

New Test Announcement

MAY 2008

Biliary Tract Malignancy, FISH Only #19701

Additional Tests

<u>Unit Code</u>	<u>Reporting Name</u>	<u>Available Separately</u>	<u>Always Performed</u>
81048	Biliary Tract Malignancy, FISH	No	Yes

Testing Algorithm

When this test is ordered, #81048 Biliary Tract Malignancy, FISH will be performed.

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 and bile aspirate specimens is superior to that of conventional cytology.

Useful For

Assessing bile duct brushing or hepatobiliary brushing specimens for malignancy

Interpretation

The chance that the patient has cancer is calculated based on the following parameters: patient age, FISH results (negative, trisomy, polysomy), and primary sclerosing cholangitis (PSC) status (non-PSC vs. PSC patient). This information is then provided in the interpretive portion of the final report.

Cautions

A positive FISH result does not identify location or type of malignancy; cytology and biopsy may help clarify such situations.

Supportive Data

Bile duct brushing and bile aspirate specimens were collected from 303 patients at the time of ERCP. Cytological specimens from these patients were evaluated for malignancy with FISH and exfoliative cytology. Among patients with malignancy on follow-up, the sensitivity of FISH was superior to cytology (44% vs. 15%, $P < 0.001$). The specificity of FISH and cytology were similar (98% vs. 100%, $P = 0.250$).

Method Description

Biliary cells are harvested, fixed, and placed on a slide. Fluorescently labeled DNA probes to the centromeres of chromosomes 3, 7, and 17, and to the 9p21 locus (UroVysion, Abbott Molecular, Inc., Des Plaines, IL) 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 scan the slide for atypical cells (eg, cells with nuclear enlargement or irregularity). These cells are assessed for gains of chromosomes 3, 7, and 17.

Cells with chromosomal gains (polysomy or trisomy) are recorded. If 5 or more cells show polysomy, then the case is considered positive for polysomy. If 10 or more cells show trisomy of 1 of the chromosomes (most often chromosome 7), the case is considered positive for trisomy. (Unpublished Mayo method)

Specimen Required

Appropriate specimen types include:

- bile duct brushing
- hepatobiliary brushing
- bile duct aspirate
- hepatobiliary aspirate

Submit each specimen in a separate ThinPrep vial containing PreservCyt or CytoLyt solution (Supply T536). If performing local cytology before processing specimen, aliquot half of the specimen into another ThinPrep vial. Retain one aliquot for local cytology. Submit the second aliquot for analysis at Mayo Medical Laboratories. Submission of the residual specimen (after processing for cytology) may compromise the sensitivity of the test.

Note: If ordering electronically, no form is required with the specimen. If not ordering electronically, please complete and submit a "Pathology/Cytology In Situ Request Form" (Supply T246) with the specimen.

Reference Values

An interpretive report will be provided.

Analytic Time

6 days

Days Set Up

Monday through Friday; 6 a.m.-9 p.m.
Sunday; 1 p.m.-9 p.m.

List Fee

\$1,026.90

this charge is for the #81048 "Biliary Tract Malignancy, FISH"

CPT Code

88368/x4