

Xpert® Breast Cancer STRAT4 RETEST PROCEDURE

for Indeterminate or Invalid Results — Concentrated FFPE Lysate Preparation

Refer to the package insert for detailed instructions, precautions, and warnings.

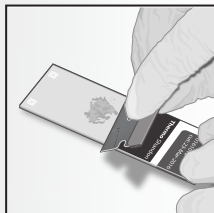
For a copy of the SDS, visit www.cepheid.com or www.cepheidinternational.com

Cepheid Technical Support
US office
(888) 838-3222, Option 2
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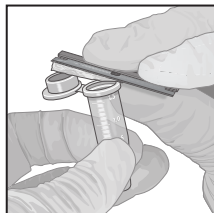
European office
+33 563 82 53 19
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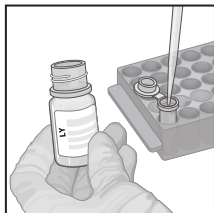
- 1 Scrape tissue section or macrodissection from slide.



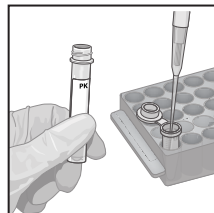
- 2 Transfer tissue to provided 1.5 mL tube.



- 3 Add 260 µL of FFPE lysis reagent to the 1.5 mL tube containing FFPE tissue.



- 4 Add 5 µL of Proteinase K (PK) to the same 1.5 mL tube. Close lid.



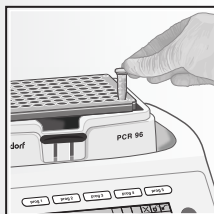
- 5 Vortex at maximum setting for 5 seconds.



- 6 Briefly microcentrifuge the tube to remove liquid from the lid.



- 7 Incubate the sample at 80 °C for 30 minutes.



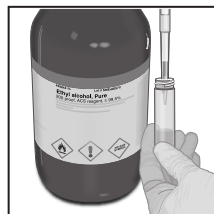
- 8 Vortex at maximum setting for 5 seconds.



- 9 Briefly microcentrifuge the tube to remove liquid from the lid.



- 10 Add 260 µL of ≥ 95% ethanol to the same 1.5 mL lysis tube.



- 11 Close lid and vortex the sample at maximum setting for 15 seconds.



- 12 Briefly microcentrifuge the tube to remove liquid from the lid.



NOTE: Prepared lysate, with ethanol, is stable at 2 to 8 °C, for up to 1 week. And at ≤ -20 °C for up to 4 weeks.

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for No Result, Repeat Test or Error Results



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- 1 Obtain one new cartridge and the retained FFPE lysate for each sample to be re-tested.



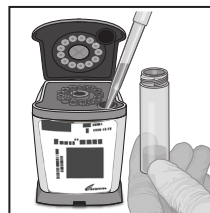
- 2 Vortex FFPE lysate for 15 seconds.



- 3 Open the Xpert cartridge lid.



- 4 Pipet 520 µl of retained lysate from the 5 mL vial and transfer into the sample chamber.



- 5 Close the Xpert cartridge lid.



- 6 Start the assay within the timeframe specified in the package insert.

