



Public Health
England

Protecting and improving
the nation's health



nexelis

disciplined agility

assay development • specialty testing

Strategic partnership focused on vaccine projects with the objective of jointly developing new preclinical and clinical assays to support R&D and clinical biopharmaceutical teams in fields such as infectious disease vaccines and immunotherapies.

We have a wide range of expertise across all types of vaccines:

- Live-attenuated vaccines
- Inactivated vaccines
- Subunit, recombinant, polysaccharide, and conjugate vaccines
- Toxoid vaccines
- VLP-based vaccines
- DNA & RNA vaccines
- Pseudoparticles
- Therapeutic vaccines





Specialized service provider with over 15 years of experience in vaccine testing whose team of experts, cutting-edge technology platforms and state of the art laboratories were instrumental in the development, qualification, and validation of more than 30 assays supporting the FDA filing of 10 marketed vaccines with cumulative sales around \$3bn.

Our unrivaled expertise in immunotools engineering and stability testing, as well as our capacity of 250k results per year on our immunochemistry, virology, and bacteriology automated platforms are devoted to personalized services and fast track method validation.

Nexelis is a preclinical and clinical immunology partner of choice for the development, qualification and validation of immunological assays, in single and multiplex formats, and sample testing to support vaccine development.

In addition, we have the expertise to support non-inferiority and epidemiology studies to accelerate regulatory approvals.

High-Throughput Capabilities

Nexelis offers multiple automated systems for high-throughput analysis capabilities to support projects from early development through large clinical trials.

Nexelis offers a key asset by having multiple automated systems for high-throughput analysis to support early development through large clinical trials.

Immunochemistry

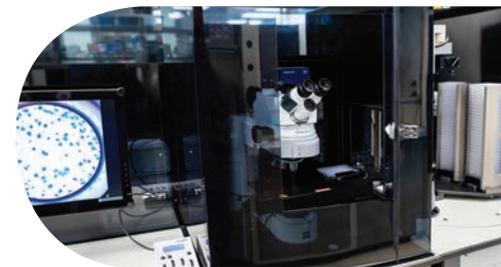
- State-of-the-art automated liquid handlers
- **Up to 2,000 samples per analyst per week**

Virology

- Automated acquisition and analysis
- **Up to 720 samples per analyst per week**

Bacteriology

- Automated acquisition and analysis
- **Up to 480 samples per analyst per week**



Laval, QC, Canada



- 45,000 sq.ft. of state-of-the-art laboratories and offices
- BSL2 laboratories
- Accreditations: GCLP, ISO 8655 standard compliant, GLP/GCP standards
- Biorepository capacity of over 1 million samples on site (-20 & -80°C)
- State-of-the-art equipment to support preclinical and clinical vaccine development
- Unique high-throughput capabilities: e.g. TECAN, image analyzers



PUBLIC HEALTH ENGLAND (PHE)

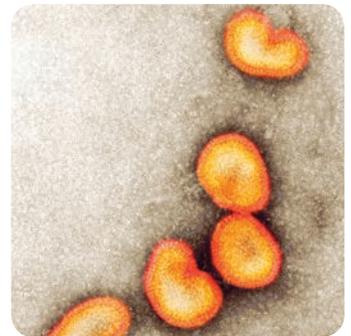
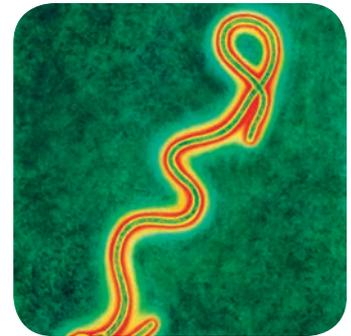
PHE Porton plays a key role in protecting the population's health from infectious diseases. There are over 600 staff at PHE Porton including scientists, managers, animal technical specialists, administrative staff and biosafety experts.

Our scientific credibility and regulatory expertise provides comprehensive preclinical and clinical services to UK and international Government, academic partners, and the global vaccine Pharma industry.

PHE Porton has extensive expertise and a proven track record in assay development, qualification and validation and the execution of these assays under GxP compliance for product and process characterization, release and stability, and in serological assessment of sera samples from clinical trials. We also provide consultancy on method feasibility, development, validation, and technology transfer.

Our laboratories provide:

- Considerable expertise in the development and validation of biological assays including functional, neutralization and cell-based assays
- Extensive experience in the development and validation of novel assays including Host Cell Protein and enzymatic activity
- Significant capabilities in development and validation of assays to evaluate cellular and memory immune responses in both clinical and non-clinical samples
- International recognition for the provision of specialist serology services including Tetanus, Diphtheria, Hib, and Pertussis (PT, Fim2+3, FHA and Pertactin) all in compliance with GCLP
- Performance of batch release and stability testing of vaccines (including seasonal Flu) and therapeutics worldwide including UK, EU and US
- Global recognition of research and development activities in infectious diseases up to and including biosafety level 3 and 4 including rare and exotic pathogens and those identified as potential bioterrorism agents
- International collaboration including academia, industry, charities and governments



In vivo activities are conducted in **BSL level 2, 3, or 4 facilities** by a dedicated team of animal technicians, a duty Named Veterinary Surgeon (NVS), two registered Veterinary Pathologists and several Named Animal Care Welfare Officers as required by UK law.

We have extensive experience in the development and application of animal models (mouse, guinea pig, ferret, rabbit and NHP) to perform studies such as pathogenesis, transmission, immunogenicity, efficacy, potency. Examples of animal models available at PHE Porton include Influenza, TB, Ebola, Lassa, CCHF, Monkeypox, Anthrax, MERS, Chikungunya, Zika, *C. difficile*, *Burkholderia pseudomallei*, *Coxiella burnetii*, etc.

Porton, Salisbury, UK



Public Health England

- 25,000 sq.ft. of state-of-the-art laboratories and offices
- Accreditations: GCLP, GCP, cGMP, ISO 9001/2015
- Porton Down houses 102 BSL2, 68 BSL3 and 2 BSL4 laboratories which include both *in vivo* and *in vitro* facilities. State-of-the-art equipment to support preclinical and clinical vaccine and therapeutic development.





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