

**K063329 ABBOTT ARCHITECT HAVAB-M**Apr 16, 2007  
164 days to decisionK063329 · Product code: **LOL** · Microbiology  
Source: <https://www.510kdatabase.net/k063329/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Hepatitis A Test (antibody And Igm Antibody) (LOL)
Date received	Nov 3, 2006
Decision date	Apr 16, 2007
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
Contact	JOSEPH C ORLOWSKI
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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