PCL ALVERNO



TEST BULLETIN SUMMARY

November 2018

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

CHANGES TO QUANTIFERON GOLD TESTING

PCL Alverno is pleased to announce the new QuantiFERON-TB Gold Plus Tuberculosis assay. If you use this test in your office, please read page 2 for the changes that occurred.

CHANGES TO GLUCOSE TOLERANCE TESTING

PCL Alverno offers testing to screen for Type 2 diabetes in gestational and non-gestational patients. As of January 4, 2019, PCL Alverno will only offer testing according to guidelines recommended by the American Diabetes Association (ADA) and the American College of Obstetrics and Gynecology (ACOG). Please see page 4 for specifics and for the effective date.

CONFIRMATION OF TESTING FOR DRUGS OF ABUSE COMES IN-HOUSE

PCL Alverno is pleased to announce that we will begin performing confirmation testing for drugs of abuse in-house. Liquid Chromatography tandem Mass Spectrometry instrumentation will allow PCL Alverno to provide quantitative drug confirmations and provide improved turnaround time. See page 3 for details.

NEW TESTING COMES IN-HOUSE: anti-Beta 2 Glycoprotein 1 antibody

PCL Alverno is pleased to bring anti-Beta 2 Glycoprotein 1 antibody testing in-house. Alverno will begin anti-phospholipid antibody testing on our BioPlex multiplex flow immunoassay analyzer. This assay can detect both anti-Cardiolipin and anti-Beta 2 Glycoprotein 1 antibodies in serum or plasma to aid in the diagnosis of primary Antiphospholipid Syndrome (APS). Please see page 5 for details.

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QuantiFERON TB Gold Plus

Currently Effective

IMPORTANT: New 4 Tube Collection Kit Required

PCL Alverno is pleased to announce the new QuantiFERON-TB Gold Plus Tuberculosis assay.

The QuantiFERON-TB Gold Plus assay detects the production of interferon-γ to identify in vitro responses associated with Mycobacterium tuberculosis infection. The Gold Plus assay includes detection of CD8 T-cell responses as well as the current detection of CD4. The inclusion of CD8 T-cell response results in improved sensitivity for Latent TB Infection over the current assay.[1]

Soft Test Code: QFTB4

CPT Codes: 86480

Collection Device: Quantiferon TB Gold Plus Pack
Item #179062

Transport: Room Temperature

Stability/Handling: Samples must be received at the Central Lab within 16 hours of collection. Please see collection manual for link to proper collection instructions.

[1] J Clin Microbiol. 2018 Jul 26;56(8). pii: e00427-18. doi: 10.1128/JCM.00427-18.



DRUGS OF ABUSE CONFIRMATION TESTING BY LC-MS/MS UPDATE

Effective November 13, 2018

PCL Alverno is pleased to announce that we will begin performing confirmation testing for drugs of abuse in-house. Utilizing Liquid Chromatography tandem Mass Spectrometry instrumentation allows PCL Alverno to provide quantitative drug confirmations for the following drug classes and provides improved turnaround time. Each drug class, its components, and the reporting cutoff values are provided in the table below.

Mass Spec Cutoff Levels:

Drug Class/Component	Cutoff Value	Soft Codes
Amphetamines		**DCAMP**
Amphetamines	200 ng/mL	
Methamphetamines	200 ng/mL	
Ecstasy		**DCECS**
MDA	200 ng/mL	
MDEA	200 ng/mL	
MDMA	200 ng/mL	
Benzodiazepine		**DCBEN**
Alprazolam	15 ng/mL	
Oxazepam	20 ng/mL	
Cocaine		**DCCOC**
Benzoylecgonine	50 ng/mL	
Methadone		**DCMED**
Methadone	30 ng/mL	
EDDP	30 ng/mL	
Opiates		**DCOPI**
Codeine	60 ng/mL	
Morphine	60 ng/mL	
Hydrocodone	60 ng/mL	
Hydromorphone	60 ng/mL	
Oxycodone		**DCOXY**
Oxycodone	60 ng/mL	
Oxymorphone	60 ng/mL	
Heroin		**DCHER**
6-acetylmorphine	10 ng/mL	
THC	15 ng/mL	**DCTH**
Barbiturates		**DCBRB**
Amobarbital/Pentobarbital	100 ng/mL	
Butalbital	100 ng/mL	
Phenobarbital	100 ng/mL	
Secobarbital	100 ng/mL	



GLUCOSE TOLERANCE TESTING

Effective January 15, 2019

PCL Alverno offers testing to screen for Type 2 diabetes in gestational and non-gestational patients. PCL Alverno will only offer testing according to guidelines recommended by the American Diabetes Association (ADA) and the American College of Obstetrics and Gynecology (ACOG).

For non-gestational screening, which includes non-pregnant women, men, and children, the ADA recommends a two-hour glucose tolerance test for selected patients with evidence of impaired glucose tolerance either on fasting or random measurements, or in the presence of elevated hemoglobin A1C.

For gestational screening of women between 24 – 28 weeks of pregnancy, the ACOG prefers the two-step approach, where an abnormal one-hour challenge with 50g of oral glucose solution is followed up with a three-hour oral glucose tolerance test (OGTT). Both the ADA and the ACOG list a one-step gestational screen that can be used as an alternative to screen pregnant women as well. The ADA has noted that measurement of hemoglobin A1C also can be used, but it may not be suitable for use alone because of decreased sensitivity compared with the OGTT approaches. The criteria and components for each test are listed below. All other glucose tolerance testing will be discontinued as of ***January 15, 2019***.

	Test Name	Dose of Oral Glucose Solution	Test Components	Reference Range
Two-Step Gestational Diabetes Screen	1-hour Gestational Diabetes Screen	50g	1-hour glucose	70 – 139 mg/dL
	3-hour Gestational OGTT	100g	Fasting glucose 1-hour glucose 2-hour glucose 3-hour glucose	70 – 94 mg/dL 70 – 179 mg/dL 70 – 154 mg/dL 70 – 139 mg/dL
Non-Gestational Diabetes Screen	2-hour Non-gestational OGTT	75g	Fasting glucose 2-hour glucose	70 – 99 mg/dL 70 – 139 mg/dL
One-Step Gestational Diabetes Screen	2-hour Gestational OGTT	75g	Fasting glucose 1-hour glucose 2-hour glucose	70 – 91 mg/dL 70 – 179 mg/dL 70 – 152 mg/dL



anti-Cardiolipin | anti-Beta 2 Glycoprotein 1
Update

November 27, 2018

PCL Alverno is pleased to bring anti-Beta 2 Glycoprotein 1 antibody testing in-house. Alverno will begin anti-phospholipid antibody testing on our BioPlex multiplex flow immunoassay analyzer. This assay can detect both anti-Cardiolipin and anti-Beta 2 Glycoprotein 1 antibodies in serum or plasma to aid in the diagnosis of primary Antiphospholipid Syndrome (APS).

Current Classification Criteria for APS[1]

Clinical criteria

1. Vascular thrombosis
   One or more episodes of arterial, venous, or small vessel thrombosis, in any tissue or organ
2. Pregnancy morbidity
   (a) One or more unexplained deaths of a morphologically normal fetus at or beyond the 10th week of gestation, or
   (b) One or more premature births of a morphologically normal neonate before the 34th week of gestation because of: (i) eclampsia or severe preeclampsia defined according to standard definitions, or (ii) recognized features of placental insufficiency, or
   (c) Three or more unexplained consecutive spontaneous abortions before the 10th week of gestation, with maternal anatomic or hormonal abnormalities and paternal and maternal chromosomal causes excluded

Laboratory criteria

1. Lupus anticoagulant present in plasma, on two or more occasions at least 12 weeks apart
2. Anti-Cardiolipin antibody of IgG and/or IgM isotype in serum or plasma, present in medium or high titer (i.e. > 40 GPL or MPL, or > the 99th percentile), on two or more occasions, at least 12 weeks apart
3. Anti-Beta 2 Glycoprotein antibody of IgG and/or IgM isotype in serum or plasma (in titer > the 99th percentile), present on two or more occasions, at least 12 weeks apart

Following the current guidelines, Alverno is replacing the three antibody panel (IgA, IgG, and IgM) Beta 2–Glycoprotein 1 with an IgG / IgM panel. All three antibodies will be individually orderable.

Please see ARUP Consult (https://arupconsult.com/content/antiphospholipid-syndrome) for detailed information of APS.

[1]*International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS).* J Thromb Haemost. 2006 Feb;4(2):295-306.