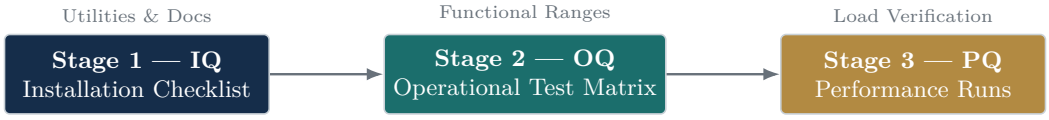
Equipment Qualification Protocol

Installation, Operational, and Performance Qualification (IQ/OQ/PQ)

Equipment: Vertex V-Max Autoclave (Model: VM-250-QS)



Equipment Information

Equipment Name: Steam Sterilization Autoclave
Manufacturer: Vertex Lab Systems
Model Number: VM-250-QS
Serial Number: V-2026-9812A
Equipment ID: EQ-ST-0045

Protocol Metadata

Protocol Number: VAL-QP-VM250-02
Version / Revision: 1.0 (Initial Release)
Sponsor: Meridian Biotech LLC
Testing Site: Suite 3B, Nimbus City Facility
Regulatory Basis: FDA 21 CFR Part 11 [3]; ISPE [2]

1 Protocol Approvals (Pre-Execution)

The signatures below indicate that this qualification protocol has been reviewed, its objectives and methodology are understood, and it is approved for execution.

Role	Name	Signature	Date
Prepared By	Priya Patel, Lead Validation Engineer	_____	2026-08-01
Reviewed By	Dr. Raymond Vance, Engineering Lead	_____	2026-08-02
Approved By (QA)	Marcus Webb, Director of Quality	_____	2026-08-04

2 Document Revision History

Rev	Date	Description of Change	Prepared By
0.1	2026-07-15	Draft generated for internal engineering review	P. Patel
1.0	2026-08-04	Initial release incorporating QA feedback and signatures	P. Patel

3 Installation Qualification (IQ)

The Installation Qualification phase verifies that the Vertex V-Max Autoclave (Model: VM-250-QS) is received and installed according to Vertex Lab Systems design specifications and local facility regulations.

3.1 Equipment Components Verification

Verify that all key hardware components are present and match specifications.

Item	Description	Specified Component	Observed	Status
1	Sterilization Chamber	250 L, Grade 316L Stainless Steel	Double-door chamber	✔ PASS
2	Steam Generator	Internal 18 kW Electric Generator	Vertex Model SG-18	✔ PASS
3	Vacuum System	Liquid ring vacuum pump	Synapse V-Pump P-120	✔ PASS
4	Controller PLC	Nexa Logic controller	Model NL-9000	✔ PASS
5	Chart Recorder	6-channel paperless recorder	Apex Rec-06	✔ PASS

3.2 Utility Connections and Environmental Verification

Verify that the utilities and environmental conditions meet the requirements outlined in the manufacturer's installation manual.

Utility	Specified Requirement	Measured Value	Instrument ID	Status
Electrical Supply	400 VAC, 3-phase, 50 Hz, 32 A	401.5 VAC, 3-phase	Fluke Multimeter MT-08	✔ PASS
Clean Steam Supply	2.5 – 3.5 bar (36 – 51 psi)	3.1 bar	Pressure Gauge PG-102	✔ PASS
Compressed Air	4.0 – 6.0 bar (58 – 87 psi)	5.2 bar	Pressure Gauge PG-104	✔ PASS
Cooling Water Input	2.0 – 4.0 bar, max 15°C	2.8 bar, 12.4°C	Temp Probe TP-09	✔ PASS
Chamber Drain	Floor drain, max temperature 60°C	Open drain with quench	Visual Inspection	✔ PASS

3.3 Documentation Verification Checklist

Verify that all required documentation is present, complete, and filed in the equipment dossier.

Doc ID	Document Title / Description	Version / Date	Presence
MAN-VM250-QS	Vertex Autoclave Operation and Maintenance Manual	Rev. 3.0 / 2026	✔ PASS
DWG-EL-ST0045	Piping and Instrumentation Diagram (P&ID) & Electrical Schematics	Rev. 1.2 / 2026	✔ PASS
CAL-ST0045-A	Calibration Certificates for Temperature & Pressure Sensors	2026-07-28	✔ PASS
SOP-LAB-0142	Standard Operating Procedure: Autoclave Operation	Draft 1.0	✔ PASS

Acceptance Criteria

To pass the Installation Qualification (IQ), all critical hardware components must be present, utility measurements must lie within the specified manufacturer ranges, and operational documentation must be verified and cataloged. Any deviation must be logged in the deviation report section.

✔ Qualification Status

The Installation Qualification has been executed successfully. All utility connections are secure and operate within manufacturer specification limits. The documentation is complete, and critical hardware matches specifications. **IQ Status: Approved.** Signed: _____ (Priya Patel, 2026-08-04)

4 Operational Qualification (OQ)

The Operational Qualification phase verifies that the controller, alarms, safety features, and functional sequences of the Vertex V-Max Autoclave (Model: VM-250-QS) operate in accordance with user requirements and technical specifications under no-load conditions.

4.1 Safety Interlock and Emergency Stop Checks

Safety tests must be performed to guarantee operator and environmental safety during cycle runs.

Test ID	Function	Method / Expected Result	Observed Result	Status
OQ-SAF-01	Door Interlock (Pressure)	Lock door, pressurize chamber to 0.2 bar. Attempt to open door. Door must remain locked.	Door mechanism remained locked; PLC alarm active.	✔ PASS
OQ-SAF-02	Door Interlock (Cycle)	Start cycle. Attempt to open door during steam heat-up. Door must remain locked.	Opening lock disabled by software; door locked.	✔ PASS
OQ-SAF-03	Emergency Stop	Press E-stop button during exposure phase. Heating must shut off; chamber must vent safely.	Power isolated immediately; pneumatic valves vented.	✔ PASS
OQ-SAF-04	Vacuum Relief Filter	Run vacuum cycle. Verify air intake is filtered during vacuum relief.	Air drawn through HEPA filter; no line vacuum.	✔ PASS

4.2 System Functional Tests and Leak Rates

Verify functional operational sequences under empty conditions.

Test ID	Operational Test	Acceptance Criteria	Observed Value	Status
OQ-FUN-01	Vacuum Leak Test	Stabilize at 70 mbar. Leak rate must be $\leq$ 1.3 mbar min^{-1} over 10 min.	0.8 mbar min^{-1}	✔ PASS
OQ-FUN-02	Steam Heat-up Rate	Chamber temperature must reach 121°C within 20 min from cycle start.	14.5 min to reach 121.3°C	✔ PASS
OQ-FUN-03	Pressure Control Stability	Maintain 2.10 ± 0.10 bar during sterilization exposure.	2.12 bar maximum fluctuation	✔ PASS
OQ-FUN-04	Temperature Control Stability	Maintain 121.0 to 124.0°C during exposure.	121.5°C to 122.1°C range	✔ PASS

4.3 Controller and Interface Verification

Verify that the touch-screen Human Machine Interface (HMI) controls and alarm logging work as expected.

Test ID	Function	Method / Expected Result	Observed Response	Status
OQ-HMI-01	User Access Security	Multi-level logins (Operator, Engineer, Administrator) function correctly.	Verified access restrictions per SOP-LAB-0142.	✔ PASS
OQ-HMI-02	Low-Water Alarm	Simulate generator low water level. Cycle must abort and display alarm.	Alarm active; generator disabled; cycle aborted.	✔ PASS
OQ-HMI-03	Temperature Sensor Fault	Disconnect probe PT-02. PLC must show sensor fault and safety-vent.	Sensor fault displayed; cycle aborted; pressure vented.	✔ PASS

Acceptance Criteria

Operational qualification requires that all safety features trip and isolate the machine immediately upon trigger, empty chamber temperature/pressure stability control remains within ±0.5°C and ±0.05 bar, and vacuum leak rates are verified below 1.3 mbar min^{-1}.

✔ Qualification Status

The Operational Qualification phase has been executed under empty conditions. All alarm loops, door locking mechanisms, and E-stops performed perfectly. The vacuum leak rate complies with guidelines. **OQ Status: Approved.** Signed: _____ (Priya Patel, 2026-08-04)

5 Performance Qualification (PQ)

The Performance Qualification phase demonstrates that the Vertex V-Max Autoclave (Model: VM-250-QS) consistently achieves thermal and biological sterilization under worst-case load conditions. Testing was conducted using three consecutive replicate runs with a standard laboratory liquid load (30 bottles of 1 L media surrogate).

5.1 Temperature Mapping and Biological Challenge Setup

A temperature mapping grid of twelve calibrated thermocouples (T1 to T12) was distributed inside the chamber. Thermocouple T12 was placed adjacent to the chamber drain (the predicted cold spot). Biological indicators (BIs, *Geobacillus stearothermophilus* 1.2×10^6 spores, Apex Lot GI-4882) were co-located with each thermocouple.

5.2 Qualification Replicate Runs Summary

Three consecutive sterilization cycles were executed using the standard 121°C Liquid Cycle with a 20-minute exposure time.

Parameter	Specification Limit	Run 1	Run 2	Run 3	Status
Exposure Temp. Range	121.0 to 124.0°C	121.3 – 122.4°C	121.4 – 122.6°C	121.2 – 122.3°C	✔ PASS
Exposure Time	≥ 20.0 min	20.2 min	20.1 min	20.2 min	✔ PASS
Cold Spot Location	Informative	T12 (Drain)	T12 (Drain)	T12 (Drain)	✔ PASS
Temp. Spread (Max)	≤ 1.5°C during exposure	1.1°C	1.2°C	1.1°C	✔ PASS
Lethality F_0 (Drain)	≥ 15.0 min	18.4 min	18.9 min	18.1 min	✔ PASS
Biological Indicators	No growth (7-day incubation)	Negative	Negative	Negative	✔ PASS
Chemical Indicators	Distinct color change (purple to black)	Satisfactory	Satisfactory	Satisfactory	✔ PASS

5.3 Lethality Calculation (F0)

Lethality was calculated at the drain thermocouple (T12) using the following standard equation [1]:

$$F_0 = \int_0^t 10^{\frac{T(t)-121.0}{10.0}}\, dt \tag{1}$$

The calculated F_0 values for all three runs exceed the minimum requirement of 15.0 minutes, verifying that thermal death conditions were successfully met in the coldest part of the chamber.

Acceptance Criteria

Performance Qualification requires three consecutive successful validation runs. In each run, the temperature spread across the twelve probes must not exceed 1.5°C, the exposure time must be at least 20 minutes, the minimum biological indicator challenge must demonstrate complete inactivation (no growth), and the calculated lethality F_0 at the drain must be ≥ 15.0 minutes.

✔ Qualification Status

Three replicate performance runs were completed without alarms. The physical mapping results and biological indicator assays demonstrate robust, repeatable sterilization. **PQ Status: Approved.** Signed: _____ (Priya Patel, 2026-08-04)

6 Qualification Deviations and CAPA

All deviations from the protocol, out-of-specification (OOS) results, or mechanical issues occurring during qualification testing must be documented here.

6.1 Deviation Log

A single minor mechanical deviation was recorded during the qualification process.

Dev ID	Phase	Description of Deviation	Corrective Action / Resolution	Impact
DEV-01	OQ	Printer spool feed jammed on the chart recorder (Apex Rec-06) during dry run OQ-FUN-02. No paper record printed.	Cleared jammed mechanism, realigned thermal roll, and ran test cycles. Electronic logs remained intact in PLC history.	None. Data verified from digital memory. Closed.

6.2 Non-Conformance Assessment

The chart recorder printer jam was assessed by validation engineering and QA. Because the controller PLC (Nexa NL-9000) stores data electronically in an encrypted database compliant with FDA 21 CFR Part 11 [3], the loss of paper output did not result in any data loss.

- The physical validation temperatures and pressures were safely archived.
- The print mechanism was adjusted and did not fail during subsequent OQ and PQ runs.
- A preventive maintenance check was added to SOP-LAB-0142.

Acceptance Criteria

Any critical deviation that affects safety, sterilization efficiency, or database integrity requires an immediate stop of qualification testing and a full CAPA investigation. Minor deviations that do not affect sterilization results can be closed with justification, subject to QA approval, before moving to the next phase.

Qualification Status

Deviation DEV-01 has been fully investigated, corrected, and closed. The justification for data integrity is technically sound, and the quality impact is verified as negligible. **Deviation Status: All Deviations Resolved and Closed.** Signed: _____ (Priya Patel, 2026-08-04)

7 Final Post-Execution Sign-Off

This section documents the final review and approval of the qualification data for the Vertex V-Max Autoclave (Model: VM-250-QS). By signing below, the review committee certifies that all qualification phases (IQ, OQ, PQ) have been successfully completed, all deviations have been resolved, and the equipment is officially released for GMP operations.

7.1 Summary of Qualification Verdicts

Phase	Objectives	Target Date	Execution Date	Final Verdict
Installation Qualification (IQ)	Component check, environmental utilities	2026-08-01	2026-08-01	✔ PASS
Operational Qualification (OQ)	Safety interlocks, functional ranges	2026-08-03	2026-08-03	✔ PASS
Performance Qualification (PQ)	Sterilization lethality mapping (3 runs)	2026-08-04	2026-08-04	✔ PASS

7.2 Authorization and System Release

Based on the results documented in this report, the Vertex V-Max Autoclave is declared fully qualified and fit for its intended use of sterilizing GMP media, laboratory components, and waste. The system is hereby released for routine use.

Role	Name / Title	Signature	Date
Validation Engineer	Priya Patel, Lead Validation Analyst	_____	_____
Engineering Review	Dr. Raymond Vance, Engineering Lead	_____	_____
Quality Assurance (QA)	Marcus Webb, Director of Quality	_____	_____

Notes

The autoclave is now subject to annual re-qualification and routine calibration. Any major modification to utilities, chamber layout, or software PLC programming will trigger an immediate change control assessment and potential re-qualification of the affected modules.

References

[1] European Committee for Standardization. *EN 285: Sterilization - Steam sterilizers - Large sterilizers.* CEN, 2015.

[2] ISPE. *ISPE Good Practice Guide: Equipment Qualification.* International Society for Pharmaceutical Engineering, second edition, 2020.

[3] US Food and Drug Administration. *21 CFR Part 11: Electronic Records; Electronic Signatures.* Department of Health and Human Services, 2003.