
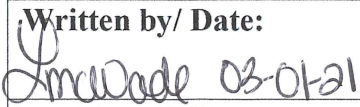

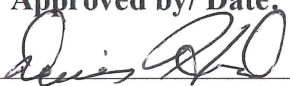


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|---|--|--|-----------------------------------|
|  | Standard Operating Procedure Compressed Air Microbial Testing | SOP Number E-707 | Revision 2 |
| | | Effective Date 05/06/21 | Page Page 1 of 5 |
| Written by/ Date:  Title: QC Laboratory Supervisor | Reviewed by/ Date:  Title: QC Laboratory Director | Approved by/ Date:  Title: VP of Quality & Regulatory Affairs | |

1.0 Purpose

The purpose of this procedure is to define the process for microbial testing of compressed air at the point of use in production to ensure that air quality is acceptable for its intended use.

2.0 Scope

This procedure is applicable to the production area(s), and is used to microbiologically analyze compressed air to determine its suitability for use.

3.0 Responsibility

- 3.1 It is responsibility of the QC Laboratory Analysts to perform sampling, incubate samples, perform analysis, and document results per this procedure.
- 3.2 It is the responsibility of the QC Laboratory Supervisor/Director to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of the QC Laboratory Supervisor/Director to keep current the SOP and to oversee validations and recovery studies.

4.0 Definitions

- 4.1 QC – Quality Control
- 4.2 CAMTU – Compressed Air Microbial Test Unit - Detection device that allows for quick and easy testing for contamination present in compressed air supplies.
- 4.3 CFU – Colony Forming Unit
- 4.4 TSA – Tryptic Soy Agar
- 4.5 OOS – Out of Specification

5.0 Frequency

- 5.1 All Compressed Air Points-of-Use will be sampled and tested at least every 6 months.

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6.0 References

- 6.1 SQF Code, Edition 7.2 - 11.5.7
- 6.2 21 CFR 111.27(a)7
- 6.3 E-707-F1, Form, Compressed Air Microbial Test Ticket
- 6.4 C-201 Deviation and Investigation Procedure



CAMTU KIT

7.0 Procedure

7.1 Cleaning

- 7.1.1 Spray gloved hands with 70% IPA prior to cleaning
- 7.1.2 Open the CAMTU cover (see Figure 1), loosen the deflector plate thumb screws and remove the deflector plate.
- 7.1.3 Liberally spray the interior of the CAMTU with 70% IPA solution and wipe dry with a lint-free cloth making sure to spray and wipe deflector plate.
- 7.1.4 Reinstall the deflector plate.



Figure 1

7.2 Performing a Control Negative Test

7.2.1 Spray gloved hands with 70% IPA prior to sampling

7.2.2 Open sample tap long enough to purge compressed air until visibly free of moisture and particulates (at least 60 seconds).

7.2.3 Assemble the tubing to the shutoff valve, disposable filter, regulator and CAMTU as shown in Figure 2 below.

7.2.4



Figure 2

- 7.2.5 Connect to the compressed air system.
- 7.2.6 Using a marker write “Negative Control”, the test location, initials of the person sampling, and the date on the bottom of the TSA plate.
- 7.2.7 Place the TSA plate inside the CAMTU and remove the cover. Immediately close the CAMTU and snap the latch closed on the end of the handle.
- 7.2.8 Open the shutoff valve and press the button on the handle to start the timer. The light will blink for 20 seconds. When the light stops blinking, the test is complete.
- 7.2.9 Close the shutoff valve.
- 7.2.10 Open the CAMTU and immediately place the cover back on the TSA plate to minimize exposure to the ambient air. Remove TSA plate and return to QC Lab for incubation.

7.3 **Sampling**

- 7.3.1 Spray gloved hands with 70% IPA prior to sampling.
- 7.3.2 Open sample tap long enough to purge compressed air until visibly free of moisture and particulates (at least 60 seconds).
- 7.3.3 Assemble the tubing to the shutoff valve, regulator and CAMTU as shown in Figure 2 above, and add disposable filter between the regulator and the shutoff valve, and connect to the compressed air system.
- 7.3.4 Using a marker write the test location, initials of person sampling, and date on the bottom of the petri dish.
- 7.3.5 Place the TSA plate inside the CAMTU and remove the cover. Immediately close the CAMTU and snap the latch close on the end of the handle.
- 7.3.6 Open the shutoff valve and press the button on the handle to start the timer. The light will blink for 20 seconds. When the light stops blinking, the test is complete.
- 7.3.7 Close the shutoff valve.
- 7.3.8 Open the CAMTU and immediately place the cover back on the TSA plate to minimize exposure to the ambient air. Remove the TSA plate and return to QC Lab for incubation.

7.4 Incubation

7.4.1 After exposure, TSA plate should be incubated inverted at 35-37°C for 48 hours.

7.4.2 Due to air flow pattern inside the CAMTU, results should be viewed qualitatively. If there are CFUs present outside of the acceptable limits on the TSA plate (see Table 1.0), it is an indication that microorganisms are present in the compressed air system and an investigation will be required by the Quality department, per SOP C-201 Deviation and Investigation Procedure.

7.4.3 Record results on E-707-F1 Compressed Air Microbial Test Ticket.

7.5 Cleaning

7.5.1 If after incubation, CFUs appear on the TSA plate surface after a Negative Control test, this is an indication that one or more components in the system are harboring microorganisms and a thorough cleaning of all components is required. The tubing is anti-microbial and should not harbor any microorganisms.

7.5.2 To clean the regulator and shutoff valve, pour 70% IPA solution into the regulator and shutoff valve through both the inlet and exit ports. Drain and allow to dry.

7.6 Results

7.6.1 Acceptable and action levels of CFU observed in Table 1.0

Table 1.0

| | |
|------------------|---------------------------------------|
| Acceptable Level | ≤ 25 CFU at 3.3 CF/sec for 20 seconds |
| Action Level | > 25 CFU at 3.3 CF/sec for 20 seconds |

8.0 Revision History

| Revision | Date | Description of Changes | CCR # | By |
|----------|----------|--|------------|---------------|
| 0 | 07/22/16 | New SOP | 16-0712 | E. Hasanbasic |
| 1 | 06/05/17 | Update specifications based upon risk level; clarified cleaning solutions. | 17-0602 | S. Millar |
| 2 | 02/23/21 | Updated responsibilities and clarified procedures. Updated form. | CC-21-0077 | L. McWade |