

**K260342 AllTest Strep A Rapid Test**Apr 30, 2026  
87 days to decisionK260342 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k260342/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Feb 2, 2026
Decision date	Apr 30, 2026
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou AllTest Biotech Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Rosa Wu
510(k) history	14 submissions · 14 cleared · 2019-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>LSI International, Inc.</b>
Contact	Jenny Xia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260342/> 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 May 13, 2026