Autoclave Sterilisation Cycle Log

Quality Operations & Validation Log Sheet

Facility: Vertex Cleanroom Facility
Location: Suite B, Analytical Wing
SOP Ref: SOP-QA-STR-042

Equipment Name: Synapse SteriPulse Steam Steriliser
Equipment ID: EQ-AC-204
Chamber Volume: 500 Liters
Model/Serial: SP-533 / SN-99420-A
Calibration Date: 2026-05-15
Next Calibration Due: 2026-11-15
Responsible Dept: Quality Operations (QO)
Log Sheet Month/Year: August 2026

1 Cycle Selection and Parameter Reference

To ensure complete microbial lethality (sterilisation validation), operators must match the load contents to the verified SOP autoclave cycles below [1, 3]:

Approved Cycle Profiles

Cycle ID	Load Types	Target Temp	Target Time
P1-GRAV	Glassware, metal instruments, dry goods	121.0°C	30 min
P2-PREV	Porous loads, garments, filters, tubing	134.0°C	4 min
P3-LIQD	Aqueous buffers, growth media, saline	121.0°C	45 min (Slow)
P4-DECN	Biohazard waste bags, spent plates	121.0°C	60 min

Key Validation Requirements

- **Chemical Indicators (CI):** Every pack or container must contain a Class 5 or Class 6 integrating indicator tape/strip [2].
- **Biological Indicators (BI):** A *Geobacillus stearothermophilus* spore ampoule must be placed in the coldest point (drain line) weekly.
- **Cycle Verification:** Physical printouts showing critical values must be signed, dated, and archived with this log.

2 Sterilisation Cycle Records

Ensure all measurements are verified against physical autoclave thermal printouts before signing off.

Date (YYYY-MM-DD)	Run No.	Cycle ID	Load Contents (Detailed Description)	Temp (°C)	Press (psi)	Time (min)	CI Status	BI ID Vial	BI Result (24h / 48h)	Oper Init	Rev Init
2026-08-01	001	P1-GRAV	Surgical instruments, stainless steel trays	121.3	15.4	30	✓ NEGATIVE (PASS)	—	—	A.M.	K.P.
2026-08-01	002	P3-LIQD	LB Miller Broth (5 x 1 L bottles)	121.1	15.2	45	✓ NEGATIVE (PASS)	BI-2041	✓ NEGATIVE (PASS)	A.M.	K.P.
2026-08-02	003	P2-PREV	Cleanroom garments, cleanroom wipes	134.2	30.5	4	✓ NEGATIVE (PASS)	—	—	R.D.	K.P.
2026-08-02	004	P1-GRAV	Empty borosilicate flasks (10 x 500 mL)	121.5	15.3	30	✓ NEGATIVE (PASS)	—	—	R.D.	K.P.
2026-08-03	005	P4-DECN	Biohazard waste bags, plates, pipette tips	121.0	15.1	60	✓ NEGATIVE (PASS)	BI-2042	✓ NEGATIVE (PASS)	A.M.	L.W.
2026-08-03	006	P3-LIQD	Phosphate Buffered Saline (10 x 500 mL)	121.4	15.3	45	✓ NEGATIVE (PASS)	—	—	A.M.	L.W.
2026-08-04	007	P1-GRAV	Polypropylene carboys, silicone tubing	120.4	14.1	12	✗ POSITIVE (FAIL)	—	—	R.D.	L.W.

3 Sterilisation Cycle Records (Continued)

Date (YYYY-MM-DD)	Run No.	Cycle ID	Load Contents (Detailed Description)	Temp (°C)	Press (psi)	Time (min)	CI Status	BI ID Vial	BI Result (24h / 48h)	Oper Init	Rev Init
2026-08-04	008	P2-PREV	Glass vials, amber serum bottles	134.1	30.2	4	✓ NEGATIVE (PASS)	—	—	R.D.	L.W.
2026-08-05	009	P4-DECN	Biohazard waste bags, plates, pipette tips	121.2	15.3	60	✓ NEGATIVE (PASS)	BI-2043	✓ NEGATIVE (PASS)	A.M.	L.W.
2026-08-05	010	P1-GRAV	Stainless steel volumetric scoops, spatulas	121.4	15.4	30	✓ NEGATIVE (PASS)	—	—	A.M.	K.P.
2026-08-06	011	P3-LIQD	Water for Injection (WFI) (5 x 2 L bottles)	121.3	15.2	45	✓ NEGATIVE (PASS)	—	—	R.D.	K.P.
2026-08-06	012	P2-PREV	PTFE syringe filters, cleanroom masks	134.0	30.1	4	✓ NEGATIVE (PASS)	BI-2044	✓ NEGATIVE (PASS)	R.D.	K.P.
2026-08-07	013	P1-GRAV	Empty glass culture tubes (100 x 15 mL)	121.2	15.1	30	✓ NEGATIVE (PASS)	—	—	A.M.	K.P.

4 Biological Indicator (BI) Incubation Log

Spore vials (*Geobacillus stearothermophilus*) must be incubated at 55 to 60 °C. A non-autoclaved control vial from the same lot number must be incubated concurrently to validate viability of the spore batch.

BI Vial ID	Control Vial ID	Vial Lot Number	Incubator ID	Temp (°C)	Date/Time In	Date/Time Out	24h Readout	48h Readout	Operator Initials
BI-2041	C-2041	GBS-889	INC-08	56.5	2026-08-01 15:45	2026-08-03 16:00	✓ NEGATIVE (PASS)	✓ NEGATIVE (PASS)	A.M.
BI-2042	C-2042	GBS-889	INC-08	56.8	2026-08-03 12:20	2026-08-05 12:30	✓ NEGATIVE (PASS)	✓ NEGATIVE (PASS)	R.D.
BI-2043	C-2043	GBS-890	INC-08	56.4	2026-08-05 14:10	2026-08-07 14:15	✓ NEGATIVE (PASS)	✓ NEGATIVE (PASS)	A.M.
BI-2044	C-2044	GBS-890	INC-08	56.6	2026-08-06 17:30	2026-08-08 17:30	✓ NEGATIVE (PASS)	✓ NEGATIVE (PASS)	R.D.

Note: Control vials must turn yellow (positive growth) to confirm viability. Test vials must remain purple (negative/no growth) to confirm successful sterilisation.

5 Deviations and Corrective Actions

Record any cycle failures, parameter deviations, alarm codes, or maintenance issues. If no deviations occurred, write "N/A" and sign.

Date	Run No.	Deviation Description / Alarm Code	Corrective Action / Resolution	Operator
2026-08-04	007	Chamber temperature drop to 120.4°C; failed to sustain sterilisation temperature for 30 min. Alarm: F04 (low steam pressure).	Cycle aborted. Load remained in chamber. Facilities cleaned the steam inlet filter screen. Repeated successfully as Run 008.	R.D.
2026-08-05	009	Wet pack observed on exterior of biohazard waste bag during load unloading.	Load was a decontamination run; materials were disposed of via hazardous waste bin. Minor steam trap blockage cleaned to prevent reoccurrence.	A.M.

6 Log Sheet Sign-off and Quality Assurance Review

By signing below, the operators and reviewers verify that the sterilisation runs listed on this log sheet were executed, monitored, and reviewed in compliance with SOP-QA-STR-042 and current Good Manufacturing Practices (cGMP) requirements.

Operator 1 Verification:

Name: Arthur Morgan
Title: Lead Microbiology Technician
Date: 2026-08-07

Operator 2 Verification:

Name: Rachel Dawson
Title: Operations Specialist
Date: 2026-08-07

Quality Assurance Review:

Name: Katherine Pierce | Lucas Wright
Title: Quality Assurance Specialist
Date: 2026-08-08

References

[1] International Organization for Standardization. Iso 17665-1:2006 sterilization of health care products – moist heat – part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. Standard ISO 17665-1:2006, ISO, Geneva, Switzerland, 2006.

[2] William A Rutala and David J Weber. Disinfection and sterilization: an overview. *American Journal of Infection Control*, 41(5):S2–S5, 2013.

[3] William A Rutala, David J Weber, Healthcare Infection Control Practices Advisory Committee, et al. Guideline for disinfection and sterilization in healthcare facilities, 2008. *Centers for Disease Control and Prevention*, pages 1–158, 2008.