

**K053289 COBAS AMPLICOR CT/NG TEST FOR NEISSERIA
GONORRHOEAE**Aug 10, 2006
258 days to decisionK053289 · Product code: **LSL** · Microbiology
Source: <https://www.510kdatabase.net/k053289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Nov 25, 2005
Decision date	Aug 10, 2006
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	THERESA M AMBROSE
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053289/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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