

**K113262 ACE CHOLESTEROL REAGENT, ACE HDL-C REAGENT, ACE LDL-C REAGENT-C, ACE-TRISLYCERIDES REAGENT**Jul 3, 2012  
242 days to decisionK113262 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k113262/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Nov 4, 2011
Decision date	Jul 3, 2012
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alfa Wassermann Diagnostic Technologies, Inc.</b>
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ
510(k) history	21 submissions · 21 cleared · 2008-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113262/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 8, 2026