

CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid's Quality System, in compliance with the US Food and Drug Administration's Quality System Requirements, ISO 13485, European IVD Directive and the Canadian Devices Regulations.

W O W O O	
Xpert® Xpress CoV-2 plus	
rt No.: XP3SARS-COV2-10	
448357	
16502	
2025-09-21	
Röntgenvägen 5	
Acceptance Criteria	Test Result
SARS-CoV-2 NEGATIVE	Passed
SARS-CoV-2 POSITIVE	Passed
ument is produced electronically and valid without a wet sign	nature.
	16502 2025-09-21 Manufacturing Facility Solna Sunnyval Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden Acceptance Criteria SARS-CoV-2 NEGATIVE

Title:

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QA Analyst