

Recommendation for Single Use Devices for Point-of Care Chlamydia Tests

National Chlamydia Laboratory Committee National Infertility Prevention Project (IPP)

Since peer reviewed journal articles with the relative sensitivity and specificity of single use device Point-of-Care chlamydia test systems are not widely available, the true sensitivity and specificity of these products appears to be unclear. Results of limited published studies have shown that these tests have significantly lower sensitivities than standard non-amplified chlamydia screening assays. Therefore, it is recommended that any use of these tests be approved by each regional advisory committee if used in the National Infertility Prevention Project.

1. Single use Point-of-Care Chlamydia Tests currently cleared by the FDA are:

	<i>Package Insert</i>		<i>Adjusted Sensitivity*</i>
Clearview (Inverness)	Sensitivity	87.0%	73.9%
	Specificity	98.8%	
Quidel QuickVue	Sensitivity	92.0%	78.2%
	Specificity	98.6%	

- * **Sensitivity and Specificity of each rapid test is based on company’s package insert literature.** Sensitivity and specificity values for these test devices are based on comparison with tissue culture, which has a sensitivity of approximately 50 to 85%. Therefore, these test devices have a sensitivity that is at best about 85% of the values stated in these test kits.
2. Point-of-Care chlamydia test systems are classified as “Non-waived.” Sites where testing is performed must be CLIA approved, participate in an approved PT program and demonstrate satisfactory performance, and meet all other CLIA regulations for performance of non-waived tests or state lab law/regulations. Point-of-care tests do not allow for grey zone testing or confirmation of positives on site.
 3. When Point-of-Care tests are used for chlamydia testing they should only be used while the patient is present for treatment and/or follow-up. If the results of testing will not be available until after the patient has left the clinic, rapid point-of-care tests are not recommended. Settings in which the use of these tests may be appropriate are:
 - a) Homeless clients,
 - b) Criminal intake facilities where individuals are released within a few hours after detention.
 - c) Clients or patients with high-risk sexual behavior who are highly unlikely to return.
 - d) Special regional evaluations, projects and/or studies.