MAYO CLINIC LABORATORIES

Test Definition: BILAO

Biliary Tract Malignancy, FISH, Varies

Overview

Useful For

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

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
BILOB	Biliary Tract Malignancy, FISH	No	No
BILOC	Biliary Tract Malignancy, FISH	No	No
BILOD	Biliary Tract Malignancy, FISH	No	No
BILOE	Biliary Tract Malignancy, FISH	No	No
BILOF	Biliary Tract Malignancy, FISH	No	No

Testing Algorithm

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

Special Instructions

- Pathology/Cytology Information

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Varies

Specimen Required

Supplies: PreservCyt Vial (T536)

Specimen Type: Bile duct brushing, bile duct aspirate, hepatobiliary brushing, or hepatobiliary aspirate (fine-needle

aspiration is **not acceptable**)
Container/Tube: Separate ThinPrep vial, containing 20 mL PreservCyt or CytoLyt solution for each specimen
Specimen Volume: Entire collection
Collection Instructions:
1. If performing local cytology in addition to fluorescence in situ hybridization testing, aliquot half of the specimen into another ThinPrep vial **before** processing the specimen.
2. Submission of residual specimen (after processing other testing) may compromise the sensitivity of the test.
3. Label each specimen with specific source (eg, right hepatic duct or common bile duct).

Forms
Pathology/Cytology Information (T707)

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
No abnormality detected by fluorescence in situ hybridization

Interpretation
An interpretive report will be provided.

Cautions
A positive fluorescence in situ hybridization (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 fluorescence in situ hybridization (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. 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. doi:10.1053/j.gastro.2015.08.046
2. Barr Fritcher EG, Kipp BR, Voss JS, et al. ST27: 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. doi:10.1053/j.gastro.2009.02.040

Performance

Method Description
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 (4',6-diamidine-2'-phenylindole dihydrochloride, a nuclear counterstain). Fluorescence microscopy with unique band filters is used to assess 100 consecutive epithelial cells for gains and losses of probe signals (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
Until reported

Performing Laboratory Location
Rochester

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
88377

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BILAO	Biliary Tract Malignancy, FISH	95229-1

Result ID	Test Result Name	Result LOINC® Value
71918	Result Summary	50397-9
71919	Result	95229-1
71920	Interpretation	69965-2
71921	Reason for Referral	42349-1
71922	Specimen	31208-2
MC029	Source	39111-0
MC030	Fixation	8100-0
MC031	Collection Method	33724-6
MC032	Clinical History	22636-5
71927	Method	85069-3

71928	Released By	18771-6