IS OUR HEPA SYSTEM REALLY FUNCTIONING AS A CONTAINMENT BARRIER?

Diagnostic Guide
GD-006

A technical diagnostic guide to filter integrity, housings, seals, bypass paths, and testability

A practical guide for evaluating whether an installed HEPA filtration system functions as a containment barrier, rather than relying only on filter efficiency.

DIAGNOSTIC GUIDE

HOW TO USE THIS GUIDE

A HEPA FILTER CAN PASS. THE SYSTEM AROUND IT CAN STILL FAIL.

This guide was created for facilities that know they have HEPA filtration but have less certainty that the complete installation can be considered a reliable containment barrier.

Why we developed it

HEPA performance is often discussed in terms of filter efficiency. In high-containment systems, the containment function depends on much more than the filter medium.

The housing, gasket or gel seal, clamping mechanism, transitions, access doors, test ports, isolation devices, duct connections, and installation quality are all part of the path contaminated air must follow.

The purpose of this guide is to help institutions evaluate the complete filtration assembly and identify where bypass, inadequate testability, or poor maintenance access may compromise the intended barrier.

Who can use it

The guide is intended for facility managers, engineers, biosafety personnel, commissioning teams, maintenance personnel, and project teams responsible for supply or exhaust systems with HEPA filtration in high-containment laboratories.

It can be used during design review, commissioning, periodic verification, filter replacement, or diagnosis following a failed integrity test.

HOW TO USE IT IN PRACTICE

Begin by defining the containment function of the HEPA stage. Then trace the complete airflow path through the housing, seals, and connections; confirm that the assembly can be tested; review integrity-test evidence; and determine whether maintenance can be performed without introducing uncontrolled bypass or exposure.

The objective is not simply to ask whether the filter is efficient. It is to determine whether contaminated air can reach the downstream side without passing through the verified filtration path.

01 DEFINE

02 TRACE

03 TEST

04 MAINTAIN

HOW THIS GUIDE MAY BE USED — AND WHAT IT DOES NOT AUTHORIZE

This guide is a general diagnostic-orientation tool. It is designed to help structure technical questions, organize evidence, and define what requires more specific evaluation.

Acceptable use

It may be used to:

- structure preliminary technical investigations;
- prepare internal reviews and multidisciplinary discussions;
- identify missing information, measurements, and documentation;
- support definition of the scope of a subsequent evaluation;
- serve as educational and internal technical reference material.

It does not constitute

This guide does not constitute a specific HEPA test protocol, acceptance criterion, certification, compliance determination, authorization to operate, or site-specific recommendation.

Technical and operational decisions

No decision regarding system acceptance, filter replacement, modification of housings or seals, continued operation, repeat testing, or return to service should be based solely on this guide.

Applicable technical basis

The content should be interpreted together with the risk assessment, Basis of Design, manufacturer instructions, applicable standards and test methods, commissioning criteria, regulatory requirements, and other site-specific documentation.

Competent personnel

Integrity testing, intervention, and maintenance of HEPA systems that form part of the containment strategy should be performed or reviewed by appropriately qualified personnel using suitable equipment and documented procedures.

Responsibility

BioLab Solutions assumes no responsibility for decisions, modifications, interventions, or actions carried out outside a site-specific evaluation and without review by competent personnel.

First published: October 2026
Current version: October 2026 | v1.0

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01 Define what the HEPA stage protects

Technical review begins with function, not the filter label.

A HEPA stage may protect the room, downstream ductwork, the environment, equipment, or another defined boundary.

Ask

- Is the HEPA stage in supply, exhaust, or both?
- Is it part of the biological containment strategy, or is its primary function cleanliness control?
- What air is upstream of the filter?
- What is the consequence if bypass occurs?
- Is the stage single or redundant?
- Is in situ testing required?

Function determines rigor

A filter used as a containment barrier has different implications from one used only to improve internal air cleanliness.

The housing, testability, maintenance access, and verification strategy should reflect the consequence of bypass.

FILTER CLASS DOES NOT DEFINE THE CONTAINMENT FUNCTION. THE AIRFLOW PATH AND THE RISK DO.

02 Review the complete filtration assembly

The filter is only one element of the containment path.

Filter medium

Correct type, dimensions, orientation, condition, certification, and compatibility with the system.

Seal interface

Condition of gasket or gel, compression, seating, continuity, and compatibility with the housing.

Housing

Structural integrity, access-door seals, clamping mechanism, internal surfaces, and connection details.

Duct connections

Upstream and downstream joints, flanges, welds, flexible connections, and transitions.

Test devices

Aerosol injection, upstream challenge access, downstream scanning or sampling access, and safe test configuration.

Isolation / maintenance

Dampers, bag-in/bag-out devices where applicable, decontamination access, and a safe replacement strategy.

> **System question:** Is there any path from contaminated upstream air to the downstream side that does not pass through the verified filter medium?

03 Identify bypass paths

Containment failure can occur around the filter rather than through it.

Potential path	What to examine
Filter-to-housing seal	Compression, gasket continuity, gel engagement, seating, and damage.
Housing access door	Door gasket, latches, flatness, compression, and wear from repeated maintenance.
Housing fabrication	Welds, joints, penetrations, test ports, and fabrication defects.
Duct-to-housing connection	Flanges, welds, sealant, flexible connections, and field-installed transitions.
Test-port closure	Caps, valves, plugs, and restoration after testing.
Parallel duct / bypass	Isolation dampers, bypass branches, temporary connections, and maintenance paths.

> **A PERFECT FILTER DOES NOT CORRECT AN UNCONTROLLED PATH AROUND THE FILTER.**

04 Ask whether the installation can actually be tested

A containment barrier that cannot be meaningfully tested creates an evidence problem.

In situ integrity testing depends on the ability to generate and measure an appropriate challenge through the installed filter system.

Review test access

- upstream aerosol-injection point;
- adequate mixing distance or strategy;
- upstream concentration measurement;
- downstream access for scanning or sampling;
- safe access to the housing;
- ability to isolate the test condition when necessary.

Design for evidence

Testability should be resolved during design and procurement, not discovered after installation.

If a housing cannot be challenged, scanned, or sampled as required, the project may have installed filtration without providing a practical means of demonstrating its integrity.

05 Interpret integrity-test results correctly

A test report is useful only when the installation tested and the test condition are clear.

Traceability

Identify the filter, housing, location, date, technician, instrument, and applicable test method.

Challenge condition

Confirm that the upstream challenge was adequate and sufficiently distributed for the intended test.

Acceptance criterion

The criterion should come from the applicable project requirement, manufacturer, or test method; it should not be invented after the result is known.

Location of failure

Distinguish penetration through the medium from leakage at the seal, housing, or connections where the method allows.

Repair and retest

When assembly integrity forms part of the containment strategy, repairs should be documented and the affected integrity should be reverified against the applicable method and criterion before return to service.

Configuration

Verify that dampers, doors, and system conditions during testing reflect the intended test configuration.

> A “pass” result has meaning only when the system tested, method, configuration, and criterion are traceable.

COMMON MISCONCEPTIONS ABOUT HEPA SYSTEMS

WHAT NOT TO ASSUME

“It is an H14 filter, so the system is safe.”

Filter classification does not demonstrate housing integrity, seal condition, or absence of bypass.

“The differential pressure looks normal.”

Pressure drop indicates resistance. It does not demonstrate filtration integrity.

“The filter was tested at the factory.”

Factory performance does not demonstrate the integrity of the installed filter-housing assembly.

“There is no visible damage.”

Small leaks at the seal or housing may not be visible.

“We can test it after construction.”

If injection and sampling access was not designed into the installation, meaningful in situ testing may be difficult or impossible.

“Replacing the filter restores the system.”

Replacement changes the sealing interface and should be followed by the required integrity verification.

FILTER EFFICIENCY IS A PROPERTY OF THE COMPONENT. CONTAINMENT INTEGRITY IS A PROPERTY OF THE SYSTEM.

06 Review maintenance and replacement as containment interventions

Opening the housing changes the verified condition.

Filter replacement is not simply a consumables task. It is an intervention on a containment boundary.

Before the intervention

- determine contamination status;
- define isolation requirements;
- apply decontamination or a safe-change procedure when required;
- confirm PPE and access controls;
- prepare the replacement filter and seals.

After the intervention

- confirm correct seating and clamping;
- restore doors, ports, and dampers;
- perform the required integrity test;
- confirm effects on airflow and pressure;
- document the result and authority for return to service.

> Where bag-in/bag-out devices or other safe-change functions are required, they should be reviewed as part of the containment maintenance strategy, not as optional accessories.

07 Review the relationship between filtration and fan performance

Filters create resistance that changes over time.

A filtration system may retain its integrity while gradually consuming a greater share of the fan's available pressure capacity.

Analyze trends in

- filter differential pressure;
- fan speed;
- exhaust airflow;
- room pressure;
- damper position;
- available fan margin.

Why it matters

A loaded filter may continue to pass an integrity test while bringing the system closer to its maximum operating point.

Periodic review should therefore consider both barrier integrity and the mechanical capacity required to maintain the containment condition.

INTEGRITY AND CAPACITY ARE DIFFERENT QUESTIONS. BOTH MATTER TO THE COMPLETE CONTAINMENT SYSTEM.

FAILURE REVIEW

WHAT HAPPENS IF THE INTEGRITY TEST FAILS?

01

Confirm the test condition and instrumentation.

Rule out invalid challenge concentration, inadequate mixing, configuration error, or an instrument problem before diagnosing the assembly.

02

Locate the failure path.

Filter medium, seal, housing, access door, port, duct connection, or another bypass path.

03

Determine whether repair is permitted and appropriate.

Follow applicable project/manufacturer criteria and competent technical judgment.

04

Correct the defect and repeat the test.

The affected system should not be considered restored until the applicable integrity criterion has been demonstrated.

05

Review the cause, not only the symptom.

Incorrect seating, damaged gasket, housing deformation, poor access, repeated maintenance damage, or an installation defect may require broader corrective action.

A confirmed failure in a valid test is not simply a filter problem. It is evidence that the required integrity of the filtration path has not been demonstrated.

DIAGNOSTIC SEQUENCE

IS THE HEPA SYSTEM A RELIABLE CONTAINMENT BARRIER?

01

Is the filtration function clearly defined?

No → establish what the HEPA stage is intended to protect and why.
Yes → continue.

02

Is the complete airflow path free of uncontrolled bypass?

No or uncertain → review housing, seals, access doors, ports, and duct connections.
Yes → continue.

03

Can the installed assembly be meaningfully tested?

No → the design has an evidence limitation that must be resolved.
Yes → continue.

04

Is there traceable evidence of in situ integrity?

No → perform the applicable verification before relying on the barrier.
Yes → continue.

05

Can maintenance preserve containment and restore the verified condition?

No → review the maintenance/isolation strategy.
Yes → continue.

06

Does the fan retain adequate capacity as resistance changes?

No → review filter loading, system resistance, and fan authority.
Yes → the HEPA stage has technical support as part of the containment system.

WHAT SHOULD BE AVAILABLE?

Design

- filter location;
- filter class/type;
- housing details;
- seal type;
- test ports;
- isolation devices.

Installation

- submittals;
- installation records;
- housing/duct inspection;
- filter identification;
- as-built condition.

Verification

- integrity reports;
- test method;
- challenge concentration;
- instrument records;
- acceptance criterion;
- repairs/retesting.

Lifecycle

- filter DP trends;
- replacement history;
- maintenance procedures;
- decontamination strategy;
- return-to-service records.

Review objective: demonstrate that the intended filtration path remains physically continuous, testable, maintainable, and verified.

08 Confirm that the installed system can support a valid integrity test

Testability is an engineering property of the installation; the test technician cannot always create it later.

A leak test of the installed system is meaningful only when the challenge aerosol can adequately reach the upstream face and the downstream side can be examined using a method appropriate to the installation.

Review the test configuration

- upstream challenge-introduction point;
- ability to establish and measure an adequate challenge concentration;
- mixing and distribution before the filter where required by the test method;
- downstream access to the filter face, perimeter, and seal;
- safe and usable test ports and sampling points;
- identification of the housing/filter being tested.

Three different questions

Filter classification/efficiency: the performance the filter medium/product is rated to achieve.

Installed-system leak test: whether the installed filter, seal, and accessible perimeter show unacceptable local penetration under the test method.

Housing/duct boundary integrity: whether the surrounding containment assembly has unintended leakage paths. This may require separate evidence.

A passing certificate for the filter medium or a normal filter differential pressure cannot substitute for an installed-system integrity test when such testing is required by the containment strategy.

EXPOSURE DURING MAINTENANCE AND RESTORATION

FILTER REPLACEMENT IS AN INTERVENTION ON THE BOUNDARY

Replacement may temporarily remove or open the barrier the HEPA system is intended to provide.

Before the intervention

- identify contamination status;
- define isolation and decontamination requirements;
- confirm safe access and work zone;
- establish PPE/RPE and waste route as appropriate.

During the intervention

- protect the open path;
- control removed filters and contaminated components;
- avoid damage to sealing surfaces;
- record unexpected defects in the housing or clamping system.

After installation

- confirm correct filter identity and orientation;
- confirm gasket/gel and clamping condition;
- restore access doors and isolation devices;
- perform the required installed-system integrity verification.

Return to service

- confirm airflow;
- review filter differential pressure;
- confirm pressure relationships where they were affected;
- document results and acceptance authority.

> **INSTALLING THE NEW FILTER DOES NOT BY ITSELF DEMONSTRATE THAT THE BARRIER HAS BEEN RESTORED. THE AFFECTED PATH MUST BE VERIFIED BEFORE ITS RESTORATION IS ACCEPTED.**

DOES THE INSTALLED ASSEMBLY FUNCTION AS A TESTABLE CONTAINMENT BARRIER?

Use this checklist as a diagnostic-support tool. A checked item does not constitute acceptance; each element must be interpreted against the risk basis, facility configuration, and applicable criteria.

□ Identify the containment function assigned to the HEPA stage and the airflow path it protects.

□ Confirm the filter type, orientation, installation condition, and compatibility with the installed housing.

□ Inspect the complete housing, access doors, transitions, duct connections, and surrounding construction for potential bypass paths.

□ Confirm the condition of the gasket or gel seal and that the clamping system provides uniform and maintainable seating.

□ Verify that upstream and downstream challenge/sampling devices are accessible and suitable for the intended installed-system integrity test.

□ Confirm that isolation devices allow safe testing, maintenance, and filter replacement where required by the risk basis.

□ Review the most recent integrity-test record, including method, instrumentation, challenge conditions, acceptance basis, and any repair or repeat testing.

□ Determine whether the housing or ductwork has been modified, filters replaced, decontamination performed, or maintenance carried out since the last accepted test.

□ Confirm that post-maintenance testing addresses both the filter and the interfaces that were disturbed.

□ Document unresolved issues involving access, testability, leakage, or maintenance before treating the assembly as an accepted barrier.

> **Technical-use note:** This review checklist is a diagnostic-support tool. It does not establish site-specific acceptance criteria, replace risk assessment or professional judgment, constitute certification, or authorize operation or return to service.

If the review identifies a condition requiring site-specific evaluation, BioLab Solutions can support technical assessment, verification, and definition of the required evidence.

RELATED BIOLAB RESOURCES

EXPLORE HEPA FILTRATION, BOUNDARIES, AND VERIFICATION IN GREATER DEPTH

NT-018
HEPA filtration as a containment boundary

NT-019
Housing, sealing, and integrity verification in HEPA filtration

NT-020
Failure modes and bypass paths in filtration systems

NT-021–024
Leak tightness, envelope continuity, and verification

NT-032–033
Commissioning and functional testing

NT-035
Documentation as a containment control

NT-037
Maintenance as a containment-risk domain

NT-039
Lifecycle drift in containment systems

BIOLAB DIAGNOSTIC GUIDES

Short technical resources organized around real containment problems rather than individual disciplines.

Series concept: symptom → system → evidence → restoration.

CLOSING DIAGNOSTIC PRINCIPLE

THE BARRIER IS THE VERIFIED PATH — NOT ONLY THE FILTER MEDIUM.

When HEPA filtration forms part of the containment strategy, it functions as a containment control only when the complete installation preserves the intended airflow path.

Filter efficiency, housing integrity, seal continuity, bypass control, test access, maintenance strategy, and fan capacity all contribute to determining whether that path remains reliable.

The diagnostic objective therefore goes beyond confirming the filter type or reading differential pressure. It is to obtain evidence that the filtration path maintains the required integrity, that no uncontrolled bypass paths have been identified under the applicable verification conditions, and that the barrier can continue to be tested and restored throughout its operational life.

BIOLAB SOLUTIONS

Independent technical support for planning, design, commissioning, assessment, and lifecycle management of high-containment laboratories.

For site-specific evaluation, BioLab Solutions can support technical review, verification, and definition of evidence requirements.

FILTER → HOUSING → SEAL → SYSTEM INTEGRITY