Health Protection Scotland

NHS National Services Scotland

Guidance on Reporting of Equivocal Results for *Clostridium difficile*

Version 1.0

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General enquiries and contact details

If you have any comments or questions, or would like further information please contact a member of the HPS *C. difficile* Working Group.

This document can be downloaded from:

http://www.hps.scot.nhs.uk/haiic/sshaip/guidelines.aspx#cdiff

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Introduction

In December 2009, consensus guidance on diagnostic testing[1] was developed and distributed by the Scottish *Salmonella*, *Shigella* and *Clostridium difficile* Reference Laboratory, HPS and the Scottish Microbiology Forum.

Due to the risks of missing true positives and the generation of false-positive results by using a single toxin immunoassay, the 'Recommended protocol for testing for *Clostridium difficile* and subsequent culture' advises the use of a confirmatory second test for all initial toxin positive results.

As per the diagnostic protocol, CDI can be reliably excluded when the first test result is negative. An initial positive test requires a confirmatory test to be performed. Samples which are positive on the first test and then negative on the second test should be reported as EQUIVOCAL (see example testing algorithm at the end of this document). Based on clinical assessment, the protocol advises further testing on a second sample. If the second sample is also equivocal laboratories should consider the use of culture (preferably toxigenic culture). Some laboratories may choose to perform toxigenic culture on the original sample, rather than reporting an equivocal result and requesting a further sample. In this latter scenario the issue of reporting an equivocal result should not arise, as the sample can then be reported as positive or negative based on the presence or absence of a toxigenic isolate in the sample.

It is anticipated that the implementation of the two-step algorithm may impact on the reported number of episodes. Therefore to ensure a consistent approach and limit variation between boards, this protocol has been developed to guide laboratories when confirming test results to HPS during the validation phase of the surveillance programme.

Confirmation of final dataset to HPS

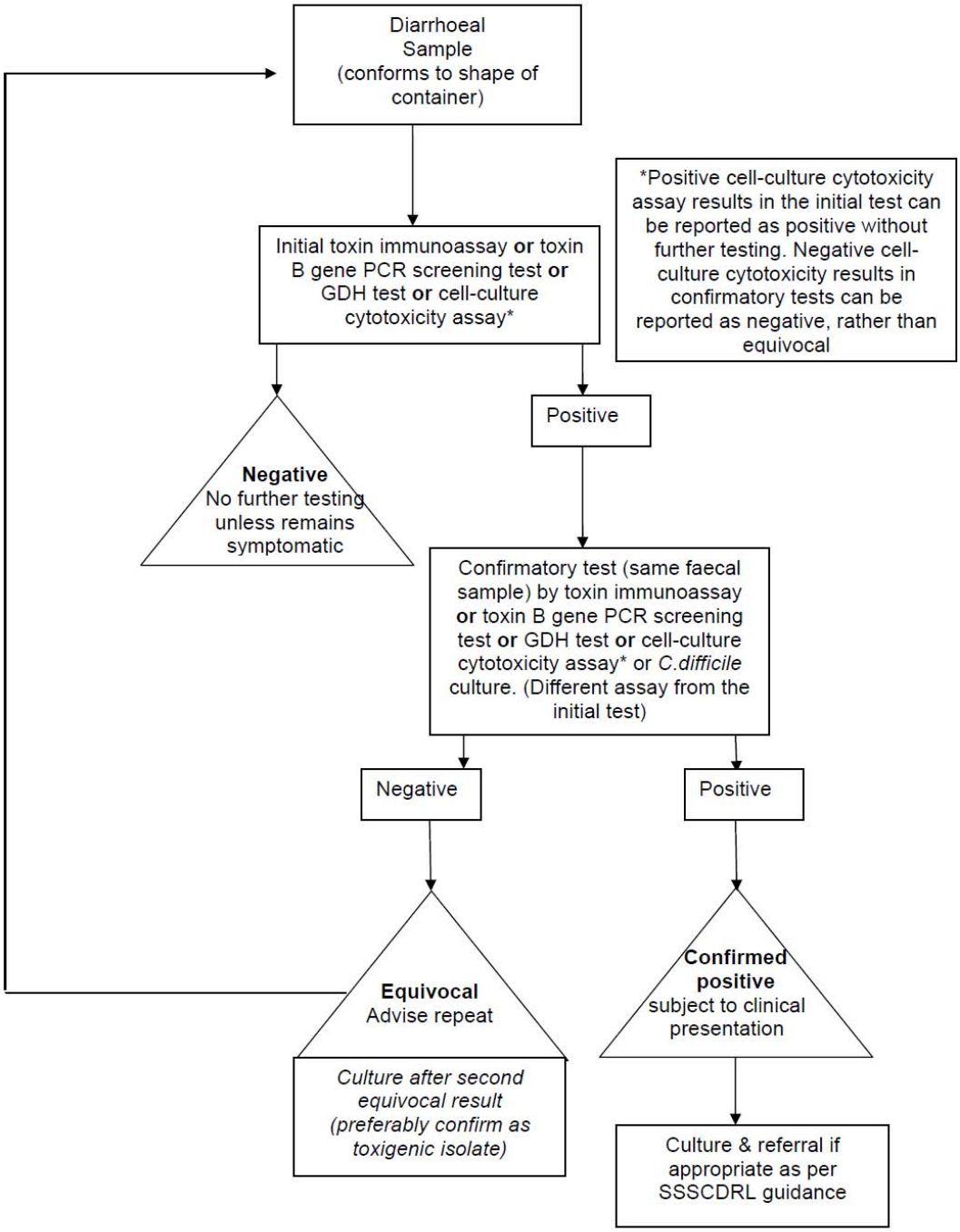
During the validation phase of the mandatory surveillance programme, HPS sends each health board a deduplicated file of patient data to be checked against the CDI patient data held on the local laboratory system. It is recommended that this validation involves an agreement between the laboratory and the consultant microbiologist/clinical scientist.

To help assess the impact of the two-step algorithm, when reporting the final dataset to HPS, each board should indicate clearly which patients (if any/if applicable) are EQUIVOCAL and therefore to be excluded from the final dataset. Equivocal results should not be stripped out before returning the final dataset to HPS.

If there are patients to be removed from final dataset for reasons other than being equivocal, this should include a short explanation for their removal.

In future publications of quarterly and annual incidence rates, HPS will only report episodes that have been confirmed as toxin positive according to the two-step diagnostic protocol. If your laboratory has not yet implemented the two-step procedure please indicate this to HPS.

Example Testing Algorithm



Reference:

1. Recommended protocol for testing for *Clostridium difficile* and subsequent culture. Available from: http://www.hps.scot.nhs.uk/haiic/sshaip/guidelinedetail.aspx?id=43436