



## 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 Medical Device Regulations (CMDR).

**Product Name:** Xpert® Breast Cancer STRAT4

**Cepheid Catalogue Part No.:** GXBCSTRAT4-CE-10

**Kit Lot No.:** 1001462370

**Cartridge Lot No.:** 22201

**Kit Expiration Date:** 2026-08-09

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

**Manufacturing Facility**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA



Solna



Sunnyvale



Lodi

**Functional Testing according to D23611 Rev. J.2**

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
IVTRNA NEGATIVE	ESR1 NEGATIVE;PGR NEGATIVE;ERBB2 NEGATIVE;MKi67 NEGATIVE	Passed
IVTRNA LOW POSITIVE	ESR1 POSITIVE;PGR POSITIVE;ERBB2 POSITIVE;MKi67 POSITIVE ESR1 POSITIVE;PGR POSITIVE;ERBB2 NEGATIVE;MKi67 POSITIVE	Passed
IVTRNA HIGH POSITIVE	ESR1 POSITIVE;PGR POSITIVE;ERBB2 POSITIVE;MKi67 POSITIVE	Passed
FFPE cell line	ESR1 NEGATIVE;PGR POSITIVE;ERBB2 POSITIVE;MKi67 NEGATIVE ESR1 POSITIVE;PGR POSITIVE;ERBB2 POSITIVE;MKi67 NEGATIVE ESR1 NEGATIVE;PGR POSITIVE;ERBB2 POSITIVE;MKi67 POSITIVE ESR1 POSITIVE;PGR POSITIVE;ERBB2 POSITIVE;MKi67 POSITIVE	Passed

■ If checked, this document is produced electronically and therefore valid without a wet signature

Zenny Santos  
Zenny Santos (Dec 6, 2024 17:53 PST)

Dec 6, 2024

**Signature of Quality Assurance**

**Date**

Zenny Santos

**Name:**

**Title:** Quality Systems Specialist