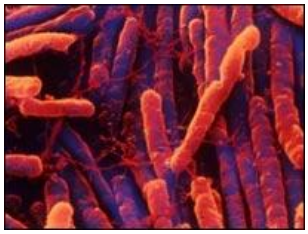
Prolisa™ *C.difficile* GDH EIA.....Update **January 2012**

The most recent addition to the growing portfolio of independent evaluation work on the Prolisa™ *C.difficile* GDH EIA is shown below. The results are currently being prepared in a full write up paper for submission for peer review in a leading scientific journal. The following statement has been prepared by Dr. V. Hall at the Public Health Wales Anaerobic Reference Unit for release following a number of requests from customers. We will of course advise as soon as the full, paper is released. We extend our thanks to Val and her team for the work carried out on behalf of Pro-Lab Diagnostics.



ARU evaluation of *C. difficile* GDH EIA kits – Val Hall & Sarah Copsey.

The Public Health Wales Anaerobe Reference Unit has recently performed an evaluation of the Prolisa *C. difficile* GDH EIA (Pro-Lab Diagnostics) and Techlab GDH EIA (Alere) kits.

In brief, 504 faeces specimens were subjected to alcohol-shock and culture on CCEY agar (E&O Laboratories) using in-house methods as per ARU SOPs. Of these, 65 (13%) yielded toxigenic *C. difficile.* These results were used as the gold standard for comparison purposes. All specimens were also tested using the Premier toxin A/B EIA (Launch Diagnostics) and in both GDH kits.

Performance of the Premier toxin A/B EIA was very poor (sensitivity 38%, specificity 99%). The two GDH tests were broadly comparable although the Prolisa outperformed the Techlab system, having a sensitivity of 94% (Techlab, 83%) and specificity of 91% (Techlab, 91%) when cytotoxic culture was used as the second-step test. However, for both GDH systems, sensitivity fell to 38% (specificity 100%) when the Premier toxin A/B EIA was used as the second-step test, due to the very high proportion (n = 40) of false negative results in the latter test.

In conclusion, the GDH EIAs examined are highly specific for the detection of toxigenic *C. difficile* and may be highly sensitive if used in conjunction with a high-performance second-step test. However, the choice of test for confirmation of toxin production is a critical factor.

Additional References available to date.

1. The Prolisa™ *C. difficile* EIA was evaluated at two microbiology laboratories in the United Kingdom. Stool samples were obtained from 713 patients with symptoms consistent with *C. difficile* infection. Samples were tested by the Prolisa™ *C. difficile* GDH EIA according to the instructions for use provided with the EIA. Test results from the EIA were compared to the results obtained with *C. difficile* culture. Data available on request.

2. The Prolisa™ *C. difficile* EIA was also evaluated at a leading hospital in Canada and was conducted in an automated ELISA system. Stool samples were obtained from 176 patients. Samples were tested by the Prolisa™ *C. difficile* GDH EIA according to the instructions for use provided with the EIA.

3. In dependent evaluation of GDH enzyme immunoassay for *C.difficile* screening. Katie Fitzsimmons. Medical Microbiology. Wirral University Teaching Hospital. Biomedical Scientist. October 2011.

4. Prolisa™ – rapid, accurate and cost effective screening for C. difficile infection CASE STUDY: Tracey Roberts. Southport and Ormskirk Hospital NHS Trust. Why screen for glutamate dehydrogenase?

More to follow.....watch this space.

For further details on the Prolisa™ range of EIA kits, please call 0151 353 1613 or contact your local technical representative.

UK Sales Manager	Peter Lucas	plucas@pro-lab.com
London / South East	Michelle Coleman	mcoleman@pro-lab.com
North West England	Steve Johns	sjohns@pro-lab.com
Scotland / North England	Rod Smith	rsmith@pro-lab.com
Wales / South West England	Charlotte Duncan	cduncan@pro-lab.com
Wales / South West England	Jennie Jones	jjones@pro-lab.com

There are many other new products in the pipeline and we look forward to introducing them to you in the very near future.

Mark *Peter*

Mark Reed

General Manager.

mreed@pro-lab.com

Peter Lucas

UK Sales Manager

plucas@pro-lab.com