

**K152679 Amplichek I, Negative , Amplichek I, Level 1,
Amplichek I, Level 2, Amplichek I, Level 3, Amplichek I, MiniPak**May 10, 2016
235 days to decisionK152679 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k152679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	Sep 18, 2015
Decision date	May 10, 2016
Days to decision	235 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories
Location	Hauts-De-Seine, FR
Contact	ELIZABETH PLATT
Website	http://www.bio-rad.com
510(k) history	46 submissions · 45 cleared · 2007-2019

Bio-Rad Laboratories is an American biotechnology firm founded in 1952 in Berkeley, California. The company develops and manufactures specialized products for life science research and clinical diagnostics, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 2007 and 2019. The company's cleared devices span chemistry devices, microbiology, and immunology categories, with notable focus on diagnostic control materials and multiplex immunoassay systems. This regulatory record reflects the company's historical activity in the c...

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