

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).

| Directive and the Car | nadian Medical Device Regulation | as (CMDR). | in The Child State of the Children Control State State (1997) State State (1997) | |
|---|----------------------------------|---|--|-------------|
| Product Name: Xpert | [®] vanA/vanB | | | |
| Cepheid Catalogue Par | t No.: GXVANA/B-CE-10 | | | |
| Kit Lot No.: 10001 | 59568 | | | |
| Cartridge Lot No.: 127 | 01 | | | |
| Kit Expiration Date: 20 |)20-06-14 | | | |
| Legal Manufacturer | | Manufacturing Facility | | Sunnyvale |
| Cepheid AB Röntgenvägen 5 SE-171 54 Solna | | Cepheid AB Röntgenvägen 5 SE-171 54 Solna | (Somu | Jumyvaic |
| Sweden | | Sweden | | |
| Functional Testing Test Description | 4 | Cuitani- | | T 10 1 |
| Positive | Acceptance Criteria | | | Test Result |
| | vanA Positive; vanB Positive | | | Passed |
| Negative | vanA Negative; vanB Negative | | | Passed |
| | | | | |
| Kambie | Juli 20190627 | | | |
| Signature of Quality Ass | surance Date | | | |
| Name: Kambiz Gha | deri | | | |
| Title: QA Analyst | | | | |