


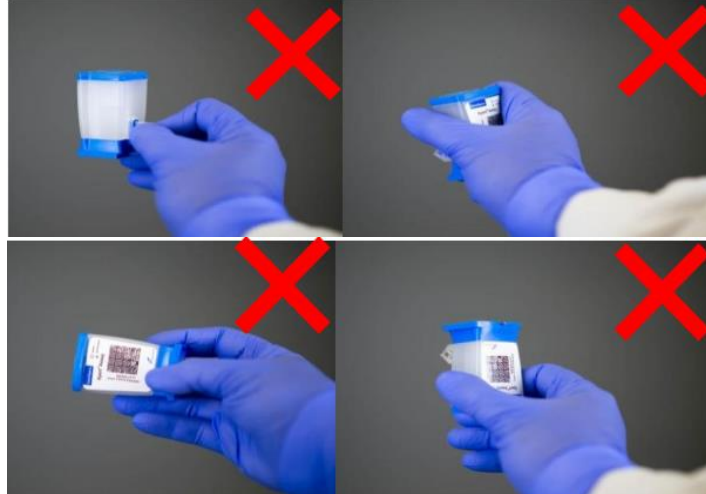


**Xpert® Xpress SARS-CoV-2 Test  
CEPHID**

**1. Introduction**






This procedure is the detection of rapid SARS-CoV-2 RTPCR test by detecting nucleic acid from SARS-CoV-2 in upper respiratory tract specimens (nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and/or nasal wash/ aspirate) run on the GeneXpert Xpress System.

**2. Proper Cartridge Handling Techniques**

Correct	Incorrect
 <ul style="list-style-type: none"><li>• Do not touch the reaction tube</li><li>• Keep the cartridge upright</li><li>• Do not tilt after sample is added</li></ul>	

**3. Cartridge preparation**

For specimen collection, please follow the nasopharyngeal swab sampling method.

<p>1 Take one Xpert cartridge for each sample.</p> 	<p>2 Rapidly invert the tube 5 times.</p> 	<p>3 Open the cartridge lid.</p> 	<p>4 Using a clean 300 µL pipette (supplied), transfer 300 µL (one draw), of the sample to the opening of the cartridge.</p> 	<p>5 Close the cartridge lid.</p> 	<p>6 Start the test within the timeframe specified in the package insert.</p>
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4. Run a Test

1 Create Test

GeneXpert



Start the test within 30 minutes after adding the sample to the cartridge

2 Scan barcode : Cartridge/ Patient and/or Sample ID



By default, do not click on Manual Entry or Cancel

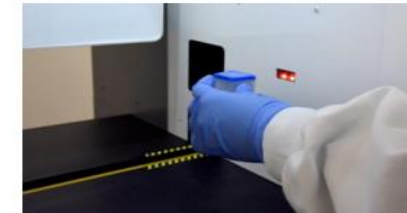
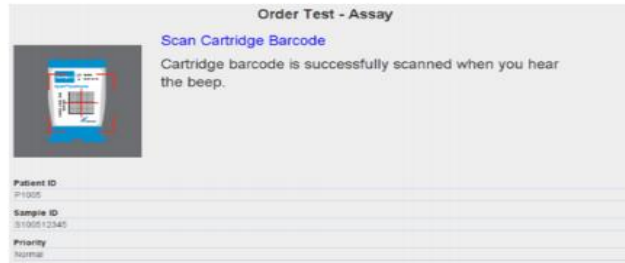
3 Scan the cartridge



GeneXpert Infinity



Place the cartridge on the conveyor within 30 minutes of adding the sample.



• Create a Test on GeneXpert® Dx Software

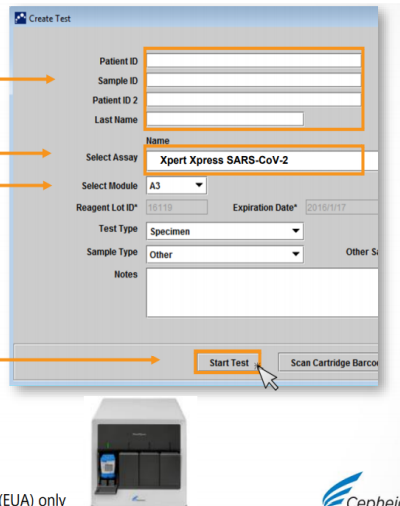
4 Complete the fields as required

5 The Assay Protocol is selected automatically

6 The module is selected automatically

7 Click on Start Test

8 A green light will flash on the module Load the cartridge into the module and close the door



For use under an Emergency Use Authorization (EUA) only



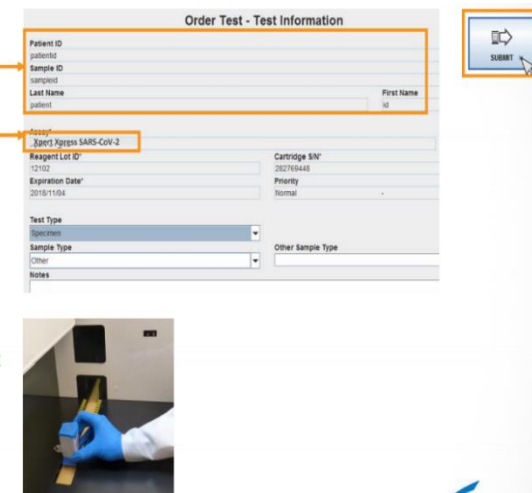
• Create a Test on Xpertise™ Software

4 Complete the fields as required

5 The Assay Name Protocol is selected automatically

6 Click on SUBMIT

7 Place the cartridge onto the conveyor belt





5. Result Summary and Interpretation

Result displayed	N2	E	SPC
<b>SARS-CoV-2 POSITIVE</b>	+	+	+/-
	+	-	
<b>SARS-CoV-2 PRESUMPTIVE POS</b>	-	+	+/-
<b>SARS-CoV-2 NEGATIVE</b>	-	-	+
<b>INVALID</b>	-	-	-
<b>ERROR</b>	NO RESULT	NO RESULT	NO RESULT
<b>No Result</b>	NO RESULT	NO RESULT	NO RESULT

**Test result SARS-CoV-2 POSITIVE**

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E	28.3	407	POS	PASS
N2	30.8	256	POS	PASS
SPC	28.3	385	NA	PASS

**Test result SARS-CoV-2 PRESUMPTIVE POS**

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E	26.3	446	POS	PASS
N2	0.0	-4	NEG	PASS
SPC	28.4	363	NA	PASS

**Test result SARS-CoV-2 NEGATIVE**

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E	0.0	3	NEG	PASS
N2	0.0	-1	NEG	PASS
SPC	28.6	329	PASS	PASS

6. References

- Assay Training: Xpert® Xpress SARS-CoV-2, Cepheid, April 2020