

**K992801 SIGMA DIAGNOSTICS INFINITY ASTBUN REAGENT,  
MODEL 51-25, SIGMA DIAGNOSTICS INFINITY AST REAGENT,  
MODELS 51-100P,51-500P,5**Sep 28, 1999  
40 days to decisionK992801 · Product code: **CIT** · Chemistry  
Source: <https://www.510kdatabase.net/k992801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Ast/sgot (CIT)
Date received	Aug 19, 1999
Decision date	Sep 28, 1999
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992801/> 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 May 14, 2026