

**K243935 Aptima CMV Quant Assay**Jan 17, 2025  
28 days to decisionK243935 · Product code: **PAB** · Microbiology  
Source: <https://www.510kdatabase.net/k243935/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cytomegalovirus (cmv) Dna Quantitative Assay (PAB)
Date received	Dec 20, 2024
Decision date	Jan 17, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hologic, Inc.</b>
Location	Waltham, MA, US
Contact	Maria Jose Cortes-Mateos
Website	<a href="https://www.hologic.com/">https://www.hologic.com/</a>
510(k) history	115 submissions · 111 cleared · 1987-2025

Hologic, Inc. is a medical device company headquartered in Waltham, Massachusetts. The company specializes in women's health, diagnostics, and medical imaging technologies. Hologic has maintained a strong FDA 510(k) regulatory record since its founding in 1987. The company has received FDA 510(k) clearances from total submissions. Recent cleared devices span microbiology, radiology, and obstetrics & gynecology categories. The latest clearance in 2025 demonstrates continued active development and regulatory engagement. Hologic's cleared device portfolio includes molecular ...

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

Device record: <https://www.510kdatabase.net/k243935/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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