

K252607 AllTest Urinary Tract Infection TestOct 30, 2025
73 days to decisionK252607 · Product code: **JMT** · Chemistry
Source: <https://www.510kdatabase.net/k252607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo (colorimetric), Nitrite (urinary, Non-quant) (JMT)
Date received	Aug 18, 2025
Decision date	Oct 30, 2025
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
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)

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