

Patient Name: Doe, Jane

DOB: 01/01/1961

Sex: Female

Order ID: X1234567

Lab ID: L987654

Type of Sample: FNA

MRN: MRN12345676

Specimen ID: SPEC9876

Date Received: 12/01/2011

Attending Provider: William Smith, MD

Date Collected: 11/28/2010

Reference Score Range		Patient Results	
Benign	0.00 – 0.49	Score	0.2
PDAC*	0.50 – 1.00	Result	BENIGN

* PDAC – Pancreatic Ductal AdenoCarcinoma. Other less common pancreatic malignancies cannot be excluded.

INTERPRETATION:

Test Result Benign: The score value less than 0.5 is consistent with a benign result. For further interpretation of this result, please contact Asuragen at 877-777-1874.

Test Result PDAC: The score value in the range of 0.5 to 1 (inclusive) is consistent with a PDAC result. For further interpretation of this result, please contact Asuragen at 877-777-1874.

ASSAY DESCRIPTION AND METHODOLOGY:

This test evaluates raw expression levels of seven miRNAs using TaqMan RT-qPCR methodology. A proprietary algorithm integrates the expression levels of the 7 miRNAs into a single score from 0 to 1 inclusive. A score value less than 0.5 is consistent with a benign result and a score value in the range of 0.5 to 1 (inclusive) is consistent with a PDAC result.

A blinded validation study on a set of 186 pancreatic FNA specimens (29 benign, 157 PDAC) using the threshold value of 0.5 resulted in an assay Se of 82.8%, Sp of 89.7%, PPV of 97.7%, NPV of 49.1% and an accuracy of 83.9%. When used in conjunction with conventional FNA cytology, this test allowed identification of PDAC with 92.5% accuracy (Se: 94.3%, Sp: 82.8%, PPV: 96.7%, NPV: 72.7%), as compared to 80.2% for FNA cytology alone. In addition, the test enabled resolution of indeterminate (atypical, suspicious, non-diagnostic) and false negative FNA cytology with an accuracy of 78.2% (Se: 67.9%, Sp: 88.9%, PPV: 86.4%, NPV: 72.7%).

Legend: Se: sensitivity; Sp: specificity; PPV: positive predictive value; NPV: negative predictive value; FNA: fine needle aspiration.

INTENDED USE

This laboratory developed test is intended to aid in the clinical diagnosis and disease management of PDAC on FNA specimens preserved in RNARetain®. The test has not been validated on other pancreatic sample types or other pancreatic malignancies.

Jennifer Skeen, PhD
 Laboratory Director

Date

Disclaimer: This laboratory developed test is intended to be used and interpreted in conjunction with all other available clinical and laboratory information. This test was developed and its performance characteristics determined by Asuragen's Clinical Laboratory. The Asuragen Clinical Laboratory is certified under CLIA'88 as qualified to perform high complexity testing and is accredited by CAP.