

**K123322 ACE BUN/UREA REAGENT, ACE CREATININE REAGENT, ACE URIC ACID REAGENT, ACE CK REAGENT**May 21, 2013  
207 days to decisionK123322 · Product code: **CDN** · Chemistry  
Source: <https://www.510kdatabase.net/k123322/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease, Photometric, Urea Nitrogen (CDN)
Date received	Oct 26, 2012
Decision date	May 21, 2013
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alfa Wassermann Diagnostics Technologies, LLC</b>
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ PH.D.
510(k) history	3 submissions · 3 cleared · 2012-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123322/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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