Laboratory Operational Update

16 January 2019

Cessation of routine confirmatory testing for extra-genital samples reactive for gonorrhoea from 21st January 2019.

Labtests has performed molecular testing for chlamydia and gonorrhoea using the Hologic Aptima Combination-2 assay (AC-2, Hologic, San Diego, USA) since late 2015. Labtests has routinely performed confirmatory testing on extra-genital samples reactive for gonorrhoea using the Aptima®Neisseria gonorrhoeae assay. Confirmatory testing was performed due to concerns around cross reactivity with commensal *Neisseria*, particularly in the pharynx, primarily associated with older molecular testing methods. However, since we rarely come across unconfirmed reactive gonorrhoea samples from these sites, and AC-2 has recently been licensed for rectal and throat swabs, we sought to verify the performance of the AC-2 as a stand-alone test for gonorrhoea at our laboratory.

The results of all extra-genital samples submitted for nucleic acid amplification testing (NAAT) over the period 01/01/2016-31/12/2018 were analysed; 11278 tests were performed, of which 439 samples were reactive for gonorrhoea using the AC-2 assay, giving a reactive test result prevalence of 3.9% (95% CI 3.6-4.3%).

Four hundred and nine (93.2%, 95% CI 90.4-95%) samples reactive by AC-2 were reactive by the confirmatory assay, 11 (2.5%, 10 throat swabs, 1 rectal swab) tested negative, 1 was equivocal, and 17 (4.4%) had invalid or indeterminate results.

Excluding those samples where confirmatory testing was invalid, indeterminate or equivocal, the positive predictive value of AC-2 for extra-genital gonorrhoea detection was 97.4% (95% CI 95.3-98.5%), and the specificity was 99.9% (95% CI 99.8-99.9%).

In summary, we analysed three years of confirmatory testing data and found that a positive AC-2 result for gonorrhoea has >90% positive predictive value for confirmation in that sample. This finding applies to the three common sites tested at Labtests: throat samples, rectal samples, and eye samples, and indicates that in the population tested, routine confirmation from these sites is no longer necessary.

Therefore, Labtests will cease routine confirmation for extra-genital samples reactive for gonorrhoea as of Monday 21st January 2019. We will indicate this on the relevant laboratory reports. Microbiologists will be available for further discussion, if required, and as usual, samples will be kept for a period of one week.

Dr Gary Mcauliffe
Medical Director Labtests and Northland Pathology

gary.mcauliffe@labtests.co.nz