

**K955797 IGM IMMUNOTRUBIDIMETRIC & CALIBRATOR**Apr 5, 1996  
105 days to decisionK955797 · Product code: **DFT** · Immunology  
Source: <https://www.510kdatabase.net/k955797/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igm, Antigen, Antiserum, Control (DFT)
Date received	Dec 22, 1995
Decision date	Apr 5, 1996
Days to decision	105 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	JULIE TAYLOR
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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