

### Case Study

# Biobanking in Virology: From Retrospective Sample Collection to Epidemiology, Diagnosis and Research

The initiation of the Cerba Research and Viroclinics-DDL "Virus Biobank" operation looks to be highly promising for advancements in epidemiology research. This recent project, focusing on processing and storing respiratory viruses, will greatly benefit current research, diagnosis, prevention, and treatment of viruses like SARS-CoV-2, Influenza virus A/B and Respiratory Syncytial Virus (RSV).

Biobanks have made monumental contributions to healthcare, biotechnology, disease control and prevention, along with bio-conservation. They represent an essential tool for the development of disease diagnosis, prevention and treatment. In light of recent virus outbreaks, the most devastating example being COVID-19, the need for virus biobanks for pathology research is becoming increasingly apparent.

However, compared to other scientific fields, such as oncology, virus biobanks are limited in number.<sup>1</sup> Cerba Research has, therefore, collaborated with Viroclinics-DDL to start the "Virus Biobank" operation through the Cerba HealthCare network, which welcomes more than 45 million patients each year in more than 1,160 laboratories throughout the world. The main aim is to create a specialized and contemporary biobank of relevant respiratory viruses that are fully characterized, have fast availability for use, and can be shared with larger cohorts and networks.



**45M** Patients per year **60+** Countries

**1,000+** Clinical pathologists

**2,500+** Types of tests

**320,000+** Tests performed/day

**130+** Tech. platforms

Figures as of June 2022

1.160 +

Laboratories

**15+** Therapeutic areas

### Unleashing the Potential of Virus Biobanking

Most pertinent research on infectious illnesses, microbial pathogenesis, and environmental microbiology depends on biological samples. Thus, there is a pressing need for banking biological material in the context of virology.

Biobanking is the process of collecting, annotating, storing and redistributing biological samples for the purpose of research to better understand health and disease. Large quantities of specimens are required to create a biobank for epidemiology research, and these specimens must include samples from a range of infected individuals, from those displaying no symptoms to individuals that suffered mortality. Samples from individuals that have been unaffected by the virus are also needed to conduct comparative studies to understand the infectivity and effects of the disease.<sup>1</sup>

### Why Biobank Viruses?

Biobanks are key to improvements in disease diagnostics, prevention and treatment. To guarantee improvements in diagnostic procedures, it is necessary to compare samples from the same individual at different points in time, as well as many individuals with similar diseases and in different geographical areas. Samples from populations that have been identified to be high-risk are also of high importance to studying and understanding pathology. Examining stored samples using new analytical techniques that could boost the sensitivity or specificity of infectious disease detection can further improve diagnosis.

Virus strains need to be fully characterized and available for assays (for research and development animal challenge models and clinical trials) and rapid access to contemporary and most relevant virus strains is key. Isolated viruses of interest should be available for keeping assays updated and for assay development, qualification and full validation when needed. All of this is necessary to improve disease diagnosis and our understanding of viral pathology.

### The "Virus Bank" Operation – Goals, Challenges and Solutions

The main goal of the "Virus Biobank" operation is to establish a specialized and contemporary collection of relevant respiratory viruses which are fully characterized and are quickly available to be used in routine assays for the study of infectious diseases. The "Virus Biobank" will be a 'one shop stop' for clients with the most relevant strains available to clients and with connected networks. Cerba Xpert – Cerba Research's specialized IVD and MD division – in combination with Viroclinics-DDL – a Cerba Research company – aims to revolutionize infectious disease diagnosis and research, founding its own virological biobanking facility characterized by different storage techniques, functional protocols and bioinformatic procedures.

Cerba hopes to achieve this by developing a first process focusing on respiratory infections and taking SARS-CoV-2, Influenza virus A/B and Respiratory Syncytial Virus (RSV) as the first targets. The protocol's design will determine the types of samples to be collected, when and how they should be processed, and how to store the processed sample in the long term to ensure their viral integrity.

One of the main challenges for Cerba Research and Viroclinics-DDL is the development of a robust protocol to cryopreserve specimens so that they retain their pathogenic properties. Cryopreservation works by cooling specimens to incredibly low temperatures at which they will preserve; for viruses, this is normally at ultra-low temperatures (-70 °C in liquid nitrogen containers). The addition of proteins, like serum, to biobank viral stocks, further protects the infectivity of virus samples.<sup>1</sup>

The cryopreservation procedure must be robust and created with an understanding of the biophysical response of the specimen to the freezing process, as the rate of cooling can easily kill the sample that needs to be preserved. To distinguish the optimal cooling conditions for cryopreservation, scientists generally compare the effects of different preservation techniques on the viability, pathogenicity, and morphological and genomic stability of cells/strains before and after different preservations.<sup>2</sup> Cerba Research and Viroclinics-DDL are designing and validating a pilot protocol for freezing and thawing serum specimens to proceed to a culture.

New virus banks are often created after a disease outbreak due to the need for preventative measures and treatments and to increase the availability of specimens to sample. However, identifying areas with a high prevalence of respiratory viruses through statistical analysis is another challenge that Cerba Research and Viroclinics-DDL are trying to combat by having access to multiple biomedical laboratories in a network in the region with the highest prevalence of respiratory viruses.

The time between sampling and preservation of a specimen is also essential to consider, as specimens become unstable after certain periods of time. Unlike other microorganisms, viruses tend to be more stable due to their non-cellular form, structural simplicity, and absence of free water.<sup>2</sup> Nonetheless, the Virus Biobank operation is working to optimize this by implementing a successful logistics circuit that enables them to meet sample preservation times < 4 hours after collection. Collection, anonymization and demographic classification of samples by age, gender, and region can be tricky at a high scale. Cerba Research and Viroclinics-DDL plan to target patients presenting for SARS-CoV-2 testing and run their samples through the PKamp<sup>™</sup> Respiratory SARS-CoV-2 RT-PCR Panel Assay from Perkin Elmer. Another important aspect of creating a successful biobank is cataloging samples and their properties. Rapid advances in technology have led to the development of high throughput molecular analysis techniques, providing more robust and detailed annotations of specimens on a tremendously larger scale. Cerba Research and Viroclinics-DDL are taking full advantage of these technological advances, using next-generation sequencing methods to precisely categorize viral strains of interest.

#### Overview of Study Process:



Patient coming in one of our routine labs for SARS-CoV-2 testing



insurance)



questionnaire (symptoms, treatments, diseases)



Sampling



- SARS-CoV-2
  RT-PCR
  Panel Assay
  PKamp™
- Respiratory Panel
- Delivered samples:
  Anonymized
- samples delivered by the required storage conditions
- Analysis results and clinical and demographic data associated
- Not delivered samples:
   Not meeting the request

## The success of the "Virus Biobank" Operation and the Future of Infectious Disease Diagnosis

The Cerba Research and Viroclinics-DDL's "Virus Biobank" operation has been initiated with agile and fast execution due to a peak in Flu (A/B) and RSV (Respiratory Syncytial Virus) in France. This has helped them to create a protocol to cryopreserve samples with a high viral positivity rate in a very short time frame – with a most recent total of 7% RSV and 28% Flu (A/B) positive samples collected in less than a month. Precise categorization of viral strains via next-generation sequencing and biobanking will allow the viruses stored by the Virus Biobank operation to be exploited for even further projects.

The digital adaptation of biobanks and their online presence is expanding communication, networking, and data sharing, increasing the research outputs of biobanks. Cerba Research and Viroclinics-DDL are opening the project to larger cohorts and diversified pathologies to help feed the biobank throughout the year via their worldwide network of laboratories.

Together, Cerba Research and Viroclinics-DDL intend to take infectious disease diagnosis and research to the next level by creating a specialized contemporary biobank of pertinent respiratory viruses that are fully characterized for routine assays for research development and clinical trials.

#### References:

- Medina, P.B., Garcia, D.L., Cheong, I.H., Lin, R.T. and Kozlakidis, Z. 2022. Construction and application of biobanks for infectious diseases: focus on SARS-CoV-2. *Innovations in Digital Health, Diagnostics, and Biomarkers*. 2(2022), pp.40-47.
- 2. De Paoli, P. 2005. Biobanking in microbiology: from sample collection to epidemiology, diagnosis and research. *FEMS microbiology reviews.* 29(5), pp.897-910.

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