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ePoster Viewing
Molecular diagnosis of bacterial gastrointestinal infections

EXTERNAL QUALITY ASSESSMENT OF LABORATORIES USING MOLECULAR DIAGNOSTIC TESTS FOR CLOSTRIDIUM DIFFICILE

E. Mcculloch[1], P.S. Wallace[1], J. Coia[2], C. Williams[3], W.G. Mackay[3]

[1]Technical, QCMD, Glasgow, United Kingdom ; [2]Glasgow Royal Infirmary, Scottish Salmonella Shigella and Clostridium difficile Reference Laboratory, Glasgow, United Kingdom ; [3]University of West of Scotland, Institute of Healthcare Associated Infection, Kilmarnock, United Kingdom

Background: *Clostridium difficile* is the leading cause of antibiotic-associated diarrhoea. *C. difficile* infection encompasses a spectrum of disease and there is a significant associated mortality. Rapid and accurate diagnosis is key to effective and timely management. Molecular tests are increasingly being utilised and offer benefits in terms of speed and accuracy of detection, although they do not always correlate with risk of development of severe disease or complications, particularly where testing is performed in patients with minimal symptoms. This external quality assessment (EQA) study reports on the performance of laboratories using molecular diagnostic tests for *C. difficile* worldwide (2009 – 2013). The programme was coordinated by Quality Control for Molecular Diagnostics (QCMD) (www.qcmd.org).

Objectives: To assess the proficiency of laboratories in the molecular detection of *C. difficile* in the clinical setting.

Methods: A panel of 10 members was distributed once a year to registered laboratories. In 2009, there were 36 laboratories, this increased to 100 laboratories worldwide in 2013: The panel composition in 2013 included three *C. difficile* 017 samples (10^4 to 10^6 CFU/ml), five *C. difficile* 027 samples (10^3 to 10^6 CFU/ml), one *C. sordelli* sample (10^5 CFU/ml). In addition there was one sample negative for *C. difficile* and *C. sordelli*. QCMD defined six of these 10 panel samples as core proficiency samples based on scientific information, clinical relevance / experience and prior EQA performance data. Participating laboratories were expected to correctly report on these six samples to show an acceptable level of proficiency.

Results: Out of the 100 laboratories that registered for the *C. difficile* EQA programme in 2013, 93 returned 108 datasets. The majority of datasets were generated using PCR assays (n=104; 96.3%), with the rest being generated using LAMP assays (n=4; 3.7%). Eighty-seven percent of datasets recorded all six core proficiency samples correctly, 9.3% reported 5/6, 2.8% reported 4/6 and 0.9% reported 3/6 correctly. Almost all datasets correctly recorded *C. difficile* 017 (n=105; 97.2%) and 027 (n=103; 95.4%) panel samples down to a concentration of approximately 10^5 CFU/ml. Four false positive results were reported on the true negative panel sample and one false positive was reported on the specificity negative panel sample (*C. sordelli*) resulting in an overall false positivity rate of 2.3% (n=5/216). This was a significant decrease compared to 2009 when false positive results on the *C. sordelli* panel sample were near to 40%.

Conclusions: The majority of laboratories that participated in this External Quality Assessment programme for *C. difficile* demonstrated an acceptable level of proficiency. In general laboratory performance has improved over the last four years. However false positive results remain an issue for some laboratories, and suggest that further improvements are required.