

**K092273 RANDOX ETHANOL ASSAY**Nov 1, 2010  
461 days to decisionK092273 · Product code: **DIC** · Toxicology  
Source: <https://www.510kdatabase.net/k092273/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method (DIC)
Date received	Jul 28, 2009
Decision date	Nov 1, 2010
Days to decision	461 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Randox Laboratories, Ltd.</b>
Location	Antrim, N. Ireland, IR
Contact	P. ARMSTRONG
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...