

**K924257 TESTOSTERONE SEROZYME(TM) ENZYME  
IMMUNOASSAY**Nov 30, 1992  
98 days to decisionK924257 · Product code: **CDZ** · Chemistry  
Source: <https://www.510kdatabase.net/k924257/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Aug 24, 1992
Decision date	Nov 30, 1992
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Serono-Baker Diagnostics, Inc.</b>
Location	Winchester, VA, US
Contact	DAVID B THOMAS
510(k) history	23 submissions · 23 cleared · 1988-1992

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k924257/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 29, 2026