pathlab

February 2017

Changes to *Clostridium difficile* Testing

This clinical update is to inform you of an impending change to the laboratory diagnosis of *Clostridium difficile* infection. This will take effect during late February 2017.

All stool samples which have been accepted for *Clostridium difficile* testing will receive two initial tests as follows:

- **Glutamate dehydrogenase test (GDH):-** Presence of this enzyme indicates the presence of *Clostridium difficile* bacteria in the bowel.
- **Toxin immunoassay**:-An immunochromatographic test looking for the presence of Toxin B in the sample.

Where both of these tests are positive, the result will go out as positive with an appropriate comment.

Where both of these tests are negative, the result will go out as negative.

Where the GDH is positive and the toxin immunoassay is negative, this can be caused either by toxin degeneration in the sample, or by the presence of a non-toxigenic strain of *Clostridium difficile*. For this result scenario we will proceed to a **molecular assay (PCR)** on the Genexpert platform, looking for the presence of the toxin genes (Toxin B and binary toxin), and the ensuing result will be reported with appropriate comments.

The full diagnostic algorithm is outlined in the accompanying flowchart.

We believe this testing model will increase the specificity of the laboratory testing process for *Clostridium difficile* infection, without affecting the sensitivity of the current methodology. Turnaround time for the test will be unaffected.

If there are any questions with regards to this approach, please feel free to contact the Clinical Microbiology department at Pathlab.

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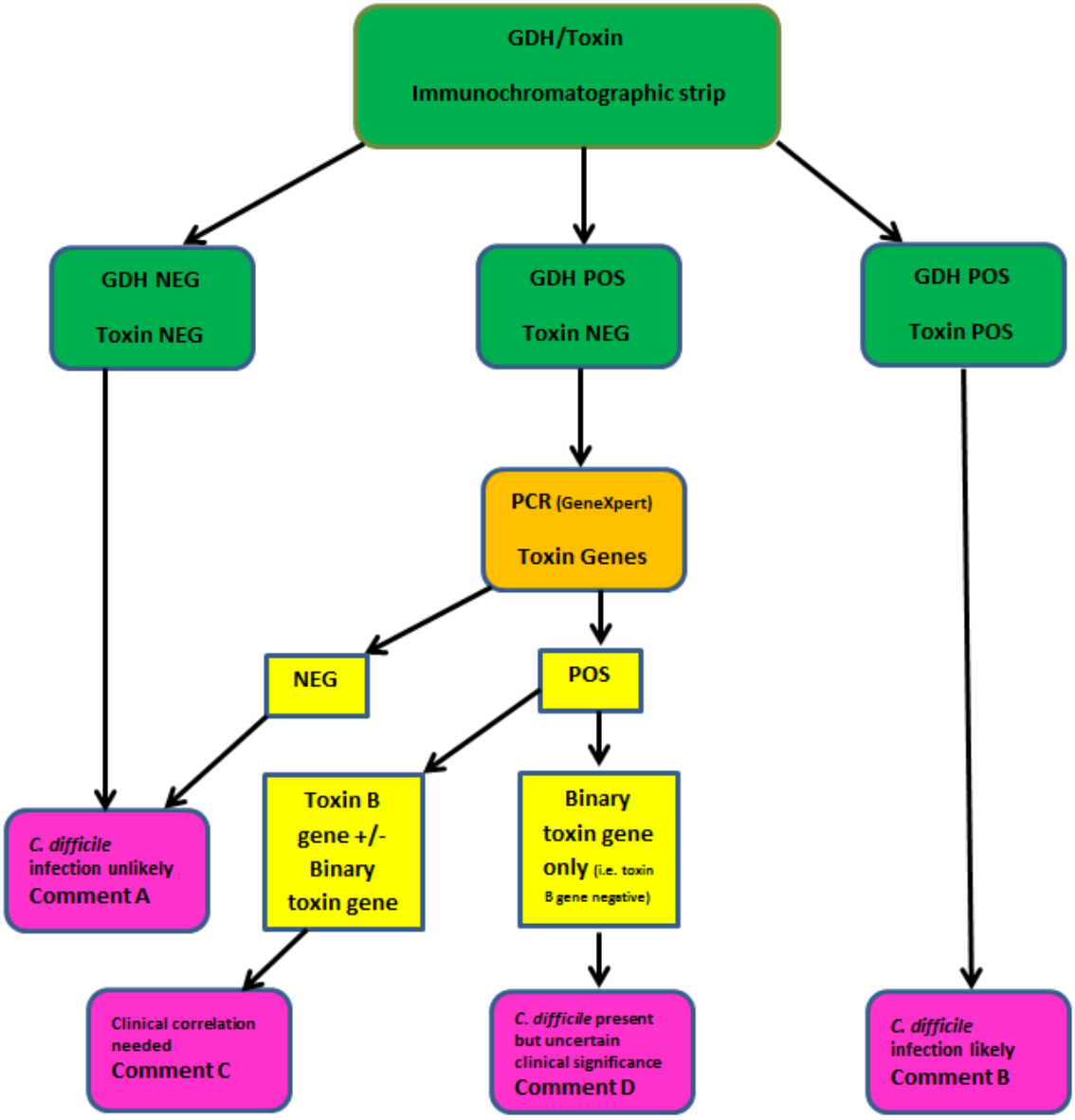
CLINICAL UPDATE

Laboratory Diagnosis of *Clostridium difficile* Infection



Comment A: Results indicate this patient does not have *C. difficile* infection.
Comment B: Results indicate this patient has *C. difficile* infection.
Comment C: Results indicate the presence of a toxigenic *C. difficile* strain, BUT the negative toxin may be due to below detectable levels or the strain is not producing toxin. Clinical correlation is essential and if necessary advice may be obtained from the Clinical Microbiologist.
Comment D: Results indicate the presence of a *C. difficile*, BUT strains only containing the binary toxin genes are of uncertain clinical significance. If necessary advice may be obtained from the Clinical Microbiologist.

CLINICAL UPDATE