



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.: 1000149842

Cartridge Lot No.: 20601

Kit Expiration Date: 2020-06-21

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


Signature of Quality Assurance

24 Apr 19
Date

Name: Tanja Reed

Title: Quality Systems Specialist