Letters to the Editor

Evaluation of a solid phase immunoassay kit for gonococcal antigen

The problem of diagnosing gonorrhoea in women attending special treatment clinics on the basis of instant Gram stain results alone is well recognised. This is particularly true of asymptomatic female carriers, who may harbour a small number of organisms and who may have to be treated on epidemiological grounds in the absence of immediate microbiological evidence provided by on the spot positive Gram stain results. The appearance of a commercial diagnostic kit for rapid diagnosis of gonorrhoea using an enzyme linked immunosorbent assay technique was therefore greeted with interest (Gonozyme, Abbott Laboratories, Chicago, Illinois, USA). This kit has been evaluated with satisfaction by other workers,[1 2] mostly outside the UK. In view of well known limitations of the Gram stain in women we have assessed the value of the Gonozyme test, if any, as a primary diagnostic tool for diagnosing gonorrhoea in our laboratory; we have compared its specificity and sensitivity with the results of Gram stain, taking results of culture as the reference point.

We looked at cervical specimens from 145 women and urethral specimens from 116 men visiting the special clinic; repeat specimens were taken from some patients as a test of cure, giving a total of 331 specimens. Most specimens, except for a few from men without a discharge, were Gram stained in the clinic and looked at by a senior medical laboratory scientific officer seconded from the laboratory. All specimens were processed for Gonozyme assay and culture. Cervical and urethral swabs, which had been plated out immediately on to modified New York media (Lab M, Salford, Greater Manchester) in the clinic were put in 120 μl of Gonozyme preservative reagent and stored in a refrigerator (4°C) for up to a week until the Gonozyme assay was performed according to the manufacturer's instruction manual.

Table 1 shows the results, which are given for men and women separately so that differences in sensitivity and specificity are better appreciated. In men the difference in sensitivity and specificity of Gram stain and Gonozyme assay compared with culture was not significant, whereas in women the difference in sensitivity in particular was appreciable. But the initial sensitivity of Gram stain in women (six out of 16 culture positive cases (37%)) improved to 62·5% on prolonged retrospective search for intracellular Gram negative diplococci in culture positive cases. It is probably unrealistic, however, to expect to devote much time in a busy clinic.

Table 2 compares the results of the Gonozyme test and culture in women. Three discordant results of a positive culture with negative Gonozyme test result (all from three sequential specimens of a single patient) are recorded, but four discordant results with negative culture and a positive Gonozyme assay result, from four different patients, are perhaps more interesting. They probably represent false positive results. It should be appreciated, however, that the culture system, although reliable, may not be 100% sensitive.[3] Moreover, the possibility of an occasional gonococci being inhibited by vancomycin incorporated in the gonococci media cannot be overlooked.[4] Incidentally, there were two false positive Gonozyme results among the men.

Despite such problems of doubtful predictive value (76% for a positive test) the Gonozyme assay may still be acceptable as a presumptive test in women in view of low sensitivity of Gram stains (37%), since this might result in earlier treatment before the culture results are available. The Gonozyme assay can never be a substitute for isolation of gonococci by culture, which is an essential prerequisite for its precise identification and testing for antibiotic susceptibilities and β-lactamase production.

Although the Gonozyme assay is well within the capability of district microbiology laboratories serving a modest special treatment clinic, many laboratories may not have the personnel to offer an on the spot service of providing rapid results within about 2 hours. More importantly, however, the cost of £2·40 per test (including the price of leasing the spectrophotometer) will be restrictive for many laboratories wanting such a service, in the present climate of financial stringency, despite its possible value as a rapid test for the presumptive diagnosis of gonorrhoea in women.

M BROOM
AK CHAUDHURI
Department of Microbiology, Royal Albert Edward Infirmary, Wigan, Greater Manchester

Table 1 *Results of Gram stain, culture, and Gonozyme test for gonococcal antigen in samples from 331 men and women*

	No of specimens	*Gram stain*			*Culture*		*Gonozyme*	
		Pos	*Neg*	*ND*	*Pos*	*Neg*	*Pos*	*Neg*
Men	142	14	90	38	14	128	16	126
Women	189	6	183	—	16	173	17	172
Total	331	20	273	38	30	301	33	298

Pos = positive result; Neg = negative results; ND = not done.

Table 2 *Comparison of results of Gonozyme test with culture findings in samples from 189 women*

Gonozyme	*Culture*	
	Pos	*Neg*
Pos	13	4
Neg	3	169
Total	16	173

Pos = positive results; Neg = negative results.

References

[1] Danielsson D, Moi H, Forslin L. Diagnosis of urogenital gonorrhoea by detecting gonococcal antigen with a solid phase enzyme immunoassay (Gonozyme). *J Clin Pathol* 1983;**36**:674–7.
[2] Aardoom HA, de Hoop D, Iserief COA, Michel MF, Stolz E. Detection of Neisseria Gonorrhoea antigen with a solid phase immunoassay (Gonozyme). *Br J Ven Dis* 1982;**58**:359–62.
[3] Schmale JD, Martin JE, Domestik G. Observations on the culture diagnosis of gonorrhoea in women. *JAMA* 1969;**210**:312–4.
[4] Windall JJ, Hall MM, Washington JA, Douglas TJ, Weed LA. Inhibitory effects of vancomycin on *N gonorrhoea* in Thayer Martin medium. *J Infect Dis* 1980;**142**:775.