



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.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Solna

Sunnyvale

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Functional Testing

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

Tanja Reed
Tanja Reed (Aug 22, 2024 13:46 PDT)

Aug 22, 2024

Signature of Quality Assurance

Date

Name:

Title:





1001442331

Final Audit Report

2024-08-22

Created:	2024-08-22
By:	Tanja Reed (tanja.reed@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAZBF3eXMFaooxuLJ2wthjn3psiVKS1bn

"1001442331" History

-  Document created by Tanja Reed (tanja.reed@cepheid.com)
2024-08-22 - 8:44:57 PM GMT- IP address: 45.62.187.244
-  Document emailed to Tanja Reed (tanja.reed@cepheid.com) for signature
2024-08-22 - 8:45:57 PM GMT
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Signature Date: 2024-08-22 - 8:46:07 PM GMT - Time Source: server- IP address: 45.62.187.244
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2024-08-22 - 8:46:07 PM GMT