

Product Information

Product Name:	ResistancePlus[®] GC Control
Catalogue Number:	95003
Product Description:	Contains positive and negative control samples. The positive control consists of synthetic DNA for <i>Neisseria gonorrhoeae</i> porA, opa, and gyrA S91 wildtype or gyrA S91F mutant targets. The negative control consists of a negative sample matrix.
Lot Number:	23010007
Manufacture Date:	2023/02/07
Expiry Date:	2024/09/20
Storage Conditions:	-15°C to -25°C

Test method:

ResistancePlus[®] GC Control components were tested with the GC+gyrA Mix from the **ResistancePlus[®] GC₍₆₁₀₎** product and using the LightCycler[®] 480 II instrument with thermal cycling conditions stated in the IFU. The amplifications data was analysed using the **ResistancePlus[®] GC (LC480)** software.

Results:

Test Samples	Specification	Result
	Software Interpretation	
GC, gyrA S91 wild type	N. gonorrhoeae detected, gyrA mutation not detected.	PASS
GC, gyrA S91F mutant	N. gonorrhoeae detected, gyrA mutation detected.	PASS
Negative Control	Negative control valid.	PASS

The Finished products were tested according to standard Quality Control methods. The results were verified against the design specifications, acceptance criteria and reviewed and approved by the Quality Department.

Quality Assurance Signature and Date:

QA Approval	 <u>Lopeti Lavulo (Feb 8, 2023 22:43 CST)</u>
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