

Validation of Laminar Flow Hoods & Microbiological Safety Cabinets

Η εταιρεία LINK LAB στην προσπάθεια της να καλύψει τις νέες ανάγκες των εργαστηρίων και συνεχίζοντας την ανάπτυξη του Τμήματος Διακριβώσεων, οργάνωσε Εργαστήριο μέτρησης Καθαρών χώρων (Cleanrooms) και Θαλάμων Νηματικής Ροής (Laminar Flow & Microbiological Safety Cabinets).

Οι απαραίτητες εργασίες που πραγματοποιούνται είναι αυτές που ορίζονται από το ISO 14644 και τα επί μέρους εθνικά πρότυπα χωρών της Ευρωπαϊκής Ένωσης, με δυνατότητα προσαρμογής στις απαιτήσεις του πελάτη.

Ο έλεγχος αποτελείται από:

- 1) Μέτρηση μικροσωματιδιακού φορτίου-Air Cleanliness Classification Test: Particle counting inside cabinets with a laser particle counter (in accordance with ISO 14644-1)**
- 2) Έλεγχος ακεραιότητας φίλτρων και διαρροών (Integrity / leak test)-HEPA Filter Integrity and Leak Test: Challenging with either DOP or PAO**
- 3) Έλεγχος ροής αέρα (smoke test)-Air Flow Smoke Patterns Test: Study and evaluate characteristic of air flow**
- 4) Έλεγχος ταχυτήτων – παροχών-Air Velocity Evaluation: Inflow and Down Flow Velocity measurement**
- 5) Έλεγχος έντασης φωτός και έντασης θορύβου - Light Level Test & Noise level Test**

OPERATIONAL QUALIFICATION ACCEPTANCE CRITERIA

HEPA Filter Integrity Test	Photometer readings downstream of the HEPA filter unit will be less than or equal to 0.01% of the upstream challenge. Repaired areas are not to exceed 5% of any filter face area.
Biosafety Cabinet Construction Certification	All welds, gaskets, plenum penetrations and seals will hold pressure within 10% for 30 minutes or be free of soap bubbles after sealed cabinet is pressurized with compressed air to 2" water gauge.
Air Velocity	Critical Areas should have laminar airflow of 90 fpm \pm 20%, or 28 m/min \pm 20%
Airflow, Laminar Flow Hoods	During average supply air velocity testing, the average reading must be between 120-130 fpm, or 35-40 m/min.
Airflow, Biosafety Cabinets	The calculated average intake air velocity must be between 100-130 fpm or 30-40 m/min

PERFORMANCE QUALIFICATION ACCEPTANCE CRITERIA

Smoke Testing	<p>Airflow will be unidirectional</p> <p>During airflow smoke pattern testing, airflow along the entire perimeter of the work access area will be inward; the smoke will flow downward with no dead spots or reflux within the cabinet; no airflow escape from the cabinet and no billowing over or penetrating the work surface.</p>
Total Particulate Counts	<p>The area meets the acceptance criteria for total particulates if the average of the particle concentrations measured at each location falls at or below the class limit.</p> <p>Any excursion of the class limit for an individual run must be noted, investigated and justified.</p>
Total Particulate Counts	<p>The area meets the acceptance criteria for total particulates if the average of the particle concentrations measured at each location falls at or below the class limit.</p> <p>Any excursion of the class limit for an individual run must be noted, investigated and justified.</p>
Slit to Agar Viable Air Sampling	less than or equal to 0.1 CFU/ft ³
Viable Surface Sampling	less than or equal to 2 CFU per 30 cm ²
Culture media testing	Culture media are positive in growth promotion studies.

