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B-274 One-step Detection of Candida Albicans, Trichomonas Vaginalis and Gardnerella Vaginalis

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BACKGROUND: *Trichomonas vaginalis* and *Candida albicans* infections and bacterial vaginosis (BV) are among the three main causes of vaginitis.The most widespread method for diagnosis is still Gram staining and culture. The disadvantages are the microscopy time required, as cultures are examined after 24–48 h. Different commercial molecular biology kits are currently available on the market to detect these pathogens in a sensitive, specific and rapid way.In vitro diagnostic products must be marketed with CE and IVD certification for marketing in the European Union and must be externally validated with clinical samples. For this reason, the company Certest Biotec proposes a collaborative study to evaluate the product VIASURE *C. albicans, G. vaginalis & T. vaginalis* Real Time PCR Detection Kit, in the Microbiology Laboratory of the Miguel Servet University Hospital (HUMS) in Zaragoza (Spain) using samples characterised by Gram and culture as positive or negative for *C. albicans, G. vaginalis* and *T. vaginalis*.

METHODS: 240 DNA extracts of clinical samples from vaginal swabs of patients with suspected vaginitis were analysed. For the validation of the kit under study, the Segene® AllplexTM Vaginitis Screening Assay was used as a reference. Discordant results will be resolved by Sanger sequencing. Preliminary results are therefore expressed as true positives, true negatives, false positives and false negatives. The use of clinical samples was approved by CEIC Aragón (CEICA): PI20/426.

RESULTS: In the absence of resolution of the discordances by sequencing, the results were as indicated in Table 1.

CONCLUSION: The main advantage of using these techniques is speed, as they can provide results on the same day and reduce the time spent on microscopy and culture reading. VIASURE products are in a stabilised, ready-to-use format, which facilitates handling, avoids possible contamination, allows storage at room temperature and transport.

		Allplex™ Vaginitis Screening Assay					
		Trichomonas vaginalis		*Candida albicans*		*Gardnerella vaginalis*	
VIASURE *C. albicans, G. vaginalis & T. vaginalis* Real Time PCR Detection Kit		+	-	+	-	+	-
	+	46	0	69	10	164	20
	-	0	194	0	161	13	43