

**K121397 OSOM IFOB 25 TEST AND PATIENT COLLECTION KIT
OSOM IFOB CONTROL KIT OSOM IFOB 50 TEST KIT**Dec 28, 2012
233 days to decisionK121397 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k121397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	May 9, 2012
Decision date	Dec 28, 2012
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	SEKISUI Diagnostics, LLC
Location	San Diego, CA, US
Contact	MARK STAVRO
Website	https://www.sekisuidiagnostics.com
510(k) history	6 submissions · 6 cleared · 2012-2025

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