

K091413 S-TEST CHOLESTEROL (CHO), MODEL RC0009, S-TEST HDL CHOLESTEROL (HDL), MODEL RC0015, S-TEST TRIGLYCERIDES (TG)Oct 26, 2009
166 days to decisionK091413 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k091413/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzymatic Esterase--oxidase, Cholesterol (CHH) |
| Date received | May 13, 2009 |
| Decision date | Oct 26, 2009 |
| Days to decision | 166 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Alfa Wassermann, Inc. |
| Location | West Caldwell, NJ, US |
| Contact | HYMAN KATZ |
| 510(k) history | 5 submissions · 5 cleared · 2007-2009 |

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