

# BioHawk LF<sup>®</sup>

## Automated Detection, Collection, and Bioidentification

The BioHawk LF<sup>®</sup> is an automated system for detecting, collecting, and identifying airborne pathogens based on bio-fluorescent detection and multi-analyte lateral flow immunoassay (ticket) identification. The system will sample a targeted air stream for a period of up to months without human intervention. Upon detection of a suspicious aerosol, the bioidentification process can be programmed to occur automatically or may alternatively be manually initiated. Results are provided via onboard display and serial digital data link.



*BioHawk LF<sup>®</sup> system for automated biodetection, collection, and pathogen identification*

The biodetector-triggered assay mode maximizes user and public safety by minimizing the time between threat detection and assay reporting. Operating costs are also much lower since bio-consumables are only used when a credible threat has been detected. This is in contrast to protocols where assays are run at fixed intervals or in batch product processing where each batch must be tested before release.

Using commercial, off-the-shelf bioassay tickets, the presence of up to eight biothreat agents may be

determined in a period of 10 to 25 minutes total elapsed time. Bioassay tickets can be provided in hermetically sealed carrier modules that are viable for several months and provide the ultimate in automated long-term bio-surveillance.

Machine vision methods are used to determine the presence of pathogens. There is no need to educate users on assay interpretation. Assays are insensitive to ambient light level or color balance. A transfer vial is standard for after-assay storage of sample fluid for use with an alternative confirmation method.

Bioassay ticket testing is perhaps the most widely used and mature technology for the identification of biothreats at trace levels. Tickets have a long shelf life, typically 12 to 18 months, and require no special storage conditions. Bioassay tickets are available for a variety of threats from multiple sources, and tests for new threats are commonly developed as the need arises. The BioHawk LF is obsolescence-resistant in that regard.

## FEATURES

- A sophisticated combination aerosol biodetector, sampler, and wet bioidentifier
- Suitable for toxins, bacteria, spores, fungi, multi-cellular pathogens
- Performs up to 8 simultaneous bioassays on collected samples
- Automatic confirmatory sample
- 325 liter/minute air sampling rate
- Weeks-long air sampling times
- Uses widely available lateral flow immunoassay tickets
- Room temperature storage of consumables
- Machine vision-based assay protocol
- Incorporates multiple novel patented technologies
- 10 - 25 minutes total elapsed time
- Auto-flush protocol for decontamination and cleaning
- Flash memory retains data for over 6,000 assays

## APPLICATION AREAS

- Mailrooms
- Air quality
- Agriculture
- Public Health
- Medical facilities
- Homeland security
- Military
- Power plants

The BioHawk LF is particularly well-suited for use as part of a complete CBRN monitoring program. It is cost-competitive, reliable, and user-friendly. Its high degree of automation results in ease of use by less experienced personnel.

The biodetector and automated ticket assay module are patented technologies that are also used in other Research International products – notably the AnCam 6100 and VBAD 3600 – systems that are currently in use by world governments to determine the presence of airborne pathogens. More detailed discussions of each subsystem follow.

## Biodetector

The biodetector is a third-generation product based on photon-counting technology as licensed from the U.S. Army in 2010. In this device, all aerosol particles in sampled air pass through a beam of UV-C excitation light with a center emission wavelength of 280nm. Each particle in the sample stream passes through the beam and is binned according to its light scattering, fluorescence emission intensity, and physical size. This information is examined every 15 seconds to determine whether a suspicious event has occurred that is not characteristic of the expected aerosol background.

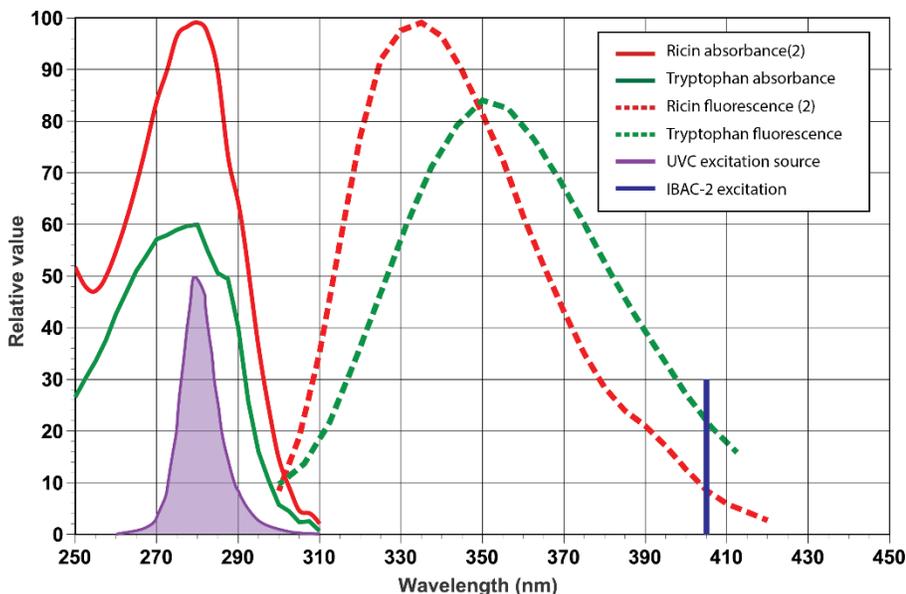


Figure 1. Absorbance and fluorescence spectra of ricin toxin and the protein tryptophan in relation to the BioHawk LF's excitation spectrum. The BioHawk LF is optimally designed to excite bio-fluorescence.

Many proteins found in toxins, viruses, and bacteria peak in fluorescence emission when excited at 280nm (Figure 1) and pulse bursts from those fluorescent photons are used to identify and characterize individual bioaerosol particles. Some non-biological aerosol materials also fluoresce at UV wavelengths, but yields are typically low with UV-C excitation.

A common problem with bioaerosol triggers has been a high level of false alarms. This issue is dealt with in the BioHawk LF by requiring that a trigger event simultaneously satisfy four different alarm criteria involving: the rate at which the bioaerosol level changes; the fraction of all particles that are biological; the intensity of the fluorescence; and the background particle concentration. The likelihood

that all trigger values exceed their limits at the same time is low, thereby significantly reducing false alarms. Alarm parameters may also be adjusted for local conditions by expert users. Software supplied with the product allows collected historical data to be used to determine optimum alarm parameter values.

This leading-edge biodetector subsystem has been granted several patents, including US 10267723 B1; US 10274410 B1; US 10444137 B2; US 10794815 B2; and US 11340153 B2.

## Wet Sampler

The BioHawk LF uses a novel wetted-wall cyclone method of aerosol collection. This is the same sampler technology that was used successfully in 2019 to collect the first Covid-19 aerosol samples in Wuhan, China at the start of the pandemic. This work was recognized in a U.S. CDC publication<sup>1</sup>.

In this device, aerosol particles in the BioHawk's 325 liter/min airflow are collected into distilled water using a combination of centrifugal and droplet impaction. The typical collection volume of 4.5 ml means that the aerosol air-to-water concentration ratio is about 72,000/min.

Most wet samplers are incapable of continuous operation since evaporation of water by the flowing sample air rapidly diminishes sample volume. This cyclone incorporates a novel patented recirculation circuit that monitors liquid volume

and adds water as needed to maintain a constant liquid inventory. A 5-minute collection time is typical without water replenishment. With the Research International cyclone, sampling can continue uninterrupted for days at a time.

A potential problem with wet samplers is that droplets containing infectious particles may be created during the sampling process. If discharged with sampled air, they may cause illness, which is of significant concern in medical facilities. The Research International sampler employs a droplet separator that reduces emission of droplets to near-zero.

*The wet cyclone module has been granted the following patents: US 6484594 B1; US 6532835 B1; and US 7261008 B2.*

## Bioanalyzer

The BioHawk LF bioanalyzer module is based on fully robotic immunoassay principles, including machine-vision reading of bioassay tickets. The time from alarm to result ranges from 10 to 25 minutes, depending on the threat's concentration.

An immunoassay approach leverages the wide availability of tickets targeting different medical and public safety threats. While less sensitive than PCR, immunoassays require no sample preparation and can be accomplished in half the time required for PCR. In addition, a first step in the assay protocol is production of a confirmatory sample so that users can quickly examine the sample using an alternative assay method of choice.

Alternative technologies often incur significant consumables costs due to a periodic sampling mindset. With the BioHawk LF, there is no interruption to work in progress until an unusual bio-event is detected.

## Using the BioHawk LF for Long-Term Unattended Monitoring

Some users need to operate the BioHawk LF in a long-term unattended setting, such as airport security areas, with a ticket loaded and ready to run an automated assay upon threat detection. But while the shelf life of immunoassay tickets ranges from 12-18 months at room temperature, assay tickets must normally be used within 48 hours of removal from their foil packaging to prevent deterioration from issues such as humidity exposure.

To solve this viability problem, Research International has developed a patent-pending hermetic shell to preserve the ticket while allowing it to remain loaded in the BioHawk LF for extended periods – even weeks or months – until it is needed for an assay.

The shell features puncturable foil seals over the sample wells for sample delivery, a large window for machine vision monitoring of the assay development process, a small desiccant pack, and passive humidity and temperature sensors to confirm ticket viability (Figure 2).

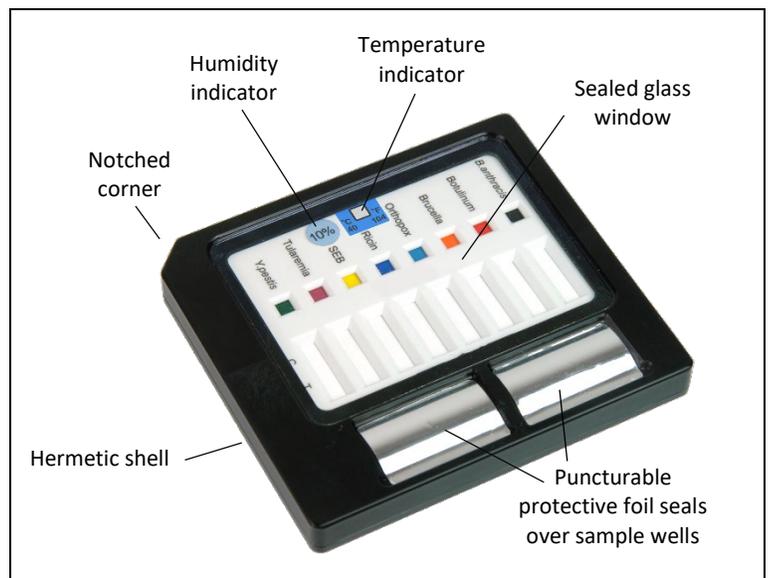


Figure 2. Hermetically sealed 8-channel immunoassay ticket.

The BioHawk's robotic transport system can accept either bare tickets with one to eight channels, or those same tickets encased in this proprietary shell. The shells are reusable; once a ticket is exhausted, a new one may be mounted.

*The bioanalyzer module is covered by the following patents: US 10318845 B2; US 11023773 B2; US 10192144 B2; US 11543405 B2; and US 10197558 B1; and US 10690660 B2.*

Refs.

1. *Aerosol and Surface Distribution of Severe Acute Respiratory Syndrome Coronavirus-2 in Hospital Wards, Wuhan, China, 2020*, Zhen-Dong Guo et al., Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 26, No. 7, July 2020.
2. <https://docslib.org/doc/13005863/ultraviolet-visible-reference-spectra>

## Typical Specifications for the BioHawk LF®

<b>Exterior aerosol sampling rate</b>	>300 liters/min. delivered to trigger and continuously operating wet collector.
<b>Targeted aerosol threats</b>	All toxins, viruses, bacteria and spores in the 1 to 15 micron size range
<b>Threat detection method</b>	UVC-excited single particle biofluorescence and optical scattering. A multi-parameter threat calculation is performed at 15 sec. intervals
<b>Detector statistics</b>	Detection limit is 1 sampled particle (U.S. patent 10267723 B1). Will alarm on 20 ACPLA bioaerosol with 90% probability at a background alarm rate of 1 per month. Natural background aerosol statistics may affect field performance.
<b>Sample preparation after trigger event</b>	Wetted wall cyclone. 72,000/min. air/water concentration ratio. Liquid sample volume is unaffected by time, temperature or humidity.
<b>Bioidentification strategy</b>	Automatic robotic lateral flow immunoassay plus confirmatory sample. Minimum/maximum total elapsed times to assay result are 10/25 mins., typ.
<b>Simultaneously identifiable biological agents</b>	Up to 8 agents in a single test cassette. Compatible with lateral flow immunoassay tickets provided by most manufacturers.
<b>Confirmatory assay sample after trigger event</b>	A confirmatory sample filling station can be instructed to automatically fill a vial immediately after an alarm or after a positive assay result. The confirmatory sample may also be transferred to the system waste bottle.
<b>Alarm events performed before system requires service</b>	Unlimited if only used to detect and notify threat event occurrences. If the bioassay option is selected, the assay ticket must be replaced after each test.
<b>Bioassay ticket life</b>	Ready-to-run hermetically sealed tickets installed in the instrument are viable for 6 months and 12-18 months in as-supplied foil pouch.
<b>Process control details</b>	Industrial PC-based control/protocol software. Touch screen control. Fully automated and integrated sampling, sample preparation, bioassay and cleaning protocols. Immediate operator alert upon any detected operating fault.
<b>Output upon alarm or positive assay</b>	Immediate light and sound alerts on initial alarm and if assay results are positive. Electronic signals transmitted as appropriate to a connected remote monitor.
<b>Data preservation</b>	All raw biodetector data and bioassay photos are time-stamped and stored
<b>Ethernet connectivity</b>	Standard RJ-45 connection to onboard computer
<b>Operating temperature range</b>	5°C to 40°C; instrument storage: -29°C to 66°C
<b>Environmental standards, shock, and vibration</b>	Appropriate sections of MIL-STD-810
<b>Power</b>	37 W at 28 VDC
<b>Dimensions and weight</b>	47.0 W x 24.8 D x 36.5 H (cm); 13 kg
<b>Exterior Noise level</b>	Less than 70 dB-a
<b>Consumables</b> <i>Purchased separately</i>	1) Bulk deionized water; 2) buffer; and 3) wash fluid. Buffer and wash fluid are available in convenient single use bottles.

*Research International, Inc. reserves the right to change product and system specifications without prior notice.*

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