

SITE HEAD Anne-Katrin Hilbert Managing Director



MARBURG, GERMANY

# **Key Features**

Our Marburg laboratory has cutting edge expertise in tailored, functional, and immuno-binding serological assays for vaccine licensures, with a staff of about 90 specialists. We have 20 years of demonstrated expertise in selecting, developing, and validating immunological assays in support of vaccine development in both Novartis and GSK global environments.

# **Key Abilities**

- All clinical serology services
- Broad range of immunochemistry and functional assays, with a focus on:
  - Neisseria Meningitidis serobactericidal assays
  - Opsonophagocytosis assays
  - Virus neutralization assays
  - Hemagglutination inhibition assays

# Laboratory

- 22,600 square foot BSL-2 labs and offices
- 750 square foot BSL-3 labs
- 2022 expansion project (10,000 square feet)
- Sample testing capacity: 200,000
- Sample storage capacity: 1,000,000
- Operate under GCLP and ISO 9001:2015 standards as an autonomous laboratory facility
- Human sample management and storage:
  - Dedicated sample logistics group
- Automated tube labeling (Scinomix) and aliquot generation (Tecan)

**Notable Certifications: GCLP** 





### **OUR STORY**

#### 1904

Foundation of the "Behringwerke" site in Marburg, Germany by Emil von Behring using the prize money for being honored with the first Nobel Prize in medicine on his discoveries of a diphtheria antitoxin.

The primary focus on vaccines extended over time to blood and plasma products (now CSL Behring) and diagnostics (now Siemens Healthcare) in conjunction the company changing hands multiple times. In 1994 the business areas split and Chiron acquired the vaccine business.

#### 1999

As part of Chiron Vaccines, a human serology lab is established in Marburg with 10 people. In 2001 the first clinical lab data are generated using antigen-binding (ELISA) and neutralization assays to support the licensure of a TD-IPV vaccine. Over time, there was expansion to add expertise in meningitis and influenza serology for vaccine development.

#### 2006

Novartis takes over the entire vaccine business from Chiron, further expanding the portfolio of influenza and meningococcal vaccines. Clinical Serology becomes the central laboratory supporting clinical immunogenicity and efficacy assessments with lab data and managing the human biological samples.

#### 2000

Clinical Serology is heavily involved in the H1N1 pandemic relief efforts. Doubling the lab team and capable of clinical testing only four months after the pandemic was announced to allow rolling submission of clinical data for quick vaccine licensure.

#### 2010

FDA inspection held in Clinical Serology on the meningitis serum bactericidal assays used for licensure of a MenACWY vaccine and successfully passed.

#### 2012

Lab business increases in size and broadens in scope, adding a dedicated sample management and a business operations team, covering all clinical trial-related lab work end-to-end, as Clinical Laboratory Sciences team. Investments are made in automation to increase the capacity of both the sample management and the clinical testing to support several strategic projects in bacteriology/meningitis.

## 2015

GSK acquires Novartis Vaccines and the clinical lab business in Marburg is fully integrated, with ISO 9001:2015 certification since 2018. Continuous improvement activities centered around assay setup, qualification, validation and performance monitoring forged close collaboration between science and the statistical teams.

## 202

GSK divests of the clinical laboratories in Marburg with approximately 70 employees transferring to Nexelis, with expertise to perform all aspects of assay life cycle management, including statistical evaluation. Within few months, 10 positions are added in order to run the Nexelis labs as an independent company on the Behringwerke campus.

### LAB EQUIPMENT AND TECHNIQUES

- BioTek Instruments ELx808, ELx808IU
- TECAN Infinite 200 Pro
- BioTek 405 TS, EL x 405 RMF, 405 SRVS
- Thermo Fisher Scientific KingFisher Duo Prime
- Synbiosis ProtoCol3, ProtoCol4, ProtoCol5, ProtoCol6, ProtoCol7, ProtoCol8
- TECAN Evo 75
- TECAN Evo 200
- TECAN Evo 100 Robotic Unit
- Luminex Flexmap 3D
- Scinomix Tube Labeler
- Microtechnix Axiolab
- Logos Biosystems Luna II
- Microtechnix Scanlab II

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## **ABOUT NEXELIS**

With unrivaled expertise in immunology, 5 operating sites in North America and Europe, and a translational offer of services covering the needs of the pharmaceutical industry from the lead selection to the late clinical stage, Nexelis is a leading provider of assay development and advanced laboratory testing services in the infectious, metabolic and oncologic fields. Our versatile team of scientists, working with state of the art technology platforms, were instrumental in the development, qualification, validation, and large-scale sample testing of assays that supported the FDA filing of almost 100 new molecular entities, including blockbuster vaccines and biologics, anti-viral drugs, immunotherapy, gene and cell therapy products.

# MARBURG, GERMANY

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