

K040431 ROCHE DIAGNOSTICS TINA-QUANT IGM GEN.2Mar 10, 2004
20 days to decisionK040431 · Product code: **DAO** · Immunology
Source: <https://www.510kdatabase.net/k040431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Igm (mu Chain Specific), Antigen, Antiserum, Control (DAO)
Date received	Feb 19, 2004
Decision date	Mar 10, 2004
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040431/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026