

K190275 GenePOC CarbaMay 10, 2019
91 days to decisionK190275 · Product code: **PMY** · Microbiology
Source: <https://www.510kdatabase.net/k190275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid Amplification Test, Dna, Carbapenem Non-susceptible Gram Negative Organism, Colony (PMY)
Date received	Feb 8, 2019
Decision date	May 10, 2019
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genepoc, Inc.
Location	Quebec, CA
Contact	Dany Leblanc
510(k) history	5 submissions · 5 cleared · 2017-2019

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