



HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology and Virology Reference Laboratories Review

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Table of Contents

Context.....	4
Overview	5
What are Public Health Microbiology and Virology Laboratory (PHMVL) Services?	5
HSE PHMV Reference Laboratory services	6
HSE Food and Water Microbiology Laboratory services.....	7
National Virus Reference Laboratory (NVRL).....	7
Methodology to Development of Report	7
Key Findings	8
Synergies	8
Gaps and Duplication of Efforts	9
Resources and costs associated.....	11
Recommendations	15
Funding	18
Accreditation.....	19
National Virus Reference Laboratory.....	19
Plan and Timeline.....	20
Appendix 1 – Terms of Reference.....	21
Appendix 2 – HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology Reference Laboratories Review	22
Appendix 3 - HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology Reference Laboratories Review Data Tables	24
Appendix 4 – Indicative Costings to Support Governments Recommendation	48
Appendix 5 – Membership of the Review Group.....	49
Appendix 6 – Glossary.....	50

List of Tables

Table 1: Summary NVRL WTE Analysis by Grade	11
Table 2: Summary PHMVLS WTE Analysis and Costings by Grade	11
Table 3: Details of WTE per National Reference Laboratory Services (HSE)	13
Table 4: Details of WTE– Food and Water Microbiology Laboratory Services (HSE).....	13
Table 5: HSE Microbiology Reference Laboratory Services Q1 to Q13.....	24
Table 6: HSE Microbiology Reference Laboratory Services Q14.....	27
Table 7: HSE Microbiology Reference Laboratory Services Q15 to Q22.....	31
Table 8: HSE Food and Water Microbiology Services Q1 to Q13.....	36
Table 9: HSE Food and Water Microbiology Services Q14	38
Table 10: HSE Food and Water Microbiology Services Q15 to Q22	42
Table 11: National Virus Reference Laboratory Q1 to Q13	46
Table 12: National Virus Reference Laboratory Q14	46
Table 13: National Virus Reference Laboratory Q15 to Q22	47
Table 14: Indicative costings	48

List of Figures

Figure 1: Executive Management Team Governance Structure	Error! Bookmark not defined.
Figure 2: Timeline for developing an integrated and comprehensive public health microbiology laboratory service	20

Context

The HSE EMT tasked the Chief Clinical Officer and AMRIC Oversight Group to carry out a review of HSE Public Health Microbiology and Virology Laboratory (PHMVL) Services in December 2019. A defined terms of reference was agreed (Appendix 1 refers). However due to the COVID-19 response and roll out of the COVID-19 vaccination programme this project was paused. The project was restarted in Quarter 4 of 2021.

In line with the requirements from the Terms of Reference, the HSE Clinical Lead for AMRIC and Clinical Lead for the National Clinical Programme for Pathology, following consultation with relevant stakeholders have prepared this report for consideration by the AMRIC Oversight Group and HSE EMT.

To help the reader navigate this report, the report is set out as follows:

Overview

- Introduction and Background
- Microbiology reference laboratory services provided by the HSE laboratories
- Food and water microbiology laboratory services provided by HSE laboratories

Key Findings

- The scope of existing services and the strengths of those services are recognised
- Potential synergies between existing publicly funded microbiology and virology laboratory services are recognised
- There are important gaps in microbiology and virology reference laboratory services and food and water microbiology laboratory services
- Pay costs and certain other resources associated with provision of /access to microbiology and virology reference laboratory services and food and water microbiology laboratory services are identified excluding costs associated with the provision of the National Virus Reference Laboratory by UCD but largely funded by the HSE

Key Recommendations

- The key recommendation is that central strategic leadership and management of these services is essential to address current and future needs. This report proposes a plan, pathway and timeline for progression towards an integrated and comprehensive PHMVL service that preserves existing strengths, optimises use of existing resources and identifies additional resource requirements

Overview

Ireland has an opportunity in the context of the current pandemic to build on existing strengths towards establishment of an integrated PHMVL service. The HSE service will focus on human health but will work closely with other public service laboratories and stakeholders to ensure a “One-Health” approach. An integrated PHMVL service provides a stronger and more resilient base and greater expertise and leadership to help identify and protect the Irish population from current and future infection risks.

What are Public Health Microbiology and Virology Laboratory (PHMVL) Services?

PHMVL services span the fields of human, animal, food, water and environmental microbiology. A “One Health” perspective is central to this work. This requires close collaboration with corresponding services related to animal health and the environment. A PHMVL service requires laboratory scientists, epidemiologists, data scientists and clinicians to work with public health to generate, integrate, analyse and communicate epidemic intelligence. A PHMVL service supports the monitoring of known and emerging threats and facilitates the evaluation of effective interventions (adapted from the ECDC consensus definition). International models of such services exist in many countries. The Statens Serum Institut in Denmark is an example of a long established national service. A Public Health Microbiology Strategy for Scotland (2018) is an example how other countries that do not have a long established service have laid out a plan to meet this need.

The PHMVL service proposed here is comprised of two key elements, reference laboratory services and food and water microbiology laboratory services.

Reference laboratory services are acknowledged as a critical element in the control of infection, including healthcare associated infection and antimicrobial resistance. This is acknowledged in the ECDC statement that reference laboratories play a central role in detection, monitoring, outbreak response and the provision of scientific evidence to prevent and control infectious diseases. (Core Functions of Microbiology Reference Laboratories for Communicable Diseases ECDC, June 2010)

Core functions of Reference Laboratory Services are grouped under 5 headings by ECDC as follows:

- Function 1: Reference diagnostics
- Function 2: Reference material resource
- Function 3: Scientific advice
- Function 4: Collaboration and research
- Function 5: Monitoring, alert and response

Reference diagnostics can be considered to include both providing primary diagnostic services that are not available in front-line diagnostic laboratories and performing confirmatory or additional analysis on samples initially processed in front-line diagnostic laboratories.

Examples of the functions, reference laboratories provide include:

1. the initial development and provision of service for detection of SARS-CoV-2 by the National Virus Reference Laboratory before commercial test systems became available.
2. primary testing of selected clinical samples for Vero-Toxigenic *E. coli* (VTEC)/*Bordetella pertussis* and causes of meningitis by the relevant reference laboratory services
3. additional analysis of certain bacteria cultured by front-line diagnostic laboratories to detect and track spread of infection

By performing these function reference laboratory services provide capacity to support surveillance and to respond to established and emerging infectious diseases. The COVID-19 pandemic has

highlighted the importance of expertise and capacity to respond rapidly to emerging threats.

Reference laboratory services are also vital to implementation of Ireland's National Action Plan (iNAP2) on Antimicrobial Resistance. It is central to strategic objective 2 of that plan which includes surveillance of antibiotic resistance. Ireland's PHMVLS capacity in this regard contributes to overall EU capacity and surveillance through sharing of expertise and data.

The food and water microbiology services are critical for assuring compliance with microbiology standards relevant to food safety, drinking and bathing water and to the capacity to respond to suspected or actual food safety incidents. Many HSE Food and Water Microbiology services have expanded their scope in recent years to support control of healthcare associated infection with monitoring of healthcare environments in particular analysis of water (for legionella) but also monitoring of air and surfaces in clean rooms and similar settings.

With respect to both reference laboratory capacity and food and water microbiology capacity Ireland has developed significant capacity for PHMVLS. However, the existing services have developed in an *ad-hoc* fashion over decades. Most of the individual laboratory services are within the Health Service Executive although dispersed through different sectors within Acute and Community Operations.

HSE PHMV Reference Laboratory services

There are currently 9 national Microbiology Reference Laboratory services within the HSE:

- National Carbapenemase Producing Enterobacterales Reference Laboratory (NCPERL), University Hospital Galway (UGH)
- National Gonococcal Reference Laboratory(NGCRL), St. James Hospital, Dublin
- Irish Meningitis and Sepsis Reference Laboratory (IMSRL), Children's Health Ireland, Temple Street, Dublin
- National Methicillin Resistant *Staphylococcus aureus* Reference Laboratory (NMRSARL), St. James's Hospital, Dublin
- Irish Mycobacteria Reference Laboratory (IMRL), St. James's Hospital, Dublin
- National Salmonella, Shigella & Listeria Reference Laboratory, (NSSLRL), UGH
- National VTEC Reference Laboratory (VTEC NRL) & National Campylobacter Reference laboratory (Camp. NRL), PHL HSE Dublin at Cherry Orchard Hospital
- National *Bordetella pertussis* Reference Laboratory (NBRL), Children's Health Ireland, Crumlin, Dublin
- *C. difficile* (established in 2021) at Cherry Orchard Hospital

All but two of these services are with the Acute Hospital Division of HSE. The VTEC and Campylobacter Reference Laboratory and the *C. difficile* reference laboratory services are within the Community Operations Division of HSE CHO 6. The current reference laboratory services are outlined in the Appendix 3. This comprises of a series of brief descriptions prepared by the individual laboratories on a standard template to describe certain key elements of their capacity and function.

When most of these reference laboratory services developed PHMVL work for each pathogen was, largely, based on a series of bespoke skills and technologies particular to each microorganism. The potential for interoperability was limited. This situation has transformed because of key technological advances in recent years. There is increasing convergence of reference laboratory work around a common suite of molecular biology techniques and platforms that are applicable to a broad range of microorganisms. Reference laboratory work has also become increasingly dependent on capacity for data storage, transfer and analysis so that information technology is now central to their effective operation.

HSE Food and Water Microbiology Laboratory services

There are currently 7 HSE Food and Water Microbiology services within the HSE:

- Galway University Hospital
- Public Analyst's Laboratory (PAL), Dublin, at Sir Patrick Dun's Hospital
- Public Health Laboratory (PHL), HSE Dublin, at Cherry Orchard Hospital
- Waterford University Hospital
- St. Finbarr's Hospital, Cork
- University Hospital Limerick
- Sligo University Hospital

Four of these laboratories are in the Acute Hospital Division of HSE and three (Dublin Public Analyst Laboratory, Cherry Orchard Laboratory and St. Finbarr's Hospital) are within the Community Operations Division of HSE. The budget for the food and water microbiology services based in St. Finbarr's Hospital Cork is managed at the national level by HSE Strategic Operations. The budget for the Dublin Public Analyst laboratory is now managed by CHO6. The current food and water laboratory services are outlined in the Appendix 3, which is comprised of a short template in which each laboratory describes certain key elements of its function.

National Virus Reference Laboratory (NVRL)

This was originally established in 1963 at the request of the Department of Health. At that time, its intended function was to carry out surveillance primarily for polio virus, following introduction of the polio vaccine in Ireland. It also became Ireland's National Influenza Centre, feeding data into the WHO's (then) Global Influenza Surveillance Network (GISN), now GISRS. In the intervening decades, the NVRL's primary diagnostic workload has increased dramatically, but it continues to fulfil Ireland's remit to the WHO as the National reference laboratory for Measles, Polio, Rubella, and Influenza.

It provides:

- Molecular and serological service to many GPs and some hospitals nationally
- Primary diagnostic virology services to some acute hospitals in particular in the Dublin area
- Confirmatory – or second-line – testing service to many acute hospital laboratories for a wide range of viral pathogens
- A cell culture and virus isolation laboratory, the NVRL offers an antiviral resistance and sequencing service (both diagnostic and surveillance)
- A DoH funded CL3 facility for the investigation of suspected imported and exotic infections
- 24/7 365 donor screening service to Organ Donation Transplant Ireland (ODTI)

Methodology to Development of Report

A data template was circulated to all HSE PHMV Laboratories (Appendix 2 refers). Data was collated from responses received; the findings and recommendations set out in this report are informed by responses received and other contributions of group members. Summary data tables setting out responses received are included in Appendix 3.

Consideration was given to the experiences of other countries that have undertaken this type of National Reference Laboratory restructuring:

- The Province of Ontario in Canada developed an integrated reference laboratory services after the SARS-Cov-1 outbreak

- Scotland has also restructured reference laboratory services in recent years to improve integration. Their experience has also strengthened recommendations.

Key Findings

Ireland's PHMVL services play a central role in health protection within Ireland and contribute to health protection within the EU. The SARS-CoV-2 pandemic has highlighted the importance of this capacity as never before. PHMVL services are also key to sustaining economic activity in particular the agri-food sector and the tourist sector by providing assurance of food safety and bathing water standards.

Ireland has good PHMVL capacity by comparison with many EU member states. It has an excellent cadre of medical and scientific expertise, strong technical capacity and high quality standards. This is evident from the accreditation status of the laboratories and from the contribution of Ireland to many ECDC surveillance activities and review groups and contributions to other international fora. There are also strong relationships with local and regional clinical services, Public Health and Environmental Health services, the Food Safety Authority of Ireland and with local authorities.

The volume of activity undertaken by PHMVL services is evident in that approximately 361,544 samples were processed by the Microbiology Reference Laboratories in 2019 and approximately 1,050,299 tests were reported. Approximately 52,756 samples were processed by the Food and Water Microbiology Reference Services and approximately 115,596 tests were reported. It should be noted that 2019 data is provided as 2020 data was reduced due to COVID 19 response.

Synergies

All reference laboratory services provide specialist reference laboratory services, led by a highly skilled scientific and medical staff with nationally and internationally recognised experience in their relevant area. Existing services and relationships have served Ireland well with limited resources. Retaining these strengths is important in a vision for future service development.

Other synergies include that all nine (9) HSE Microbiology Reference Laboratory services are accredited with the same accreditation standard with INAB ISO 15189. All seven (7) Food and Water Reference Laboratories are accredited with INAB ISO 17025 standard.

The ECDC identify five core functions and activities of microbiology reference laboratories as part of public health microbiology, these core functions are as follows:

- Reference Diagnostics
- Reference Material Resources
- Scientific Advice
- Collaboration and Research
- Monitoring, alert and response

The reference laboratories address these core functions but many of the services are limited in the ability to deliver fully on these functions by resources available within the existing model. Some of these functions, for example provision of reference material resources may be more easily managed in an integrated service.

Increasingly reference laboratories use a common suite of molecular biology techniques, specifically nucleic acid amplification tests and nucleic acid sequencing and related data processing. There is considerable scope to share expertise and information systems and to enhance resilience through shared access to equipment and data management.

All Reference Laboratories have identified similar key users and have established external stakeholders, some of which includes research collaboration and EU data collaborations.

All seven (7) HSE Food and Water Microbiology Laboratory Services are EU Official Designated Food testing laboratories under legislation and have a service level agreement/contract with Food Safety Authority of Ireland. These services interact regularly in a well-structured process of engagements. They have a common software system (Labware) although as separate instances. They frequently use the same or very similar methods of analysis and analyse similar sample types. The engagement of all of the laboratories with the FSAI provides them with forum within which they share learning and experience and support each other.

Gaps and Duplication of Efforts

The following service gaps and/duplication of efforts were evident.

Governance and Integration

PHMVL services have developed in an ad-hoc fashion. They are dispersed both geographically and organizationally. This pattern is based on the history of service development rather than on a strategic assessment of the services required and their location now and in the future.

At present there is no national hub that reference laboratory services can associate their service with or access for support/collaborative working. This is a key operational requirement to support an integrated governance model approach.

The current service model does not support robust interoperability or planning requirements. There is no agreed mechanism to manage key internal and external scientific and business relationships regarding the PHMVL service. As funding arrangements for the PHMVL services are fragmented there is no process for regular review of existing funding to ensure economies of scale are being achieved and developments are aligned to national priorities. For the nine (9) Microbiology Reference Laboratories there are seven (7) discrete cost centres. There is no central coordination of the vision for the future or for the allocation of existing funding or applications for new funding to address current and future needs. The lack of an integrated leadership and governance model is a key challenge to the delivery of a sustainable, efficient, co-ordinated reference laboratory service.

Previous reviews of the service have highlighted these issues but have not progressed to substantial restructuring. In the context of recent experience, it is clear that there is a need to revisit how PHMVL services are organised and delivered. Of note the Public Analyst Laboratory Service, which provides chemical analysis services (in addition to microbiology services in the Dublin Public Analyst Laboratory) has already implemented a plan to integrate their work. The Department of Agriculture has likewise extensively restructured the veterinary laboratory services in recent years. There is therefore national and international experience of the challenges and benefits of developing an integrated service that can be drawn upon to support this project.

The case for integration into a single service, although on multiple sites, is strengthened by the convergence of laboratory technologies in recent years and the pace of change that is now required. In addition, global and national transport and IT connectivity has established an environment in which there are greater gains to be expected from development of an integrated service. The challenges of globalisation, climate change, antimicrobial resistance and the recent pandemic highlight the need for an integrated service that can respond in a more agile manner to emerging threats and address regulatory challenges.

Food and water microbiology laboratories predominantly use traditional culture-based microbiology methods however, the technological transformation experienced in the reference laboratory service is also increasingly relevant to the work of food and water microbiology services. This is because of increasing demand for rapid detection methods and detection of organisms (including virus) that are not readily cultured.

For all of these reasons there is a need to establish a leadership and governance structure that will drive progress towards an integrated and more efficient PHMVL service. This will strengthen capacity for the prevention and control of infectious diseases and protection of health in Ireland in line with the standards outlined by the European Centre for Disease Control¹ (ECDC) and the World Health Organisation (WHO)². This will underpin the delivery of safe, patient centred care and support delivery of iNAP2 and the HSE 2022-2025 AMRIC Action Plan.

Data Integration

All PHMVLS services generate and process large amounts of data. At present most of this data is in laboratory information systems that are unique to each laboratory. In the case of the Food and Water Microbiology Laboratories although there is a common system (Labware) each laboratory has a unique instance.

There is no standardised principal laboratory information system in use across the Reference Laboratory services. This is associated with a lack of data standardisation, integration and duplication of ICT efforts. The limitation of data management is a key risk to the delivery of a safe, efficient, co-ordinated reference laboratory service.

Annual Report Publication

Of the nine (9) Microbiology Reference Laboratories, seven (7) have published 2019 Annual Reports, which are available on their webpage. Two (2) Reference Laboratories have indicated their 2019 Annual Reports are delayed due to COVID-19 response. One (1) Reference Laboratory does not have a website. There are opportunities to address duplication of efforts and develop a harmonised approach to annual reporting.

National Virus Reference Laboratory (NVRL)

One major laboratory service that is critical to the health service is provided by University College Dublin (UCD). This is the National Virus Reference Laboratory (NVRL) based on the UCD Belfield Campus.

The NVRL is vital to the delivery of health services and the response to emerging disease such as COVID-19. The vast majority of the work of NVRL is performed on behalf of the HSE and funded by the HSE. The HSE accounts for over 95% of NVRL work. In 2020 NVRL processed 464,378 samples and provided 1,003,584 tests reports.

All 105.32 NVRL WTE's hold contracts with UCD. A summary of WTE analysis by grade is set out in **Table 1**.

¹ ECDC Technical Report - Core Functions of microbiology reference laboratories for communicable diseases
https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/1006_TER_Core_function_s_of_reference_labs.pdf

² GLASS - Global Antimicrobial Resistance and Use Surveillance System
<https://scanner.topsec.com/?d=1527&r=show&t=cbc776aee8e0ca9875c4bc4a85fb627150724450&u=https%3A%2F%2Fwww.who.int%2Fpublications-detail-redirect%2F9789240010581>

Table 1: Summary NVRL WTE Analysis by Grade

Summary by Post/Grade	WTE Approved	WTE Filled	WTE Vacant
Medical Consultants	2.80	2.80	0.00
Clinical Scientists (basic - principal)	6.90	6.90	0.00
Technical Officers (basic - Chief)	44.29	44.29	0.00
Administrative Grade	33.33	33.33	0.00
Laboratory Attendants	18.00	18.00	0.00
Totals	105.32	105.32	0.00

Outsourcing this service from the HSE merits review as it is core health service function.

Resources and costs associated:

Staffing

The sixteen (16) HSE PHMVL Services are each overseen by Director. However, most Directors perform this role as one part of their commitments within the laboratory and or hospital where they work.

The PHMVLS's are supported by 130.29 WTEs of which 119.84 WTEs are reported as being filled with 10.45 WTEs vacant (as at October 2021). A summary of WTE analysis by grade is set out in **Table 2**.

Table 2: Summary PHMVLS WTE Analysis and Costings by Grade

Summary by Post/Grade	WTE Approved	WTE Filled	WTE Vacant	Minimum Costings ³	Maximum Costings
Consultant Microbiologist	2.95	1.80	1.15	622,293	622,293
Deputy Public Analyst	1.00	1.00	0.00	89,688	99,399
Lab Manager	1.20	0.70	0.50	113,447	129,311
Chief Medical Scientist	8.80	8.80	0.00	728,064	829,866
Specialist Medical Scientist	4.00	4.00	0.00	302,947	338,196
Senior Medical Scientist	29.12	25.12	4.00	2,014,319	2,305,695
Basic Medical Scientist	41.32	39.12	2.20	2,132,415	2,709,311
Basic Surveillance Scientist	5.00	5.00	0.00	258,037	327,845
Analytical Chemist	4.00	4.00	0.00	293,537	348,212
Senior Lab Technician	1.00	1.00	0.00	48,304	55,475
Staff Grade Lab Technician	12.00	12.00	0.00	505,523	576,284
Medical Lab Aide	8.10	8.10	0.00	344,195	375,064
Administrative Grade	8.60	8.60	0.00	363,993	456,637
Data Manager	0.50	0.50	0.00	30,702	33,866
Caretaker	0.10	0.10	0.00	3,639	3,866

³ Please note the following in relation to Minimum and Maximum calculations. 2021 October DoH salary scales used. Employers PRSI costed at 13.05%. No allowances or overtime have been costed, therefore minimum to maximum costings calculated based on mid-point and max point of each salary scale. Assumptions have been made on grade codes for a number of posts for costing purposes where submitted data was incomplete. It should be noted that this review did not seek to consider operational costs.

Other (not specified)	2.60	0.00	2.60	95,016	120,782
Totals	130.29	119.84	10.45	7,946,117	9,332,101

Table 3: Details of WTE per National Reference Laboratory Services (HSE)

As of October 2021	NCPerl, National Salmonella, Shigella & Listeria Reference Laboratory GUH, Saolta			National Gonococcal Reference Laboratory (GCRL) St. James Hospital, DML			National MRSA Reference Laboratory (NMRSARL) St. James's Hospital, DML			Irish Mycobacteria Reference Laboratory (IMRL) St. James's Hospital, DML			Irish Meningitis and Sepsis Reference Laboratory (IMSRL), Temple St. Hospital, CHI			National VTEC Reference Laboratory (VTEC NRL) Cherry Orchard Hospital, CHO 6			National C. difficile Reference Laboratory Cherry Orchard Hospital, CHO 6			National Bordetella pertussis Reference Laboratory Crumlin Hospital, CHI			Total		
HSE Microbiology Reference Laboratory Service	WTE Approved	WTE Filled	WTE Vacant	WTE Approved	WTE Filled	WTE Vacant	WTE Approved	WTE Filled	WTE Vacant	WTE Approved	WTE Filled	WTE Vacant	WTE Approved	WTE Filled	WTE Vacant	WTE Approved	WTE Filled	WTE Vacant	WTE Approved	WTE Filled	WTE Vacant	WTE Approved	WTE Filled	WTE Vacant	WTE Approved	WTE Filled	WTE Vacant
Consultant Microbiologist	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.5	0.0
Deputy Public Analyst	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Lab Manager	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Chief Medical Scientist	0.0	0.0	0.0	0.00	0.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	0.5	0.5	0.0	0.0	0.0	0.0	1.0	1.0	0.0	4.5	4.5	0.0
Specialist Medical Scientist	1.0	1.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	1.5	1.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.5	3.5	0.0
Senior Medical Scientist	1.0	1.0	0.0	1.00	1.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	6.0	6.0	0.0	1.0	1.0	0.0	2.0	0.0	0.0	3.0	2.0	1.0	15.0	12.0	3.0
Basic Medical Scientist	2.5	2.5	0.0	1.00	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.3	4.3	0.0	0.0	0.0	0.0	1.0	1.0	0.0	8.8	8.8	0.0
Basic Surveillance Scientist	0.0	0.0	0.0	1.00	1.0	0.0	1.0	1.0	0.0	2.0	2.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0	5.0	0.0
Analytical Chemist	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Senior Lab Technician	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Staff Grade Lab Technician	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Medical Lab Aide	0.0	0.0	0.0	0.00	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	2.0	0.0
Administrative Grade	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	1.5	1.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	2.5	0.0
Data Manager	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.00	0.0	0.0	0.5	0.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.5	0.0
Caretaker	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other (not specified)	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Totals	4.5	4.5	0.0	3.0	3.0	0.0	4.0	4.0	0.0	4.00	4.0	0.0	10.5	10.5	0.0	9.3	9.3	0.0	2.0	0.0	2.0	5.0	4.0	1.0	42.3	39.3	3.0

Table 4: Details of WTE– Food and Water Microbiology Laboratory Services (HSE)

	Galway University			Public Health Lab Dublin			Waterford University			St. Finbarr's Hospital			University Hospital			University Hospital			Cherry Orchard Hospital					
As of October 2021	Hospital			Sir Patrick Dun's CHO 6			Hospital			CHO 4			Sligo			Limerick			CHO 6 Incl. Micro Ref Lab WTEs			Total		
HSE Food and Water Microbiology Service	WTE Appro ved	WT E Fill ed	WTE Vaca nt	WTE Appro ved	WT E Fill ed	WTE Vaca nt	WTE Appro ved	WT E Fill ed	WTE Vaca nt	WTE Appro ved	WT E Fille d	WTE Vaca nt	WTE Appro ved	WT E Fill ed	WTE Vaca nt	WTE Appro ved	WT E Fill ed	WTE Vaca nt	WTE Appro ved	WT E Fill ed	WTE Vaca nt	WTE Appro ved	WT E Fille d	WTE Vaca nt
Consultant Microbiologist	0.3	0.3	0.0	0.0	0.0	0.0	1.0	0.2	0.8	0.35	0.0	0.35	0.30	0.3	0.0	0.2	0.2	0.0	0.3	0.3	0.0	2.45	1.3	1.15
Deputy Public Analyst	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.00
Lab Manager	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.5	0.5	0.0	0.0	0.0	0.1	0.1	0.0	0.1	0.1	0.0	0.0	0.0	0.0	1.2	0.7	0.50
Chief Medical Scientist	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	0.3	0.3	0.0	4.3	4.3	0.00
Specialist Medical Scientist	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.5	0.0	0.5	0.5	0.00
Senior Medical Scientist	2.0	2.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	6.12	6.1 2	0.0	2.0	1.0	1.0	1.0	1.0	0.0	2.0	2.0	0.0	14.12	13. 12	1.00
Basic Medical Scientist	3.0	3.0	0.0	0.0	0.0	0.0	8.0	8.0	0.0	6.42	6.4 2	0.0	6.0	3.8	2.2	4.6	4.6	0.0	4.5	4.5	0.0	32.52	30. 32	2.20
Basic Surveillance Scientist	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.00
Analytical Chemist	0.0	0.0	0.0	4.0	4.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.0	4.0	0.00
Senior Lab Technician	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.00
Staff Grade Lab Technician	1.0	1.0	0.0	11.0	11. 0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12.0	12. 0	0.00
Medical Lab Aide	0.0	0.0	0.0	0.5	0.5	0.0	2.0	2.0	0.0	0.8	0.8	0.0	1.0	1.0	0.0	0.8	0.8	0.0	1.0	1.0	0.0	6.1	6.1	0.00
Administrative Grade	1.0	1.0	0.0	1.5	1.5	0.0	0.5	0.5	0.0	0.9	0.9	0.0	0.7	0.7	0.0	0.0	0.0	0.0	1.5	1.5	0.0	6.1	6.1	0.00
Data Manager	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.00
Caretaker	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.1	0.1	0.00
Other (not specified)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.6	0.0	2.6	0.0	0.0	0.0	2.6	0.0	2.60
Totals	7.3	7.3	0.0	19.0	19. 0	0.0	14.5	13. 2	1.3	15.59	15. 24	0.35	11.1	7.9	3.2	10.4	7.8	2.6	10.1	10. 1	0.0	87.99	80. 54	7.45

Accommodation

All reference laboratories are supported with combination of permanent or prefabricated structures built between 1950s and 2011. A detailed inventory of accommodation is not provided as part of this report but many of the facilities are far from ideal.

Recommendations

This section sets recommendations to work towards the future development of the PHMVL Service

Recommendation 1:

Develop an PHMVL Service Management Group

Resource: 7 WTEs - €726,374

Costings to support above Management Group is set out in Appendix 4.

The national PHMVL Management Group will work to coordinate the service, manage the progressive integration and development of the service. This will enhance understanding and transparency in the organisations approach to service provision, enhance service delivery and identify efficiencies. It will improve resilience and ability to respond to emerging threats and improve alignment with key national and EU policy issues. This approach will also support linkage with the Department of Agriculture, the Food Safety Authority of Ireland and the Environmental Protection Agency which is a key to a “One Health” approach to managing infection promoted by the WHO, OIE and European Commission.

The PHMVL service will be within the portfolio responsibility of the National Director for Public Health (currently being recruited). It will work closely with the Health Protection Surveillance Centre (HPSC) which is also within the portfolio of the National Director for Public Health.

The PHMVL service will have **Director** who will be a Consultant Microbiologist or Consultant Virologist with 80% commitment to this role and 20% clinical commitment in a HSE or HSE associated voluntary hospital to maintain clinical experience. An academic affiliation would also be appropriate to support an ethos of development and research in the PHMVLS. This could be on an honorary basis. The Clinical Director will report to the National Director for Public Health. The role of the Director will be to chart the pathway to a more integrated service, to coordinate the work of the existing laboratories and to identify future needs. As additional laboratory services are developed at a National Hub (see below) they will be directed by the PHMVL Director.

Note that in the process of consultation the options of having the Director as a fixed-term secondment or as a senior non-clinical post (at Assistant National Director) were proposed as options but are not recommended here.

The PHMVLS will have **General Manager** to manage the business and financial operations of the PHMVLS. The General Manager will report to the Director.

The service will have two divisions these are

- a) **the Food and Water Division and**
- b) **the Reference Laboratory Division**

Each division will be led by a Division Manager (Reporting to the General Manager). The Division Manager is expected to have a relevant scientific background. A Laboratory Manager is proposed for the Reference Laboratory Division. For the Food and Water Laboratory Division the Manager role

should be open to any of the scientific grades that work in the Food and Water Microbiology services. An academic affiliation would also be appropriate to support an ethos of development and research in the PHMVLS. This could be on an honorary basis. The Division Managers will report to the General Manager.

The PHMVLS will have a **Data Manager** who will work closely with the Office of the Chief Information Officer (OoCIO) to improve data management and integration through the PHMVLS. The Data Manager will report to the General Manager. Direct reporting of Division Managers and Data Manager was proposed during the process of consultation but is not accepted in this report

Clerical Support will be required for the Management team (2 staff at Clerical Grade 4).

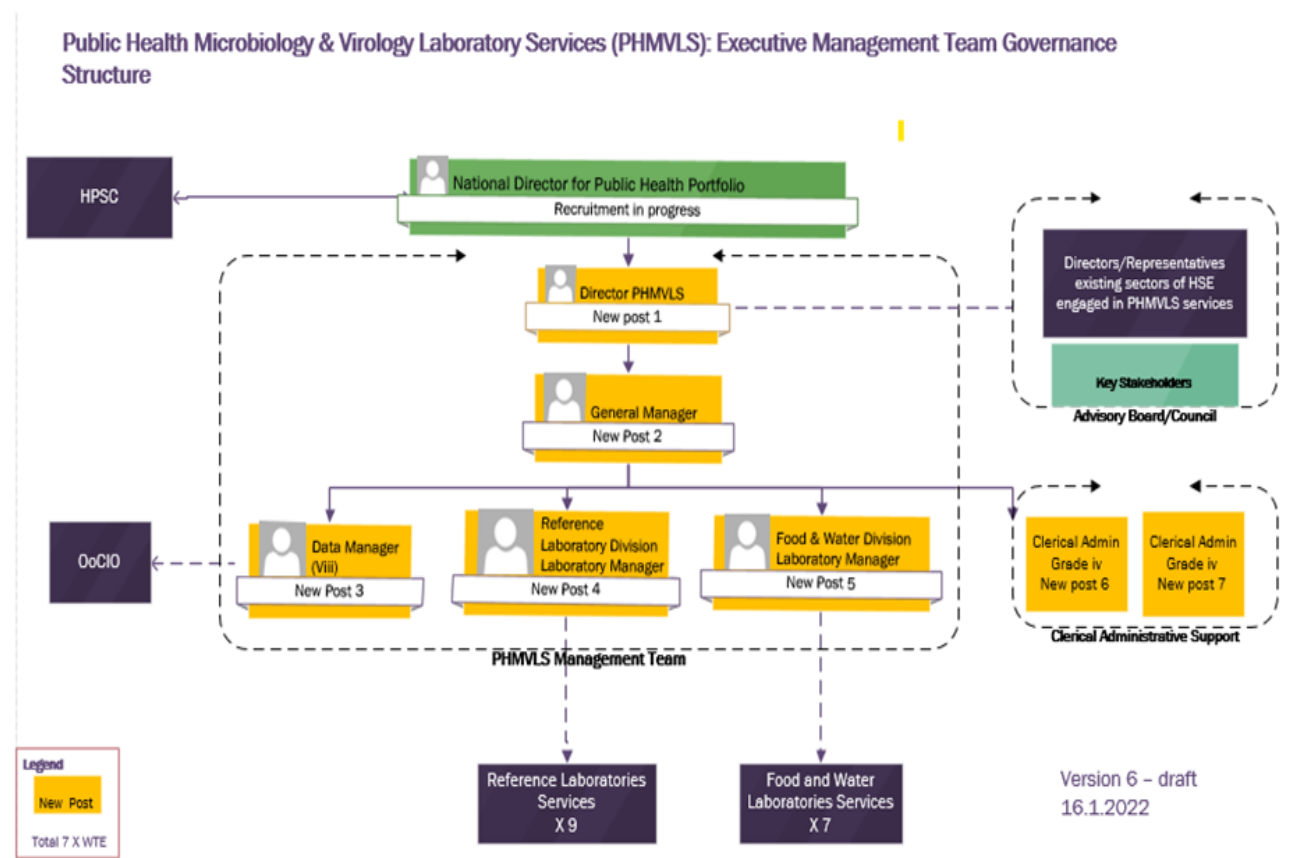
The PHMVL service Director and General Manager should be the first appointments and they should build the **Management Team**.

The Management Team will convene an Advisory Board/Council including Directors/Representatives of all of the existing sectors of HSE engaged in the provision of PHMVL services. The Terms of Reference of the Advisory Board/Council will be agreed by the HSE Executive Management Team.

During the consultation process it was proposed that the option should be considered of having this Board or Council as having an executive function rather than an advisory function. This would mean that the Management Team would be accountable to the Board/Council. This option was not adopted in this report as it is not consistent with the HSE Governance and Accountability Framework.

Figure 1. Below outlines a proposed integrated governance model for PHMVLS services

Figure 1. Proposed integrated governance model for PHMVLS services



Recommendation 2:

The reporting relationships of existing staff working in the PHMVL service within their existing services should be retained (unless changed by agreement).

The relationships between the PHMVL service management group and existing services directors and accountability were raised as an issue of concern during consultation (see above re proposed executive board or council).

The role and reporting relationships of existing PHMVLS directors and staff in post will not change. The relationship between the services and the national management group will be addressed by developing a Service Level Agreements (SLA's) with each hospital/hospital group or CHO as appropriate. There are existing models that can be adapted for this purpose. All funding for PHMVL services will progressively be channelled through the Management Group who will work with existing services to adapt the SLA's to meet needs for new services, integration, data management and working with external stake holders.

The clinical and academic freedom of current service directors to represent their services, their work and their aspiration for future development is a strength of the service. The central management group and the overall clinical director will not function as an obstacle to effective communication and engagement between existing services and service directors and key internal and external stakeholders.

Recommendation 3:

Establish a national hub for the PHMVLS
Resource required – to be determined

There is no national hub that reference laboratory services can associate their service with or access for support or to coordinate collaborative working. This is a key operational requirement to support an integrated governance model approach. In the first instance the hub will serve as the base for the PHMVLS Management Group. As new services are developed the hub will develop as laboratory base for some services and provide centralised services including data management.

The national hub for the PHMVLS will be in a central location that is readily accessible by public transport to facilitate access and delivery. An options appraisal will be undertaken to identify a suitable location. The PHMVLS hub will have connectivity to key entry points to the jurisdiction, to Infectious Disease Isolation facilities and to key security agencies. The hub will have or work to develop containment facilities for handling pathogens to Containment Level 3. The PHMVLS hub will have excellent IT connectivity and laboratory information systems.

Clinical and scientific engagements with key stakeholders will be facilitated by the hub. The value of direct liaison between existing laboratory directors and key stakeholders is also acknowledged.

Recommendation 4:

The PHMVLS governance model should have the authority to manage key internal and external scientific and business relationships in a hub and spoke model through Service Level Agreements. This will include working with existing laboratories to enhance capacity to support each other and to adapt their services to meet national needs.

The existing model does not provide a common point that coordinates and represents the interests and role of the PHMVL services. Reference Laboratories and Food and Water Laboratory Services will function as spokes of the PHMVLS hub with functions governed by Service Level Agreements. Service Level Agreements will adapt over time to ensure that individual laboratory services are aligned to national service needs. The PHMVLS governance model will support a structure that will manage key internal and external business relationships regarding public health microbiology and virology laboratory services for the HSE such as those with the Food Safety Authority of Ireland, and UCD and HSE Clinical and Public Health Services and Environmental Health Services.

Recommendation 5:

New funding submissions and allocations for PHMVLS services should be managed through the PHMVL Management Group.

Existing relevant budgets and costs should migrate, over time to a central PHMVLS budget that will manage funding relationships with internal and external service providers.

Funding

In line with current governance arrangements, reference laboratories submit funding issues and/business cases through their acute hospital/group/CHO governance arrangements and line management. There is no clear governance arrangement that reference laboratory services can use to develop and submit integrated funding bids to promote an integrated service or to provide support for specialist training opportunities such as the ECDC EUPHEM fellowship programme.

All proposals for new funding (Capital and Recurrent) for the PHMVL service will be through the PHMVL Management Group. In addition existing funding that supports existing PHMVLS will be identified. Relevant budgets and costs will gradually be migrated to a central PHMVLS budget that will manage funding relationships with internal and external service providers. This will achieve optimum economies of scale benefits. Funding arrangements will need to support existing post holders and services until new models of service are developed, agreed and implemented. Services (spokes) required to meet current commitments will not lose current funding required to deliver on that service. Laboratories will continue to perform work for external clients and retain income generated to support their own laboratory.

Recommendation 6:

The PHMVLS MT should work with existing laboratories to make the scientific and clinical case for new services, to eliminate redundancy and to consolidate services taking account of the need for regional access to services, clinical and regional relationships and expertise.

The PHMVL Management Team supported by the Consultative Council and wider stakeholder engagement will identify gaps and emerging trends and articulate the clinical and scientific case for additional PHMVL services. They will also consider if new service needs can be met by repurposing existing resources and consolidation of existing services.

Colocation and consolidation of certain new services at the hub may be appropriate but for other services regional distribution service may be preferable or may be indispensable to meet requirements for sample handling prior to analysis.

Accreditation

Recommendation 7:

The PHMVL services should continue to place a high value on accreditation with the Irish National Accreditation Board (INAB) to the relevant ISO standards (ISO 17025 /ISO 15189).

Recommendation 8:

Data management systems for the PHMVL service should be managed by the Management Team working with the OoCIO to ensure data management systems work together and are secure

National Virus Reference Laboratory

Recommendation 9:

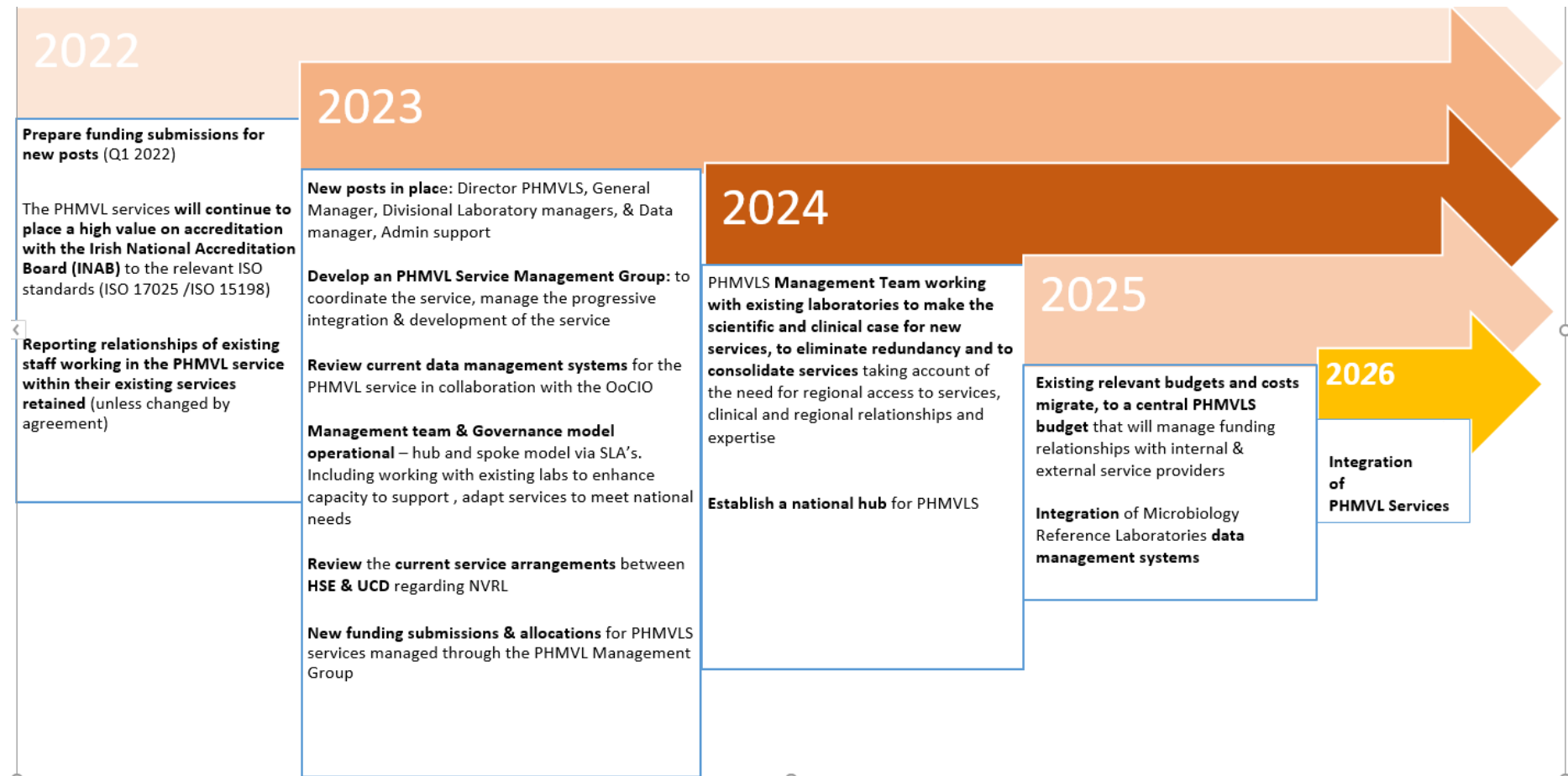
The current arrangements between HSE and UCD regarding the National Virus Reference Laboratory should be reviewed.

This arrangement requires review as this is a critical core health service function.

A plan and timeline for developing an integrated and comprehensive public health microbiology laboratory service is outlined below in figure 2.

Plan and Timeline

Figure 2. Timeline for developing an integrated and comprehensive public health microbiology laboratory service



Appendix 1 – Terms of Reference

Report on Microbiology Reference Laboratory Services and Food and Water Microbiology Laboratory Services in the HSE

Project proposal was:

- Considered by Antimicrobial Resistance and Infection Control Oversight Group at meeting dated 30th July 2019.
- Agreed for submission by Chief Clinical Officer to Executive Management Team at meeting dated 27th August 2019.
- Agreed by Executive Management Team at meeting dated 8th October 2019.

Proposed Terms of Reference

The HSE Clinical Lead for AMRIC and Clinical Lead for Pathology, following consultation with relevant stakeholders will prepare a report according to the following terms of reference:

- a) Describe the current use of microbiology reference laboratory services by the HSE including those services provided by HSE laboratories and those provided to HSE by other service providers.
- b) Describe the food and water microbiology laboratory services provided by HSE laboratories.
- c) Identify critical gaps in microbiology reference laboratory services and food and water microbiology laboratory services.
- d) Identify resources and costs associated with provision of /access to microbiology reference laboratory services and food and water microbiology laboratory services including National Virus Reference Laboratory.
- e) Identify areas of duplication of service provision and reasons for duplication of service.
- f) Identify potential synergies with other publicly funded microbiology laboratory services
- g) Propose recommendations, including a plan and timeline for developing an integrated and comprehensive public health microbiology laboratory service that optimises use of existing resources and identifies additional resource requirements

A draft report should be provided to AMRIC Oversight Group by end of Q4 of 2020.

10th December 2019

Appendix 2 – HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology Reference Laboratories Review

Microbiology Reference Laboratory Services & Food and Water Microbiology Laboratory Services in the HSE

Please note the intention is to include the completed return for each individual laboratory as an appendix to the report. This means that each laboratory has the opportunity to describe its own service in its own words. It is important that there is a consistency in relation to presentation and the length of the description for each laboratory therefore we would be grateful if you keep within the word limits and retain the font and font size in the template and return the completed form as a word document. If any edits are made to achieve consistency, they will be returned to you for review and approval.

This page will not be part of the content included in the appendices.

We would be grateful if you could return the completed form by: Friday 8th October 2021.

Name of Laboratory:

Address of the Laboratory:

Name of Laboratory Director:

Name of the Institution /Organization the laboratory is associated with:

Accreditation status Accredited /Not Accredited

Accreditation Body:

Accreditation Standard(s):

Number of samples processed in 2020:

Number of test results report in 2020:

Name and version of Principal Laboratory Information System in Use:

Approximate footprint of the laboratory:

Year of construction of the laboratory:

The laboratory building is a permanent structure/a prefabricated structure intended for temporary use [Delete as appropriate]

Overview of service: (200 word limit)

Insert text here:

Laboratory Staffing Please provide details of the following:

WTE's Number	Details of WTE's grade
Total:	

Do you have a discrete cost Centre: Yes ☐ No ☐

Is your cost Centre part of another cost Centre? Yes ☐ No ☐

The laboratory's key users are:

Insert text here:

The other key external relationships of the laboratory are with:

Insert text here:

The laboratory service has a website as follows /does not have website:

An annual report for 2019 /2020 is available /is not available

The annual report is available at the following link /is not available on the internet

Appendix 3 - HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology Reference Laboratories Review Data Tables

This section sets out all responses to the data questionnaire sent out on [insert date] to each Reference Laboratory, **Table 5 – Table 7** are the responses from HSE Microbiology Reference Laboratory services and **Table 8 to Table 10** set out the responses from the HSE Food and Water Microbiology Services. **Table 11 to Table 13** set out responses for the NVRL.

Table 5: HSE Microbiology Reference Laboratory Services Q1 to Q13

	Q 1 Name of Reference Laboratory	Q 3 Name of Laboratory Director	Q 2 and 4 Name of Associated Institution/ Organisational	Q 5, 6 and 7 Accreditation Status Accreditation Body Accreditation Standard	Q 8 and 9 No. of samples* processed in 2019 No. of tests reported in 2019 (approx.)	Q 10 Name and version of Principle Laboratory Information System in Use	Q 11, 12 and 13. Approx. footprint of lab, Year of construction, Structure of building
1	National Carbapenemase Producing <i>Enterobacterales</i> Reference Laboratory (NCPERL)	Prof. Martin Cormican, Consultant Microbiologist	University Hospital Galway – Saoilta Hospital Group	Accredited INAB ISO 15189	2549 samples processed 2549 tests reported For CPE and Salmonella, Shigella & Listeria Reference Laboratory Service	APEX, iLAB version 5.8	39.62 M2 1950s and 1980s Combination of permanent and prefab structure
2	National Salmonella, Shigella & Listeria Reference Laboratory	Prof. Martin Cormican, Consultant Microbiologist	University Hospital Galway, Saoilta Hospital Group	Accredited INAB ISO 15189	551 samples processed 551 tests reported	As above	As above
3	National Gonococcal Reference Laboratory	Dr. Brendan Crowley, Consultant Microbiologist	St. James's Hospital, Dublin Midlands Hospital Group	Accredited INAB ISO 15189; 2012	876 samples processed 876 tests reported	Telepath	36 M2 1980 Permanent structure

	Q 1 Name of Reference Laboratory	Q 3 Name of Laboratory Director	Q 2 and 4 Name of Associated Institution/ Organisational	Q 5, 6 and 7 Accreditation Status Accreditation Body Accreditation Standard	Q 8 and 9 No. of samples* processed in 2019 No. of tests reported in 2019 (approx.)	Q 10 Name and version of Principle Laboratory Information System in Use	Q 11, 12 and 13. Approx. footprint of lab, Year of construction, Structure of building
	(GCRL)						
4	National Methicillin- Resistant <i>Staphylococcus aureus</i> (MRSA) Reference Laboratory (NMRSARL)	Dr. Brian O’Connell, Consultant Microbiologist	St. James’s Hospital, Dublin Midlands Hospital Group	Accredited INAB ISO 15189; 2012	1062 samples processed 1,800 tests reported	Access database 2016	215 M2 2001 Permanent structure
5	Irish Mycobacteria Reference Laboratory (IMRL)	Dr. Brian O’Connell, Consultant Microbiologist Dr. Johannes Wagener, Associate Professor/Consultant Microbiologist (Interim Director)	St. James’s Hospital, Dublin Midlands Hospital Group	Accredited INAB ISO 15189; 2012 (3 rd edition)	600samples processed 600 tests reported	Telepath	139.2 M2 Early 1980s Permanent structure
6	Irish Meningitis and Sepsis Reference Laboratory (IMSRL)	Dr. Robert Cunny, Consultant Microbiologist	Childrens Health Ireland at Temple Street	Accredited INAB ISO 15189	4556samples processed 9,440 tests reported	iLAB version 5.8.1	300 M2 1996 Permanent structure
7	National VTEC Reference Laboratory (VTEC NRL)	Dr. Eleanor McNamara, Consultant Microbiologist	Public Health Laboratory – HSE Cherry Orchard Dublin, CHO 6	Accredited INAB ISO 15189	5,719 samples processed 43,464 tests reported	LabWare LIMS version 7	673 M2 1958 Combination of permanent

	Q 1 Name of Reference Laboratory	Q 3 Name of Laboratory Director	Q 2 and 4 Name of Associated Institution/ Organisational	Q 5, 6 and 7 Accreditation Status Accreditation Body Accreditation Standard	Q 8 and 9 No. of samples* processed in 2019 No. of tests reported in 2019 (approx.)	Q 10 Name and version of Principle Laboratory Information System in Use	Q 11, 12 and 13. Approx. footprint of lab, Year of construction, Structure of building
			Community Healthcare East				and prefab structure
8	National <i>C. difficile</i> Reference Laboratory	Dr. Eleanor McNamara, Consultant Microbiologist	Public Health Laboratory – HSE Cherry Orchard Dublin, CHO 6 Community Healthcare East	Reference lab being established in Q4 2021	Reference lab being established in Q4 2021	Reference lab being established in Q4 2021	Reference lab being established in Q4 2021
9	<i>Bordetella pertussis</i> Reference Laboratory	Dr. . Niamh O’Sullivan, Consultant Microbiologist	Childrens Health Ireland at Crumlin	Accredited INAB ISO 15189; 2012	846 samples processed (PCR samples and serology samples) 846 tests reported	Winpath version 5.32 SP (build 137)	200 M2 2010/2011 Permanent

*Impact of COVID-19 was noted to have significant reduction of reference laboratory workload in 2020, therefore 2019 data used in Table 5 above. Impact of COVID-19 is not a representative year for sample and isolate referrals due to the global COVID-19 associated fall in invasive infections due to bacteria associated with respiratory carriage.

Table 6: HSE Microbiology Reference Laboratory Services Q14

	Name	Q 14 Overview of Service
1	National Carbapenemase Producing Reference Laboratory (NCPERL)	<p>The NCPERL Salmonella, Shigella and Listeria Reference Laboratory service provides the following services:</p> <ul style="list-style-type: none"> ▪ Receives and types isolates of Salmonella, Shigella, Listeria and Carbapenemase Producing/Resistant Enterobacterales and other resistant bacteria. ▪ Whole genome sequencing is performed on isolates matching criteria stated in user guide and analysed for various characteristics including sequence type, antibiotic resistance genes, etc. ▪ Primary role is to determine relatedness between isolates to detect clusters both of pathogens and of specific antibiotic resistance gene containing plasmids. ▪ Data is shared with users by LIMS report, regular line listings and annual reports.
2	National Salmonella, Shigella & Listeria Reference Laboratory	As above.
3	National Gonococcal Reference Laboratory (GCRL)	<p>The GCRL (interim) provides the following services:</p> <ul style="list-style-type: none"> ▪ Reference diagnostics: Antimicrobial susceptibility testing – provision of extended antimicrobial susceptibility testing for <i>Neisseria gonorrhoeae</i> (<i>N. gonorrhoeae</i>), monitoring the high-level azithromycin resistance. Also to identify and monitor current resistance profiles in Ireland. ▪ Scientific advice/technical advice to other laboratories that carry out <i>N. gonorrhoea</i> nucleic acid amplification testing ▪ Clinical advice to clinicians and laboratories in relation to the diagnosis, treatment and infection control of <i>N. gonorrhoeae</i> infections. ▪ Collaboration and research both locally and internationally. ▪ Monitoring, alert and response in collaboration with the Health Protection Surveillance Centre (HPSC). ▪ GCRL is a designated laboratory contributing to and participating in the European - Gonococcal Antimicrobial Surveillance Programme (Euro-GASP), providing 200 representative isolate and susceptibility data as part of their annual sentinel surveillance ▪ Provision of early warning occurrences to national surveillance body (HPSC) and relevant Public Health Departments. ▪ Participation and provision of technical advice/expertise in the context of an outbreak.

	Name	Q 14 Overview of Service
4	National MRSA Reference Laboratory (NMRSARL)	<p>The NMRSARL reference laboratory provides the following services:</p> <ul style="list-style-type: none"> ▪ Outbreak investigation/ Epidemiological typing of strains to track circulating strains. ▪ Monitoring of MRSA strains prevalent through the epidemiological typing of isolates submitted to EARS-Net. In outbreak situations spa typing is applied. Whole genome sequencing has been recently introduced for cases where spa typing lacks discriminatory power. WGS has also been utilised to investigate VRE and MSSA recovered from healthcare environments. ▪ Screening for the presence of virulence factors or toxins. ▪ Real-time PCR has been utilised to confirm the presence of common resistance determinants including <i>mecA</i>, <i>mecC</i>, <i>cfr</i>, <i>optrA</i> and <i>poxA</i> in staphylococci and enterococci. For other determinants, the NMRSARL utilises DNA microarray or WGS to investigate isolate. These methods are also applied to the investigation of virulence determinants including PVL, TSST, exfoliative toxins and enterotoxins. ▪ Antimicrobial resistance monitoring. ▪ Disk diffusion antimicrobial resistance testing is performed on all <i>S. aureus</i> isolates received for surveillance purposes. Newer antibiotics are investigated using broth microdilution. All isolates are screened for glycopeptide resistance using screening plates, macromethod and if required a modified population analysis profile. ▪ Investigation of VRE isolates. ▪ Investigation of Enterococci isolates for resistance and outbreak investigations using real time PCR and WGS.
5	Irish Mycobacteria Reference Laboratory (IMRL)	<p>The IMRL reference laboratory provides the following services:</p> <ul style="list-style-type: none"> ▪ Provides expertise to laboratories in the diagnosis of <i>M. tuberculosis</i> and other mycobacterial infections. ▪ It provides a specimen and culture referral service to clinical microbiology laboratories throughout the country. Approximately 5,000 diagnostic specimens are processed annually, with the IMRL receiving approximately 500 mycobacterial cultures per annum for reference tests. These include identification, drug susceptibility testing and epidemiological strain typing using specialised molecular techniques. ▪ Provides advice to clinicians and laboratories in relation to diagnosis, treatment and infection control of tuberculosis. It works very closely with clinical Tuberculosis (TB) Services especially Supra-Regional Centre for Tuberculosis, to deliver fast and effective treatment for complex tuberculosis cases. This interaction is essential for driving service delivery and research. ▪ Refers resistant <i>M. tuberculosis</i> complex isolates for additional drug susceptibility testing and refers NTM isolates for drug susceptibility testing as requested by clinical teams. ▪ Supports teaching and research and endeavours to keep informed of the most recent scientific, clinical and epidemiological trends in mycobacterial infections providing a cost effective and quality assured service.

	Name	Q 14 Overview of Service
6	Irish Meningitis and Sepsis Reference Laboratory (IMSRL)	<p>The IMSRL reference laboratory provides the following services:</p> <ul style="list-style-type: none"> ▪ National PCR diagnostic service for invasive bacterial pathogens (<i>N. meningitides</i>, <i>S. Pneumoniae</i>, <i>H. influenzae</i>, <i>S. pyogenes</i>, <i>S. agalactiae</i>, <i>S. aureus</i>, <i>E. coli</i>, <i>K. kingiae</i>, <i>L. monocytogenes</i>). ▪ Syndromic PCR diagnostic service (sepsis, meningitis, bone and joint infections, pleural empyema, deep tissue abscess) ▪ National WGS-based typing and epidemiology service for invasive bacterial pathogen ▪ Reference identification, antimicrobial susceptibility testing, and typing of invasive bacterial isolates ▪ Direct typing and characterisation of invasive bacterial pathogens from samples or PCR extracts (e.g. meningococcal typing for potential vaccine coverage) ▪ 16s sequence-based identification of bacterial isolates (direct characterisation from samples currently being validated) ▪ Molecular characterisation of bacterial isolates from suspected outbreaks ▪ Provision of support to diagnostic laboratories in establishing and troubleshooting bacterial PCR (e.g. investigation of discordant or unusual results) ▪ Maintenance of nation type culture and PCR product repository for key invasive bacterial pathogens ▪ Provision of expert clinical and scientific advice in relation to the diagnosis and management of bacterial meningitis/sepsis
7	National VTEC Reference Laboratory (VTEC NRL)	<p>The VTEC NRL reference laboratory provides the following services:</p> <ul style="list-style-type: none"> ▪ Surveillance and investigation of outbreaks (e.g. gastro-enteric, legionella, COVID). It is a national reference laboratory site for Verocytotoxin <i>E. coli</i> (2001), <i>Campylobacter</i> spp (2019) and soon <i>C.difficile</i> (tender just awarded), incorporating diagnostic and molecular characterisation services. ▪ Investigation of Public health emergencies e.g. initiating COVID testing and national heater cooler units (HCU) water testing for <i>M. chimaera</i>.
8	National <i>C. difficile</i> Reference Laboratory	Reference lab being established in Q4 2021.
9	<i>Bordetella pertussis</i> Reference Laboratory	<p>The <i>Bordetella pertussis</i> reference laboratory provides the following services:</p> <ul style="list-style-type: none"> ▪ Routine <i>Bordetella pertussis</i> and <i>Bordetella parapertussis</i> real-time PCR and culture on nasopharyngeal aspirate and pernasal swabs. ▪ Routine <i>B. pertussis</i> IgG testing for infectious status.

	Name	Q 14 Overview of Service
		<ul style="list-style-type: none"> ▪ Additional PAN-Bordetella real-time PCR assay covering <i>B. petrii</i>, <i>B. bronchiseptica</i>, <i>B. pertussis</i>, <i>B. trematum</i>, <i>B. hinzii</i>, <i>B. parapertussis</i> and <i>B. holmesii</i>. ▪ Specific PCR tests available for <i>B. holmessi</i>, <i>B. bronchiseptica</i>. ▪ VNTR and MLST typing capabilities. NGS based typing under development. ▪ Pertactin analysis - Pertactin ELISA detection on <i>B. pertussis</i> isolates is available and prn gene mutation analysis is available. ▪ Future developments - ELISA for detection of toxin and FHA deficient isolates. ▪ NGS based typing under development.

Table 7: HSE Microbiology Reference Laboratory Services Q15 to Q22

	Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users, (excl internal and external acute hospital services)	Q 19, External Relationships	Q 20, 21 and 22, Name of website, Availability and source of Annual Report
1	National Carbapenemase Producing Reference Laboratory (NCPERL)	WTE Approved 1.0 1.0 2.5 4.5	WTE Filled 1.0 1.0 2.5 4.5	Grade Specialist Medical Scientist Senior Medical Scientist Medical Scientists	No discrete cost centre Part of Laboratory cost centre	<ul style="list-style-type: none"> Clinical pathology laboratories Public Health Departments Health Protection Surveillance Centre 	<ul style="list-style-type: none"> Central Veterinary laboratory Food Safety Authority of Ireland European Centre for Disease Control and Prevention 	Annual Report published https://saolta.ie/sites/default/files/publications/NSSLRL%20Annual%20Report%202018.pdf
2	National Salmonella, Shigella & Listeria Reference Laboratory	Included in the above.						
3	National Gonococcal Reference Laboratory (GCRL)	WTE Approved 1.0 1.0 1.0 3.0	WTE Filled 1.0 1.0 1.0 3.0	Grade Basic Medical Scientist Senior Medical Scientist Basic Surveillance Scientist (HPSC)	Discrete Cost Centre	<ul style="list-style-type: none"> STI Clinics (GUIDE at SJH, Gay Men's Health Service) 	Euro-GASP and reporting AMR data in the European surveillance system (TESSy)	Annual Report published https://www.stjames.ie/media/Gonococcal%20Reference%20Laboratory%20annual%20report%202019%20new%20(2).pdf
4	National MRSA Reference Laboratory	WTE Approved 1.0	WTE Filled 1.0	Grade Chief Medical Scientist	No data provided	No data provided	Research collaborators include:	Annual Report published

	Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users, (excl internal and external acute hospital services)	Q 19, External Relationships	Q 20, 21 and 22, Name of website, Availability and source of Annual Report
	(NMRSARL)	1.0	1.0	Senior Medical Scientist			<ul style="list-style-type: none"> Microbiology Research Unit, Dublin Dental University Hospital, Trinity College, Leibniz Institute of Photonic Technology, Jena, Germany European Study Group for Staphylococci (ESGS) Inter laboratory isolate exchange schemes for Quality Control purpose Irish Meningitis and Sepsis Reference Laboratory 	https://www.stjames.ie/media/NMRSARLAnnualReport2019.pdf
		1.0	1.0	Basic Surveillance Scientist				
		1.0	1.0	Medical Laboratory Aid				
		4.0	4.0					

	Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users, (excl internal and external acute hospital services)	Q 19, External Relationships	Q 20, 21 and 22, Name of website, Availability and source of Annual Report
							<ul style="list-style-type: none"> AMRHAI, Public Health England European Study Group for Staphylococci 	
5	Irish Mycobacteria Reference Laboratory (IMRL)	WTE Approved 1.0 1.0 <u>2.0</u> 4.0	WTE Filled 1.0 1.0 <u>2.0</u> 4.0	Grade Chief Medical Scientist Specialist Medical Scientist Clinical Scientist	Discrete Cost Centre	<ul style="list-style-type: none"> Health Protection Surveillance Centre Public Health Departments 	<ul style="list-style-type: none"> Department of Clinical Microbiology, TCD (translational research projects) European Reference Laboratory Network for TB (ERLTB-NET) 	Annual Report published https://www.stjames.ie/services/laboratory-medicinelabmed/irish-mycobacteriareferencelaboratory/
6	Irish Meningitis and Sepsis Reference Laboratory (IMSRL),	WTE Approved 1.0 6.0 1.0 1.0 1.0	WTE Filled 1.0 6.0 1.0 1.0 1.0	Grade Chief Scientist Senior Scientists Basic Surveillance Scientist Laboratory Aide Administrative	Discrete Cost Centre	<ul style="list-style-type: none"> Health Protection Surveillance Centre Public Health Departments 	<ul style="list-style-type: none"> RCPI National Immunisation Advisory Committee European Centre for Disease Control (ECDC) 	2019 Annual Report published https://www.cuh.ie/irish-meningitis-sepsis-reference-laboratory-imsrl/

	Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users, (excl internal and external acute hospital services)	Q 19, External Relationships	Q 20, 21 and 22, Name of website, Availability and source of Annual Report
		0.5 10.5	0.5 10.5	Data Manager			<ul style="list-style-type: none"> European Monitoring Group on Meningococci European Public Health Microbiology (EUPHEM) & European Field Epidemiology (EPIET) Universities of Oxford and Cambridge Maternity services and reproductive Health 	
7	National VTEC Reference Laboratory (VTEC NRL)	WTE Approved 0.5 0.5 1.5 3.0 4.3 0.0	WTE Filled 0.5 0.5 1.5 1.0 4.3 0.0	Grade Consultant Microbiologist Chief Medical Scientist Specialist Medical Scientist Senior Medical Scientist Basic Medical Scientist Medical Laboratory Aids	Discrete Cost Centre	<ul style="list-style-type: none"> Health Protection Surveillance Centre Public Health Departments Community COVID test laboratory CHO 7 longterm care facilities (covid testing) 	<ul style="list-style-type: none"> ECDC 5 Nations Public Health group. UK and EU reference labs UK PH 	2019 Annual Report delay due to COVID-19 workload https://www.hse.ie/eng/services/list/5/publichealth/publichealthlabs/public-health-laboratory-dublin/

	Name	Q 15 Laboratory Staffing (WTEs and grades)	Q 16 and 17 Cost Centre	Q 18, Key Users, (excl internal and external acute hospital services)	Q 19, External Relationships	Q 20, 21 and 22, Name of website, Availability and source of Annual Report
		<u>1.5</u> <u>1.5</u> Administrative 11.3 9.3 Note: included in above 2.0 WTEs Senior Medical Scientist support <i>C. Difficile</i> Reference Laboratory				
8	National <i>C. difficile</i> Reference Laboratory	WTE WTE Grade Approved Filled 2.0 0.0 Senior Medical Scientist				
9	Bordetella pertussis Reference Laboratory	WTE WTE Grade Approved Filled 1.0 1.0 Chief Medical Scientist 3.0 2.0 Senior Medical Scientist <u>1.0</u> <u>1.0</u> Basic Medical Scientist 5.0 4.0	No discrete cost centre	<ul style="list-style-type: none"> ▪ GPs 	<ul style="list-style-type: none"> ▪ EUPERT-labnet Network ▪ EQA. ▪ EUPertStrain network ▪ PERTINENT project 	2019 Annual Report delay due to COVID-19 workload No website

Table 8: HSE Food and Water Microbiology Services Q1 to Q13

	Q 1 Name of Reference Laboratory	Q 3 Name of Laboratory Director	Q 2 and 4 Name of Associated Institution/ Organisational	Q 5, 6 and 7, Accreditation Status, Accreditation Body Accreditation Standard	Q 8 and 9 No. of samples processed in 2020 No. of tests reported in 2019 (approx.)	Q 10 Name and version of Principle Laboratory Information System in Use	Q 11, 12 and 13. Approx. footprint of lab, Year of construction, Structure of building
1	Galway University Hospital	Prof. Martin Cormican, Consultant Microbiologist	University Hospital Galway – Saolta Hospital Group	Accredited INAB ISO 17025; 2017	7,324 samples processed 19,993 tests reported	LabWare7	90 M2 1950s and 1980 Combination of permanent and prefab structure
2	Public Health Laboratory, Dublin Sir Patrick Dun's Hospital	Dr. Andrew Flanagan, Public Analyst	CHO 6	Accredited INAB ISO/IEC 17025; 2017	2,345 samples processed 9,244 tests reported	LabWare7	180 M2 1808 Permanent structure
3	Cherry Orchard Hospital	Dr. Eleanor McNamara, Consultant Microbiologist	CHO 6	Accredited INAB ISO 17025	6,986 samples processed 26,664 tests reported	LabWare7	673 M2 1958 and 2001 Combination of permanent and prefab structure
4	Waterford University Hospital	Dr. Nigam Shah, Consultant Histopathologist	University Hospital Waterford – South South West Hospital Group	Accredited INAB ISO 17025	16,234 samples processed 21,225 tests reported	LabWare6	49 M2 1970s and 2020 Combination of permanent and prefab structure
5	St. Finbarr's Hospital, Cork	Ms. Niamh Philips	St. Finbarr's Hospital, CHO4	Accredited INAB ISO 17025; 2017	4,151 samples processed	LabWare7	300 M2 1998

	Q 1 Name of Reference Laboratory	Q 3 Name of Laboratory Director	Q 2 and 4 Name of Associated Institution/ Organisational	Q 5, 6 and 7, Accreditation Status, Accreditation Body Accreditation Standard	Q 8 and 9 No. of samples processed in 2020 No. of tests reported in 2019 (approx.)	Q 10 Name and version of Principle Laboratory Information System in Use	Q 11, 12 and 13. Approx. footprint of lab, Year of construction, Structure of building
					10,641 tests reported		Permanent structure
6	University Hospital Limerick	Dr. Nuala O'Connell, Consultant Microbiologist	University Hospital Limerick – UL Hospital Group	Accredited INAB ISO 17025	3,577 samples processed 9,480 tests reported	LabWare7	300 M2 2006 Permanent structure
7	Sligo University Hospital	Dr. Anna Rueda Benito, Consultant Microbiologist	Sligo – Saolta Hospital Group	Accredited INAB ISO 17025; 2017	12,139 samples processed 18,349 tests reported	LabWare7	133 M2 1940s Permanent structure

Note: Impact of COVID-19 was noted to have significant reduction of reference laboratory workload in 2020 therefore 2019 workload is reflected in Table 8 above.

Table 9: HSE Food and Water Microbiology Services Q14

	Name	Q 14 Overview of Service
1	Galway University Hospital	<p>Services provided include:</p> <ul style="list-style-type: none"> ▪ Food Testing Service – Provides microbiological analysis of food, environmental swab samples, bottled water and water as ice under a raft of food safety legislation including Regulation (EC) No 178/2002 and Commission Regulation (EC) No 2073 2005. ▪ Potable Water Testing Service – Provides a water testing service for the microbiological analysis of drinking water for 'Official samples' taken by the Environmental Health Service (EHS) in Galway, Mayo and Roscommon and local sanitary authorities (Galway County Council, Galway City Council) under drinking water legislation European Council Directive 98/83/EC of 1998 and Council Directive 2000/60/EC of 2000 and the relevant Irish legislation S.I No 122 of 014 and S.I. No 464 of 2017. It also provides a potable water testing service for 'Private' customers. ▪ Recreational Water Testing Service - Swimming Pools, Spas, Hydrotherapy Pools etc. Provides a testing service for Swimming Pools, Spas, and Hydrotherapy Pools etc. submitted by the EHS in Galway, Mayo and Roscommon. ▪ Bathing Water Testing Service (Sea and Lake Water) - Provides a testing service for Galway City Council and Galway County Council in conjunction with the EHS Galway for the analysis of bathing water under the European Union Bathing Water Quality Regulations 2008 giving full effect to Directive 2006/7/EC and S.I No 79 of 2008. This provides all the microbiological data for the Blue Flag and Green Flag awards for beaches and swimming areas. ▪ Legionella Testing in Hospital Water Distribution Systems - Provides a testing service for the detection and enumeration of Legionella in the UHG and MPH sites on a weekly basis. ▪ Endoscopy Rinse Water Testing - Provides a testing service for Endoscope Water Disinfectant Units in UHG, MPH, MUH, Portlincula and Roscommon as well as the private hospital in Galway. ▪ Dialysis Water - Provides a service for the testing of water from dialysis units from UHG, MPH and MUH. ▪ Environmental Testing - Provides a service for the Environmental testing of the HSSD and EDU units in UHG for both bio-contamination and particle counts.
2	Public Health Laboratory, Dublin Sir Patrick Dun's Hospital	<p>Services provided include:</p> <ul style="list-style-type: none"> ▪ Full-service chemical and microbiological analysis laboratory where, inter alia, official food and water sample analysis is carried out in a fully accredited environment;

	Name	Q 14 Overview of Service
		<ul style="list-style-type: none"> Analyses food complaints, cosmetics, environmental swabs, 'dental' waters and is accredited for <i>Legionella spp.</i> & <i>Vibrio parahaemolyticus</i> analysis. Reports all results on a single certificate both in 'hard' and 'soft' copy. Carries-out official microbiological analysis for the Health Products Regulatory Authority on cosmetics. The microbiology service is overseen by a Deputy Public Analyst (DPA) and individual analytical sections (food, water, etc.) are managed by Executive Analytical Chemists (EAC) who supervise the bench-work of senior and staff-grade laboratory technicians. The DPA and EACs are 'Approved Examiners' under the relevant legislation (e.g. the Official Control Regulation) and issue laboratory certificates to our customers.
3	Cherry Orchard Hospital	<p>Services provided include:</p> <ul style="list-style-type: none"> Provides accredited water testing services (potable, recreational, therapeutic including legionella) to the EHS and a variety of healthcare facilities. ECDC designated training site for EUPHEM (European public health microbiology) Fellowship in Ireland, training for other health care professionals is facilitated. Research programmes are actively pursued.
4	Waterford University Hospital	<p>Services provided include:</p> <ul style="list-style-type: none"> Statutory food control duties for the Environmental Health Service (EHS) in Waterford / Dungarvan, Carlow/ Kilkenny, South Tipperary & Wexford. Provides a public water testing service for the EHS and a bathing water testing service for Waterford County Council during May-September. Provides specialist support services for Pharmacy, Theatre, Dialysis, Catering, Endoscopy, Infection Control, and Technical Services departments for the four acute hospitals in the Southeast region.
5	Cork University Hospital	<p>Services provided include:</p> <ul style="list-style-type: none"> Provide a wide range of specialist microbiological tests, across an array of different food and water matrices, as well as environmental swabs. Operating as an official control laboratory (as designated in S.I.69 of 2020) Provides testing to support food safety monitoring, surveillance programmes, investigation of outbreaks, incidents, food alerts and consumer complaints.

	Name	Q 14 Overview of Service
		<ul style="list-style-type: none"> Supports hospital services in Cork and Kerry through Legionella monitoring, as well as microbiological examination of endoscopy, cardiac renal, dialysis and dental water supplies, ensuring the quality of water used in patient care.
6	University Hospital Limerick	<p>Services provided include:</p> <ul style="list-style-type: none"> The laboratory is a designated Official Laboratory under S.I. 79 of 2020. SLA with the Sea Fisheries Protection Agency (SFPA) to provide testing for fishery products, swabs, ice and water. Testing of bottled waters for the National Standards Authority of Ireland. Testing of food samples from HSE hospital and community sites. Provides accredited testing facilities for weekly environmental samples taken by Hospital Departments e.g. Endoscopy, Respiratory, Dialysis, Pharmacy, Technical services. Provides testing for water samples in response to infectious disease notifications from the Department of Public Health. This laboratory is accredited for legionella testing which is performed in response to local outbreaks. Routine legionella surveillance of local supplies is contracted to an outside company at a cost to the HSE. Accreditation for STEC testing in water samples by Real-time PCR was achieved in 2021. Provides laboratory tests water samples for members of the public.
7	Sligo University Hospital	<p>Services provided include:</p> <ul style="list-style-type: none"> Provides testing of food, water, environmental for Sligo, Leitrim, Donegal and West Cavan for compliance with European and national legislation and/or National guidelines. Provides routine monitoring of microbiological safety of food, water and environmental samples by risk based sampling strategies and according to agreed sampling plans Provides testing of food, water and environmental samples for surveillance and investigation of food and water borne associated illnesses/incidents. Participates member of Outbreak Control Teams. Provides expert technical and clinical advice to customers. Participates in annual National Food Surveillance Surveys co-ordinated by Food Safety Authority of Ireland for assessing microbiological safety of foodstuffs in Ireland. Provides daily environmental testing of air quality and surfaces of Pharmacy Aseptic unit, SUH. Holds a service level agreement for provision of environmental testing of air quality and surfaces of Endoscopy Dept. and Theatre Endoscopy, Sligo University Hospital.

	Name	Q 14 Overview of Service
		<ul style="list-style-type: none"> ▪ Holds a service level agreement for provision of Final Rinse Water testing for Endoscopy Dept. and Theatre Endoscopy, Sligo University Hospital to national guidelines. ▪ Provides testing of Hydrotherapy pool samples for compliance with national guidelines. ▪ Holds a service level agreement for provision of food testing for Food Business Operator compliance to European Legislation EC 2073 as amended for Catering Depts. in Sligo University Hospital and Letterkenny University Hospital.

Table 10: HSE Food and Water Microbiology Services Q15 to Q22

	Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users (excl internal and external acute hospital services)	Q 19 External Relationships	Q 20, 21 and 22 Name of website Availability and source of Annual Report
1	Galway University Hospital	WTE Approved	WTE Filled	Grade	No discrete cost centre Part of Laboratory cost centre	<ul style="list-style-type: none"> Environmental Health Service in Galway Mayo and Roscommon Sea Fisheries Protection Agency Galway County Council and Galway City Council - Water and Environmental Services Saolta Hospital Group – UHG, MPH, MUH, RUH, Portiuncula Hospital Bon Secours Hospital Galway 	<ul style="list-style-type: none"> Food Safety Authority of Ireland and associated agencies Environmental Protection Agency An Taisce DAFM Reference Laboratories, Backweston VTEC Reference Laboratory, Cherry Orchard NSSLRL Reference Laboratory, Galway PHE Reference Laboratory, Colindale, London 	2019 Annual Report available No website
2	Public Health Laboratory, Dublin Sir	WTE Approved	WTE Filled	Grade	Discrete cost centre	<ul style="list-style-type: none"> Environmental Health Services National Reference Laboratories 	<ul style="list-style-type: none"> Health Products Regulatory Authority 	Annual Report Published https://www.hse.ie/eng/service

	Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users (excl internal and external acute hospital services)	Q 19 External Relationships	Q 20, 21 and 22 Name of website Availability and source of Annual Report
	Patrick Dun's Hospital	1.0	1.0	acting) Senior Lab Technician*			<ul style="list-style-type: none"> Local Authorities Private Customers (incl. Export Certification) Sea Fisheries Protection Authority Other Government Departments, European Food Safety Agency (via FSAI). 	s/list/1/public-analyst-laboratory/
		11.0	11.0	Staff Grade Lab Technician*				
		0.5	0.5	Laboratory Aide				
		1.5	1.5	Administrative				
		19.0	19.0					
		*Not CORU registered						
3	Cherry Orchard Hospital	WTE Approved	WTE Filled	Grade	Discrete cost centre	<ul style="list-style-type: none"> Environmental Health service, HPSC, ECDC – Surveillance & EPIS alerts etc. FSAI Food and Water testing: Environmental Health service, Hospital Catering departments, Hospital endoscopy units, Hospital perfusion departments 		
		0.3	0.3	Consultant Microbiologist				
		0.3	0.3	Chief Medical Scientist				
		0.5	0.5	Specialist Medical Scientist				
		2.0	2.0	Senior Medical Scientist				
		4.5	4.5	Basic Medical Scientist				
		1.0	1.0	Laboratory Aide				
		1.5	1.5	Administrative				
		10.1	10.1					

	Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users (excl internal and external acute hospital services)	Q 19 External Relationships	Q 20, 21 and 22 Name of website Availability and source of Annual Report
4	Waterford University Hospital	WTE Approved	WTE Filled	Grade	Discrete cost centre	<ul style="list-style-type: none"> Environmental Health Service 	<ul style="list-style-type: none"> Local authority FSAI 	2019 Annual report is not available. No website
		1.0	0.2	Consultant Microbiologist				
		1.0	0.5	Laboratory Manager				
		1.0	1.0	Chief Medical Scientist				
		1.0	1.0	Senior Medical Scientist				
		8.0	8.0	Basic Medical Scientist				
		2.0	2.0	Laboratory Aide				
		0.5	0.5	Administrative				
		14.5	13.2					
5	St. Finbarr's Hospital, Cork	WTE Approved	WTE Filled	Grade	Discrete cost centre	Environmental Health Service, UCC Dental Hospital Public Health), NRLs within HSE,	Sea Fisheries Protection Authority FSAI, SFPA, NRLs within DAFM, Safefood, Third level institutions (MTU and UL)	2019 Annual report is not available. No website
		0.35	0.0	Consultant Microbiologist (CUH)				
		1.0	1.0	Chief Medical Scientist				
		6.12	6.12	Senior Medical Scientist				
		6.42	6.42	Medical Scientist				
		0.8	0.8	Multi task Attendant				
		0.9	0.9	Administrative (Grade III)				
		15.59	15.24					
6	University Hospital Limerick	WTE Approved	WTE Filled	Grade	Discrete cost centre	Environmental Health Service	Sea Fisheries Protection Agency , National Standards Authority of Ireland, Private customers	2019 /2020 Annual report is not available. No website
		0.2	0.2	Consultant Microbiologist				
		0.1	0.1	Laboratory Manager				
		1.0	1.0	Chief Medical Scientist				
		1.0	1.0	Senior Medical Scientist				

	Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users (excl internal and external acute hospital services)	Q 19 External Relationships	Q 20, 21 and 22 Name of website Availability and source of Annual Report
		4.6	4.6	Medical Scientist				
		0.8	0.8	Laboratory Assistant				
		0.1	0.1	Caretaker				
		<u>2.6</u>	<u>0.0</u>	Posts not detailed				
		10.4	7.8					
7	Sligo University Hospital	WTE Approved	WTE Filled	Grade	Discrete cost centre	Environmental Health Service, Public Health Dept., National Reference Laboratories,	Food Safety Authority of Ireland (FSAI), Irish national Accreditation Board (INAB),	2019 /2020 Annual report is not available. No website
		0.1	0.1	Laboratory Manager				
		0.3	0.3	Consultant Microbiologist				
		1.0	1.0	Chief Medical Scientist				
		2.0	1.0	Senior Medical Scientist				
		6.0	3.8	Basic Medical Scientist				
		1.0	1.0	Laboratory Aide				
		<u>0.7</u>	<u>0.7</u>	Administrative				
		11.1	7.9					

Table 11: National Virus Reference Laboratory Q1 to Q13

Q 1 Name of Reference Laboratory	Q 3 Name of Laboratory Director	Q 2 and 4 Name of Associated Institution/ Organisational	Q 5, 6 and 7 Accreditation Status Accreditation Body Accreditation Standard	Q 8 and 9 No. of samples processed in 2020 No. of tests reported in 2020	Q 10 Name and version of Principle Laboratory Information System in Use	Q 11, 12 and 13. Approx. footprint of lab, Year of construction, Structure of building
UCD National Virus Reference Laboratory	Cillian De, Gascun, Clinical Director	University College Dublin, Belfield Campus, Dublin 4,	Accredited INAB ISO 15189	464,378 samples processed 1,003,584 tests reported	CliniSys WinPath	2400 M2 1980s/2000's Permanent structure

Table 12: National Virus Reference Laboratory Q14

Name	Q 14 Overview of Service
UCD National Virus Reference Laboratory	<ul style="list-style-type: none"> Originally established in 1963 at the request of the Department of Health. At that time, its intended function was to carry out surveillance primarily for Polio virus, following introduction of the polio vaccine in Ireland. It also became Ireland's National Influenza Centre, feeding data into the WHO's (then) Global Influenza Surveillance Network (GISN), now GISRS. In the intervening decades, the NVRL's diagnostic workload has increased dramatically, but it continues to fulfil Ireland's remit to the WHO as the National reference laboratory for Measles, Polio, Rubella, and Influenza. Provides a molecular and serological service to many GPs and some hospitals nationally. Provides a confirmatory – or second-line – testing service to many acute hospital laboratories for a wide range of viral pathogens. Provides a cell culture and virus isolation laboratory, the NVRL offers an antiviral resistance and sequencing service (both diagnostic and surveillance). Provides a DoH funded CL3 facility for the investigation of suspected imported and exotic infections. Provides a 24/7 365 donor screening service to Organ Donation Transplant Ireland (ODTI).

Table 13: National Virus Reference Laboratory Q15 to Q22

Name	Q 15 Laboratory Staffing (WTEs and grades)			Q 16 and 17 Cost Centre	Q 18, Key Users (excl internal and external acute hospital services)	Q 19 External Relationships	Q 20, 21 and 22 Name of website Availability and source of Annual Report
UCD National Virus Reference Laboratory	WTE Approved 2.8 6.9 44.29 33.33 <u>18.0</u> 105.32	WTE Filled 2.8 6.9 33.33 <u>18.0</u> 105.32	Grade Medical Consultants Clinical Scientists (basic grade to principal) Technical Officer (basic grade to chief) Administrative staff Laboratory Attendants	Discrete cost centre Yes part of other cost centre	The HSE accounts for over 95% of NVRL work, although our service is available to private hospitals and laboratories. Department of Health	Health Protection Surveillance Centre WHO, ECDC, INAB UCD – all NVRL staff hold UCD contracts	Annual Report published, 2019/2020 not yet available https://nvrl.ucd.ie/search/node/annual%20report

Appendix 4 – Indicative Costings to Support Governments Recommendation

Table 14: Indicative costings

Governance	Post	Grade Name	Grade Code	Pay €	EPRSI € (13.05%)	Non-Pay € 10%	Total €	WTE	Total €
New Post 1	Chief Clinical Director	Consultant Micro/Virologist		186,596	24,351	18,660	229,606	1.00	229,606
New Post 2	Clerical	Grade IV	0058	38,989	5,088	3,899	47,976	1.00	47,976
New Post 3	Lab Manager, Reference Lab	Laboratory Manager	393X	83,626	10,913	8,363	102,902	1.00	102,902
New Post 4	Lab Manager, Food and Water Ref Lab	Laboratory Manager	393X	83,626	10,913	8,363	102,902	1.00	102,902
New Post 5	General Manager	General Manager	0041	81,912	10,690	8,191	100,793	1.00	100,793
New Post 6	Data Manager	Grade VIII	0655	76,570	9,992	7,657	94,219	1.00	94,219
New Post 7	Clerical	Grade IV	0058	38,989	5,088	3,899	47,976	1.00	47,976
		Total		590,308	77,035	59,031	726,374	7.00	726,374

Note: October 2021 DOH Salary Scales used. Mid-point applied. Employers PRSI (EPRSI) costed at 13.05% and non-pay costed at 10%. Allowances not included.

Appendix 5 – Membership of the Review Group

- Professor Martin Cormican, National Clinical Lead Antimicrobial Resistance and Infection Control (AMRIC), Office of the Chief Clinical Officer (Chair)
- Professor Mary Keogan, National Clinical Lead, Pathology
- Anne Mannion, Laboratory Manager, National Clinical Programme, Pathology

Reference Laboratory Leads

- Dr. Niall DeLappe, Medical Scientist, NCPERL, University College, Hospital Galway,
- Dr. Brendan Crowley, Medical Director, NGRL, St. James Hospital, Dublin
- Antoinette Power, Chief Medical Scientist, NGRL, St. James Hospital, Dublin
- Dr. Robert Cunney, Consultant Microbiologist, IMSRL, Children's Health Ireland, Temple Street, Dublin
- Dr. Brian O'Connell, Medical Director, NMRSARL, St. James's Hospital, Dublin
- Professor Johannes Wagner, Consultant Microbiologist, Irish Mycobacterial Reference Laboratory, St. James's Hospital, Dublin
- Dr. Eleanor McNamara, Consultant Microbiologist, Public Health Laboratory, Cherry Orchard Hospital, Dublin
- Dr. Niamh O'Sullivan, Consultant Microbiologist, Bordetella pertussis Reference Laboratory, Children's Health Ireland, Crumlin, Dublin
- Dr. Cillian De Gascun, Director, National Viral Reference Laboratory

Food & Water Laboratory Services Leads

- Dr. Andrew Flanagan, Public Analyst, Public Analyst Laboratory, Sir Patrick Dunn's Hospital, Dublin
- Dr. Vivian Murphy, Consultant Microbiologist, Waterford University Hospital
- Dr. Anne Carroll, Chief Medical Scientist, Public Health Laboratory, Cherry Orchard Hospital, Dublin
- Enda Burke, Technical Manager, University College Hospital Galway
- Dr. Ana Rueda Benito, Consultant Microbiologist, Sligo University Hospital
- Dr. Patrick Stapleton, Consultant Microbiologist, University Hospital Limerick
- Niamh Phillips, Chief Medical Scientist, St. Finbarr's Hospital, Cork

- Shirley Keane, Programme Manager, AMRIC
- Mike Corbett, Assistant National Director, Acute Operations
- Aileen O'Brien, Head of Infection & Prevention Control, Community Operations
- Naomi Petty-Saphon, Specialist in Public Health Medicine, HPSC
- Margaret Culliton, Project Manager, AMRIC

Appendix 6 – Glossary

ACDP:	Advisory Committee on Dangerous Pathogens.
AMRHAI:	Antimicrobial resistance and healthcare associated infections
AMRIC:	Antimicrobial Resistance and Infection Control
<i>C. difficile</i> :	<i>Clostridioides difficile</i>
CHI:	Children’s Health Ireland
CHO:	Community Healthcare Organisation
COVID- 19:	SARS-CoV-2
DAFM:	Department of Agriculture, Food and the Marine
DoH:	Department of Health
DPA:	Data Processing Agreement
EAC:	Executive Analytical Chemists
EARS-NET	European Antimicrobial Resistance Surveillance Network
ECDC:	European Centre Disease Control
EEA:	European Economic Area
EFSA:	European Food and Safety Authority
EHS:	Environment Health and Safety
ELISA:	Enzyme-linked immunosorbent assay
EMT:	Executive Management Team
EPIET:	European Field Epidemiology
EPIS:	Epidemic Intelligence Information System
EQA:	External Quality Assessment
ERLTB-NET:	European Reference Laboratory Network for TB
ESGS:	European Study Group for Staphylococci
EU:	European Union
EUPERT:	European Pertussis Laboratory Surveillance Network (Lab/Strain)
EUPHEM:	European Public Health Microbiology
FSAI:	Food Safety Authority Ireland
GISN:	Global Influenza Surveillance Network
GISRS:	Global Influenza Surveillance and Response System
GLASS:	Global Antimicrobial Resistance and Use Surveillance System
GP:	General Practitioner
HPRA:	Health Products Regulatory Authority
HPSC:	Health Promotion Surveillance Centre
HSE:	Health Service Executive
INAB:	Irish National Accreditation Board
iNAP:	Ireland’s National Action Plan
ISO:	International Organization for Standardization
IT:	Information Technology
LIMS:	Laboratory Information Management System
M2	Metres squared
MLST:	Multilocus sequence typing
MRSA:	Methicillin Resistant <i>Staphylococcus aureus</i>

<i>M. chimaera</i> :	<i>Mycobacterium chimaera</i>
NCPERL:	National Carbapenemase Producing Enterobacterales Reference Laboratory
NGCRL:	National Gonococcal Reference Laboratory
NGS:	Next generation sequencing
NIMRL:	National Irish Mycobacteria Reference Laboratory
NIMSRL:	National Irish Meningitis and Sepsis Reference Laboratory
NVRL:	National Virus Reference Laboratory
PCR:	Polymerase chain reaction
PH:	Public Health
PHL:	Public Health Laboratory
PHVLS:	Public Health Microbiology & Virology Laboratory Services
RCPI:	Royal College of Physician in Ireland
RCSI:	Royal College of Surgeons in Ireland
SFPA:	Sea Fisheries Protection Authority
SJH:	St. James Hospital
STI:	Sexually Transmitted Infections
TB:	Tuberculosis
TESSy:	The European Surveillance System
UCD:	University College Dublin
UHG:	University Hospital, Galway
UK:	United Kingdom
VNTR:	Variable number of tandem repeats
VTEC:	Verocytotoxin <i>E. coli</i>
WGS:	Whole Genome Sequencing
WHO:	World Health Organisation
WTE:	Whole time equivalent

ENDS