

**K043095 ROCHE DIAGNOSTICS ELECSYS AFP CALSET II**Nov 23, 2004  
14 days to decisionK043095 · Product code: **JIT** · Immunology  
Source: <https://www.510kdatabase.net/k043095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	Nov 9, 2004
Decision date	Nov 23, 2004
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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