

**K161954 Atellica Solution, Atellica A-LYTE Integrated Multisensor Na<sup>+</sup>/K<sup>+</sup>/Cl<sup>-</sup>, Atellica CH Albumin BCP Reagent (Alb\_p), Atellica IM Thyroid Stimulating Hormone TSH, Atellica CH Vancomycin (Vanc)**Mar 9, 2017  
234 days to decisionK161954 · Product code: **JGS** · Chemistry  
Source: <https://www.510kdatabase.net/k161954/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	Jul 18, 2016
Decision date	Mar 9, 2017
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Siemens Healthcare Diagnostics</b>
Location	Newark, DE, US
Contact	Justin DiValentino
510(k) history	92 submissions · 92 cleared · 2008-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161954/> 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 May 13, 2026