

**K091859 AESKU PR3**Jun 3, 2010  
349 days to decisionK091859 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k091859/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jun 19, 2009
Decision date	Jun 3, 2010
Days to decision	349 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aesku Diagnostics</b>
Location	Miami, FL, US
Contact	SASCHA PFEIFFER
510(k) history	9 submissions · 9 cleared · 2004-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091859/> 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 June 7, 2026