

**K141458 SIMPLEXA HSV 1&2 DIRECT/POSITIVE CONTROL PACK**

Jul 1, 2014  
29 days to decision

K141458 · Product code: **PGH** · Microbiology  
Source: <https://www.510kdatabase.net/k141458/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hsv-1 And Hsv-2 Cns Nucleic-acid Based Panel (PGH)
Date received	Jun 2, 2014
Decision date	Jul 1, 2014
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Focus Diagnostics</b>
Location	Cypress, CA, US
Contact	SHARON YOUNG
510(k) history	4 submissions · 3 cleared · 2014-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k141458/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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