

**K131975 ACE DIRECT TOTAL IRON-BINDING CAPACITY (TIBC)  
REAGENT, ACE TOTAL IRON REAGENT, ACE LDH-L REAGENT**Oct 2, 2013  
96 days to decisionK131975 · Product code: **CFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k131975/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Lactate Dehydrogenase (CFJ)
Date received	Jun 28, 2013
Decision date	Oct 2, 2013
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131975/> 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 8, 2026