

**K942458 PRECISION-MULTI-SERA - HUMAN - NORMAL AND ELEVATED**Mar 13, 1995  
293 days to decisionK942458 · Product code: JJY · Chemistry  
Source: <https://www.510kdatabase.net/k942458/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	May 24, 1994
Decision date	Mar 13, 1995
Days to decision	293 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Randox Laboratories, Ltd.</b>
Location	Antrim, N. Ireland, IR
Contact	John Lamont
Website	<a href="http://www.randox.com/">http://www.randox.com/</a>
510(k) history	116 submissions · 115 cleared · 1992-2025

Randox Laboratories, Ltd. is a global diagnostic company specializing in chemistry devices and laboratory solutions. The company operates with a manufacturing facility in Antrim, Northern Ireland, and has over 40 years of expertise in diagnostic innovation. Randox has received FDA 510(k) clearances from total submissions since its first clearance in 1992. The company's regulatory portfolio is dominated by chemistry devices, including clinical chemistry analyzers, reagents, controls, and electrodes. The latest clearance on record dates to 2023. Recent FDA 510(k) cleared de...

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Device record: <https://www.510kdatabase.net/k942458/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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