

K123953 ACE CARBON DIOXIDE REAGENT, ACE DIRECT BILIUBIN REAGENT, ACE TOTAL BILIRUBIN REAGENT, ACE MAGNESIUM REAGENTMay 2, 2013
132 days to decisionK123953 · Product code: **KHS** · Chemistry
Source: <https://www.510kdatabase.net/k123953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic, Carbon-dioxide (KHS)
Date received	Dec 21, 2012
Decision date	May 2, 2013
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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