

**K113438 ACE DIRECT TOTALIRON-BINDING CAPACITY (TIBC)  
REAGENT, ACE SERUM IRON REAGENT, ACE LIPASE  
REAGENT**Jun 1, 2012  
193 days to decisionK113438 · Product code: **JMO** · Chemistry  
Source: <https://www.510kdatabase.net/k113438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ferrozine (colorimetric) Iron Binding Capacity (JMO)
Date received	Nov 21, 2011
Decision date	Jun 1, 2012
Days to decision	193 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/k113438/> 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