

Cleanroom Characterisation



What is Cleanroom Characterisation?

Cleanrooms characterisation and controlled flow equipment, such as biological safety cabinets and laminar flow cabinets, is essential to ensure that these spaces meet the required standards of cleanliness and safety. These controlled environments must maintain strict levels of particulate matter in the air, as well as ensure the proper containment of potentially hazardous substances or prevent samples from being contaminated.

Fume extraction fume cupboards are to ensure the correct containment of potentially hazardous substances towards the user.

At Applus+ Laboratories, we offer characterisation services in accordance with standards such as UNE-EN ISO 14644-1, UNE-EN 12469 or UNE-EN 14175, guaranteeing that the facilities are suitable for the critical activities that take place in them, such as scientific research processes, manufacturing of [pharmaceutical products](#) and quality control in biological and chemical environments.

Testing Performed in the Characterisation of Cleanrooms

We offer a wide range of tests to ensure that rooms and cabinets meet regulatory requirements:

- **Particle size and concentration:** Assessment of airborne particles in a range of 0.3 μm to 5 μm , according to the Standard UNE-EN ISO 14644-1 (Not applicable to fume cupboards).
- **Pressure differentials:** Measurement of differential pressure in rooms and cabinets to ensure adequate containment (0-100 Pa).

- **Filter tightness:** Checking the effectiveness of the filtering system, ensuring that there is no leakage of contaminating particles.
- **Air velocity and flow rate:** Verification of air velocity and flow rate between 0.10 m/s and 20 m/s.
- **Class recovery:** Evaluation of cleanroom recovery time to return to specified purity levels after particulate introduction (Cleanroom only).
- **Laminar flow determination:** Testing to ensure that airflow follows a correct laminar pattern, minimising particle recirculation (Not applicable to fume cupboards).
- **Barrier determination:** Testing to ensure that the airflow does not leave the containment area, preventing contamination of users (test only for biological safety cabinets and fume cupboards).
- **Temperature and humidity certification:** Verification of climate control in the room, in ranges from -15°C to 46°C for temperature, and 15% to 90% RH for relative humidity.

Benefits of Cleanroom Characterisation

The benefits are as follows:

- **Regulatory compliance:** Ensures compliance with ISO 14644 and UNE-EN 12469 standards for cleanrooms and safety and laminar flow cabinets.
- **Safety:** Ensures the correct containment of biological and chemical agents, protecting personnel and/or products.
- **Operational efficiency:** Optimises environmental conditions for critical processes, reducing risks of contamination of products and/or samples.
- **Customer confidence:** Certifies the quality and safety of facilities, generating confidence in clients and regulators.
- **Cost reduction:** Minimises errors and rework, ensuring a controlled environment from the outset.

Why Choose Applus+ Laboratories for Cleanroom Characterisation?

At Applus+ Laboratories, we are committed to providing the highest quality critical environment characterisation services. Here we tell you why we are the trusted partner for the characterisation of cleanrooms and environmental control equipment:

- **ENAC Accreditation:** We are accredited under the UNE-EN ISO/IEC 17025 Standard, which guarantees that all our tests meet the highest standards of quality and accuracy.
- **Proven experience:** With more than 10 years of experience in the characterisation of critical environments, we offer in-depth knowledge and solutions adapted to every need.

- **State-of-the-art equipment:** We use advanced equipment to ensure accurate and reliable measurements, providing reliable results in every test.
- **Operational Flexibility:** We offer on-site services, adjusting to the operational needs of our Clients, allowing us to work without interrupting their processes.
- **Comprehensive Coverage:** Our Testing covers all critical aspects of quality control in cleanrooms and controlled flow equipment, ensuring a safe and compliant environment.