

CARB-X Priority Product Requirements for a *Neisseria gonorrhoeae* (Ng) focused diagnostic

Variable	Minimal Requirement	Ideal Requirement
Intended use	Confirm at least Ng (other high priority STI pathogens are a bonus)	Confirm at least Ng and determine antibiotic susceptibility (AST) or antimicrobial resistance (AMR)
Sample type/collection	Vaginal swab (women) and urethral swab or urine (men) on the same test	Also, rectal and pharyngeal samples on the same test
Species differentiation	Detect geographically and genetically diverse Ng; no cross reactivity to closely related <i>Neisseria</i> and other genital commensals	
Diag./clin. sensitivity	≥ 90%	≥ 98%
Diag./clin. specificity	≥ 90%	≥ 98%
Time to result	<60 minutes	<30 minutes

- **Additional details:**
- Technology compatible with both male and female sample types on the same test will be prioritized
- Technology targeting all levels of the health system will be considered
- Technology solutions for LMIC or HIC settings will be considered
- *ID+AST/AMR:*
 - Particular interest in phenotypic AST solutions, but AMR gene detection solutions are also acceptable
 - Combination products are preferred (ID+AMR/AST)
 - AST/AMR only proposals will be considered for technologies with existing pathogen ID capabilities for at least Ng
- Preference for leveraging existing technology platforms that have demonstrated commercial success
- Note to developers: a CARB-X Portfolio Acceleration Tool to provide to access clinical samples for regulatory studies is under consideration