

K133002 i-STAT Total beta-hCG Test, i-STAT Total beta-hCG Controls, i-STAT Total beta-hCG Calibration Verification MaterialsApr 16, 2015
569 days to decisionK133002 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k133002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Sep 24, 2013
Decision date	Apr 16, 2015
Days to decision	569 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Point of Care, Inc.
Location	Princeton, NJ, US
Contact	MELISSA ROBINSON
510(k) history	19 submissions · 19 cleared · 2011-2025

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