IMMF358 Version 2

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Dear RUH Immunology Service Users,

Anti-cardiolipin (aCL) & anti-β2 glycoprotein 1 (β2Gp1) IgG & IgM antibody tests: notification of change in method (aCL only) and location of testing (both aCL and β2Gp1)

What is changing? From **Tuesday 5th May** some of the methods and the location of aCL and β2Gp1 testing in Bath is changing. The current QUANTA Lite ACA IgG and IgM ELISAs (Inova Diagnostics) are changing to the EliA ACA IgG and IgM Phadia 250 FEIA methods (Thermo Fisher Scientific).

The method for β2Gp1 IgG and IgM antibody testing will remain the EliA β2Gp1 IgG and IgM Phadia 250 FEIA methods (Thermo Fisher Scientific).

Also, from this date the location of testing will change from RUH Bath (aCL) and PRU Sheffield (β2Gp1) to the Department of Immunology & Immunogenetics, Southmead Hospital. We expect the repatriation of β2Gp1 antibody testing to within the region to result in a significantly improved turnaround of results.

The switch will align us with the majority of other UK clinical laboratories using automated immunoassays and will also harmonise methods of testing anti-phospholipid antibodies across NBT and RUH.

Will I notice any differences to my aCL and B2Gp1 antibody results? Yes, specifically the aCL antibody results.

Although the numerical results reported by the new aCL methods use the same units as the current assay (GPL-U/mL or MPL-U/mL for IgG aCL and IgM aCL respectively) **the numerical results are not comparable and should not be considered interchangeable.** The β2Gp1 antibody methods are not changing, so these results remain interchangeable.

When the aCL assay changes occur, any patients having repeat measurements of IgG and/or IgM aCL antibody titres may experience a significant change in the results because of the method switch. The antibody concentrations are typically lower for both IgG and IgM aCL using the new methods, but the direction of bias can be patient-dependent, and aCL results may go up or down because of the switch.

This difference is significantly more pronounced for the IgM aCL assays where the vast majority of results will be lower using the new methods. The clinical impact of this shift should be limited given the low clinical significance of IgM aCL antibodies when detected in isolation, even at high titres.

Please consider that these changes could impact any confirmatory aCL antibody measurements (i.e., recommended repeat confirmatory testing after 12 weeks) if the assay change falls in between when the two measurements are taken.

The clinical utility of serial monitoring aCL antibodies is uncertain. If repeat antibody measurements are required, consider repeat testing on the new methods to establish baseline serum aCL antibody concentrations.

The **reference intervals** (ranges) are also changing. The current ranges are being replaced by the following:

- **Negative: <10 GPL-U/mL or MPL-U/mL**
- **Equivocal: 10 - 40 GPL-U/mL or MPL-U/mL**
- **Positive: >40 GPL-U/mL or MPL-U/mL**

There is further piece of work taking place to standardise reporting of anti-phospholipid antibody results across the region using interval-specific likelihood ratios. Additional communications on this matter will be circulated later this year.

Qualitative comparison of the results showed good concordance between IgG aCL methods (84%) with lower concordance between the IgM aCL methods (48%). **Our evaluation data indicates the new IgM aCL method will generate significantly fewer low, medium and high positive results compared to the historical methods**. Retrospective review of the IgM aCL discordant results at NBT indicated that the majority of the patients with an isolated positive result on the current method and negative on the new method had not received a definitive diagnosis of anti-phospholipid syndrome.

When? These changes will be implemented on **Tuesday 5th May.**

Please feel free to contact me if you wish to discuss this matter further.

Kind regards

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