

**K935307 DADE(R) THROMBIN-ANTITHROMBIN (TAT) COMPLEX
ELISA**Nov 22, 1994
385 days to decisionK935307 · Product code: **DDQ** · Hematology
Source: <https://www.510kdatabase.net/k935307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Antiserum, Control, Antithrombin Iii (DDQ)
Date received	Nov 2, 1993
Decision date	Nov 22, 1994
Days to decision	385 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Diagnostics, Inc.
Location	Miami, FL, US
Contact	RADAMES RIESGO
Website	https://www.baxter.com/
510(k) history	72 submissions · 72 cleared · 1988-1995

Baxter Diagnostics, Inc. is a diagnostic device manufacturer based in Miami, US. The company specialized in microbiology and chemistry diagnostic solutions. Baxter Diagnostics received FDA 510(k) clearances from total submissions between 1988 and 1995. The company's regulatory focus centered on microbiology devices, particularly dried antimicrobial susceptibility testing panels and related diagnostic assays. This historical record reflects the company's core expertise in microbial identification and resistance testing. The company is no longer active in FDA 510(k) submiss...

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Device record: <https://www.510kdatabase.net/k935307/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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