

**K041227 MODIFICATION TO: ROCHE DIAGNOSTICS  
PRECINORM UNIVERSAL AND PRECIPATH UNIVERSAL  
CONTROL SERA**May 27, 2004  
17 days to decisionK041227 · Product code: **JJY** · Chemistry  
Source: <https://www.510kdatabase.net/k041227/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	May 10, 2004
Decision date	May 27, 2004
Days to decision	17 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/k041227/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 9, 2026