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Dear Colleague, 22/06/2023

Measurement of anti-GBM antibodies on the Phadia test system – update to protocol

We have recently received a field safety notice from the company that provide our anti-GBM antibody assay. This is in relation to an increase in the number of false positive results on their Phadia GBM assay that has affected both weak and strong positive anti-GBM antibody results.

Some of our service users (and other customers across Scotland) had reported a few patients that appeared to have false positive anti-GBM antibody results; these were patients who did not have any clinical evidence of anti-GBM disease and further testing by an alternative method did not identify anti-GBM antibodies. The manufacturer has now identified that the cause is likely to be due to a reaction towards the BSA component used in the coating solution of the GBM test system. They state that there has been no change in design or component of BSA used in the GBM test system but that their local investigation confirmed that some samples produced a 'positive result' even when these samples were tested against the coating solution alone (i.e. without the GBM antigen). Consequently, they have concluded that "*There is a known inherent risk due to assay design that may contribute to false positive GBM results for specific samples containing anti-BSA antibodies*".

The following guidance has been recommended to all customer using the Phadia GBM assay:

- For GBM test results >10 U/mL (i.e. positive results): verify these positive anti-GBM antibodies using an alternative method.
- For GBM results ≤10 U/mL (i.e. negative and equivocal results): these are not impacted by this issue and therefore these values can be reported without further action.

Changes to our GBM screening protocol: As a result of this field safety notice we are now routinely sending all first time positive anti-GBM antibodies (results >10 U/mL) to Tayside for confirmation by an immunoblot assay. Tayside have confirmed that they perform this immunoblot assay weekly.

All first time positive anti-GBM antibody results will now include an additional comment stating '*Sample has been sent to Tayside for anti-GBM antibody testing by immunoblot. Result to follow.*' Once we have received the immunoblot result from Tayside the report will be scanned onto NHS GGC Clinical Portal. Any requests from external users will also be posted to the relevant external laboratory. As is our routine practice we will continue to phone all first time positive anti-GBM antibody results to the requesting clinician/ward/external lab. At this point we will also inform the clinician/ward/external lab that the sample will be sent to Tayside for confirmation by immunoblot.

Additionally, we have gathered a list of positive anti-GBM antibodies identified in 2022 & 2023 and if samples are still available we will endeavour to send these to Tayside for retrospective GBM testing. Unfortunately we do not routinely store samples for longer than 4 weeks so this will only benefit a handful of patients.

We would be grateful if you could share this letter with colleagues and contact us if you have any further questions.

Yours sincerely,

Lauren Hennessy
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Clinical Lead for Immunology & Neuroimmunology Laboratory