

DISTURBANCE TEST AND EXHAUSTED AIR TEST

Cleanroom and controlled environment bio decontamination: General principles and methods

Introduction

ISO 14698 regulation sets that:

1. Unidirectional airflow disturbance by the sampling device should be limited.
2. Exhausted air from the sampling device should not contaminate the environment or be re-aspirated from the air sampler.

The SAS air sampler has been designed by our experts to be used in compliance with sampling devices regulations.

In order to respect airflow disturbance specifications, regulated by ISO 14698, they have been tested with a "Low-Speed Wind Tunnel LSWT."

Low-Speed Wind Tunnel LSWT

Tests have been performed at low speed in the wind gallery, specifically developed and designed for the air sampler.

The wind gallery is made up of a tunnel, which is a big horizontal stainless-steel cylinder. All processes can be monitored inside the tunnel by means of two big windows. Air is aspirated at the end of the tunnel by an adjustable electrical engine. A HEPA filter at the entrance of the tunnel produces a sterile unidirectional air flow.

Exhausted air is filtered by a HEPA filter.

Air speed is regulated by electronic devices with two independent probes. Temperature is monitored by an electronic probe.

A special lighting help to capture images.

Microorganism culture (or smoke) is conveyed and dispersed homogeneously inside the tunnel, in the front part of the tested air sampler, through a special door. The air sampler to be tested is positioned in the central part of the tunnel with the aspirating head directed toward the airflow. It is possible to monitor different air samplers at the same time.



A. Air Turbulence Test

The purpose of this air turbulence test is to check that the unidirectional airflow (air laminar flow) is not disturbed by the air exiting the air sampler. The sampler is considered compliant if the air disturbance is below 10-12 cm from the outlet of the device. The test has been performed using a "smoke tracer."

First test - "Smoke tracer"

Test	T°	Minimum turbulence (cm around the head)	Maximum turbulence (cm around the head)	Average turbulence (cm)
Test 1 - 09:32 a.m.	20	8	12	10
Test 2 - 09:50 a.m.	21	7	13	10
Test 3 - 10:00 a.m.	22	9	10	9,5
Test 4 - 10:43 a.m.	21	8	10	9
Test 5 - 10:55 a.m.	20	5	9	7
Test 6 - 11:10 a.m.	19	6	12	9
Test 7 - 11:25 a.m.	20	7	10	8,5
Test 8 - 11:40 a.m.	21	6	9	7,5
Test 9 - 11:53 a.m.	21	7	12	9,5
Test 10 - 12:15 p.m.	20	6	11	8,5

Second test - "Smoke Tracer"

Test	T°	Minimum turbulence (cm from instrument outlet)	Maximum turbulence (cm from instrument outlet)	Average turbulence (cm)
Test 1 - 09:32 a.m.	22	9	14	11,5
Test 2 - 09:50 a.m.	23	8	13	10,5
Test 3 - 10:00 a.m.	21	11	16	13,5
Test 4 - 10:43 a.m.	21	12	14	13
Test 5 - 10:55 a.m.	22	10	13	11,5
Test 6 - 11:10 a.m.	20	8	10	9
Test 7 - 11:25 a.m.	21	7	16	11,5
Test 8 - 11:40 a.m.	21	7	19	13
Test 9 - 11:53 a.m.	21	8	10	9
Test 10 - 12:15 p.m.	21	12	12	12



FIGURE 1: Average smoke deviation confirms that the airflow deviation is minimal, with no impacts on cleanroom applications.

B. Exhausted Air Test

The purpose of the exhausted air test is to check that exhausted air from the air sampler is not contaminated and not being re-aspirated from the air sampler device. The following images show that exhausted air is not re-aspirated but follows the unidirectional airflow.

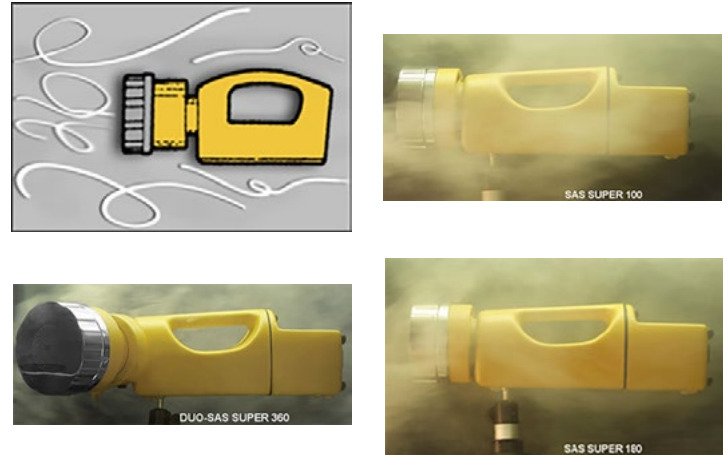


FIGURE 2: Aspirated air by SAS Super 100 USB, SAS Super 180 USB and DUO SAS Super 360 is not re-aspirated.

C. Environmental Contamination Test

The purpose of this test is to check if the exhausted air from the air sampler is not contaminating the environment subjected to air sampling.

The test, performed with a particle counter positioned on a laminar flow bench, in the back part of the SAS Super 100 air sampler, during a programmed 1000 air liters sampling, confirms there is no particle emission.

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