

**K073309 ABX PENTRA HBA1C WB, CALIBRATOR, CONTROL  
AND HEMOLYSIS REAGENT**Oct 17, 2008  
329 days to decisionK073309 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k073309/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Nov 23, 2007
Decision date	Oct 17, 2008
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Horiba Abx</b>
Location	Montpellier, FR
Contact	OLIVIER DUCAMP
510(k) history	19 submissions · 19 cleared · 2005-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073309/>; 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 24, 2026