PCL ALVERNO



TEST BULLETIN

May 2017

Dear Healthcare Provider,

The information contained here may be very important to your practice. Please take a moment to review this document.

ANTIPHOSPHOLIPID SYNDROME REFLEX PANEL

This panel will replace the Anti-Phospholipid Antibody assay on June 1, 2017. For details on why this change is taking place, please see page 2.

ROS1 by FISH

To better serve you, PCL Alverno brought ROS1 by FISH testing in-house. For details, please see page 3.

CA 15-3 UPDATE

One of the serum tumor markers used to monitor and detect breast cancer recurrence includes CA 15-3. Like other biochemical markers, CA 15-3 is neither highly sensitive nor specific and is, therefore, recommended to be used in conjunction with other measurable modalities and the clinical picture of the patient.

The manufacturer of this assay specifically states the limitations include the following:

- The assay should not be used as a cancer screening tool. A value below the cutoff limit does not indicate the absence of breast cancer.
- Serum or plasma CA 15-3 antigen concentrations should not be interpreted as absolute evidence for the presence or absence of cancer.
- This assay is indicated for use in the measurement of CA 15-3 antigen to aid in the management of breast cancer patients. Serial testing for CA 15-3 antigen concentrations should be used in conjunction with other clinical methods for monitoring breast cancer.
- Results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.
- Values obtained with different assay methods cannot be used interchangeably. The concentration of CA 15-3 antigen in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.

An investigational study is currently being performed for the upper reference limit (URL), which is currently 31.3 U/mL. Any change to the URL is expected to be completed in the third quarter of 2017 after completion and analysis of the study. We will keep you informed of any changes to this assay or the URL as they become available to us.

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ANTIPHOSPHOLIPID SYNDROME REFLEX PANEL
Replacing Antiphospholipid Antibody
Effective June 1, 2017

New Assay: **Antiphospholipid Syndrome Reflex Panel**
Discontinued Assay: **ANPLA: Anti-Phospholipid Antibody**

The new assay panel meets international guidelines and classification criteria for antiphospholipid syndrome (APS) established by the International Society on Thrombosis and Haemostasis.[1]

For detailed information on APS, please see ARUP Consult (see URL below) or visit our blog in the Media Center at www.PCLAlverno.com for a direct link.
https://arupconsult.com/content/antiphospholipid-syndrome/?tab=tab_item-0

SPECIMEN REQUIREMENTS

Specimens:
Minimum 2 mL Sodium Citrate Platelet Poor Plasma - FROZEN
Minimum 1 mL Serum (Serum Separator Tube)

Stability:
Plasma, FROZEN -20°C, 3 months
Serum, REFRIGERATED, 2 weeks

Cause for Rejection:
Platelet Poor Plasma specimen: EDTA Plasma, clotted or hemolyzed.
Serum specimen: Plasma, body fluids, heat-inactivated, hemolyzed or lipemic

CPT code*: 86147x2; 86146x2; 85610; 85730; 85613
If reflexed, additional CPT codes may apply: 85670; 85635; 85730; 85525; 85732; 85597; 85613 x2; 85598

SOFT code: ANPSR (code may be different in your EMR)

[1]Miyakis S, Lockshin MD, Atsumi T, Branch DW, Brey RL, Cervera R, Derksen RH, DE Groot PG, Koike T, Meroni PL, Reber G, Shoenfeld Y, Tincani A, Vlachoyiannopoulos PG, Krilis SA. International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). J Thromb Haemost. 2006; 4(2): 295-306. PubMed

***CPT codes provided are for informational purposes only. Questions regarding coding should be directed to the payor.**



ROS1 BY FISH
Non-Small Cell Lung Cancer
April 2017

CLINICAL USE

The ROS1 SureFISH Break Apart Probe is a qualitative test to detect rearrangements involving the ROS1 gene in non-small cell lung cancer tissue specimens via Fluorescence in situ hybridization (FISH). ROS1 FISH is intended to aid in identifying those patients eligible for treatment with XALKORI (Crizotinib). The ROS1 FISH test can be ordered in conjunction with EGFR mutation testing by PCR and ALK FISH testing as a Lung Cancer Panel.

CLINICAL BACKGROUND

Rearrangements of the ROS1 gene have been identified in approximately 1-2% of NSCLC tumors. Patients with ROS1 rearrangements tend to be young never-smokers with adenocarcinoma. The ROS1 gene can fuse with other genes to form an abnormal, constitutively active tyrosine kinase receptor. This “fusion protein” results in continuous cell proliferation signaling. ROS1 rearrangements rarely present simultaneously with EGFR, KRAS or ALK alterations. Crizotinib, a targeted tyrosine kinase receptor inhibitor, has shown inhibitory growth effects on ROS1-rearranged NSCLC. In recent clinical studies, patients with advanced NSCLC harboring ROS1 rearrangements derived great benefit from crizotinib treatment. However, due to the low frequency of ROS1 fusion in lung cancers, efficient determination of ROS1 status in NSCLC patients is critical for directing patient care.

SPECIMEN REQUIREMENTS:

Specimen:	FFPET – formalin-fixed, paraffin-embedded NSCLC tissue
Stability:	Room temperature (15-30°C) indefinitely; 5 micron sections mounted on slides may be stored at 15-30°C for up to 60 days.
Cause for Rejection:	Absence of tumor cells
Method:	Fluorescence in situ hybridization (FISH).
Turnaround Time:	Testing is batched once a week.
CPT code*:	88377
SOFT code:	ROS1 (This code may be different in your EMR)

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