

The BSL-4 Laboratory

- An important part of the Nordic Public Health Emergency Preparedness



Folkhälsomyndigheten
PUBLIC HEALTH AGENCY OF SWEDEN

The Public Health Agency of Sweden is always on standby to conduct microbiological analyses of high-consequence infectious agents that pose a danger to society. For this purpose, the Agency operates a high-containment laboratory to process samples from patients suspected to be infected with haemorrhagic fever viruses or other highly pathogenic viruses. Samples are received mainly from Swedish healthcare facilities, but the Agency also has agreements with several Nordic and Baltic countries to handle and analyse specimens. In addition, the Agency can provide analyses of samples from other countries, outside any specific agreement, if requested.



Effective communicable disease control requires access to advanced laboratories

The high-containment laboratory at the Public Health Agency of Sweden in Solna is the only biosafety level 4 (BSL-4) facility in the Nordic countries and one of few in Europe. At the laboratory, haemorrhagic fever viruses and other highly infectious pathogens in risk group 4 can be identified and further analysed. The laboratory also has the capability to identify hitherto unknown infectious agents by next generation sequencing (NGS) and advanced bioinformatics support. There are approximately 20 staff members working either at or in connection with the facility, which consists of two separate modules. This unique BSL-4 laboratory has been in operation since 2001, and it constitutes an important role in national preparedness for high consequence viral pathogens. The laboratory was established as a resource to enable work focused on infectious agents that are known to cause serious or fatal diseases that have high mortality rates, are highly contagious, pose a risk for nosocomial spread into society if not contained, and in most cases cannot be prevented by vaccination or have specific treatment.

Preparedness and diagnostics

The Public Health Agency of Sweden monitors current outbreaks of infectious diseases around the world, and its service is available 24 hours a day,

seven days a week for analysis of specimens from patients suspected to be infected with a high consequence viral pathogen. The laboratory is always operational, and within two hours of notification from a healthcare facility, laboratory staff can initiate analyses of samples suspected to contain viral haemorrhagic fever viruses such as Ebola and Marburg viruses, Crimean-Congo haemorrhagic fever virus, and Lassa virus as well as pathogens causing severe respiratory tract infections such as the viruses causing Middle East Respiratory Syndrome (MERS), Severe Acute Respiratory Syndrome (SARS) and highly pathogenic influenza. A comprehensive list of the diagnostic tests that are offered can be found online at www.folkhalsomyndigheten.se

The following methods are available for diagnostic testing of viruses in risk group 4.

- Molecular biological analyses (Q-PCR, conventional PCR, partial or complete sequencing of virus genomes, NGS)
- Serological analyses (including virus neutralisation)
- Electron microscopy
- Virus cultivation/isolation
- Experimental biomedicine

The combination of experimental biomedicine and the capacity to conduct detailed analyses of the genome of an infectious agent provides a unique opportunity to identify unknown, or altered, infectious

agents and thereby establish new specific diagnostic methods as well as evaluate new antiviral compounds *in vitro* and *in vivo*. The diagnostic techniques are quality assured through participation in European networks of high containment laboratories.

A virology laboratory as well as a bacteriology laboratory (both biosafety level 3 [BSL-3]) are located adjacent to the BSL-4 facility. At the BSL-3 laboratories it is possible to perform differential diagnostics for instance malaria and dengue fever, or bacterial diseases like anthrax, melioidosis and brucellosis.

Laboratory networks and research

The Public Health Agency of Sweden conducts research aimed at strengthening national and European preparedness for outbreaks of severe communicable diseases. The Agency leads or participates in several international research projects concerning haemorrhagic fevers, and it is a member of several national and European networks. Within these networks, joint projects are being conducted that focus on developing methods for analysis and identification of high-risk pathogens. These networks also enable the Public Health Agency of Sweden to receive early information about outbreaks and cases of infectious diseases, and to collaborate in managing outbreaks that cross, or have the potential to cross, national borders. Moreover, by participating in the networks, the Public Health Agency of Sweden has access to quality assured,

well-evaluated diagnostic methods. The Agency can also offer external researchers the opportunity to conduct projects in the high-containment laboratories.

Biorisk management

The Public Health Agency of Sweden has the expertise, and the national responsibility, to advise other agencies on biosecurity and biosafety (collectively known as biorisk management). Knowledge about biorisk management is required in diagnostic laboratories, universities, life science biotechnology companies, and other organizations where microbiological laboratory work is performed. The Public Health Agency of Sweden can provide education and training in biorisk management and our Agency is disseminating information and offering guidance on implementation of the CEN Workshop Agreement regarding laboratory biorisk management CWA 15793. The CWA document is an international agreement describing a management system aimed at identifying and dealing with biological risks in laboratories. To facilitate implementation of CWA 15793 the Public Health Agency of Sweden has developed a web-based tool called *Securing biorisks* (*Säkra biorisker in Swedish*) to be used for self-assessment of biorisk management in individual organizations. The tool is free of charge and is available online at <http://sakraborisker.se>, both in Swedish and in English.



BIOSAFETY LEVEL 4 is the highest level of protection for laboratories. A BSL-4 laboratory is physically isolated from the surroundings, and access is restricted to a small group of specially trained staff members. Laboratory personnel wear positive pressure protective suits, and the air they breathe is provided externally. Haemorrhagic fevers are serious diseases that are characterised by fever and often varying amounts of bleeding from different organs in the body, as well as varying but high mortality rates. These illnesses can be caused by a wide range of viruses.





The Public Health Agency of Sweden

The Public Health Agency of Sweden is nationally responsible for matters concerning public health and to evaluate the effectiveness of methods and strategies within the field. Its mandate is to promote health, prevent ill health and protect against health threats. The Agency collaborates with other actors to generate scientific data and support for implementation and monitoring of applied methods and initiatives. Important partners include other national government agencies, county councils and municipalities.

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On the frontline of communicable disease control

The Public Health Agency of Sweden performs microbiological analyses and offers laboratory knowledge support within the field. The Agency contributes to the development and maintenance of quality controlled methods at laboratories conducting diagnostic testing that is critical for national communicable disease control. It also performs diagnostic tests for communicable diseases on submitted patient samples.

In addition, the Agency carries out research required to meet its mandate in the area of communicable disease control. One important role is to provide expert support on confirmed or suspected outbreaks and to maintain the laboratory preparedness that is required for effective communicable disease control.



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