

**K140522 RANDOX IMMUNOASSAY PREMIUM PLUS CONTROL LEVELS 1,2 AND LEVEL 3 AND IMMUNOASSAY PREMIUM PLUS TRI-LEVEL CONTROL**May 22, 2014  
79 days to decisionK140522 · Product code: **JJY** · Chemistry  
Source: <https://www.510kdatabase.net/k140522/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Mar 4, 2014
Decision date	May 22, 2014
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radox Laboratories Limited</b>
Location	Crumlin, GB
Contact	PAULINE ARMSTRONG
510(k) history	18 submissions · 18 cleared · 2004-2026

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