

**K233454 ONLINE TDM Methotrexate**Feb 20, 2024  
123 days to decisionK233454 · Product code: **LAO** · Toxicology  
Source: <https://www.510kdatabase.net/k233454/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methotrexate (LAO)
Date received	Oct 20, 2023
Decision date	Feb 20, 2024
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Operations</b>
Location	Indianapolis, IN, US
Contact	Elina Voronovsky
510(k) history	5 submissions · 5 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233454/> 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 14, 2026