

**K042389 MODIFICATION TO PRECINORM UNIVERSAL PLUS  
AND PRECIPATH UNIVERSAL PLUS CONTROL SERA**Sep 14, 2004  
12 days to decisionK042389 · Product code: JJY · Chemistry  
Source: <https://www.510kdatabase.net/k042389/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Sep 2, 2004
Decision date	Sep 14, 2004
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	THERESA M AMBROSE
510(k) history	264 submissions · 263 cleared · 1999-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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