

**K042676 NICHOLS ADVANTAGE HYPERGLYCOSYLATED
HUMAN CHORIONIC GONADOTROPIN (H-HCG) ASSAY**Dec 17, 2004
79 days to decisionK042676 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k042676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Sep 29, 2004
Decision date	Dec 17, 2004
Days to decision	79 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Nichols Institute Diagnostics
Location	Mchenry, IL, US
Contact	XIE QIYL
510(k) history	68 submissions · 68 cleared · 1977-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042676/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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