & Interpretive

Clinical Information

Endoscopic retrograde cholangiopancreatography (ERCP) is used to examine patients with biliary tract obstruction or stricture for possible malignancy. Biopsies and cytologic specimens are obtained at the time of ERCP. Cytologic analysis complements biopsy by sometimes detecting malignancy in patients with a negative biopsy. Nonetheless, a number of studies suggest that the overall sensitivity of bile duct brushing and bile aspirate cytology is quite low.

Fluorescence in situ hybridization (FISH) is a technique that utilizes fluorescently labeled DNA probes to examine cells for chromosomal alterations. FISH can be used to detect cells with chromosomal changes (eg, aneuploidy) that are indicative of malignancy. Studies in our laboratory indicate that the sensitivity of FISH to detect malignant cells in biliary brush specimens is superior to that of conventional cytology.

Reference Values

Negative for malignancy.

Interpretation

An interpretive report will be provided.

A positive cytology diagnosis is normally definitive for the presence of malignancy.

Suspicious or atypical results need further confirmation by clinical observation, repeat cytology, or perhaps appropriate biopsy.

Cautions

A positive FISH result does not identify location or type of malignancy. FISH abnormalities may be associated with high-grade dysplasia or carcinoma in situ. Cytology and biopsy may help clarify such situations.

Supportive Data

Cell counts using the biliary FISH probe set on pancreatobiliary brushings were compared between 49 patients with malignancy and 41 patients without malignancy to determine normal value cutoffs for this assay. The cutoff values were independently validated in a blinded study from brushing samples collected from 112 patients at the time of endoscopic retrograde cholangiopancreatography (ERCP). Among patients with malignancy on follow-up, the sensitivity of a polysomy FISH result was significantly superior to cytology (74% vs. 28%, P<0.001). The specificity of FISH and cytology were similar (96% vs. 100%).

Clinical Reference

1. Barr Fritcher EG, Voss JS, Brankley SM, et al. An optimized set of fluorescence in situ hybridization probes for detection of pancreatobiliary tract cancer in cytology brush samples. Gastroenterology. 2015;149(7):1813-1824
2. Barr Fritcher EG, Kipp BR, Voss JS, et al. The development of a tailored pancreatobiliary fluorescence in situ hybridization (FISH) assay to improve detection of malignancy in pancreatobiliary brushings. J Mol Diagn. 2013;15(6):909
3. Barr Fritcher EG, Kipp BR, Halling KC, et al. A multivariable model using advanced cytologic methods for the evaluation of indeterminate pancreatobiliary strictures. Gastroenterology. 2009;136(7):2180-2186

Performance

Method Description

Standard brush cytology sampling is performed on patients undergoing endoscopic retrograde cholangiopancreatography for suspicious biliary tract strictures. Brushes are placed in a ThinPrep vial containing PreservCyt or CytoLyt solution. The specimen is sent in a single vial with or without the brush. If brush is present, it is removed, and cells are collected from it by scraping them into a single vial containing 20 mL of PreservCyt solution. Two aliquots are prepared and used for each portion of the test. The cytology specimen is processed using the ThinPrep processor. Specimens are stained using a Papanicolaou stain and analyzed microscopically by a cytotechnologist and pathologist.

Biliary cells are harvested, fixed, and placed on a slide. Fluorescently labeled DNA probes to 1q21 (*MCL1*), 7p12 (*EGFR*), 8q24 (*MYC*), and 9p21 (*CDKN2A*) (Abbott Molecular Inc) are hybridized to the cells on the slide. The slide is then washed and stained with DAPI (a nuclear counterstain). Fluorescence microscopy with unique band filters is used to assess 100 consecutive epithelial cells for gains and losses of probe signals (ie, chromosomal loci). Specimens are considered abnormal if cell counts exceed predetermined cutoff values for one or more of the following abnormalities: polysomy, homozygous 9p21 loss, single locus gain, single locus gain with 9p21 loss in the same cells, and/or tetrasomy. If the

cutoff for polysomy is not attained in the 100-cell enumeration, then the remainder of the slide is assessed for polysomy until the cutoff is reached or the slide is exhausted.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
7 to 10 days

Specimen Retention Time
Up to 1 week depending on the results

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
88112
88377 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FBILM	Biliary Tract Malignancy-Cyto/FISH	95230-9

Result ID	Test Result Name	Result LOINC® Value
CY070	Collection Procedure	33724-6
CY042	Source	22633-2
CY043	Clinical History	22636-5
CY044	Fixative	8100-0
71816	Case Number	80398-1

71291	Interpretation	69965-2
71292	Participated in the Interpretation	No LOINC Needed
71293	Report electronically signed by	19139-5
71294	Addendum	35265-8
71295	Gross Description	22634-0
71570	Disclaimer	62364-5