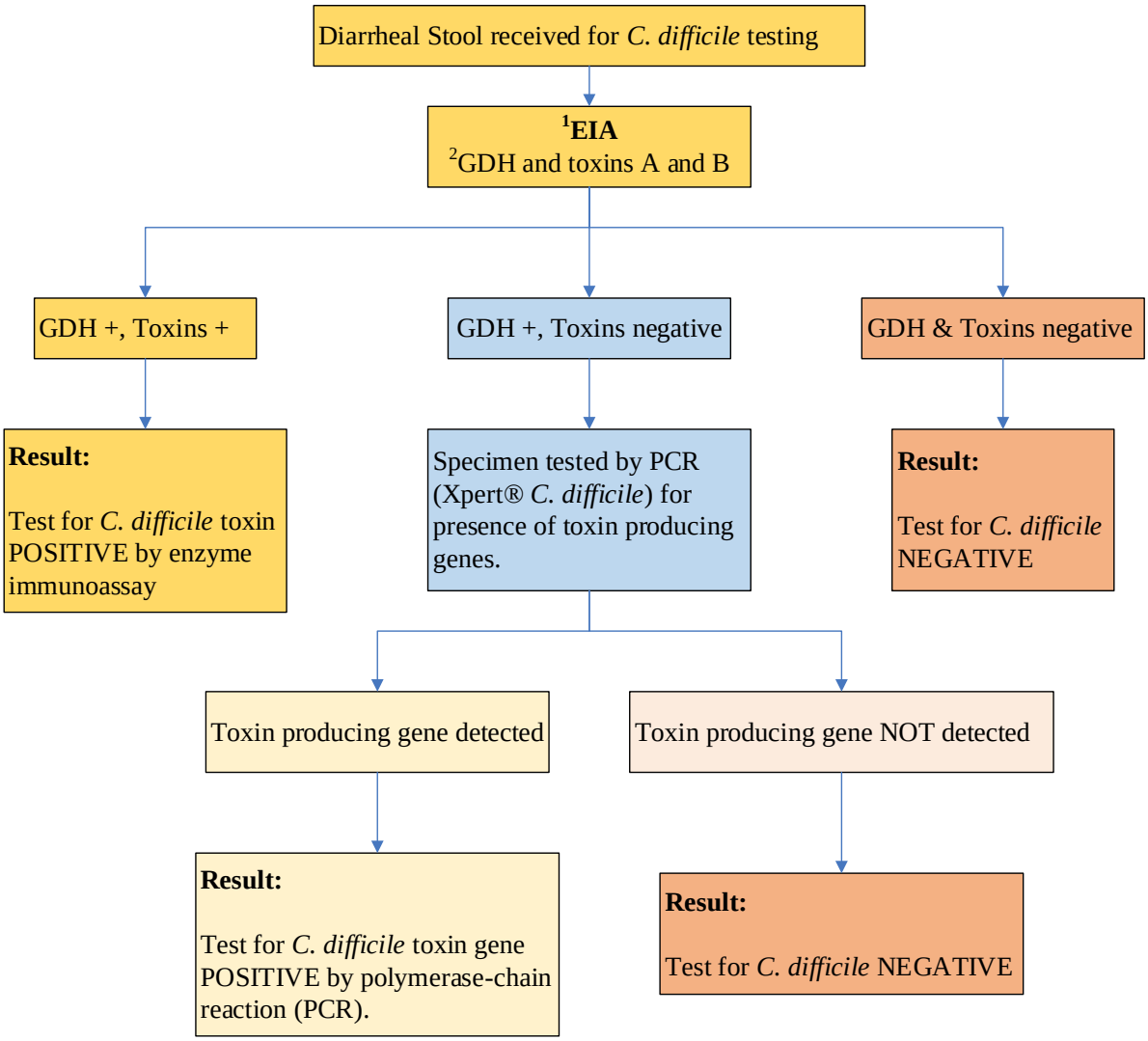
# ProvLab *C. difficile* Testing, Results and Comments

## *C. difficile* Testing Algorithm




**Legend**
[1]EIA = Enzyme immunoassay
[2]GDH = glutamate dehydrogenase, an enzyme found in all *C. difficile* organisms

**Result 1**

Test for *C. difficile* NEGATIVE

Testing performed with C. DIFF QUIK CHEK COMPLETE® (Enzyme Immunoassay).

or

Test for *C. difficile* NEGATIVE

Testing performed with C. DIFF QUIK CHEK COMPLETE® (Enzyme Immunoassay) and Xpert® C. difficile (PCR).

***Interpretation:***
**Testing did not detect toxin producing *C. difficile* in the specimen submitted.**

**Result 2**

Test for *C. difficile* toxin POSITIVE by enzyme immunoassay.

Testing performed with C. DIFF QUIK CHEK COMPLETE® (Enzyme Immunoassay).

***Interpretation:***
**Testing by EIA detected the presence of *C. difficile* toxin in the specimen submitted.**

**Result 3**

Test for *C. difficile* toxin gene POSITIVE by polymerase-chain reaction (PCR).

This result can be seen in colonization, past infection, or possibly current infection. If the patient has diarrhea, the diagnosis of *C. difficile* infection and decision to treat should take into consideration other causes. IPC precautions are recommended for any patient with diarrhea.

Testing performed with C. DIFF QUIK CHEK COMPLETE® (Enzyme Immunoassay) and Xpert® C. difficile (PCR).

***Interpretation:***
**Testing by EIA detected the presence of *C. difficile*, but NOT toxin A or B in the specimen submitted. PCR performed on the specimen detected the presence of the**

**toxin B producing gene of *C. difficile*. The clinical significance of this combination of results varies depending on whether the patient clinically fits the picture of colonization, past infection, or current infection. Other causes of diarrhea should be considered.**

## Note:

**The production of *C. difficile* toxins is necessary for *C. difficile* colitis.**

Due to the high sensitivity and the inability of nucleic acid amplification tests to distinguish *C. difficile* infection from asymptomatic carriage, over diagnosis of *C. difficile* colitis is a risk, with the added potential risk of treating patients with antibiotics when they may not require such therapy [1,2].

### Result 4

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| CD toxin INCONCLUSIVE. Unable to confirm presence of *C. difficile* toxin. Indicates the presence of non-toxigenic *C. difficile*. Repeat if clinically indicated.<br><br>Testing performed with C. DIFF QUIK CHEK COMPLETE® (Enzyme Immunoassay) and Xpert® C. difficile (PCR). |

***Interpretation:***

**Testing by EIA was indeterminate for *C. difficile* and PCR performed on the specimen did NOT detect the presence of the toxin B producing gene of *C. difficile*; or the tests were invalid due to interfering substances in the specimen.**

## Note:

**The production of *C. difficile* toxins is necessary for *C. difficile* colitis and there is no evidence that non toxigenic *C. difficile* can cause disease.**

Colonization rates vary for different patient populations. Some published rates are:

- general population of healthy adults: 0 - 15%[5, 10-20]
- long term care facility residents: 5 – 51%[3-9, 20]
- acute care hospital inpatients: 4 – 29%[20]
- healthy newborns and infants: 18 – 90%[10,11]

Thus a patient with diarrhea and a *C. difficile* GDH antigen only positive, requires investigation for causes of diarrhea other than *C. difficile*.

**References**


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