

# Notification of Changes to Service Provision

# 13/12/2019

## Immunology

### York Teaching Hospital NHS Foundation Trust

### Introduction

In 2018 following a competitive tender that was awarded to Werfen Limited, Autoimmune serology undertook a major laboratory equipment upgrade replacing all platforms. Verification is still ongoing; however we are now in the position for several assays to go live on the 16<sup>th</sup> of December 2019. This will involve changes to reference ranges of all assays (see below).

Only information regarding expected significant changes that may impact on patient management has been included in this notification. Where changes have occurred we will alert you to these using automated comments that will appear on reports.

If you have any queries regarding the content of this notification then please do not hesitate to contact the laboratory using the contact details below.

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### **Anti-Phospholipid Antibodies**

#### Anti-Cardiolipin (IgG/IgM)/ β2-Glycoprotein-1 (IgG) antibody

A definitive clinical diagnosis cannot be made on the basis of an aCL IgG positive result, and patient history and clinical findings must also be considered. A negative aCL IgG results also cannot be interpreted in isolation. The patients clinical signs and symptoms and the results from other anti-phospholipid assays must be considered as recommended in the revised classification criteria determined by the International Committee for the diagnosis of APS in the meeting held in 2006'

Reference Limits for ACA (IgG/IgM)		
ACA (IgG)	<20.1 CU	
ACA (IgM)	<20.1 CU	
β2GP1 (IgG)	<20.1 CU	

#### ACL/B2GP1 positive

Positive anti-phospholipid Ab should be confirmed after 12 weeks

Positive aPL are associated with anti-phospholipid syndrome. aPL results must be interpreted alongside patient history, clinical findings and LA results.

#### ACL/B2GP1 negative

A negative aPL result cannot be interpreted in isolation. Also consider patient history, clinical findings and LA results.