

K191889 NG-Test CARBA 5Oct 2, 2019
79 days to decisionK191889 · Product code: **PTJ** · Microbiology
Source: <https://www.510kdatabase.net/k191889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Phenotypic Test Kit, Non-susceptible/elevated Mic Organisms, Cultured Isolates (PTJ)
Date received	Jul 15, 2019
Decision date	Oct 2, 2019
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ng Biotech
Location	Guipry, FR
Contact	Milovan Stankov-Puges
Website	https://www.ngbiotech.com/
510(k) history	2 submissions · 2 cleared · 2019-2025

Ng Biotech develops and manufactures rapid diagnostic tests for infectious disease detection. Founded in 2012 by pioneers in the rapid test industry, the company operates from Guipry, France with two 5,000 m² industrial facilities. The company specializes in point-of-care diagnostics using a proprietary immunoassay platform, delivering results in minutes from minimal sample volumes. Ng Biotech has received FDA 510(k) clearances from total submissions since 2019. The company's regulatory portfolio focuses exclusively on Microbiology devices, with recent cleared products ta...