

**K060678 VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HAV
TOTAL REAGENT PACK,CALIBRATOR,CONTROLS**Sep 14, 2006
184 days to decisionK060678 · Product code: **LOL** · Microbiology
Source: <https://www.510kdatabase.net/k060678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hepatitis A Test (antibody And Igm Antibody) (LOL)
Date received	Mar 14, 2006
Decision date	Sep 14, 2006
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	SARAH PARSONS
510(k) history	106 submissions · 104 cleared · 1997-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k060678/>; Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026