

**K841319 ROTALEX LATEX AGGLUTINATION TEST**Sep 14, 1984  
165 days to decisionK841319 · Product code: **LIQ** · Microbiology  
Source: <https://www.510kdatabase.net/k841319/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rotavirus (LIQ)
Date received	Apr 2, 1984
Decision date	Sep 14, 1984
Days to decision	165 days
Third-party review	No

**APPLICANT**

---

Company	<b>Orion Diagnostica, Inc.</b>
Location	Mchenry, IL, US
510(k) history	28 submissions · 28 cleared · 1980-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k841319/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026