

**K130189 XTAG CYP2D6 KIT V3 (INCLUDING TDAS CYP2D6 SOFTWARE)**May 21, 2013  
116 days to decisionK130189 · Product code: **NTI** · Chemistry  
Source: <https://www.510kdatabase.net/k130189/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Metabolizing Enzyme Genotyping Systems (NTI)
Date received	Jan 25, 2013
Decision date	May 21, 2013
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Luminex Molecular Diagnostics, Inc.</b>
Location	Toronto, Ontario, CA
Contact	LUBNA SYED
510(k) history	26 submissions · 22 cleared · 2008-2024

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