

K042485 TINA-QUANT CRP (LATEX) HS TEST SYSTEM (C-REACTIVE PROTEIN (LATEX) HIGH SENSITIVE)Oct 29, 2004
46 days to decisionK042485 · Product code: **NQD** · Chemistry
Source: <https://www.510kdatabase.net/k042485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cardiac C-reactive Protein, Antigen, Antiserum, And Control (NQD)
Date received	Sep 13, 2004
Decision date	Oct 29, 2004
Days to decision	46 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/k042485/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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