

**K111904 ARK METHOTREXATE ASSAY, ARK METHOTREXATE CALIBRATOR, ARK METHOTREXATE CONTROL, ARK METHOTREXATE CONTROL (CALIBRATION RAN**Oct 18, 2011  
105 days to decisionK111904 · Product code: **LAO** · Toxicology  
Source: <https://www.510kdatabase.net/k111904/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methotrexate (LAO)
Date received	Jul 5, 2011
Decision date	Oct 18, 2011
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ARK Diagnostics, Inc.</b>
Location	Sunnyvale, CA, US
Contact	KENNETH C KASPER
510(k) history	17 submissions · 16 cleared · 2009-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111904/>; 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 26, 2026