

ResistancePlus[®] GC

N. gonorrhoeae + ciprofloxacin susceptibility

Smarter Diagnostics. Simplified Patient Care.



Up to 70% of gonorrhoea infections could be treated with ciprofloxacin, a simple oral antibiotic.¹⁻⁴

- ▶ Guidelines for gonococcal infection (GC) management call to preserve ceftriaxone and recommend use of ciprofloxacin when susceptibility information is available.^{5,6}
- ▶ Azithromycin resistance is rising, compromising dual-therapy options.^{5,7,8}
- ▶ Ciprofloxacin has higher efficacy for pharyngeal infections, a site where ceftriaxone is less effective.^{9,10}

ResistancePlus[®] GC is a multiplex qPCR test for detection of *Neisseria gonorrhoeae* and *gyrA* markers linked to ciprofloxacin susceptibility.¹¹⁻¹³ Dual *N. gonorrhoeae* targets improve clinical specificity, while ciprofloxacin resistance and susceptibility targets are included for additional confidence. **ResistancePlus**[®] GC is validated for a range of specimen types¹⁴ and powered by proprietary **PlexPCR**[®] technologies demonstrating improved multiplex performance compared with other probe-based tests.¹⁵

Single-well **PlexPCR**[®] test

Channel	Target
1	<i>N. gonorrhoeae</i> (<i>opa</i>)
2	<i>N. gonorrhoeae</i> (<i>porA</i>)
3	<i>gyrA</i> S91F mutation
4	<i>gyrA</i> S91 wild type
5	Internal Control

Demonstrated clinical performance¹⁴

	GC Detection	<i>gyrA</i> Detection
Sensitivity	96.9%	100%
Specificity	99.7%	98.6%

Validated for urine, swabs (anal, rectal, cervical, vaginal, urethral, pharyngeal, eye) and extracts.¹⁴

- ▶ A unique triple target, single-well test solution, ideal for confirming GC positives or for upfront testing with simultaneous resistance status.
- ▶ Genotype confirmation to inform ciprofloxacin susceptibility as an alternative treatment pathway.
- ▶ Easily obtain resistance/susceptibility data on difficult to culture specimen types.
- ▶ Positive, negative, and amplification control materials available.

SpeedX Analysis for **ResistancePlus**[®] GC

Improve laboratory productivity with a validated software solution for automated result calling and simple data processing. Streamlined workflow to support rapid, routine diagnostics with audit trails and user traceability. Included in contract pricing and installed on a high security and GDPR compliant platform, with LIS compatibility.

Product	Compatible	Size	Cat#
ResistancePlus [®] GC*	LC480 II	100 reactions	2011001
		25 reactions	2011025
	ABI 7500/ 7500 Fast/Dx	100 reactions	2013001
		25 reactions	2013025
	CFX96 IVD/ CFX96 Touch	100 reactions	2015001
		25 reactions	2015025
ResistancePlus [®] GC Control	All platforms	10 reactions	95003
PlexPCR [®] Amplification Control	All platforms	400 reactions	90002

References: 1. Harris SR et al. Lancet Infect Dis Published online May 15th 2018. 2. Lahra MM et al. Australian Gonococcal Surveillance Programme annual report, 2015 3. Heffernan H et al. Antimicrobial resistance and molecular epidemiology of gonococci in NZ, 2014-5 4. Kirkcaldy RD et al. MMWR Surveillance Summaries July 15, 2016 / 65(7):1-19 5. Fifer H. et al. 2018 UK national guideline for the management of infection with *Neisseria gonorrhoeae* (Draft). 6. Bignell C & Unemo M. 2012 European Guideline on the Diagnosis and Treatment of Gonorrhoea in Adults. 7. Wi T et al. PLoS Med 2017;14(7). 8. Bolt H et al. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/567602/GRASP_Report_2016.pdf 9. Lewis DA. Sex Transm Infect 2015;91:234-237. 10. Whittles LK et al. Lancet Infect Dis. 2018 Jul;18(7):716-717. 11. Allan-Blitz LT et al. Sex Transm Dis. 2017 May;44(5):261-265. 12. Trembicki E et al. Lancet Infect Dis. 2016 Sep;16(9):1005-1006. 13. Allan-Blitz LT et al. Clin Infect Dis. 2017 May 1;64(9):1268-1270. 14. **ResistancePlus**[®] GC Instructions for use 15. Tan LY et al, PLOS ONE. 2017; 12(1): e0170087.

*TGA cleared, not for sale in USA. **ResistancePlus**[®] GC kits are developed and manufactured by **SpeedX** Pty Ltd, Sydney. **PlexPCR**[®] & **ResistancePlus**[®] are trademarks of **SpeedX** Pty Ltd. Other copyright and trademarks are the property of the respective owners. **SpeedX** Pty Ltd products may be covered by one or more local or foreign patents. Visit www.plexpcr.com/patents for comprehensive patent information.

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