

K254121 Colli-Pee•Dx Urine Collection KitJun 10, 2026
173 days to decisionK254121 · Product code: **SIH** · Microbiology
Source: <https://www.510kdatabase.net/k254121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Dec 19, 2025
Decision date	Jun 10, 2026
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DNA Genotek, Inc.
Location	Ottawa Ontario, CA
Contact	Jonathan Chan
510(k) history	8 submissions · 7 cleared · 2011-2026

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