

K100304 ST AIA PACK HBA1CAug 27, 2010
205 days to decisionK100304 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k100304/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Assay, Glycosylated Hemoglobin (LCP) |
| Date received | Feb 3, 2010 |
| Decision date | Aug 27, 2010 |
| Days to decision | 205 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Tosoh Bioscience, Inc. |
| Location | Grove City, OH, US |
| Contact | Judith Ogden |
| 510(k) history | 20 submissions · 20 cleared · 2007-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100304/> 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 20, 2026