



# 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<br>Pancreatic cyst<br>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

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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         |