

**K080618 DIRECT HBA1C, FRUCTOSAMINE, GLUCOSE  
OXIDASE LIQUID**May 23, 2008  
79 days to decisionK080618 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k080618/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 5, 2008
Decision date	May 23, 2008
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Jas Diagnostics, Inc.</b>
Location	Miami, FL, US
Contact	SAMUEL BURGOS
510(k) history	20 submissions · 20 cleared · 2000-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080618/>; 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 6, 2026