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Title Modification of the Nomenclature of Procedures in Laboratory Medicine for the diagnostic laboratory procedures for *Clostridium difficile* infections.

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Aim

The aim of this work is to evaluate the detection of *C. difficile* glutamate dehydrogenase using an enzyme immunoassay or immunochromatography method and the detection of this bacterium's deoxyribonucleic acid, more specifically that which codes the toxins A and/or B, using a nucleic acid amplification test (NAAT). This study was conducted with a view to inclusion in the List of Procedures in Laboratory Medicine reimbursed by the national health insurance system in France.

Conclusions and results

The two tests studied are part of the current valid diagnostic tools used to identify a *C. difficile* infection (CDI). However, it was not possible to precisely define their place in the diagnosis among the other diagnostic tools.

The detection of *C. difficile* glutamate dehydrogenase by an enzyme immunoassay or immunochromatography method can only be used as a screening test, to be followed in the case of a positive result by a NAAT to determine if the identified *C. difficile* is toxigenic or not.

The NAAT used must target the *C. difficile* toxin B gene and/or the preserved section of the toxin A gene to identify the greatest possible number of strains, with the knowledge that with this type of test:

- a negative result should not exclude the possibility of a *C. difficile* infection caused by a strain producing the binary toxin (coded by a specific gene);
- a positive result should not exclude the possibility of asymptomatically carrying a toxigenic strain of *C. difficile*;
- a positive result does not necessarily identify the presence of the 027 strain, this requires targeting of its regulator gene.

Consequently, the diagnosis and the decision if treatment is required should be based on all the data available to the clinician, and not just on the result of the NAAT, which must be discussed between the physician and biologist. The NAAT techniques are PCR type (most studied and most used) or LAMP type; the result of a NAAT is qualitative.

In addition, the indication to test for *C. difficile* as a suspected CDI should be made in the presence of:

- diarrhoea occurring after antibiotic therapy;
- nosocomial diarrhoea;
- persistent community-acquired diarrhoea which either shows no improvement after 3 days despite symptomatic treatment or which is initially associated with signs of severity with or without antibiotic therapy;
- pseudomembranous colitis.

Testing for *C. difficile* is not useful in monitoring treatment.

Methods

The method was to perform a critical analysis of the identified summary literature (good practice guidelines, technological assessment reports, systematic reviews and meta-analyses) after a systematic and selected document search on methodological quality criteria, then collect the views of the professional health organisations concerned (general medicine, hepato-gastroenterology, geriatrics, hygienist, infectious diseases, clinical biology and the laboratory associated with the National Reference Centre for Anaerobic Bacteria and Botulism).

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