

K193604 Aptiva Celiac Disease IgA ReagentJun 16, 2021
541 days to decisionK193604 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k193604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Dec 23, 2019
Decision date	Jun 16, 2021
Days to decision	541 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inova Diagnostics, Inc.
Location	San Diego, CA, US
Contact	Andrea Seaman
Website	https://www.inovadx.com
510(k) history	138 submissions · 136 cleared · 1988-2026

Siemens Healthcare Diagnostics, Inc. is a leading diagnostic device manufacturer based in New York. The company specializes in laboratory diagnostics and clinical chemistry solutions. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. Chemistry devices and immunology assays represent the core focus of its regulatory portfolio. The latest FDA 510(k) clearance in 2026 reflects continued active development and market engagement. Recent cleared devices include automated chemistry analyzers, immunoassay systems, and special...

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Device record: <https://www.510kdatabase.net/k193604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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