

K241220 Tina-quant Lipoprotein(a) Gen.2 MolarityJan 24, 2025
268 days to decisionK241220 · Product code: **DFC** · Chemistry
Source: <https://www.510kdatabase.net/k241220/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	May 1, 2024
Decision date	Jan 24, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations
Location	Indianapolis, IN, US
Contact	Leslie Patterson
510(k) history	5 submissions · 5 cleared · 2012-2025

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