

**K203748 SeptiCyte RAPID**Nov 29, 2021  
341 days to decisionK203748 · Product code: **PRE** · Microbiology  
Source: <https://www.510kdatabase.net/k203748/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rt-qpcr Assay For Mrna Transcript Immune Biomarkers (PRE)
Date received	Dec 23, 2020
Decision date	Nov 29, 2021
Days to decision	341 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immunexpress, Inc.</b>
Location	Seattle, WA, US
Contact	LaKesha Hunt-Dickens
510(k) history	3 submissions · 3 cleared · 2017-2023

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