

**K100015 VYSIS CLL FISH PROBE KIT (VYSIS LSI TP53 SPECTRUMORANGE/ATM SPECTRUMGREEN) AND LSI D135319 SPECTRUMORANGE/13Q34**Aug 9, 2011  
582 days to decisionK100015 · Product code: **OVQ** · Pathology  
Source: <https://www.510kdatabase.net/k100015/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chronic Lymphocytic Leukemia Fish Probe Kit (OVQ)
Date received	Jan 4, 2010
Decision date	Aug 9, 2011
Days to decision	582 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Molecular, Inc.</b>
Location	Des Plaines, IL, US
Contact	PAMELA L SWATKOWSKI
510(k) history	17 submissions · 16 cleared · 2008-2025

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