

K254059 Access anti-HBc IgMMar 13, 2026
86 days to decisionK254059 · Product code: **SEI** · Microbiology
Source: <https://www.510kdatabase.net/k254059/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Qualitative And Quantitative Hepatitis B Virus Antibody Assays (SEI)
Date received	Dec 17, 2025
Decision date	Mar 13, 2026
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	Veronica Colinayo
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...

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Device record: <https://www.510kdatabase.net/k254059/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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