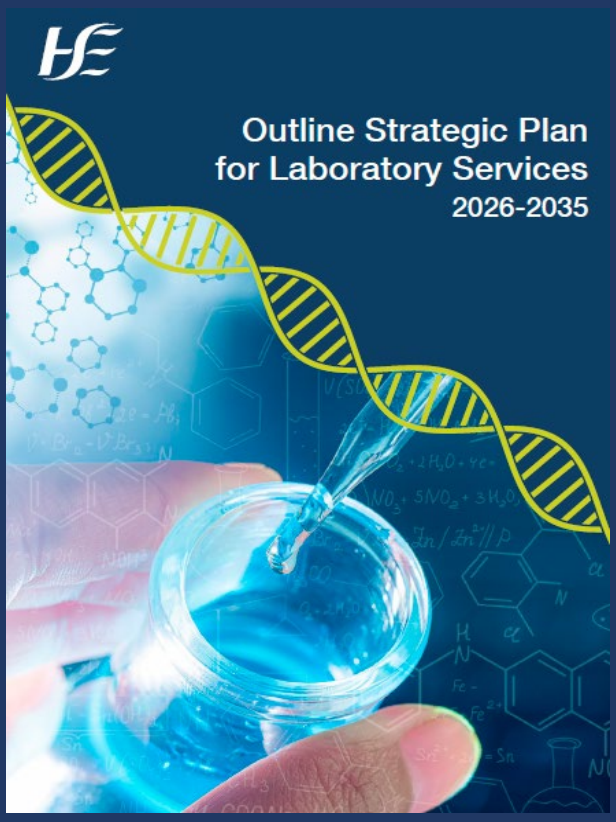
Laboratory Services Reform Programme



HSE Outline Strategic Plan for Laboratory Services (2026 – 2035)

Contents

This is the final version of the HSE Outline Strategic Plan for Laboratory Services 2026-2035, approved by the HSE Senior Leadership Team and presented to the HSE Board in March 2025

Foreword from the Chief Clinical Officer

Laboratories play a central part in the delivery of health services by the Health Service Executive. The multidisciplinary teams that work in laboratories, through their skill and commitment, support diagnosis, treatment and monitoring of disease and programmes for screening for disease. They are important in protecting health through the provision of Reference Laboratory Services and the analysis of food, water, medicines and other products.

The achievements of the Laboratory Services in the health sector in Ireland to date are impressive. They have grown in size and sophistication of service over many decades, adapting to new analytic and data management technologies and responding to clinical need. They have implemented quality systems with accreditation to International Standards by the Irish National Accreditation Board. The importance of laboratory teams and services that are expert, agile and resilient was never more apparent than in the response to the recent cyberattack and the COVID-19 pandemic. Laboratories are and will be key to pandemic preparedness, ensuring our ability to detect and supporting our ability to respond to emerging health threats.

There are opportunities to build on the achievements of the people working and leading the HSE laboratory services. New ways of working are increasingly the norm in international laboratory practice. There are opportunities for laboratory staff to expand their skills and competencies to broaden their scope of practice. This will be supported by the potential to release people from many repetitive manual tasks through increased us of automation. There are rapidly emerging new technologies, platforms and information systems with potential to improve health and patient care and improve efficiency and sustainability. The reorganisation of the HSE into six Health Regions, each responsible for delivery of both community and hospital services to the population of the Health Region, affords an excellent opportunity to integrate laboratory services at the Health Region Level as well as for the Health Regions to collaborate on developments of National Level services such as Reference Laboratory Services that are most effectively provided for whole population by a single integrated service.

This plan sets out an ambitious ten-year roadmap, 2026-2035 for HSE laboratory services addressing the challenges and opportunities that lie ahead. Its implementation promises improved services to patients and the public and will make HSE Laboratories a more fulfilling workplace.

I wish to thank all those who have developed and sustained the existing HSE laboratory services that are the foundation for implementation of this plan and those who have contributed to the development of the plan through the extensive consultation process conducted during 2024. This builds on the previous engagements on the *Review to Inform the Strategic Direction of Laboratory Medicine* published in January 2024.

Dr Colm Henry,
Chief Clinical Officer, HSE

Foreword from Clinical Lead, HSE Laboratory Services Reform Programme

I want to thank all of those who have made it possible to develop this Outline Strategic Plan for Laboratory Service Reform which was presented to the Board of the HSE in March 2025. In particular my thanks to Pat Mulhare, Marie Culliton and Jane Boxberger who form the core team for the Laboratory Services Reform Programme. The work was also supported by the Clinical Advisors to the Programme (Niall Conlon, Melanie Cotter, Sorcha Ní Loingsigh, Meaghan Cotter, Niamh Leonard and Shari Srinivasan) and the members of the Clinical and Scientific Advisory Group. Beyond the Programme team and advisors the development of this plan benefited from discussions and written contributions from diverse stakeholders including the Department of Health, public bodies, professional bodies, trade unions, international colleagues and others. I especially want to thank the people in all professional groups who work in HSE Laboratory Services who brought their experience and expertise to the table by participating in large numbers in the round of consultations in eight hospitals in early 2024 and through written feedback.

These are challenging times in HSE Laboratory Services. The workload is heavy and growing in volume and complexity. We are experiencing challenges with recruitment and retention and with facilities and equipment. In the face of those challenges, HSE Laboratory Services continue to support patient care with delivery of quality services and innovation. This Outline Strategic Plan provides a framework to build on that foundation over the next ten years. The return on the investment in people, technology and facilities called for in the plan will more than justify that investment in service to patients, improved efficiency, resilience and sustainability.

Professor Martin Cormican,
Clinical Lead, HSE Laboratory Services Reform Programme

Achoimre Fheidhmeach

Is é misean FSS agus sheirbhísí saotharlainne cistithe FSS seirbhísí ardchaighdeáin anailíseacha agus léirmhínitheacha a chur ar fáil ar bhealach inbhuanaithe mar bhunchloch na sláinte agus an chúraim sláinte. Sásaítear an misean seo faoi láthair trí bhreis agus 40 saotharlann aonair dhiagnóiseach chliniciúil agus trí roinnt seirbhísí scoite saotharlainne tagartha cliniciúla. Tá roinnt Saotharlanna Anailísí Phoiblí agus Saotharlanna Micribhitheolaíochta Sláinte Poiblí ag FSS chomh maith, a dhéantar a ghrúpáil mar Shaotharlanna um Chosaint Sláinte sa Phlean Straitéiseach seo.

Is iomaí deis agus dúshlán atá le tapú agus le sárú ag seirbhísí saotharlainne. I measc na gceisteanna is mó, tá

- éileamh ar sheirbhísí atá ag dul i méid go mear
- tairbhí forbairtí eolaíochta agus teicneolaíochta a uasmhéadú
- freagairt d'athrú eagraíochtúil FSS
- daoine a bhfuil scileanna bunriachtanacha acu a earcú agus a choinneáil
- comhtháthú na seirbhíse
- bonneagar
- leanúint de chórais ardchaighdeáin a chur ar fáil
- a chinntiú go bhfuiltear ullamh d'éigeandálaí sláinte poiblí.

Cé gur fhreagair saotharlanna aonair go cruthaitheach do na deiseanna agus na dúshláin sin, ní leor é sin a thuilleadh chun freagairt don éileamh a bhíonn ag ospidéil agus ag an bpobal. Is den bunriachtanas anois cur chuige straitéiseach a bheith ann ar fud na heagraíochta chun feabhas a chur ar chomhordú agus chun infheistíocht a phleanáil le seirbhís inbhuanaithe agus éifeachtúil a chinntiú.

Is é seo an chéad Phlean Straitéiseach ag FSS maidir le seirbhísí saotharlainne. Forbraíodh an Plean tar éis dul i gcomhairle le go leor príomhpháirtithe leasmhara. Is ionann an plean seo agus togra mór agus tiomantas chun an bealach a n-eagraítear agus a soláthraítear seirbhísí saotharlainne FSS a athrú ó bhonn as seo go ceann 10 mbliana.

Tá sraith prionsabal agus moltaí mionsonraithe sa phlean faoi 15 theideal. I measc na bprionsabal siúd, tá seirbhísí saotharlainne a shainaithint mar chroífheidhm FSS ar cheart í a sholáthar laistigh de FSS mar ghné lárnach de sholáthar cúraim sláinte agus de chosaint sláinte.

Catagóirítear gach ceann de na moltaí mar ‘anois’ (bliain 1 agus 2), ‘ina dhiaidh seo’ (bliain 3 go bliain 5) nó amach

anseo (bliain 6 go bliain 10) ar mhaithe leis na hamlínte a threorú maidir le cur i bhfeidhm. Cé go bhfuil tograí sa phlean le haghaidh Réigiúin Sláinte, aithnítear ann nach féidir le gach togra freastal ar gach duine agus go bhfuil idir deiseanna agus dúshláin ar leith ann do gach Réigiún Sláinte a dteastóidh cur chuige ina dtaobh a chuirtear in oiriúint dá riachtanais.

I measc na bpríomh-mholtaí, tá:

- An Clár Oiliúna Iarchéime d’Eolaithe Míochaine a forbraíodh roimhe seo a chur i bhfeidhm
- Seirbhís Saotharlainne Tagartha Cliniciúla Náisiúnta (CNRLS) chomhtháite a fhorbairt
- Campas Lárshaotharlann FSS a fhorbairt
- Ba cheart Seirbhísí Saotharlainne um Chosaint Sláinte a bhainistiú mar aon seirbhís náisiúnta amháin
- Líonraí Saotharlann (Mol agus Spócaí) a fhorbairt laistigh de na Réigiúin Sláinte
- foireann bainistíochta seirbhíse saotharlainne a fhorbairt do gach Réigiún Sláinte
- Saotharlann Réigiúin Sláinte a fhorbairt i ngach Réigiún
- córais cháilíochta scoite a chomhtháthú
- an infheistíocht a bharrfheabhsú in uathoibriú na gcéimeanna uile ullmhaithe agus próiseála samplaí, Paiteolaíochta Digití agus teicneolaíochtaí nua eile
- Cumarsáid ordaithe leictreonaigh agus aistriú leictreonach faisnéise idir saotharlanna a chur i bhfeidhm chun ullmhú do chórais saotharlainne a chomhcheangal leis na Taifid Leictreonacha Cúraim Sláinte (EHRanna)
- córais agus próisis a fhorbairt chun teacht slán a thabhairt d’othair ar a sonraí féin saotharlainne
- seirbhísí fleibeatóime a fhorbairt agus a shíneadh mar chuid lárnach den tseirbhís saotharlainne
- ba cheart seirbhísí a sholáthar d’othair sa phobal i seirbhís saotharlainne atá i ngar dóibh, nuair is féidir
- comhaontú seirbhíse agus a chomhionann d’acmhainní chun tacú le seirbhísí a sholáthraítear don Chróinéir
- Ba cheart do Phaiteolaithe Comhairleacha agus d’Eolaithe a oibríonn i róil cheannaireachta i ngach disciplín feidhmiú mar fhoireann i Líonraí Saotharlann (Mol agus Spócaí)

- clárú do gach Eolaí a oibríonn i seirbhísí saotharlainne cliniciúla a chur chun cinn
- deiseanna chun dul chun cinn ina ngairmeacha beatha a chur ar fáil d'Eolaithe Míochaine agus d'eolaithe eile, ardchleachtas agus cleachtas uathrialaitheach ina measc
- ról Cúntóirí Saotharlainne a fhairsingiú agus deiseanna dul chun cinn a chur ar fáil
- ba cheart do gach grád foirne i mbun oibre cur mar is gá le seirbhís a sholáthar lasmuigh de na gnáthuaireanta oibre
- ioncam agus cistiú caipitil do sheirbhísí saotharlainne a shainmhíniú go soiléir
- ba cheart go n-aithneofaí i samhlacha cistithe fiúntas an róil atá ag saotharlanna i dtaobh maoirseacht dhiagnóiseach a dhéanamh agus mar chomhpháirtithe i gcúram sláinte agus i gcosaint sláinte
- ba cheart go gcuimseofaí i bhforbairtí seirbhíse nua óna dteastaíonn seirbhísí saotharlainne soláthar airgeadais faoi leith chun tacú leis an tseirbhís nua

Tús, seachas ceann scríbe, atá sa phlean straitéiseach seo. Chun dul chun cinn a dhéanamh, teastaíonn foireann láidir bainistíochta cláir chun idirchaidreamh a dhéanamh le páirtithe leasmhara i dtaobh plean tosaíochta cur chun feidhme a chur le chéile.

Ráiteas Misin

Is é misean sheirbhísí saotharlainne FSS seirbhísí ardchaighdeáin anailíseacha agus léirmhínitheacha a chur ar fáil ar bhealach inbhuanaithe mar bhunchloch na sláinte agus an chúraim sláinte. Tá baint lárnach ag an gcuspóir seo le spreagadh agus le tiomantas na bhfoirne oilte a sholáthraíonn na seirbhísí.

Executive Summary

The mission of HSE and HSE funded laboratory services is to provide quality analytical and interpretive services in a sustainable manner as a foundation for health and healthcare. At present, this mission is accomplished through more than 40 individual clinical diagnostic laboratories and a number of discrete clinical reference laboratory services. The HSE also has number of Public Analyst Laboratories and Public Health Microbiology Laboratories that are grouped as Health Protection Laboratories in this Strategic Plan.

Many opportunities and challenges exist for laboratory services. Key issues include

- rapidly growing demand for services
- maximising benefits of scientific and technological developments
- responding to HSE organisational change
- recruitment and retention of people with essential skills
- service integration
- infrastructure
- maintaining quality systems
- ensuring preparedness for public health emergencies.

Although individual laboratories have responded creatively to these opportunities and challenges, this is no longer sufficient to respond to the demands of hospital and community. An organisation wide strategic approach to improve coordination and to plan investment is now essential for a sustainable and efficient service.

This is the first HSE Strategic Plan for laboratory services. The plan was developed with extensive consultation with key stakeholders. This plan represents a major undertaking and a commitment to transform of how HSE laboratory services are organised and delivered over a period of 10 years.

The plan includes a series of principles and detailed recommendations under 15 headings. Among those principles is the identification of laboratory services as a core HSE function that should be delivered within the HSE as an integral element of healthcare delivery and health protection.

To guide the timelines for implementation each of the recommendations is categorised as now (years 1 and 2), next (years 3 to 5) or future (years 6 to 10).

While the plan includes proposals for Health Regions, it acknowledges that one size does not fit all and that each Health Region has specific opportunities and challenges that will require an approach tailored to its needs.

Key recommendations include:

- implementation of the previously developed Postgraduate Training Programme for Medical Scientists
- development of an integrated Clinical National Reference Laboratory Service (CNRLS)
- development of a HSE Central Laboratory Campus
- Health Protection Laboratory Services should be managed as a single national service
- development of Laboratory Networks (Hub and Spokes) within the Health Regions
- development of a laboratory service management team for each Health Region
- development of a Health Region Laboratory in each Region
- integration of discrete quality systems
- enhancement of investment in automation of all stages of sample preparation and processing, Digital Pathology and other new technologies
- Implementation of electronic order communications and inter-laboratory electronic transfer of information in preparation for integration of laboratory systems with the Electronic Health Record(EHR)
- development of systems and processes to provide patients with secure access to their own laboratory data
- development and extension of phlebotomy services as an integral part of the laboratory service
- services for patients in the community should be provided by nearby laboratory service when practical
- service level agreement and matching resources to support services to the Coroner
- Consultant Pathologists and Scientists working in leadership roles in each discipline should function as a team in Laboratory Networks (Hub and Spokes)
- promote registration for all Scientists working in clinical laboratory services
- career progression opportunities for Medical Scientists and other scientists including advanced and autonomous practice
- expansion of the role of Laboratory Aides and provide opportunities for progression
- all grades of staff working in the laboratory service should contribute as necessary to the delivery of service outside of normal working hours

- clear definition of revenue and capital funding for laboratory services
- funding models should recognise the value of the role of laboratories in diagnostic stewardship and as partners in health care and health protection
- new service developments requiring laboratory services should include a defined financial provision for laboratory supports required for the new service

This strategic plan is a beginning not an end point. Progress requires a strong programme management team to engage with stakeholders in developing a prioritised implementation plan.

Mission Statement
The mission of HSE laboratory services is to provide quality analytical and interpretive services in a sustainable manner as a foundation for health and healthcare. This purpose is central to the motivation and commitment of the skilled teams that deliver the services.

Some Background on Laboratory Services

Comprehensive laboratory services are a foundation for health policy and promotion, health protection, screening for disease, care of those who are ill, emergency preparedness and for research to improve future health and healthcare. To deliver on its mission the HSE and HSE funded laboratory services include clinical diagnostic laboratory services, transfusion services, screening services, reference laboratory services, public health microbiology laboratories (incorporating the Official Food Microbiology Laboratories/OFMLs) and Public Analyst Laboratories (PALs).

Quality laboratory services are critical to modern health systems and healthcare. Several decades ago, laboratory services were leaders in the implementation of quality systems in healthcare through internal quality control and participation in External Quality Assurance programmes. HSE laboratories have implemented quality systems that conform to international standards (ISO) addressing areas of governance, qualifications to practice, training and competence assessment, equipment and method verification along with batch acceptance of reagents and robust systems for tracking and resolving deviations from standard and complaints. Quality laboratory services play a central role in the precise diagnosis of disease, predicting the outcome, choice of treatment and monitoring of treatment response. The centrality of laboratory services to delivery of healthcare was dramatically illustrated during the recent pandemic and the 2021 cyberattack on the HSE.

Laboratory services include a pre-analytic phase, an analytical phase and a post-analytical phase. The pre-analytical phase includes guidance on what test request and what sample type is appropriate and why. It also includes storage and transportation of the sample to the laboratory and sample accessioning and preparation in the laboratory. The analytical phase, in the laboratory or near the patient, generates the analytical result. The post-analytical phase includes clinical review and communicating both the result and its significance to the laboratory user.

The time interval between sample collection and reporting of the results of tests performed is one important aspect of the quality of laboratory service to patients and laboratory users. The turnaround time for a test must meet the clinical need of the patient. For monitoring of patients in an Intensive Care Unit or Emergency Department it may need to be under one hour while for other scenarios, for the same range of tests, a same day (or within 24 hours) result may meet the clinical need.

A key contributor to the interval between sampling and access to a result is the time interval between a sample being taken and its arrival in the laboratory. This interval and the conditions in which the

sample was stored and transported are important. This may affect the quality of the sample for analysis, the reliability of the test result as well as the interval to reporting a result. Sample transport challenges are very significant for many community based sample collection services including GPs, in particular in regions serving dispersed rural populations.

Where the volume of tests for a particular analyte is low, the laboratory may often wait to accumulate a sufficient number of samples to analyse as a batch. In some cases the time from beginning to end of the analysis may be hours but the turn-around-time may be days depending on how often a batch is processed. Therefore, centralised analysis of samples that are tested as a batch may support more frequent processing of batches and may deliver results more quickly than on-site analysis.

Laboratory services have a major environmental impact through energy consumption, use of disposable plastics and other waste. The National Health Sustainability Office outlines seven domains as follows (a) climate change and health, (b) energy efficiency, (c) water conservation, (d) waste prevention, (e) sustainable transport, (f) green procurement and (g) designing the built environment. All of these are relevant to delivery of laboratory services. The management and staff of laboratories should make an important contribution to developing sustainable health care with reduced carbon footprint. As laboratories use large quantities of disposable plastics, reduction of plastic waste requires a particular focus.

An important element of sustainable laboratory services is reducing testing that does not add value. Most laboratories in all healthcare systems perform some unnecessary testing due to inappropriate requests. Patients generally have confidence in the ability of their doctor or nurse to select appropriate tests for their care. The concept of the laboratory as a gate-keeper in managing requests (see below ‘What matters to patients and the public?’) is not familiar to many patients and members of the public. However, given the range and complexity of laboratory services, it is not practical for most laboratory users to have a complete understanding or ready access to information on the role and limitations of each test. This contributes to testing without a sound clinical indication for testing.

Unnecessary laboratory testing delays essential testing services. Testing of people without a sound clinical indication, outside of established structured screening programmes, may do harm because minor deviations from reference ranges may lead to additional investigations or interventions with potential adverse effects. Guiding and curating appropriate use of analytical tests is therefore a core part of the role of the laboratory. Medical and scientific professionals working in laboratories need to engage more with laboratory users and the public to promote awareness of the laboratory

professional's role in guiding use and interpretation of testing services. There is perhaps an analogy with the role of the pharmacist in support of medication use.

Laboratory services are provided by multidisciplinary teams including administrative staff, Anatomical Pathology Technicians, Biochemists, Clinical Scientists, Haemovigilance Officers, Laboratory Aides, Medical Scientists, Mortuary Technicians, Pathologists, Phlebotomists, Surveillance Scientists/Epidemiologists, Public Analysts, Executive Analytical Chemists and other public analyst staff. Laboratories also depend on staff who provide cleaning, porter, reception and other essential roles. These multidisciplinary teams have delivered on service to patients and service modernisation over many years. They have demonstrated commitment, resilience and the ability to innovate rapidly in the face of both the recent pandemic and cyberattack.

What Matters to Patients and the Public?

In preparing this strategic plan, a questionnaire (Appendix 3a) was prepared and distributed to patients through multiple channels. The message also included a link to the initial draft document for consultation. Forty one (41) people completed the questionnaire. No respondent chose to respond to the link to the full document provided for consultation. It is not possible to state how representative the respondents are of the diversity of the views of the general population. As an on-line written questionnaire in the English language, it is likely to have been less accessible to people with limited English language skills and limited digital access. The nature of the responses is likely to have been influenced by the format of the questions.

Questions were framed as related to your sample (5 questions), your laboratory service (4 questions), your result and your doctor (6 questions) and general statements (25 statements). The questionnaire is provided as an appendix. The following is a subjective summary of the responses the detail of which is available in appendix 3b.

In relation to the sample, the responses indicate that key issues that are important or very important are ensuring that the sample is not mislaid and that the correct result is returned in a timely manner. These concerns link with key quality measures of traceability, turn-around time and the validity and reliability of analyses. Many respondents were less concerned about discomfort when providing a sample than they were about the risk of loss or error in reporting.

In relation to the laboratory service, the training of laboratory staff emerged as the most important issue. Respondents also assigned importance to adequate equipment and staffing of the laboratory but less importance to laboratory opening hours in evenings and at weekends.

In relation to your result and your doctor, every respondent considered it important or very important that their result should be available if they choose to attend a different doctor and almost all also considered it important that their doctor should be able to compare their result with previous results. Respondents were less concerned regarding issues of payment for testing.

In relation to general statements some points of note are as follows

The majority of respondents strongly agreed (and all or most other respondents agreed) that:

- laboratories need to keep my personal information safely
- laboratories should be safe places for staff to work in
- samples should be disposed of safely
- a number to identify them should be used so that all their test results can be easily found
- laboratory tests should be free for people who need them

Most respondents also agreed or strongly agreed that:

- samples from the GP should be recognised as equally important to samples from the hospital
- their doctor or nurse knows best which test they need
- they should be able to look up their own results
- they do not want to have to travel far to get a blood test

Respondents expressed a preference for their sample being tested in a HSE laboratory and in Ireland but most also indicated that they don’t mind where the sample is tested provided the result is correct. Many respondents are prepared to accept some delay in processing of their sample in evenings and at weekends

Most respondents do not agree with laboratory services declining to provide a test requested by their doctor or nurse because the test is not considered appropriate by the laboratory professionals.

Laboratory Services and Emerging Health Threats

Subsequent to the COVID-19 pandemic, the Government agreed to the appointment of an independent expert reporting directly to the Minister for Health to design a dedicated, emerging health threats function that builds on existing assets and infrastructure to focus on infectious diseases, pandemic preparedness and other emerging threats to public health. The Report of the Emerging Health Threats Function Expert Steering Group recognises the essential role of laboratory services in the early detection of and response to public health emergencies [https://www.gov.ie/en/publication/0dbee-report-of-the-emerging-health-threats-function-expert-steering-group/].

In addition to identifying the precise cause of disease in the individual and thus establishing the relationship to a potential public health emergency, further laboratory work is often required to characterise in very fine detail the agent (microbial or other) associated with disease. This detailed characterisation is usually performed in Reference Laboratories. This characterisation is essential to understand links between individual cases of conditions emerging within Ireland. It is also essential to fulfil Ireland's international obligations within the European Union and the world. For example, in the context of infectious disease, the fine detail provided by whole genome sequencing of the microorganism and bioinformatic analysis of the data can reveal unsuspected chains of transmission, can discount suspected chains of transmission and can identify changes in the organism that may be important for developing or modifying vaccines and vaccination programmes.

Laboratory collaboration to track spread of infection must include exchange of information related to humans, animals and environment ("One-Health" approach). This requires exchange of information between different sectors (human health, animal health and environmental health) in Ireland as well as exchange within the European Union and with third countries. As public health emergencies are not limited to infection, laboratory capacity to analyse food, water, drugs and medicines and other products is also essential to an all hazards approach to protection of public health.

A comprehensive laboratory service is therefore an essential support for a credible Emerging Health Threats Function. The foundation of a comprehensive laboratory service is adequate diagnostic laboratory capacity to manage and to deliver on the need for laboratory services in normal times. This includes capacity to validate and verify new technologies and services efficiently. A diagnostic service must have adequate human and technical resources and facilities for business as usual and to be well placed to reprioritise and redeploy to deliver surge capacity in an emergency. Diagnostic laboratories

that operate on a large scale and/or as part of a networked service are better placed to respond to an emergency than a fragmented service provided by a large number of laboratories, including many small laboratories. Likewise, adequate capacity for business as usual is the foundation for Reference Laboratories and laboratories that analyse food, water, drugs and medicines to deliver on the demands they will face in an emergency.

HSE Clinical Laboratory Services

The HSE provides clinical diagnostic laboratory services from 42 hospital-based laboratories and the National Drug Treatment Centre. The laboratories provide a very broad range of services. The main clinical disciplines are Chemical Pathology, Haematology, Histopathology, Immunology, Microbiology and Transfusion. Additionally, there are a growing number of sub-disciplines and emerging disciplines such as Genetics and Genomics. The range of services provided is very broad. In addition to performing analysis and interpretation of analytical results, services may include providing products for transfusion and phlebotomy.

The scope of the service is very dynamic, constantly evolving in response to new developments, changes in technology and changing needs. It is therefore not defined in detail in this document. Section 1 of *Review to Inform the Strategic Direction of Laboratory Medicine* published by the HSE in January 2024 indicates the range of services provided and details of staffing. The scope of services provided by each HSE accredited medical laboratory is configured for the needs of its patient population and is itemised on their certificate of accreditation available at https://www.inab.ie/inab-directory/laboratory-accreditation/medical-testing-laboratories/ Additional services may be provided as they are evaluated and verified before they are added to scope of accreditation.

There are clinical laboratories in each of the six Health Regions with a wide variation in the number and scope of laboratories between the regions. HSE laboratories vary in size from fewer than 10 staff to hundreds of staff. There is variation in the scope and hours of services provided. Most laboratories operate to the ISO15189 (clinical) or ISO17025 (non-clinical) quality standards although this is mandated only for Transfusion Services and for certain non-clinical laboratory services that are designated official laboratories for non-clinical samples.

There has been no previous HSE strategic plan for laboratory services. The current pattern of service organisation is largely historically determined. It was based mainly on organic development of discrete laboratory services to support individual hospital requirements and requirements of nearby community

services. Likewise, a number of separate clinical reference laboratory services have been developed within hospital laboratories in response to specific needs and reflecting local expertise and capacity.

In recent decades, some areas have established networks with a hub and spoke model that provide a significant degree of consolidation of services that lend themselves to consolidation of those services at the hub. These networks retain essential services as spokes on each hospital site other than the hub. In other areas there is very limited integration of service. Less progress on integration may in some cases relate in part to challenges related to independent governance systems for the hospitals where the laboratories are based.

There is significant variation between laboratories on progress in the development of near-patient testing (NPT) in both the acute and community settings. There is also variation in the extent to which NPT services are integrated into the laboratory quality system.

The variation within and across regions in relation to integration and NPT is a challenge but there is also an opportunity for peer-to-peer learning from those services that have or are pioneering new approaches.

HSE laboratory services also include important structured screening programmes such as the long established new-born infant screening programme, screening for cancer of the uterine cervix and colon cancer. In addition, the service supports diagnostic testing for patients identified for further assessment by the cancer screening programmes mentioned above and for breast cancer.

Care of the deceased is an important aspect of HSE laboratory services. It is established practice that many HSE Histopathology services provide post-mortem examination services for the Coroner. Although some post-mortem examinations may be performed at the request of a hospital practitioner with agreement of the family of the deceased, most post-mortem examinations performed in HSE facilities are carried out on behalf of the Coroner. This often relates to deaths that have occurred in the community. In addition to the Consultant Pathologist, HSE Anatomy Pathology Technicians, Mortuary Technicians, Non-Consultant Hospital Doctors and bereavement services play an important role in performing autopsy, preparing the remains for removal and supporting families. The examination of tissue samples and other samples taken at autopsy involves other staff in the histopathology service and other laboratory disciplines. The Coronial service is currently reviewing how these services will be organised and delivered in the future. It is likely that there will continue to be a significant reliance on HSE staff and HSE facilities in a number of Health Regions.

HSE Health Protection Laboratory Services

There are seven public health food and water microbiology laboratories. These laboratories serve a key function in delivering on the Official Food Microbiology Laboratory (OFML) obligations of the HSE contract with the Food Safety Authority of Ireland (FSAI). The OFMLs are essential to support FSAI in protecting the population of Ireland from food borne infection and ensuring the safety and reputation of food produced in Ireland and consumed in other countries. These laboratories also support the work of the Sea Fisheries Protection Authority (SFPA). In addition to testing food samples in their capacity as OFMLs, the public health food and water microbiology laboratories also provide testing of drinking water and of bathing water samples and services to monitor healthcare environments and equipment.

There are three Public Analyst Laboratories (PAL) one of which incorporates one of the seven OFMLs. The PALs support the protection of public health by providing chemical analytical services on water, food, medicinal products, cosmetics, tobacco and nicotine inhaling products. These services help to assess compliance with EU requirements. The PALs are based in Cork, Dublin and Galway and have functioned within community services. In addition to their primary work on non-human samples some PALs provide support for clinical services by measuring analytes such as heavy metals where they have specific skills and equipment that may not be available in clinical laboratories.

In relation to the food safety role performed by the OFMLs and PALs on behalf of FSAI, the laboratories must operate in compliance with the Official Controls Regulation (Regulation 2017/625). This includes maintaining laboratory accreditation in accordance with Article 37(4)(e), the Official Controls Regulations requirement for National Reference Laboratories for food testing.

In this report the public health food and water microbiology laboratories and the PAL services are referred to together as the HSE Health Protection Laboratory Services.

Laboratory Services and Related Services External to the HSE

There are a number of publicly funded laboratory services that play important roles in analysis of human and non-human samples. Examples include the National Virus Reference Laboratory (UCD), the State Laboratory, the Medical Bureau of Road Safety and the Irish Blood Transfusion Service. Working with the laboratories of the Department of Agriculture Food and Marine will become increasingly important as the “One Health” approach is increasingly accepted nationally and

internationally as central to health policy. Building on existing collaborations with these services presents important opportunities to improve the range and efficiency of public service laboratory provision.

There are a large number of private laboratory service providers in Ireland providing clinical and other health-related laboratory services. Services are provided from within Ireland in many cases but in some instances the providers are international companies that refer certain samples for testing to laboratories in other countries. The HSE has significant dependence on private laboratory providers for delivery of routine clinical testing, for response to surge and for certain specialised testing. The HSE laboratory service is also critically dependent on private services for sample transport between HSE and HSE funded laboratories and to private providers.

Opportunities for HSE Laboratories

There are many opportunities for HSE laboratory services over the coming years. Scientific and technical advances will provide opportunities to improve detection and management of disease. These advances will contribute to improved safety of food, medicines and water. There are opportunities to expand on cooperation with other countries on service development and health protection. Innovation and research can improve service and enhance skills transfer. These changes will also stimulate the interest of those currently working in the service and attract the next generation of skilled personnel.

The development of six Health Regions delivering integrated care for the population of the region offers an opportunity to redesign service delivery. There is an opportunity to develop networked laboratory services where these do not already exist. Consolidation of certain services on to a smaller number of hub sites can reduce redundant duplication of skills and equipment, improve service to patients and help to manage costs. If the required turn-around-time for an analysis is 24 hours or longer, it is likely that there is no technical barrier to consolidation of the analytical service onto one or two hubs per Health Region if the issues of governance and clinical integration of service are addressed.

Digital laboratory systems that provide seamless access for health care workers, and for patients, to previous laboratory results will help to avoid unnecessary repeat sample collection and testing arising from uncertainty regarding previous results. Laboratories were pioneers in the deployment of information technology in healthcare. Laboratory staff generally have a high level of digital literacy.

Developing and applying these systems and skills will be essential to deliver on the vision of *Digital for Care: A Digital Health Framework for Ireland 2024-2030* and the *HSE Digital Health Strategic Implementation Roadmap*.

Laboratory practitioners can also use information systems to guide appropriate choice of sample type and test request based on clinical details and previous laboratory results. This helps to focus laboratory resources on performing essential work thus improving turn-around-times and improving sustainability. It is clear from engagement with patients and the public that there is a need for outreach work from the laboratory services to raise awareness of the value laboratory practitioners add for patients and the public by guiding test requests and interpretation.

Digitalisation of images has transformed diagnostic imaging. A similar transformation is now progressing rapidly with digitalisation of images from microscope slides in histopathology and other laboratory disciplines. As with diagnostic imaging, digitalisation makes images easy to store and to transfer and enables the application of artificial intelligence within laboratories to undertake some review of microscopic images. Artificial intelligence also has the potential to create algorithms combining results of analytes from different areas together with clinical data to guide patient care decisions. This approach is currently being used in some countries, using algorithms termed iLFTs (Liver Function Tests) or iLipids where i denotes intelligent. Emerging technologies will provide additional opportunities for evidenced based structured screening programmes that will improve the health and life expectancy of the population.

There are opportunities to build on existing collaboration with other publicly funded laboratory services outside the HSE. For example, the State Laboratory is designated by the Department of Health to perform analysis related to testing Tobacco Products as per S.I. No. 271 of 2016 including analysis of e-liquids and cigarettes. This service is essential for the HSE Environmental Health Service – Tobacco Control Network Support Unit. The State Laboratory performs analysis of samples for Novel Psychoactive Substances (NPS) to support the HSE in harm reduction programmes, connected to the Early Warning and Emerging Trends subcommittee, chaired by the Department of Health. Likewise, there is scope to build on existing collaboration with the laboratory services provided by the Irish Blood Transfusion Services and the Department of Agriculture Food and Marine.

The HSE Climate Action Strategy provides an opportunity for HSE laboratory services to provide leadership in sustainability and reducing the carbon footprint and plastic waste generated by healthcare services.

This changing environment provides an opportunity for all those working in HSE laboratory services to advance their knowledge and skills and to expand their professional horizons.

Challenges for HSE Laboratories

The HSE laboratory services face many challenges now and over the next ten years.

Training, recruitment and retention of medical and scientific staff with the mix of skills required to deliver the service is a key challenge and a central driver of the need to progress implementation of this strategic plan. Of note, the *Medical Workforce Planning for the Specialties of Pathology Review 2023* points to a current unmet demand for an additional 173.6 Whole Time Equivalent (WTE) consultants. Demand for consultants is projected to increase at a rate of 2.7% per year to 2035 requiring an additional 191 WTE.

There are too many stand-alone laboratories. Many deliver an unnecessarily broad range of services from inadequate facilities and with teams that are too small to provide resilience and a full range of expertise.

For historical and practical reasons, almost all clinical laboratory services are funded and operated primarily as units within an acute hospital. The relationships with the community services they support, in particular GPs, are poorly defined and are not associated with a specific funding stream. As the demands on laboratories for service from the community are often as great or greater than the need of the hospitals, there is a need to redesign service organisation around the move to greater care in the community including virtual wards.

Provision of appropriate infrastructure suitable for a modern laboratory service is a challenge given the number of and wide variation in existing clinical laboratory facilities. Many services are operating from buildings that are not configured, and cannot be configured, to support modern laboratory services. Many facilities fail to meet reasonable expectations of staff in relation to their working environment, in particular for personal security when working alone during evenings and nights.

The go live of the first laboratory with the new national laboratory information system, MedLIS, in August 2024 is a major milestone for the HSE however many laboratories are currently using information systems that are not satisfactory. Lack of order communications systems and systems for

communication between laboratories constrains the ability to improve use of existing human and material resources and delays receipt of result by the requestor. The deficiencies in systems limit the ability to streamline services, to eliminate redundant duplication of testing and to make better use of data for quality improvement, planning, policy and health protection. The deficiencies also limit seamless access to results in a user-friendly format for healthcare workers or for patients using the HSE Health App (patient portal app) developed by the HSE and the Department of Health [https://www2.hse.ie/health-app/]. Likewise, most systems currently in operation are not designed to support the development of virtual wards which require greater integration of laboratory results directly into other clinical systems for patient monitoring.

There are significant gaps in capacity with respect to adequately resourced and integrated clinical Reference Laboratories. As discussed earlier, this is important in relation to the ability to detect and respond to emerging health threats. There is a limited number of formally established reference laboratory services in Ireland, most in the field of Microbiology. Other than the National Virus Reference Laboratory (based in UCD), these microbiology reference laboratory services operate as functions within a hospital based clinical laboratory. These discrete services for individual pathogens on several sites reflect a past in which technologies for each pathogen were very distinct rather than the present and future in which sequence based approaches are broadly applicable to most organisms. There are also significant reference laboratory services within Ireland for domains other than microbiology where clinical laboratory services have developed specialised capacity.

There is an over dependence on Reference Laboratories in other countries. For historical reasons relationships with the United Kingdom are particularly important in this regard. These relationships may need to be reconsidered in the context of regulatory and customs implications of the UK exit from the European Union. There is also a critical dependence on capacity in the USA for the national cervical cancer screening programme. Regulation (EU) 2017/746 on in vitro diagnostic medical devices has significant implications for the use of clinical laboratory services outside of the EU/EEA (Article 6, Distant Sales) that are relevant to services procured in the UK and USA.

There are gaps in relation to Reference Laboratory Services for health protection laboratory services. Although the three Public Analyst Laboratories have an agreed arrangement to coordinate how they divide specialised work for each other and thus function as reference laboratories, this requires further development and extension to the Public Health Microbiology Laboratories.

Assessment of the Need for Change

This Strategic Plan builds on the foundation of the work captured in the *Review to Inform the Strategic Direction of Laboratory Medicine* published in January 2024 [https://www.hse.ie/eng/about/who/cspd/lsr/resources/hse-review-to-inform-the-strategic-direction-of-laboratory-medicine.pdf.]

The ***Review to Inform the Strategic Direction of Laboratory Medicine*** (Review to Inform) presents a comprehensive description of the status, diversity of service, opportunities and challenges for the HSE and HSE funded laboratory medicine services from the perspective of the professions working in those services. This review includes an assessment of the need for change.

Change is needed to realise the full benefits of the application of laboratory medicine to improve patient outcomes both now and in the future. This includes the capacity to support and guide chronic disease management, disease prevention, effective use of medication, near patient testing, maternity care, cancer care and solid organ transplant, testing for congenital and rare disease and the capacity to respond to future public health emergencies or cyberattack.

- Section 1 of the Review to Inform maps out current services and structures with a focus on national services, to identify and understand the current practice in pathology departments.
- Section 2 considers education and credentialing pathways to support professional development of laboratory staff with a broad-based educational approach that is reflective of their area of competence and expertise and aligned to evolving best practice standards and service requirements.
- Section 3 is a review of scientific and technologically enabled advances in laboratory medicine.
- Section 4 considers relevant international models of care and lessons learned to inform future direction regarding models of care and funding.
- Appendix 1 of the Review to Inform summarises key legislation relevant to the practice of laboratory medicine.

In addition to the Review to Inform, this Strategic Plan builds on the *HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology and Virology Reference Laboratories Review* agreed by the HSE Executive Management Team in 2022. This report identified a need for an integrated service for public health microbiology services and reference laboratory services for microbiology and infection.

The need for change is also highlighted in the National Strategy for Accelerating Genetic and Genomic Medicine in Ireland. https://www.hse.ie/eng/about/who/strategic-programmes-office-overview/national-strategy-for-accelerating-genetic-and-genomic-medicine-in-ireland/. The requirement for coordinating a national approach to genetics and genomics, building the genetics and genomics workforce for the future and strengthening infrastructure to drive advance in genetics and genomics represent important areas of synergy and models relevant to the overall strategic plan for reform of HSE laboratory services.

The creation of six Health Regions in 2024 and the integration of community health services and hospitals is another important factor driving the need for change. Networking of laboratory services within Health Regions aligned where appropriate with the Integrated Health Areas is needed to meet the needs of their population and to help deliver on the vision of integrated community and hospital based care and seamless patient journeys.

Responding to workload pressures is a key driver on the need for change. Given the scale and diversity of services and absence of uniform workload measurement system, it is difficult to collate a comprehensive representation of HSE laboratory workload and growth in laboratory workload at a national level. For this reason, this is addressed in this report with respect to a specific example as follows.

The clinical laboratory service based at University Hospital Waterford (UHW) provides comprehensive services for UHW (model 4 hospital). It also provides many services for model 3 hospitals in the hospital network and provides services to GPs and other community based services in an extensive catchment area. The data on workload from the clinical laboratory based at University Hospital Waterford is therefore used in this report as representative of HSE clinical laboratory services (Appendix 4). This has been sense checked with data on the volume of a number of specific tests performed in 12 other hospitals that show a broadly similar pattern (data not included).

Based on the data from UHW laboratory, a conservative estimate is a doubling of test volumes every 7 years. Although there is scope to work with laboratory users to make better use of laboratory services, this cannot be expected to address the scale of this challenge. Among the impacts of the increased demand, a number of hospital based laboratory services are increasingly dependent on out-sourcing of all or a large proportion of the samples they receive from the community. There is therefore a compelling need to increase capacity to reduce dependence on out-sourcing and to cope with future demands.

Table 1 Summary data on laboratory workload by discipline at University Hospital Waterford for 2021, 2022 and 2023.

Discipline	2021		2022		2023	
	Test number	% Increase on previous year	Test number	% Increase on previous year	Test number	% Increase on previous year
Clinical biochemistry	7,183,985	15	8,166,761	14	9,090,170	11
Haematology	821,075	12	940,933	15	1,044,018	11
Histology	48,867	8	57,058	17	64,213	13
Immunology	23,459	14	26,431	13	28,976	10
Microbiology	Not available	Not available	773,947	11*	828,454	7
Point of care blood gas testing	55,595	17	60,310	8	68,633	12
Transfusion	Not available	0.5*	24,380	-6*	27,926	15

Note, University Hospital Waterford has confirmed that this trend has continued through Q1 of 2024.

* The estimate of % increase was provided but the data on number of tests for 2021 was not provided.

Key areas in need of change identified in the process of developing this document are:

- improving the comfort and convenience of sample collection and the quality of samples collected

- improving the transport of samples from source to the laboratory
- growing the number of people in the service with the skills required to provide the service
- further development and training opportunities for the people in all disciplines who provide the service
- supporting the productivity of people in the service through use of information and communications technology, automation, and improved coordination and skills mix
- reducing the number of full-service stand-alone laboratories by developing Networks with a hub, spoke and near-patient testing (NPT) model
- information and communications technology including order communications, digital pathology and inter-laboratory communication
- expanding capacity and resilience for response to emergencies
- development of near-patient testing and other supports for more care in the community
- enhancing sustainability and capacity to respond to emerging threats
- greater equity of access to services for marginalised population groups including people living in rural or disadvantaged areas.

This Strategic Plan is intended to outline changes that can be expected to deliver the best clinical and value for money service for patients and the public. Ensuring that this change is realised will require committed leadership, investment in people, information and communications technology, facilities and ongoing engagement with all stakeholders to develop and deliver a prioritised implementation plan.

Change brings challenges and concerns as well as opportunities. Some changes proposed in this strategic plan ask stakeholders in the laboratory services to consider significant change in established roles and work practices. Overall, the changes proposed in this strategic plan will provide a more rewarding working environment and greater professional opportunity for those who will implement the change and deliver the service. Given the challenges of educating, recruiting and retaining the people who are the foundation of the service, this is a critical factor in the need for change.

The Objectives – A Vision for the Service

Objective 1

Quality networked clinical laboratory services in the Health Regions that support delivery of integrated care, chronic disease management and Government Policy and priorities including Sláintecare, a Digital Health Framework for Ireland 2024-2030 and Emerging Health Threats

Objective 2

A national networked health protection laboratory service that supports the protection of health

Objective 3

Laboratory services that support the education, training and development of motivated and skilled staff to deliver a quality service and to innovate

Objective 4

Laboratory services that make full use of sample collection services, transport, information and communications technology and automation to deliver a quality service that is equitable, efficient and environmentally sustainable, *HSE Climate Action Strategy 2023-2050*: https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/climate-change-and-health/hse-climate-action-strategy-2023-50.pdf)

Objective 5

An integrated National Clinical Reference Laboratory Service that provides those analytical and advisory services that are most appropriately and efficiently delivered at national level

Objective 6

Enhanced health service resilience through repatriation of critical services currently provided outside of the state and EU and improved capacity to respond to emergencies.

Achieving our Objectives

Achieving the objectives set out above for the HSE laboratory services requires consideration of the needs of the public and a consensus for change in the HSE laboratory services, the HSE, the Department of Health, patients and other key stakeholders. The process of development of this Strategic Plan including the *Review to Inform the Strategic Direction of Laboratory Medicine* and the extensive consultation on the document was designed to build that consensus.

More than 1000 people attended in person or online at eight fora to discuss the draft for consultation. Over 100 submissions of written feedback were received. The feedback from that consultation process is reflected in this document.

Patients and members of the public were consulted as outlined above to ensure the issues important to them are reflected in this document.

This Strategic Plan identifies 12 key principles that guide the detailed recommendations under 15 headings. This document provides a basis for development of an implementation plan to maximise the benefits of the existing resources committed to laboratory services and secure the investment required to meet the needs of patients and the public. While the plan includes proposals as to how Health Regions should approach laboratory service development, it is important to acknowledge that one size does not fit all and that each Health Region has specific opportunities and challenges that will require an approach tailored to its needs.

Key Principles guiding the HSE Laboratory Strategic Plan

1. The HSE should support patients and public access to diagnosis, screening for disease, surveillance, public health and health policy by providing clinical laboratory, transfusion services and health protection laboratory services as a core function of the HSE
2. HSE Laboratory services should innovate and adapt on an ongoing basis to drive the agenda of healthcare reform and to support integrated care in the Health Regions. Withdrawal of obsolete methods of analysis and implementation of new methods are part of that dynamic process.
3. HSE laboratories should harmonise services to the greatest extent practical, including guidance to users, analytical methods and reporting to support equity of access and comparability of results from different laboratory services. Harmonisation of clinical laboratory services is particularly important within each Health Region as patient movement within a Health Region will be common.
4. HSE laboratory outputs should be integrated and available to the teams providing multidisciplinary care across the patient journey in primary, community and residential/hospice/hospital care to support the Electronic Health Record.
5. The HSE should provide access to clinical laboratory services to healthcare practitioners working for HSE and HSE affiliated services, for healthcare practitioners working in partnership with the HSE or with other public services. Providing appropriate services to General Practice should remain a key part of the service.
6. Access to HSE clinical laboratory services should be based on clinical or public health priority.
7. The HSE should provide equitable access to essential laboratory services that are quality assured, delivered when and where needed and in an environmentally and financially sustainable way.
8. The HSE laboratory services, in partnership with other programmes and services, should guide and support appropriate requests for analysis of samples and discourage inappropriate requests. Requests for testing should be based on evidence, authoritative guidance, regulatory requirements or sound rationale.

9. The HSE should optimise the use of modern information and communications technology for communication with laboratory users, between laboratories and within laboratories.
10. Given that access to relevant laboratory results is essential for patient safety and for other purposes the HSE should ensure that the data managed by HSE laboratory services is used for these purposes as needed in compliance with legal obligations with respect to data protection
11. Samples such as tissue and body fluids should be transported, stored, processed and disposed of in a manner that meets regulatory requirements and is respectful and consistent with good practice.
12. When centralisation of laboratory services is required, the HSE should progress this in a manner that maintains service to patients and the public and that avoids or minimises adverse impacts on staff.

Recommendations

Each recommendation is marked as now, next or future, reflecting a suggested order of implementation. "Now" refers to the 2 years following adoption of the strategic plan by the HSE, "Next" refers to years 3 to 5 after adoption and "Future" refers to years 6 to 10 after adoption. In practice, the order of implementation is likely to be determined by practical considerations and circumstances and the order of priority may differ between Health Regions.

1. Key Elements of Interface with Patients and the Public

Now [Years 1-2]

a. All laboratory services that are likely to receive samples delivered by laboratory users, patients, taxi-services or others should ensure that there is a readily identifiable, accessible and safe drop off point for samples so that samples can be deposited at any time. The drop off points should have systems to alert the laboratory staff to drop off and they should be checked at appropriate intervals to ensure that samples are promptly processed or stored appropriately.

Next [Years 3-5]

b. The HSE should explore the feasibility of a parcel locker type service for accessible and safe drop off samples in areas that are remote from laboratories. The drop off points should be checked at appropriate intervals to ensure transport samples to the laboratory in a time frame that is appropriate for processing or storage.

c. Laboratory services should develop or extend phlebotomy services for hospitals as part of the Laboratory Network governance so as to improve comfort and enhance patient safety by reduction in sampling and labelling errors.

d. The HSE should provide access to phlebotomy services for people cared for in the community from whom particular expertise is required to collect a sample with minimal discomfort.

e. Laboratory services should develop systems and processes to provide patients with secure access to their own laboratory data in an understandable format to support the Digital Strategy of the DOH and the HSE *Digital for Care: A Digital Health Framework for Ireland 2024-2030*.

Future [Years 6-10]

f. Where practical, provision of phlebotomy services in community-based hubs under laboratory governance should be considered to enhance patient experience and patient safety.

2. Quality, Continuity and Sustainability of Service

Now [Years 1-2]

a. In accordance with legal requirements, HSE laboratories providing transfusion and haemovigilance services must be accredited by the Health Products Regulatory Authority (HPRA). HPRA has delegated this function to the Irish National Accreditation Board (INAB). Laboratories designated as official laboratories in accordance with EU Regulations must be accredited to the relevant standard.

b. All HSE laboratories and near-patient-testing services should operate a quality system consistent with an appropriate standard such as the EN ISO 15189 (2022) or EN ISO 17025 standard. INAB plays a vital role by accreditation of laboratories to these standards.

c. Clinical Laboratory Network hubs should integrate discrete quality systems to operate a single quality system for all disciplines provided at the network hub. In addition, it is appropriate to include smaller spoke laboratories that operate with the network hub in the quality system of the network hub whenever practical to do so.

d. Laboratory services should ensure that sustainability is central to all their operations in accordance with the objectives of the National Health Sustainability Office and the whole-of-government approach for implementation of the Sustainable Development Goals. Given the volume of disposable plastics used in laboratory practice, laboratories should have a particular focus on setting targets to reduce the volume of plastic waste.

Next [Years 3-5]

e. All medical devices and *in vitro* devices (IVDs) (including relevant digital health products) used in HSE laboratories and for near patient testing by the HSE should comply with legislative requirements, namely Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) and other regulations as they come into effect (see https://www.hpra.ie/), recognising the key role of the Health Products Regulatory Authority in this area.

f. HSE Laboratory Services should coordinate at Health Region and National level to mitigate the effects of interruptions to supply from manufacturers or distributors which may have the potential to impact the capacity of clinical laboratories to provide services.[1]

g. The HSE should define context-specific quality indicators including target turn-around-times (TATs) for common and critical laboratory tests. These indicators should be defined by clinical requirements rather than current capacity. HSE laboratories should measure their performance against these indicators. If failure to meet indicators is not resolved internally, laboratories should escalate under-performance through the appropriate pathway.

h. The HSE should define context specific retesting intervals for common laboratory tests where appropriate, and integrate this guidance into IT systems where possible to guide and support laboratory users.

3. Workload and Operations

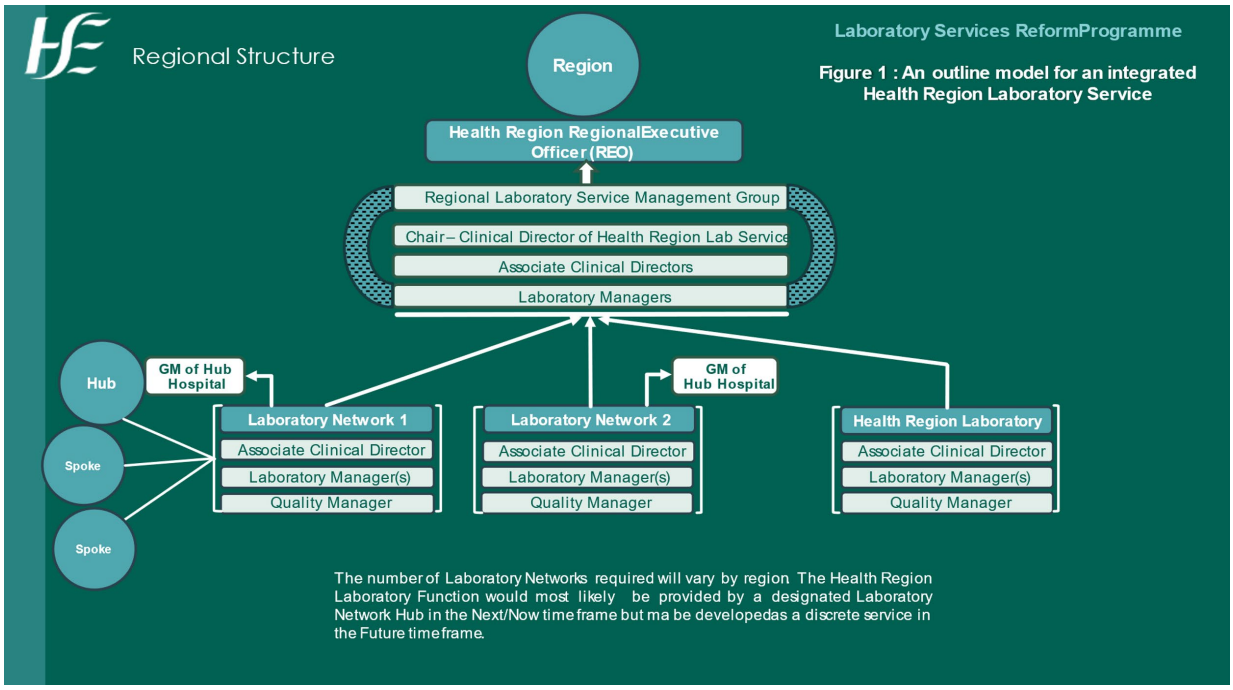
Now [Years 1-2]

a. Each Health Region should develop an approach to coordinate and integrate laboratory services for the Health Region. One approach to this is recommended in this strategic plan but it is expected that the structures proposed will be adapted to meet the specific requirements of each Health Region.

[1] In the context of proposed amendments to Regulation (EU) 2017/746 introducing requirements for economic operators to notify relevant entities in the supply chain, including hospitals, of a pending interruption of supply, this may become a more frequent issue.

b. A Health Region should have a Regional Laboratory Service Management Group to provide leadership for the Health Region laboratory service. The group should include a Clinical Director, Associate Clinical Directors and Laboratory Managers from the Health Region. [Figure 1] The Management Group should coordinate the work of the Laboratory Networks and Health Region Laboratory.

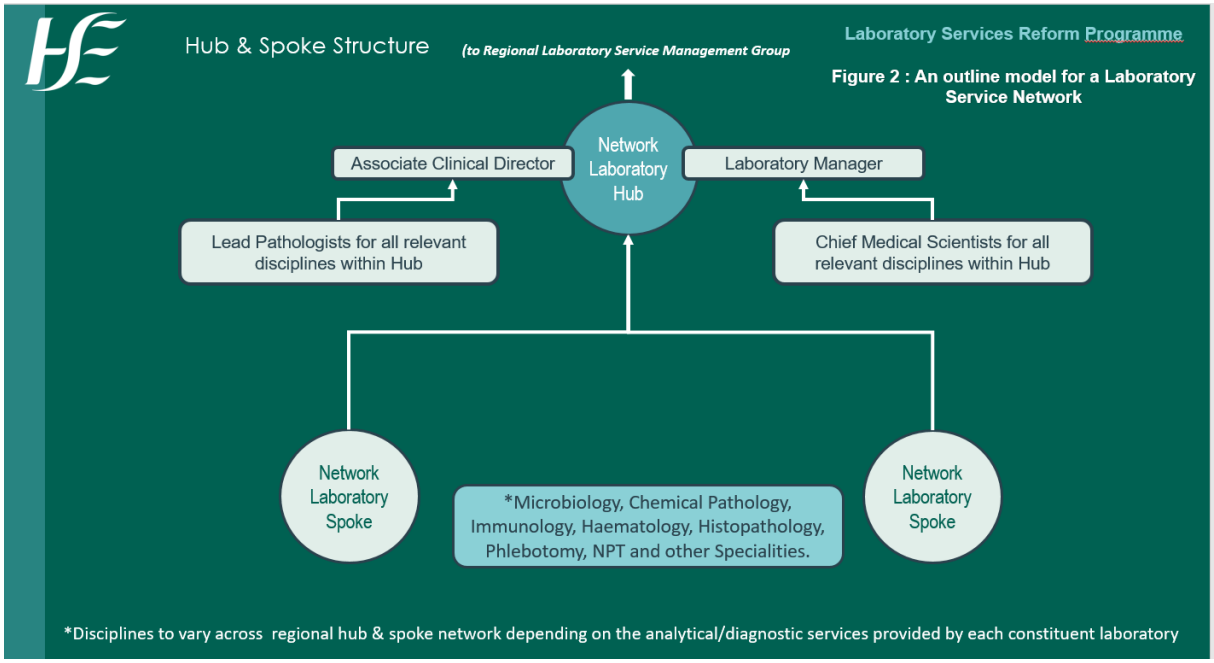
Figure 1



c. Each Laboratory Network (Hub and associated Spokes) should have a management team including an Associate Clinical Director, a Laboratory Manager and Quality Manager to coordinate the work of the disciplines within that Laboratory Hub and the associated Spoke laboratories and NPT services [Figure 1]. The Network Management Team should link with the Regional Management Team and General Manager for the Hub site. Spoke laboratories should link with their site General Manager as well as with the Network Management team.

d. Within each Laboratory Network each major discipline (such as clinical biochemistry, haematology, histopathology, immunology, microbiology, transfusion) should have clearly defined appropriate medical and scientific leadership for services provided by that discipline in the Hub, Spokes and NPT [Figure 2]. The discipline lead within a Laboratory Network will be a Consultant Pathologist or Autonomous Scientist with appropriate training and competence in the discipline concerned.

Figure 2



e. The discipline leadership team should have the authority and responsibility to guide the service for that discipline and should work with the Laboratory Network management team to determine the range of services provided taking account of relevant national guidance and practice norms.

f. The Laboratory Network management team, in consultation with discipline leads and laboratory users, should ensure that the requirements (sample type, clinical details) for access to laboratory services including limitations on access and criteria for sample rejection are readily available to laboratory users and the public.

g. Access to HSE laboratory services should be provided to Healthcare Practitioners in accordance with *Access to Laboratory Services provided by the HSE and HSE affiliated Agencies* available at https://www.hse.ie/eng/about/who/cspd/lsr/resources/access-to-laboratory-services-provided-by-hse-and-hse-affiliated-agencies.pdf).

h. The management team for the Laboratory Service Network should ensure that information on the range of services provided, requirements for sample submission and target TATs for key tests are readily accessible to users of laboratory services.

i. Services that are provided by HSE laboratories should be supported by a body of evidence of clinical relevance and of assay performance. Tests that are not supported by evidence should not be offered as routine services. This should not impede research and development relating to assessing the value of new services.

j. Where a Laboratory Network operates a number of Spoke laboratories, each Spoke should have a designated site lead that coordinates the services provided on that site.

k. All users of laboratory services should provide relevant details of their practice location, contact details and hours of operation to the laboratory service to support traceability and reporting of results as specified in *Access to Laboratory Services provided by the HSE and HSE affiliated Agencies*.

l. Where demand exceeds service capacity, the Regional Management Team and Laboratory Network Management Teams, in consultation with the discipline leads, should have the responsibility and authority to identify to users of the laboratory those services which must be curtailed to ensure that the quality of the service is not compromised by the volume of samples submitted.

m. If service restrictions are considered necessary, the clinical risk assessment should be documented and communicated in the first instance to relevant senior management at Health Region or National Level (as appropriate) before communication with laboratory users.

n. If service restrictions are needed, they should be based on clinical need and take account of relevant national standards and guidance. Service restrictions should recognise that samples from other hospitals and from the community services normally supported by that

laboratory are considered on an equal basis to samples from the hospital where the service is based.

Future [Years 6-10]

o. The HSE should work to develop consistent and transparent systems of metrics for common laboratory services and consider changes in workload as a basis for resource allocation. Workload metrics should reflect complexity, quality and timeliness of analytical and advisory services rather than focus solely on counting tests.

4. Sample Collection and Laboratory Related Transport Services

Now [Years 1-2]

a. Health Regions should continually improve processes to re-route blood products to optimise safe use of blood stocks and minimise loss of units.

b. The HSE should work to continuously improve the quality of systems for storage, transport and tracking of transfusion products including meeting the specific transfusion requirements of patients who transfer between hospitals for clinical care. These patients may require blood transfusion during the transfer, may have blood components transferred with them or have blood transferred as it is a “rare” unit – highly matched to a patient and not easily replaceable.

c. In so far as is practical, scheduled blood sample collection should be performed by phlebotomists with requisite skills for the collection of high quality samples with minimum discomfort for the patient and with good communication with the patient regarding the process.

Next [Years 3-5]

d. The HSE should work with off campus users of laboratory services to put in place sample storage, pre analytical sample preparation (for example centrifugation) if required and a safe transportation process that ensures regulatory compliance, preservation of sample quality and that samples reach the laboratory in a timely manner to support the efficient

operation of the laboratory analytical services. This is relevant to clinical samples and samples for health protection laboratories.

e. Laboratory services should ensure that transportation related to their operation has the lowest practical carbon footprint.

Future [Years 6-10]

f. The HSE should consider broadening the scope of the phlebotomy service to include collection of other samples including oral fluid, nasopharyngeal and other respiratory samples, skin scraping, hair and nail clippings, urine and faeces samples and wound samples.

5. Organisation

5.1 Services to Support Care in the Community

Now [Years 1-2]

a. Planning for service developments in the community, and for clinical programmes, should take account, at the planning phase, of the laboratory services required to support the development and how these will be accessed and delivered. Planning should consider both laboratory services required directly by the service development and services required as a result of further investigation or follow up arising from the new service development.

b. Laboratory services for people cared for in primary and community care should be provided on the basis that these services have equal importance to services for people cared for in hospital although the clinically acceptable turn-around-time will often be longer for less acutely ill people.

c. Laboratory services should provide a facility for GPs and others practising in the community to readily identify samples that require urgent attention and rapid reporting.

d. Laboratory services for patients cared for in primary and community care should be provided by a laboratory in a conveniently located hospital laboratory (Hub or Spoke)

where this meets the needs of people cared for in the community. This approach supports integrated service delivery across patient journeys.

e. Laboratory services for patients cared for in primary and community care should be provided by another HSE laboratory service (for example from a Health Region laboratory) if the nearby hospital laboratory is unable to meet the needs of the service.

f. There should be consistent clinical guidance, advisory services and governance of laboratory services for people when they are cared for in primary and community care and when they are cared for in a hospital that serves that community.

g. Laboratory services and laboratory service users in the community should work together to optimise benefits of electronic requesting and report of laboratory tests, facilitated by rapid roll out of MedLIS. The goal is to make relevant, comparable results accessible to healthcare workers whether the person is being cared for in the community or the hospital.

Next [Years 3-5]

h. The HSE in consultation with General Practitioners should define a minimum test catalogue that should be available as a routine service to all General Practitioners from the HSE or HSE funded laboratory service, subject to provision of appropriate samples and the required request details.

i. Laboratories that provide services to the Coroner related to post-mortem examination after deaths in the community should have service level agreements with the relevant Coroners that address the resources required to provide that service. This includes the post-mortem examination and analysis of samples taken at the examination.

Future [Years 6-10]

j. Laboratory services should consider how reports and reporting systems can be configured to deliver reports directly to a patient portal or application.

5.2 Services to Support Care in the Hospital

Now [Years 1-2]

a. Planning for service developments in the hospital should take account of the laboratory services required to support the development and how these will be resourced, accessed and delivered.

b. The planning and delivery of laboratory services for patients in hospital should take account of quality indicators including the turn-around time required to meet clinical need in different contexts, for example ICU.

c. The planning and delivery of laboratory services for patients in hospital should take account of the range of services and turn-around-time required to facilitate patient flow through Emergency Departments, to facilitate early patient transfer and discharge and the development of virtual wards.

d. The planning and delivery of laboratory services for patients in hospital should support hospital wide quality of care and patient safety programmes including medication safety and infection prevention and control.

e. Laboratory services should address the needs of co-located mental health, maternity and paediatric services as well as general adult services.

Next [Years 3-5]

f. Laboratories providing post-mortem examination after deaths in the hospital should be adequately resourced to provide that service including the post-mortem examination and analysis of samples taken at the examination.

5.3 Services to Support Clinical Programmes

Next [Years 3-5]

a. The HSE should ensure that laboratory capacity is provided to meet the demands of national clinical programmes that provide for integrated care of patients.

6. Clinical Laboratories including Clinical Reference Laboratories

Now [Years 1-2]

a. Clinical laboratory services should normally be delivered as an integral part of the HSE. Outsourcing should be an alternative only where the service is so specialised that delivery within the HSE is not reasonably practical or in a context where the required quality and turn-around-time cannot be met within the HSE at reasonable cost[2].

Next [Years 3-5]

b. The HSE Laboratory Services should be structured in three levels (1) Laboratory Network (serving one hospital or a network of hospitals), (2) Health Region level and (3) National level. The structure of services should ensure that there is equitable access to laboratory services within and among s.

6.1 Laboratory Network (Hospital Level)

Now [Years 1-2]

a. A menu of laboratory services defined as core services required on site should be specified for each hospital in each Laboratory Network. The core services should be defined in the context of the clinical services provided on that site[3].

b. Efficient arrangements for exchange of information (electronic) and transport of samples between laboratories should be in place to achieve effective integrated function of Laboratory Network, Health Region and National services[4].

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[2] In the case of outsourcing, the arrangements should address the need for resilience to manage risks related to dependence on a single laboratory. The requirement related to outsourcing as set out in the Haddington Road Agreement. Consultation with staff representatives conform to the Outsourcing Provisions of the Public Service Agreement 2024-26 S. 2.7.

[3] This is to support turnaround time that meets clinical need and to ensure that the laboratory service are integrated as partners in delivery of care.

[4] The Individual Health Identifier (IHI) and/or PPS number is essential to support optimal function of these systems.

Next [Years 3-5]

c. General hospital laboratory services providing small scale services that must be provided at hospital level should be managed as spokes of a Laboratory Network or spokes of a Health Region laboratory. This will require agreed levels of service and governance arrangements[5].

d. Centralisation of laboratory services to Hub, Health Region or National level should be considered where this improves the service. This requires that the quality of preparation and processing of samples is maintained and the process of reporting and interpreting can be appropriately integrated into clinical decision making including multidisciplinary team (MDT) meetings.

6.2 Health Region Laboratory Services

Now [Years 1-2]

a. Health Region laboratory services should have formal agreed communication systems and processes for liaison with Regional Departments of Public Health, National Environmental Health Services, Health Protection Surveillance Centre, HSE Antimicrobial Resistance and Infection Control (AMRIC), the Irish Blood Transfusion Service (IBTS) and other relevant services to support use of laboratory data for decision making and disease surveillance.

Next [Years 3-5]

b. The Health Region should determine the number of Laboratory Networks delivering each type of analysis. This should support the provision of services to address identified gaps in the Health Region (including repatriation of tests) and to ensure that unnecessary duplication and redundancy is minimised[6].

[5] For this purpose, laboratories with about 30 whole time equivalent staff in medical and scientific grades combined are considered small scale.
[6] This should take account of the advice of the Medical and Scientific leads regarding clinically required quality and turn-around-time, the equipment and skill sets required to deliver the service, the volume of service required at each site and the cost-benefit associated with provision from one or a small number of sites.

c. Health Regions should identify which laboratory services should be delivered at a single site for the region. This should be reviewed regularly to take account of changing needs and technology. Designated Health Region laboratory services should be funded and delivered at a regional level.

d. Two or more Health Regions should engage with each other to provide specific laboratory services at a single site where this meets the clinical need in a cost efficient manner. This should support the provision of services to address identified gaps in the Health Regions and to ensure that unnecessary duplication and redundancy is minimised[7].

6.3 National Clinical Laboratory Services

Now [Years 1-2]

a. The HSE should continue its work with the National Virus Reference Laboratory(NVRL) and UCD to enhance integration of service delivery between HSE and the NVRL.

Next [Years 3-5]

b. An integrated Clinical National Reference Laboratory Service should be established to manage and deliver specified laboratory services as an integrated national service for all HSE and HSE associated services. This should support the provision of services to address identified gaps in service at National level (including repatriation of tests) and ensure that unnecessary duplication and redundancy is minimised.

c. Laboratory services for delivery by the Central National Reference Laboratory Service should be designated by the office of the CCO and the relevant National Director based on medical and scientific advice from the relevant National Clinical Programmes. This should be reviewed regularly to take account of changing needs and technology[8].

[7] In such cases, the Health Regions will agree on the mechanisms to share associated costs. This approach should facilitate the introduction of new technologies and minimise redundancy. If a service has been designated for national service provision it should not generally be duplicated by Health Regions.
[8] Examples include the National Clinical Programme for Pathology, National Cancer Control Programme, the National Women's and Infant's Programme, National Healthy Childhood Programme and Organ Donation and Transplant Ireland.

d. In general, laboratory services should be considered suitable for delivery by the Central National Reference Laboratory Service if the clinically required quality and turn-around-time can be met adequately by central service provision, and

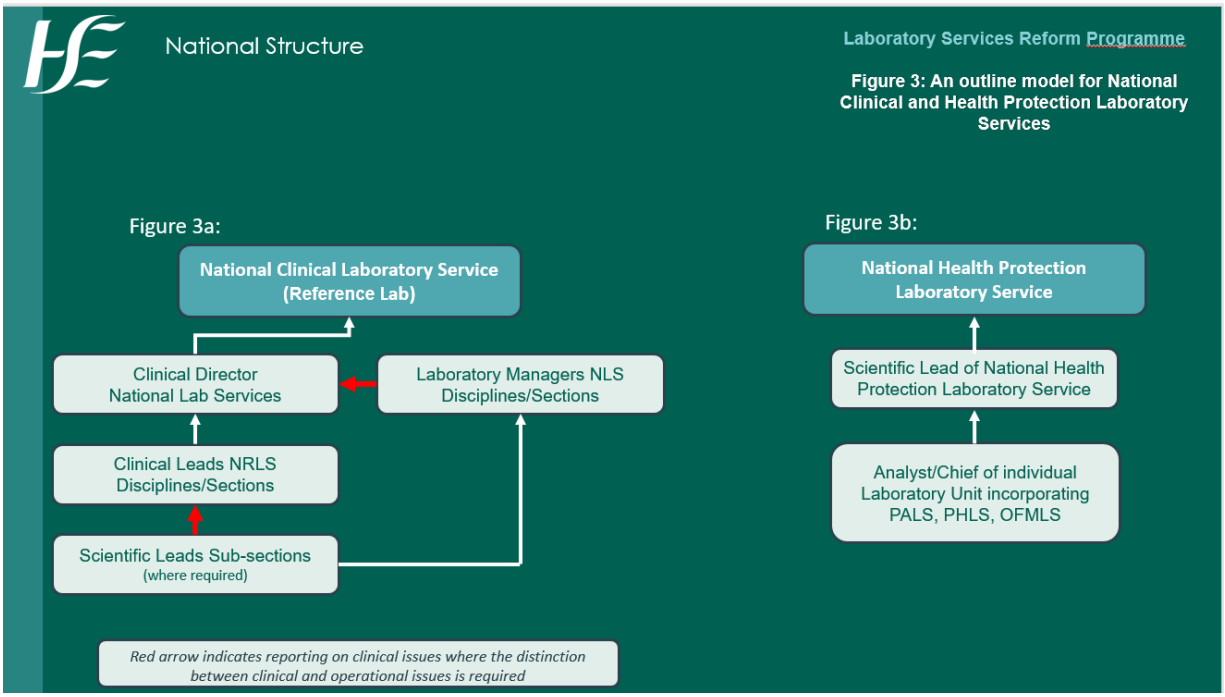
    1) the delivery of the service requires specialised equipment or skill sets that need not be duplicated OR,
    2) the total volume of service required at Health Region level is low to moderate OR,
    3) there is a significant quality, cost or sustainability premium associated with centralised provision.

e. The integrated Clinical National Reference Laboratory Service should encompass all laboratory disciplines required for screening and diagnosis and should provide clinical, technical and IT support for Health Region services, Laboratory Networks and, where relevant, other private and public service laboratories[9].

f. The Clinical National Reference Laboratory Service should be led by a Clinical Director working with a multidisciplinary medical and scientific team. A possible structure for management is outlined in Figure 3 (a & b) below.

[9] The European Centre for Disease Prevention and Control (ECDC) has defined core functions for microbiology reference laboratories for communicable diseases. Many of those core functions are also applicable for reference laboratory services in other disciplines.

Figure 3 (a & b)



g. The Clinical National Reference Laboratory Service should have a formal process for consultation with the National Director of Public Health and the National Director of Health Protection to ensure that the Service functions as an integral element of Public Health capacity for surveillance of all hazards, planning and emergency response.

h. The Clinical National Reference Laboratory Service should be funded and managed at a national level as an integrated service. Some Clinical National Reference Laboratory services may be provided by service level agreement between the Central National Reference Laboratory and one or more Health Region laboratories. Laboratories should not self-designate as national services.

i. The HSE Clinical National Reference Laboratory Service should work closely with non-HSE public service laboratories sharing expertise, technology and data within a “One Health” ethos. This should maximise the synergy and value of public sector service skills, equipment and data for surveillance, action, education, training and policy and leverage

scale to achieve best value for money in procurement of services. This also maximises capacity to support Health Protection and emergency planning and response.

j. Pending establishment of a building/campus for the Central National Reference Laboratory Service, an integrated service should progress by linking existing designated national services. These include the Newborn Bloodspot Screening Laboratory and associated Metabolic Laboratory services in Children's Health Ireland, Cervical Cancer Screening Laboratory in the Coombe Women & Infants University Hospital and pathogen specific reference laboratory services based in hospital laboratories. This should progress through development of service level agreements with existing host institutions to ensure that the levels of service required for current and future services are defined and have matching resources.

k. Specialised laboratory services required by the HSE from other jurisdictions (clinical and health protection) should be organised and procured at national level [10]. Consultation as appropriate with those with relevant expertise is required.

l. The Central National Reference Laboratory Service and Health Region Laboratories should collaborate to maintain plans, skills and capacity to provide an integrated response and to scale up services in the event of a public health emergency.

Future [Years 6-10]

m. A multidisciplinary HSE Central Laboratory Campus should be developed. This should be located to support road and rail and public transport links with all areas of the country.

n. The HSE Central Laboratory Campus in its design and operation should provide a model and leadership for other HSE laboratories in the sustainable delivery of laboratory services.

o. The HSE Central Laboratory Campus should provide a base for the Central National Reference Laboratory Service (above), for the National Genetics and Genomics services and for certain other key national services that are or will be provided by the HSE. It should

[10] The Individual Health Identifier number, this will help minimise redundancy in clinical testing and with appropriate IT and sample transport this should maintain appropriate turn-around-times.

provide a central unit for processing and storage of data, records and clinical material (e.g. histology slides)[11].

p. The HSE Central Laboratory Campus should have defined processes to ensure that there is optimal sharing of skills, equipment and facilities and the capacity to redirect/redeploy in an emergency.

q. In addition to Reference Laboratory services, the HSE Central Laboratory Campus should provide surge capacity to support Health Region or Laboratory Networks when necessary. This should include capacity to develop in-house tests and upscale tests in an emergency, capacity to generate and manage images for digital pathology and generate sequence data for analysis by Health Region or Laboratory Networks

7. HSE Health Protection Laboratories and Non HSE Public Laboratories

Now [Years 1-2]

a. In keeping with the report *HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology and Microbiology Reference Laboratories Review* of February 2022, integrated management of HSE Health Protection Laboratory Services should be established. In the context of this strategic plan, the governance for that integrated service should be expanded to include the Public Analyst Laboratories.

b. The HSE Health Protection Laboratory Services should be led by an appropriately qualified analyst or scientist appointed at a senior level [See Figure 3 a & b].

c. The analysis of drinking water and bathing waters (chemical and microbiological) should be delivered by the laboratory services for analysis of food within the Health Protection Laboratory Service.

d. Laboratory support for monitoring of health care environments (surfaces, air and water in the healthcare setting) and equipment should be linked with clinical laboratory services

[11] It may be pragmatic to accommodate other HSE laboratory services that require new laboratory facilities in any such development

(Laboratory Network, Health Region or National Reference Laboratories as appropriate to the nature and volume of analysis performed).

Next [Years 3-5]

e. The management team for the HSE Health Protection Laboratory Services should review the potential for consolidation of the services provided by the seven Official Food Microbiology Laboratories. It is likely that this could be delivered efficiently by a smaller number of laboratories and could be aligned more closely with the Public Analyst Laboratory service.

f. The HSE Health Protection Laboratory Services should support the provision of new services in Ireland to address gaps that currently result in dependence on analytical and reference laboratory services outside of Ireland and also to ensure that unnecessary duplication is minimised.

g. The HSE should develop or maintain service level agreements or other formal arrangements to support its existing and future collaboration with other state funded laboratory services. Examples include the State Laboratory, the Medical Bureau of Road Safety, the Irish Blood Transfusion Service and the laboratories of the Department of Agriculture, Food and Marine.

8. Infrastructure

Now [Years 1-2]

a. Design and build of all laboratories should take account of health and safety challenges intrinsic in some areas of laboratory practice including potential exposure to toxic substances, pathogenic organisms and heat generated by instruments. Adequate well-designed workspace for non-analytical work (writing, quality management, data analysis, reporting) separate from areas where analysis is performed should be provided to ensure that potential exposure to hazards associated with analysis is limited to periods when performing analysis.

Next [Years 3-5]

b. Laboratories that are staffed during unsocial hours should make appropriate provision for security, rest and refreshment needs for staff. Particular consideration should be given to how the design can support interactive team working during anti-social hours to avoid lone working in isolated sections of the laboratory.

c. Laboratory buildings should include access to learning and teaching facilities for students on placement and practice educators as well as meeting the needs for continuing education and training of staff.

Future [Years 6-10]

d. A HSE Central Laboratory Campus should ideally be co-located with a hospital service to maintain a clinical ethos and to support ongoing clinical engagement of and continuing education for staff working in the Central Laboratory Service[12].

e. The HSE Central Laboratory Campus should be designed to provide capacity to redeploy space and expand footprint rapidly in the event of a public health emergency and to provide capacity for centralised storage (data and any strategic reserve of consumables) and processing capacity.

f. The HSE Central Laboratory Campus should be designed to facilitate security, secure communication and autonomous function for an extended period in the event of a public health emergency or conflict.

g. The HSE Central Laboratory Campus should accommodate NRLs, including non-clinical NRLs, other than those already provided with suitable facilities on other sites.

h. Health Regions should develop a Health Region Laboratory to provide those services that are designated by the Health Region for provision at regional level. The Health Region

[12] This is subject to identifying a location with adequate space on or adjacent to a hospital campus that facilitates development of the Central Laboratory Campus in efficient and cost-effective manner in consultation with the Expert Laboratory Advisory Group (ELAG).

Laboratory should be designed with surge capacity and ease of expansion to support response to a public health emergency.

i. The HSE Health Region clinical laboratories should preferentially be co-located with a hospital site to preserve a clinical ethos and partnership in patient care however this may not be practical given the premium on space on some hospital sites.

j. The Health Region clinical laboratories should be developed at locations that facilitate access for materials, supplies and deliveries and ease of access for visiting healthcare workers from other HSE services.

k. The Health Region clinical aboratories should include facilities for collection of blood and other readily collected clinical samples so that sample collection services for patients may be provided as appropriate.

l. Public Analyst Laboratory and other HSE Health Protection Laboratory Service infrastructure should be developed or extended to accommodate the service remit outlined in this strategic plan including repatriation of services currently sourced outside of Ireland. The facilities provided should meet the requirements of Article 37(4) of Regulation (EU) 2017/625 for Official Laboratories.

m. Laboratories should be based in secure permanent buildings that are designed and built with flexibility to facilitate, install and operate high throughput automated systems and multidisciplinary working of teams, to support sustainable service delivery.

n. Laboratory buildings should provide adequate accessible storage space for supplies and equipment to ensure that hallways and areas where analyses are performed are free of clutter.

o. Laboratory buildings should provide adequate space for secure lockers for storage of personal items that should not be taken into areas where analytical work is performed.

p. Design of new or refurbished buildings for delivery of patient facing services, in particular Emergency Departments, Critical Care Units, Integrated Care Hubs, and Elective Hospitals should take account of the requirements of that service for Near Patient Testing. Provision for Near Patient Testing may also be relevant to large Primary Care Centres.

9. Information Communication Technology for Safe and Efficient Laboratory and Transfusion Service Delivery

Now [Years 1-2]

a. Delivery on the HSE objective of full implementation of national laboratory information system (MedLIS) by the end of 2028, linked to electronic GP test requests and Digital Pathology, provides a critical support to the delivery of other elements of this plan. Delivery on this target will require adequate resourcing of MedLIS and laboratory based teams.

b. All enhancements and changes to the digital environment within which laboratories operate should be carefully planned to ensure security and continuity of services.

c. Given the emphasis on the rapid implementation of MedLIS, changes to existing laboratory information systems, other than those already in progress, should be limited to those essential to maintain continuity of service until MedLIS implementation is complete.

d. During the roll out period of MedLIS, any systems deployed in laboratories or to interface with laboratory systems, should be interoperable with MedLIS to achieve the goals of access to all patient results wherever the patient attends for care. These should also support the use of laboratory generated data for National Clinical Surveillance Systems, planning and management, crisis response and research.

Next [Years 3-5]

e. The HSE should continue to deploy Electronic Health Care Record (EHR), with integration of laboratory results a central requirement, as quickly as is practical to do so. Laboratory diagnostics and transfusion management systems should be integrated within the EHR. This will be facilitated by use of the IHI Number[13].

[13] The EHR for a single patient has diagnostics from multiple laboratory services across disciplines, laboratory sites (both national and international) and over time. These all contribute to the patient's longitudinal record, which enables clinicians to assess and optimally manage care.

Future [Years 6-10]

f. In order to leverage and maximise the benefits of integrated laboratory information systems, laboratory services should be supported by dedicated teams of engineers and scientists with relevant skills in information technology data analytics, Artificial Intelligence and bioinformatics to maximise the benefits of the systems provided.

10. Information Governance

Next [Years 3-5]

a. Information governance should ensure secure seamless sharing of patient laboratory records between healthcare service providers in Ireland. Duty of Care is Duty to Share is the underlying principle. Appropriate mechanisms to deliver on this principle should be established so that the patient identifiable laboratory records can be both secure and readily accessible to the patient's chosen healthcare provider. These should also be available to those who need to access them in relation to protection of public health.

b. Information governance arrangements should ensure laboratory information is efficiently shared between the HSE and HSE funded healthcare service providers and with Irish or EU public health agencies to support audit, quality improvement, surveillance, workload metrics, policy development and research[14].

11. Automation, Digital Pathology and Other New Technologies

Now [Years 1-2]

a. The HSE should enhance investment in automation of all stages of sample preparation and processing. The existing commitment to implement Digital Pathology and investment

[14] Sharing of laboratory information for purposes of audit, quality improvement, surveillance, workload metrics, policy development and research should not include personal identifiers other than when necessary and consistent with obligations to protect personal data.

in other new technologies will improve patient care and improve efficiency of laboratory services. This is already well established in other countries.

b. Automation should be used to release the existing highly qualified scientific staff from repetitive manual tasks, allowing them to deploy and expand their skills to practice at the top of their licence. This should have the added advantage of enhancing staff wellbeing.

c. When analytical services traditionally provided by different disciplines can be provided to the required standard on common platforms, this should be done. This should not be constrained by traditional laboratory discipline boundaries. The use of common (shared) analytical platforms is consistent with continued application of discipline specific expertise in test reporting and interpretation as required.

d. Managed service contracts should be used when appropriate to support rapid acquisition of facilities and equipment to progress automation and other new technologies. As managed Services Contracts are also associated with significant risks, the risk and benefits should be considered in each instance[15].

Next [Years 3-5]

e. Digital Pathology should be used to improve ease and rapidity of seeking second opinions (including from experts outside of Ireland), reduce preparation time for multidisciplinary team meetings and support sharing and distribution of the work of reporting across different centres to optimise use of time and expertise. This can be particularly valuable when turn-around-times are extended due to insufficient number of reporting Pathologists.

Future [Years 6-10]

f. The HSE should progress the evaluation and application of Artificial Intelligence as a potentially powerful diagnostic aid in histopathology, blood sciences and other laboratory disciplines.

[15] At National level, the HSE should consider the risks and benefits of dependence on an exclusive or a small number of providers.

12. Workforce

Now [Years 1-2]

a. The HSE should engage with stakeholders including CORU and the Department of Health to progress registration for all Scientists working as health care workers in clinical laboratory services.

b. At entry level, scientific staff recruitment to clinical laboratories should include a mix of Medical Scientists (multidisciplinary training) and other healthcare scientists graduating from other honours level (NFQ level 8) courses in specific relevant single disciplines such as bioinformatics, clinical biochemistry, coagulation, epidemiology/surveillance science, haematology, histopathology, immunology, microbiology, molecular biology, quality management and transfusion science.

c. Advancement from entry level scientist grades to senior scientist grades should require a Master's degree or equivalent (NFQ Level 9) qualification or higher and specified experience and be based on a competitive process. The required duration of experience for advancement should be the same for all scientists.

d. New entry Laboratory Aide staff should require a relevant NFQ level 6 qualification or higher in a relevant field such as life sciences or healthcare for entry.

e. The HSE should define an expanded range of tasks that may be assigned to Laboratory Aides. This should include roles in Health Protection Laboratories (PALs and Public Health Microbiology Laboratories) as well as clinical laboratories. This should include Laboratory Aides supporting services outside of normal working hours. This should assist in ensuring that medical, scientific, analytical and other grades can focus on tasks that require their existing skills and provide opportunities to develop new skills.

f. The range of pre-analytical and analytical tasks assigned to Laboratory Aides should be as broad as is supported by their demonstrated competency. This is subject to appropriate scientific or medical supervision of their work. Final review and authorisation of results is generally not appropriate for assignment to Laboratory Aides.

g. HSE Laboratory Networks should evaluate existing phlebotomy services and develop a plan to recruit, train and retain a sufficient cadre of permanent phlebotomy staff to provide the core service for the hospitals they serve over an extended working day and weekends and to ensure training and supervision of all staff recruited to support the service[16].

h. Health Protection Laboratories should not preferentially recruit Medical Scientists. Medical Scientists may be particularly suited to some roles in those laboratories and should remain eligible for appointment to such laboratories where they have the appropriate skills.

i. The staffing structures in Public Analyst Laboratories that are currently in place should be revised in accordance with agreements reached through the Public Analyst's Laboratory Review process.

j. Opportunities for training and development should be provided for staff of all grades in HSE Health Protection Laboratories similar to those provided for laboratory staff in clinical laboratories and relevant to the service within which they work.

Next [Years 3-5]

k. Consultant Pathologists and appropriately qualified scientists in each discipline should function within Laboratory Networks as part of sub-regional or regional teams providing support for the Hub and Spokes. This should provide more equitable access to expertise, more resilient service to patients and more equitable and sustainable rotas for out of hours work[17].

l. The productivity of existing Consultant Pathologists and Specialist Registrars should be maximised by reassignment of tasks as appropriate to other staff grades. International experience has examples of success in enhancing skill of non-medical staff to perform tasks in sample processing, interpretation and reporting traditionally limited to medical staff[18].

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[16] As per section 3d, phlebotomy services should also be developed to support phlebotomy for patients cared for in the community, in particular for those from whom collection of blood samples requires particular expertise.
[17] With appropriate IT and harmonisation of practice multi-site team service should not require frequent travel between sites.
[18] This aligns with general measures to review productivity and task allocation across healthcare.

m. The HSE should provide comparable opportunities and support (training and pathways for advanced qualification and career progression while in post) for scientists of all disciplines whatever their primary degree. This should build on existing national and regional structures and processes to implement the Health and Social Care Professions Advanced Practice Framework

n. Advancement from senior grades to higher grades should be provided for Medical Scientists, Biochemists and other healthcare scientists in all clinical laboratory disciplines and for staff of Health Protection Laboratories. Training should offer options designed to prioritise development of skills in (1) clinical, (2) scientific or (3) management (see section 13) as appropriate to the service and recognising that there are significant areas of overlap.

o. Career progression along the chosen pathway should be supported with competitive access to structured defined numbered temporary rotating training posts (similar to the model for basic and higher specialist training in medicine). This should include support for training programmes with protected time and costs.

p. The HSE should work with partners in professional bodies and Higher Education Authorities to develop appropriate post-graduate training programmes to support career progression as above.

q. Career progression for Laboratory Aides should be facilitated by competitive access to defined numbered training posts that support them in acquiring the necessary qualifications that make them eligible to compete for entry to Medical Scientist or other healthcare scientist grade posts.

r. The HSE should engage with Higher Education Institutes to enhance training and development opportunities for Anatomical Pathology Technicians and Mortuary Technicians.

s. HSE Laboratory services should develop a cadre of laboratory professionals in addition to medical and scientific staff including engineers, information technologists and administrative support staff specialising in the optimal costing and delivery of laboratory services and working with the laboratory governance system to support the efficient operation and maintenance of the laboratories.

t. HSE laboratory staff (medical, scientific and laboratory aide) working in a service that delivers an out of hours service should contribute as necessary to the delivery of service outside of normal working hours as a matter of obligation[19].

u. To ensure that a comprehensive range of clinical diagnostic services is provided to support clinical care, adequately staffed rosters should be established to provide a comprehensive service from eight a.m. to twelve midnight together with arrangements to provide urgent services from twelve midnight to eight a.m.

13. Education and Training

Now [Years 1-2]

a. The HSE should implement the previously developed Postgraduate Training Programme for Medical Scientists (developed in consultation with relevant Higher Education Institutes) as soon as practical to address the current challenges in recruitment of Medical Scientists.

b. The HSE should maintain and develop partnerships with the Higher Education Institutes and professional bodies to support undergraduate and postgraduate education and training of people needed to work in the HSE laboratory services. This includes contributing to the teaching programme and supporting student placements required as part of their training.

c. The existing training structures and career pathways for medical staff are broadly appropriate but should be scaled to meet the anticipated demands of the service for medically qualified Consultant Pathologist appointments. The requirements are outlined in the *2023 National Doctors Training and Planning Report:* https://www.hse.ie/eng/staff/leadership-education-development/met/plan/specialty-specific-reviews/pathology%20specialty%20review.pdf

[19] If, at a particular time, there are sufficient people offering to work out of hours to cover the service and the burden on those offering to work out of hours is not too onerous on those people, then there is no requirement to assign everyone to work out hours while the service can be maintained. Some staff may be advised not to work out of hours after Occupational Health assessment.

d. Participation in educational activities with partner institutions should be recognised as a part of the work of laboratory staff. There is a requirement for formal Practice Educator/Practice Tutor roles in laboratories in addition to protected time for other staff to participate in these activities.

e. Given the importance of life-long learning and requirements for registration with CORU and the Medical Council, continued professional education is essential and should be supported for all laboratory staff with protected time, in-house opportunities for learning and appropriate funding support for external training relevant to their role in the laboratory.

f. Ongoing training and emphasis on health and safety should be provided given the health and safety risks associated with laboratory practice and the specific risks associated with certain areas of practice. This should be supported by access to appropriate Occupational Health services.

g. As part of their diagnostic stewardship, laboratory services should provide ongoing education and training and tools to support laboratory service users to make appropriate use of laboratory services and to support communication on these issues with patients.

h. As part of their diagnostic stewardship, laboratory services should engage with patients and the public to promote understanding of the benefits and limitations of laboratory services.

i. The HSE should work with partners in the Higher Education sector to expand training programmes for phlebotomy including training for expanded scope of practice.

Next [Years 3-5]

j. Expanded opportunities for training to advanced practice for Scientists within the HSE laboratory services should be provided consistent with *HPSC Deliver, A Strategic Guidance Framework for Health & Social Care Professions 2021-2026* https://www.hse.ie/eng/about/who/health-and-social-care-professionals/hscp-strategic-framework/hscp-deliver-a-strategic-guidance-framework-for-hscp-2021-2026.pdf and the

Health and Social Care Professions Advanced Practice Framework 2023 [20]. This should expand the opportunity to progress to autonomous practice including unsupervised clinical scientific practice and independent scientific direction of laboratory services to all scientific disciplines.

k. The scientific training programmes for scientists in clinical laboratories and health protection laboratories (Food and Water and Public Analyst) should make full use of EU funded training opportunities and should support training to doctoral level in specific scientific and data analysis skills as relevant to the development and delivery of the laboratory services.

l. Managerial training programmes for scientists and medical staff in clinical laboratories and non-clinical laboratories should provide training including relevant qualification in health services management.

m. Education and training should be provided to support sufficient staff in developing the Irish language skills required to support compliance with the requirements Official Languages Act 2023.

14. Research, Innovation, Development, Audit and Quality Improvement

Now [Years 1-2]

a. Research, innovation, development, audit and quality improvement should be an integral part of HSE laboratory service delivery. These are essential to support improvement of service and enhance patient safety. They also play an important role in promoting the development and retention of people working in the service.

[20] In the Health and Social Care Professions Advanced Practice Framework 2023 a high degree of autonomy is underpinned by a National Framework of Qualifications level 9 award or equivalent and evidence of learning that encompasses the four pillars of:(i) Clinical practice, (ii) Leadership and management, (iii) Education and facilitation of clinical learning, and (iv) Evidence, research, and development.

b. HSE laboratories should maintain and expand partnerships with third level institutes, regulators, industry and international partners and networks to support research, innovation and development with appropriate ethical oversight.

c. All staff should be supported to participate in research, innovation development, audit and quality improvement as part of their work. This would benefit from defined leadership and linking the laboratory work in these domains with the wider hospital and community research and audit agenda.

Next [Years 3-5]

d. Partnerships with patients and the public on research and innovation should be developed to ensure that patient perspectives and patient safety are built in to service development.

Future [Years 6-10]

e. With appropriate consent and controls, the HSE Central and Health Region laboratories should consider the practicality of developing and maintaining a bank of material (biobank), compliant with the ISO 20387:2018 standard, for use in research and development.

15. Financing of Laboratory Services

Now [Years 1-2]

a. All new service developments requiring laboratory services should include an adequate financial provision to support the additional laboratory service required. This should become part of the budget for the laboratory/laboratories providing that service. This should address both revenue and capital funding requirements.

b. Funding models should reflect the value of diagnostic stewardship and the role of laboratory services as partners in health care and health protection as distinct from simply test providers.

c. HSE laboratories should provide diagnostic services to other Health Regions in particular where they can offer specific services that are not otherwise readily accessible. The Health Regions should agree a mechanism to ensure that funding follows the service provision.

d. HSE laboratories that are designated and funded as National Reference Laboratory Services providers should not charge fees to public sector laboratories for reference laboratory services that they provide[21].

e. HSE laboratories should continue to provide clinical and health protection laboratory services to private providers on request, subject to a Service Level Agreement, if the HSE laboratory provides specific services that are not otherwise readily accessible and if this does not compromise services to HSE. The private provider should cover the full cost of the service with fees generated used to support the laboratory providing the service.

Next [Years 3-5]

f. HSE laboratory services at all levels should be financed by a laboratory services revenue budget clearly defined within the overall institution/governance unit that hosts the laboratory service unit[22].

g. HSE Laboratory Networks, Health Region Laboratories and National Reference Laboratory Services should have defined capital funding that allows for multi-year planning for acquisition and replacement of laboratory equipment based on the laboratory service priorities.

h. Priorities for laboratory equipment should be defined at National, Health Region and Laboratory Network level based on an understanding of existing facilities and equipment and should avoid wasteful duplication.

i. Agreements for service provision from private laboratory providers should be coordinated at Health Region or National level to manage costs by ensuring that alternative provision

[21] Fee per service is appropriate for certain services provided to the private sector but should be waived where there is a public health or policy interest in receiving the samples from the private sector. Examples include surveillance for specific pathogens. Where there is public health or policy interest in receiving samples from the private sector fees for service may deter sample submission and therefore undermine the public health/policy objective of comprehensive surveillance.

[22] In most cases, the host institution will be a hospital or a group of hospitals that function as a Laboratory Service Network within a Health Region. The revenue budget should cover human resources, laboratory supplies, cost per unit managed service contracts and other laboratory specific services. Combined with workload measurement, this will support greater transparency in relation to costs of provision of laboratory services, value for money and ensuring that service demand is managed within a defined resource.

from other HSE laboratories is explored and that the HSE fully uses the volume of service it procures to leverage best value for money.

Future [Years 6-10]

j. The HSE should develop systems to estimate the cost of laboratory services delivered to each service user or functional area within hospital and community service to support accountability and management of costs associated with each service user/functional area.

Figure 4 – Overview of the Recommendations in the Suggested Order of Implementation

- Now = 1-2 years (2026-2027)
- Next = 3-5 years (2028-2030)
- Future = 6-10 years (2031-2035)

Recommendation Group	Now 2026-2027	Next 2028-2030	Future 2031-2035
1	a	b-e	f
2	a-d	e-h	
3	a-n		o
4	a-c	d-e	f
5.1	a-g	h-i	j
5.2	a-e	f	
5.3		a	
6	a	b	
6.1	a-b	c-d	
6.2	a	b-d	
6.3	a	b-l	m-q
7	a-d	e-g	
8	a	b-c	d-p
9	a-d	e	f
10		a-b	
11	a-d	e	f
12	a-j	k-u	
13	a-i	j-m	
14	a-c	d	e
15	a-e	f-i	j

Conclusions and Next Steps

This document is the first HSE strategic plan for laboratory services. This strategic plan is a beginning not an end point. It is intended to guide the development of HSE laboratory services over the next decade. This is accepting that it may need to be adapted over that time frame in the context of changing circumstances and that Health Regions will consider how to apply the recommendations in a way that is appropriate to the requirements of the Region.

The plan will require strong programme management to engage with stakeholders in developing a prioritised implementation plan with achievable timelines. Staging of implementation will need to take account of staff perceptions. Staff support for change is likely to be linked to appropriate consultation in line with the Public Service Agreement/s (2010-2026) and their perception of a balanced approach to implementation of changes that ask more of them and those changes that support their professional aspirations.

Individual business cases to support the investments required to implement major elements of the strategic plan will be needed to secure the support of the Government and the public for each investment. Central to each business case should be the value proposition that these investments will deliver value for money with a more efficient, equitable and sustainable laboratory service that is fit both for business as usual and response to emergencies.

Appendix 1 - Glossary of Terms used in this Report

Autonomous Scientist refers to a Scientist who has been appointed to an autonomous clinical practice role based on their training and qualifications.

Clinical Director refers to a medically qualified Consultant employed by the employer and who has overall clinical responsibility for the direction of a laboratory or diagnostics service and whose functions include (among others) functions relating to the deployment and management of consultants. In the context of this strategic plan, a Clinical Director will work with a Laboratory Manager and other team members as required to provide leadership for the laboratory services.

Associate Clinical Director refers to a medically qualified Consultant who is appointed to this role within the terms of the Consultant Contract. In the context of this strategic plan the Associate Clinical Director will work with a Laboratory Manager and other team members as required to provide leadership for a Laboratory Service Network (hub, spokes and NPT)

Discipline Lead refers to a Medical Consultant or Autonomous Scientist who provides leadership for a discipline within a Laboratory Network (hub, spokes and NPT). A Discipline Lead role may also be required in emerging cross disciplinary units such as Blood Sciences, Near-Patient-Testing services, Molecular Biology and Information and Communications Technology and in other major emerging sub-specialty areas.

Health Care Practitioner refers to a person working as a healthcare provider including, but not limited to, Health and Social Care Professionals, Nurses, Midwives and Medical Practitioners.

Health Protection Laboratory refers to laboratories that primarily provide testing of samples of food, water, air, medicines, drugs and environmental surfaces to support protection of the public from harm related to contamination or adulteration of products and equipment. These include the Public Analyst Laboratories and the Public Health Microbiology Laboratories.

Hospital Laboratory Service refers to a laboratory service based on a hospital or other health service campus and managed as part of that hospital (hospital network). It will often provide community and regional services as required by the Health Region. It may provide a national service if designated and resourced to do so. Hospital laboratory services will normally encompass support for near-patient testing in that hospital.

Health Region Laboratory Service refers to laboratory services designated as such by the Health Region REO to provide designated centralised services for that region as a whole. A Health Region Laboratory Service may be delivered from within an existing Hospital Laboratory or from a separate Laboratory Building/Campus. The Health Region Laboratory Service may provide centralised Referral Laboratory or Reference Laboratory services for that region (other than those designated for provision at national level). The Health Region Laboratory Service should provide support for community based near patient testing that is delivered as part of the regional plan for laboratory services.

Individual Health Identifier (IHI) this a number given to residents and former residents in Ireland with a Personal Public Services Number (PPSN) in accordance Health Identifiers Act 2014. It is used to uniquely identify each person engaging with the Health Service Executive and relevant social care agencies.

Laboratory Manager refers to a Medical Scientist who is appointed to provide scientific and operational leadership for a Laboratory Service. The Laboratory Manager will work with Clinical Director or Associate Clinical Director providing complementary Medical Leadership.

Laboratory Network refers to a multidisciplinary management unit that, at a minimum, includes all of the clinical laboratory services on one campus (a hub) but may also include services on other sites that operate as spokes of an integrated service.

Laboratory turn-around-time (TAT) refers to the time from time zero to end point of the test measured as when the results are available in an authorised state. Time zero is the when the sample is received into the laboratory with all appropriate information and other required samples. Time zero can also be the day that a specific investigation is activated if a request is made by a clinician for a test on a stored sample. [Modified from definition of Association for Clinical Genomic Science available at https://www.acgs.uk.com/media/11649/acgs-general-genetic-laboratory-reporting-recommendations-2020-v1-1.pdf

Managed Service Contract refers to a contractual agreement for a period of years for the provision of specified services by an external provider who has contractual responsibility for end-to-end delivery of the specified services required to support the delivery of the laboratory service. The services provided may include some or all of provision, maintenance, repair and replacement of equipment, provision of consumables and management of stock, user training and building and enabling works.

To date, in HSE laboratories managed service contracts have been used mainly in relation to blood sciences but are not limited to that domain.

National Reference Laboratory Services refers to laboratory services in any discipline designated as such by the HSE to support care in the hospital and community for the country as a whole. A National Reference Laboratory Service (NRLS) may be delivered by agreement from a Health Region or from a future HSE Central Laboratory campus as this is developed. A NRLS will provide primary testing for certain categories of test (low volume or requiring highly specialised skills or equipment) in addition to secondary/confirmatory testing for hospital and Health Region laboratories.

Near-Patient Testing refers to clinical analytical services provided by healthcare workers outside of laboratory setting and at or near to the place where the patient is receiving care in hospital or community. It does not encompass self-testing. Governance of near patient testing is best delivered jointly by a laboratory service and the clinical lead(s) for the patient care areas supported by the near patient testing service.

One Health refers to an "an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent." https://www.who.int/health-topics/one-health#tab=tab_1

Order Communications Systems refers to electronic systems for requesting laboratory tests and providing the required patient identification and clinical details.

Pathologist refers to a medical practitioner or scientist with specialist clinical training in pathology (definition based on https://www.rcpath.org/discover-pathology/what-is-pathology.html). A **Consultant Pathologist** is a medical practitioner registered with the Irish Medical Council in one of the recognised pathology specialties or a Scientist employed by the HSE as a Consultant Pathologist.

Private Healthcare Provider refers to a healthcare service provider working outside of the public health services that provides access to services based on payment of the substantial cost of the services provided by or on behalf of the person who receives care.

Reference Laboratory refers to laboratories that provide services primarily related to samples referred from other laboratories (referring laboratories) and /or that provide specialist services that are not generally available in most direct service laboratories. Examples include the reference laboratories for

analysis of disease markers, medication, other drugs or toxins, complex immune-haematological analysis of transfusion, those for specific microbial pathogens, those for mycotoxins, plant toxins, processing contaminants and food contact materials and those for metals and nitrogenous compounds.

Reference Laboratory (Designated) refers to a laboratory that is designated (for example by the HSE, relevant Government Department or EU Agency) to provide Reference Laboratory Services.

Referral Laboratory refers to laboratories that accept essentially routine samples from other laboratories for processing because it is not practical or efficient for the referring laboratory to provide that routine service on site. For example, a Referral Laboratory may provide certain routine hormone assays or ante-natal serology testing for one or more referring laboratories if remote provision can meet the required Turn-Around-Time.

Appendix 2 Terms of Reference

Terms of Reference for Development of a HSE Strategy for Laboratory Services 2025-2029

Project was:

- Proposed by HSE Clinical Lead for Laboratory Services Reform on November 24 2023.
- Endorsed for submission to the Executive Management by Chief Clinical Officer on 5 December 2023.
- Agreed by HSE Executive Management Team on 12 December 2023.

Terms of Reference

On behalf of the Chief Clinical Officer the HSE Clinical Lead for Laboratory Services Reform will convene and chair a group to prepare a draft HSE strategy for Laboratory Services 2025-2029 for consideration by the HSE Executive Management Team.

The group will include the following or their nominee, Clinical Lead for Integrated Care, National Leads for Services and Schemes, Access and Integration, People, Finance, Technology and Transformation, Communication and Public Affairs and Major Capital Infrastructure.

The review will take account of the "Review to Inform the Strategic Direction of Laboratory Medicine" and following consultation with relevant internal and external stakeholders will prepare a draft five-year for consideration by EMT. Consultation will include opportunities for written submission and discussion.

The Department of Health is a key partner in developing the strategy

The group will be supported by the Scientific Lead, Programme Manager of the National Clinical Programme for Pathology and the Administrator supporting the HSE Clinical Lead for Laboratory Services Reform.

The strategy should articulate a concise integrated vision for the role of HSE Laboratory Services and HSE funded laboratory services including those based in voluntary hospitals and section 38/39 settings. The goal of the strategy is to support the HSE to meet the needs of laboratory users, patients

and the public with respect to quality, equity of access across, timeliness, efficiency and sustainability of laboratory services.

The strategy should be prepared according to the following terms:

a) The strategy should address all HSE Laboratory Services including Clinical Advisory and Diagnostic Services, Population Screening Services, Public Health Laboratory Services and services that are funded by the HSE through outsourcing/referral of samples
b) The strategy should reflect relevant Government policies and HSE priorities including Sláintecare, enhanced care in the community, primary care development, the implementation of HSE Regional Health Authorities, pandemic preparedness, the establishment of the National Genetics and Genomic Office, expansion of fertility services and the future relationship with the National Virus Reference Laboratory (UCD)
c) The strategy should consider if there is redundancy in existing HSE laboratory service provision including consideration of unnecessary or potentially harmful testing and how this can be reduced or eliminated to provide a more sustainable service
d) The strategy should consider if there are gaps in existing HSE laboratory service provision and the options and relative priority of addressing those gaps
e) The strategy should address laboratory services are funded and resourced
f) The strategy should address how HSE laboratory services should be governed, organised and delivered at National and Regional level. It should address the balance between centralised and reference laboratory services (national and regional), integration of services with teams where care is delivered and near patient testing.
g) The strategy should address the role of outsourcing of laboratory services and the role of managed service contracts.
h) The strategy should address staff structures and staffing requirement including clerical and administrative, medical, scientific, information technology and other staff
i) The strategy should address the role of new and emerging technologies including molecular diagnostics, mass spectrometry, automation and Information Services including digitisation of pathology and the role of artificial intelligence
j) The strategy should address infrastructure requirements (facilities and IT) for laboratory services

k) In the event that a consensus is not achieved by the group on specific points in the strategy the majority view will be reflected in the draft strategy for consideration by EMT with an accompanying paper identifying the alternative viewpoints and the rationale

A draft report should be provided to the EMT by end of June 2024.

ENDS

Appendix 3a – Patient and Public Engagement - Survey Questions

Tell us your ideas about the future of HSE labs

The HSE is developing a new strategy to improve laboratory services in Ireland. The HSE has over 40 clinical labs in hospitals around the country that do tests for and give advice to doctors, nurses and other professionals. These tests are used every day to help to find out,why someone is sick, to check if treatment is working or sometimes to check for a disease before the person gets sick. The HSE also has labs that do tests on food, water and air to check that they are up to standard.

We are asking as many people as possible to give their opinion so that we can develop the best strategy possible. This will help us to understand what is most important to you when getting tests done as part of your health care journey.

We have prepared a draft strategy that is available on the HSE website at: https://www.hse.ie/eng/about/who/cspd/lsr/resources/programme-documents-resources.html

This is not the final strategy.

We would be grateful if you could answer the questions on the following pages. The survey should take no more than 5-10 minutes to complete.

In this section we want to ask you some questions about your sample and the how this sample is taken and sent to the laboratory.

1. *Imagine that you have been told by your Doctor or GP that you need a blood test or another type of test. In relation to the statements below please indicate how important each is to you*.

   [Not Important / Important / Very Important]

   1. Will it hurt when they take my sample
   2. Could my sample get lost before being tested in the laboratory
   3. Will the results of my sample be back quickly
   4. Will the results of my sample be the correct result
   5. Could there be a mistake with the results of my sample

2. *Imagine that your sample has been sent to the Laboratory. What is your level of concern in relation to each of the following statements*.

   [Not Concerned / Concerned / Very Concerned]

   1. Does the lab have enough staff and equipment to do my test CORRECTLY
   2. Does the lab have enough staff and equipment to do my test QUICKLY
   3. Does the laboratory open in the evenings and weekends to test my sample
   4. Are the staff in the laboratory well trained

3. *Imagine that your result has been sent to your GP. What is your level of concern in relation to each of the following statements.*

   [Not Concerned / Concerned / Very Concerned]

   1. Do I have to pay for my test
   2. Would my Doctor know if I already had this test done recently e.g. last week?
   3. Can my Doctor compare this result with my previous test results.
   4. If I go to a different doctor will they be able to get my previous test results
   5. Will my doctor be able to talk to the laboratory about my test.

4. *Please indicate your level of agreement with the following statements:*

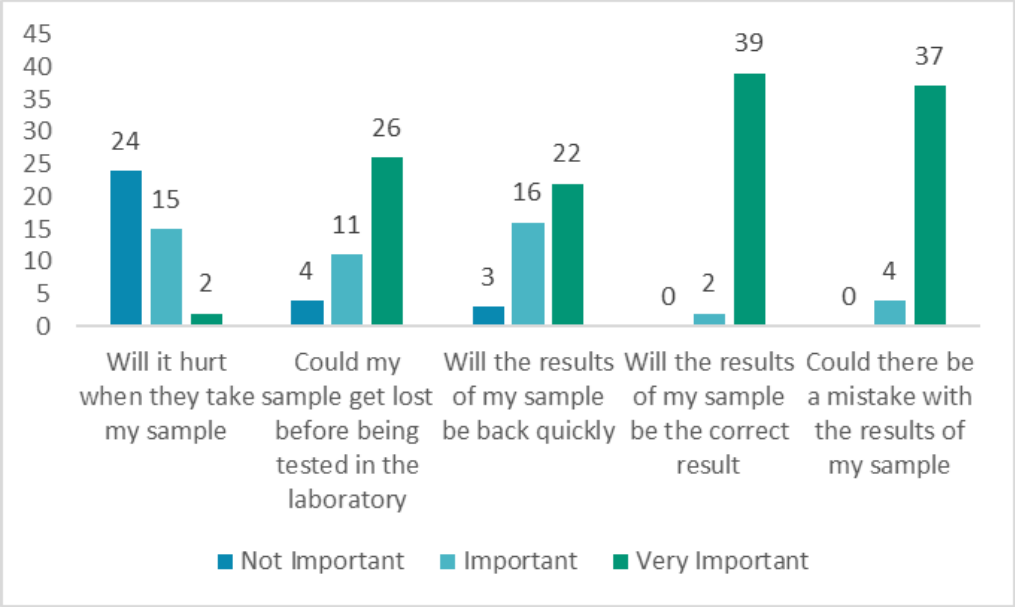
   [Disagree / Agree / Strongly Agree]

   1. The sample from my GP is just as important as a sample from a hospital patient
   2. It is fair that my test is delayed because the lab can only do emergency testing in the evenings and at the weekends
   3. Samples from hospital patients are more important than samples from GP
   4. Labs should be safe places for the staff to work in
   5. Labs should store the sample as long as they need to but no longer
   6. Labs should not use my sample for research without asking me

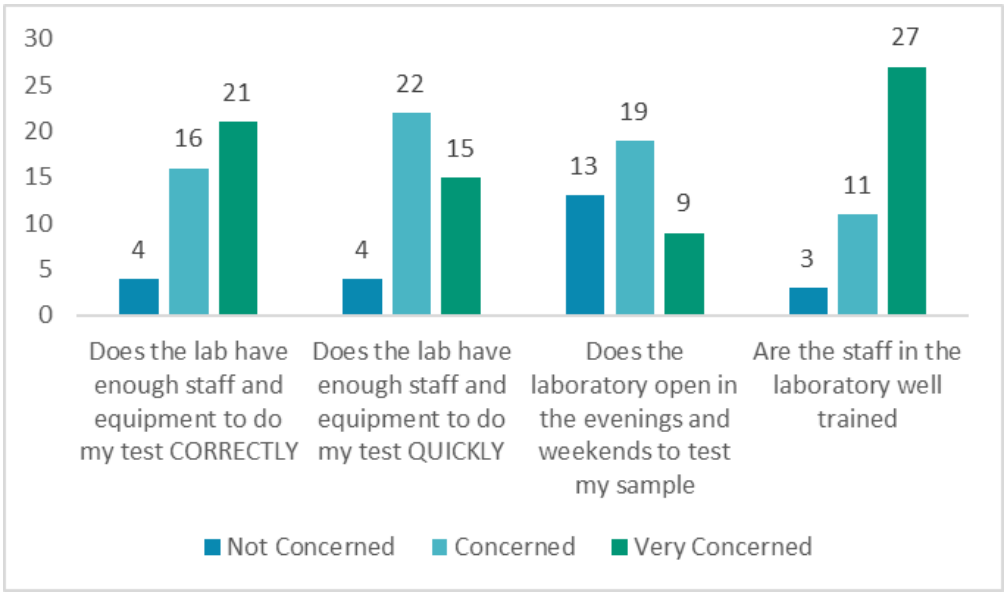
7. Samples need to be disposed of safely when the lab is finished with them
8. It makes sense for tests to be done in one big lab if it is faster
9. It makes sense for tests to be done in one big lab if it is cheaper
10. I don't care where the test is done as long as it is done correctly
11. Labs need to keep my personal information safe.
12. I am happy if the lab uses a number to identify me so that all my test results can be easily found and looked at together
13. I should be able to look up all of my own test results when and if I want to
14. I would like my sample to be tested in Ireland if possible
15. I would like my sample to be tested in a HSE lab if possible
16. I don't mind if my sample is tested in a private lab or a HSE lab.
17. Lab tests should be free for people who need them
18. I think my doctor or nurse knows best which tests I need
19. If the lab says the test is not useful they should not do it
20. Labs need to be careful about how they can harm the environment
21. I do not want to travel very far to get a blood test
22. I do not mind travelling further for a test if it will hurt less
23. The lab should pick up samples from my GP every day.
24. I do not mind taking my own samples to the lab
25. It should be ok to drop off samples to the lab at evenings and weekends.

Appendix 3b – Patient and Public Engagement - Survey Results

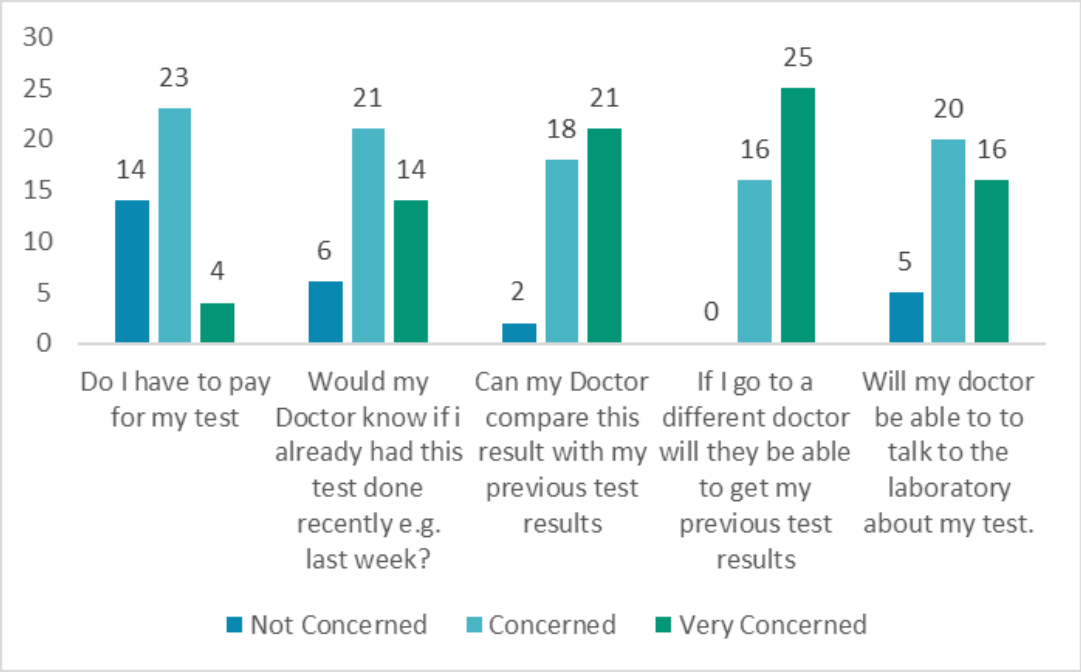
Imagine that you have been told by your Doctor or GP that you need a blood test or another type of test. In relation to the statements below please indicate how important each is to you.



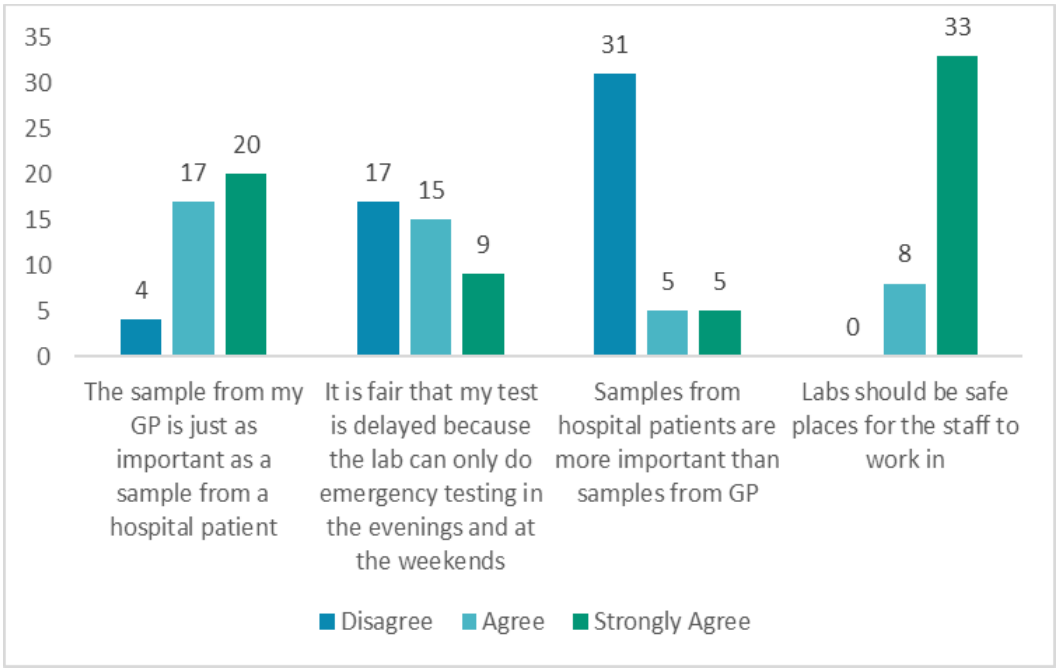
Imagine that your sample has been sent to the Laboratory. What is your level of concern in relation to each of the following statements:



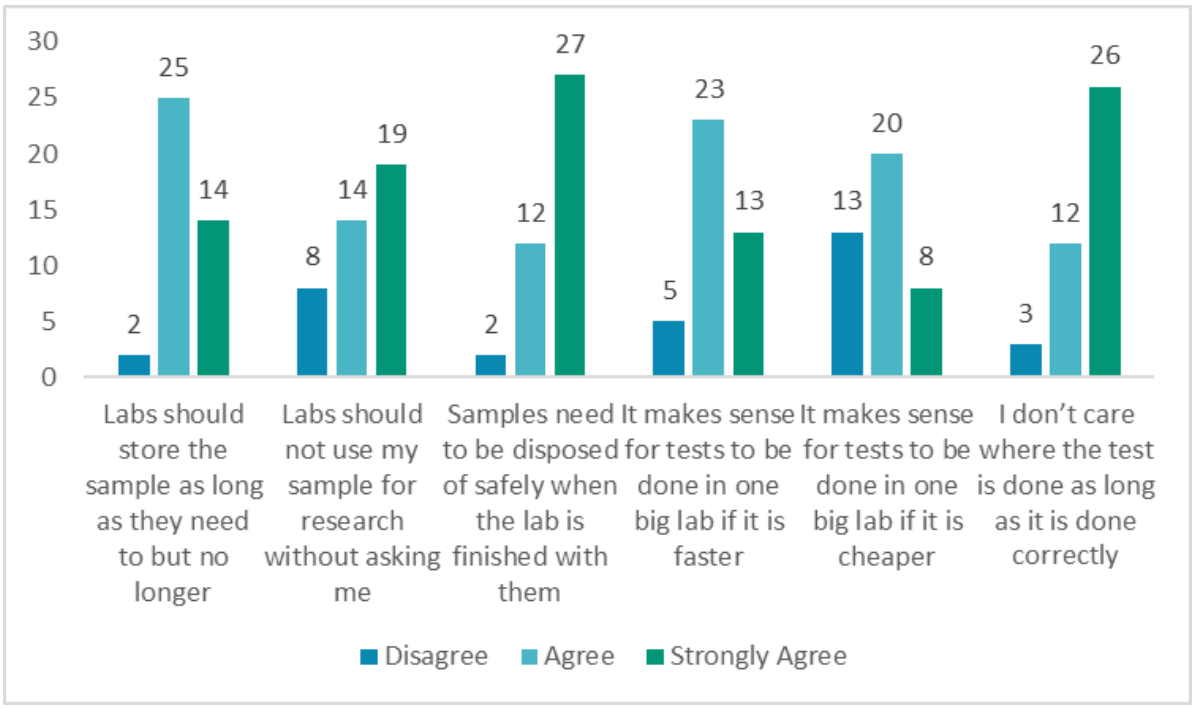
Imagine that your result has been sent to your GP. What is your level of concern in relation to each of the following statements.

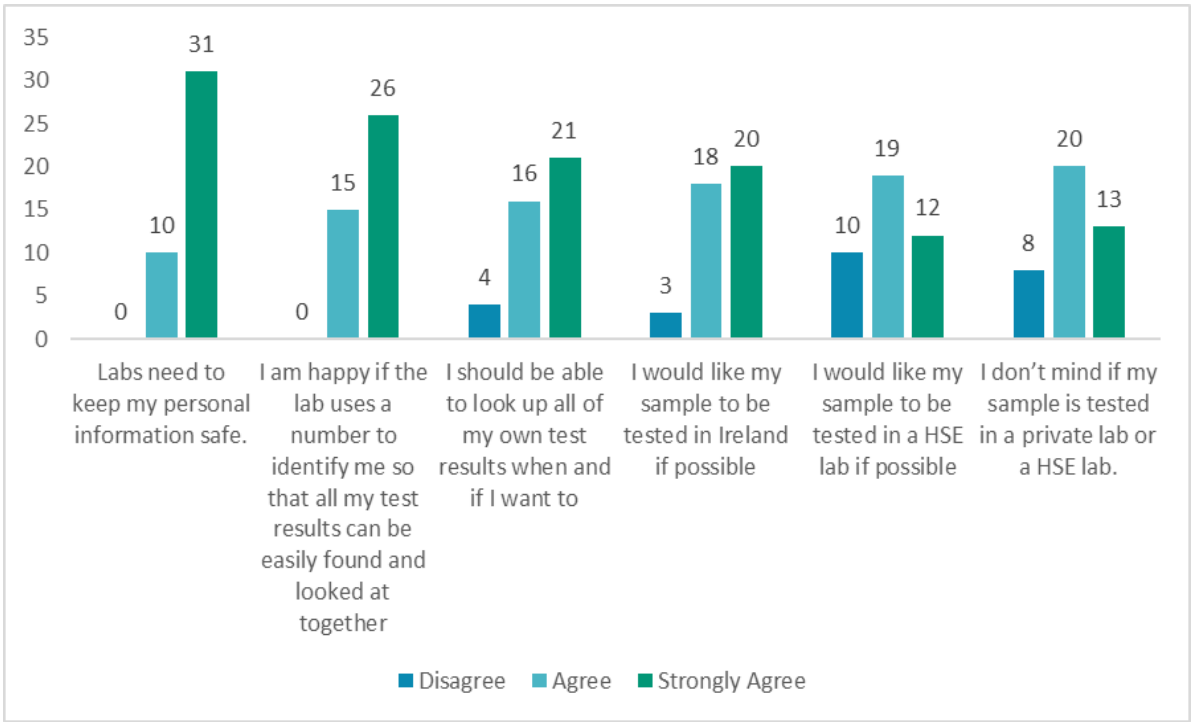


Please indicate your level of agreement with the following statements:

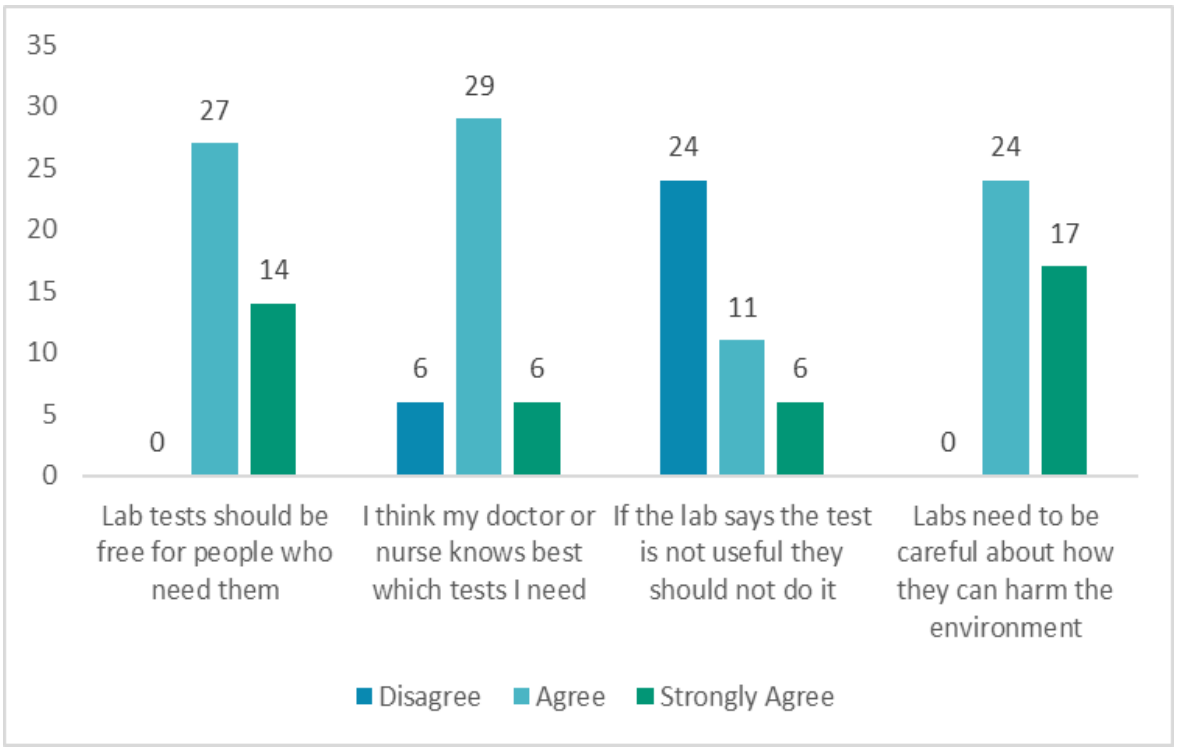


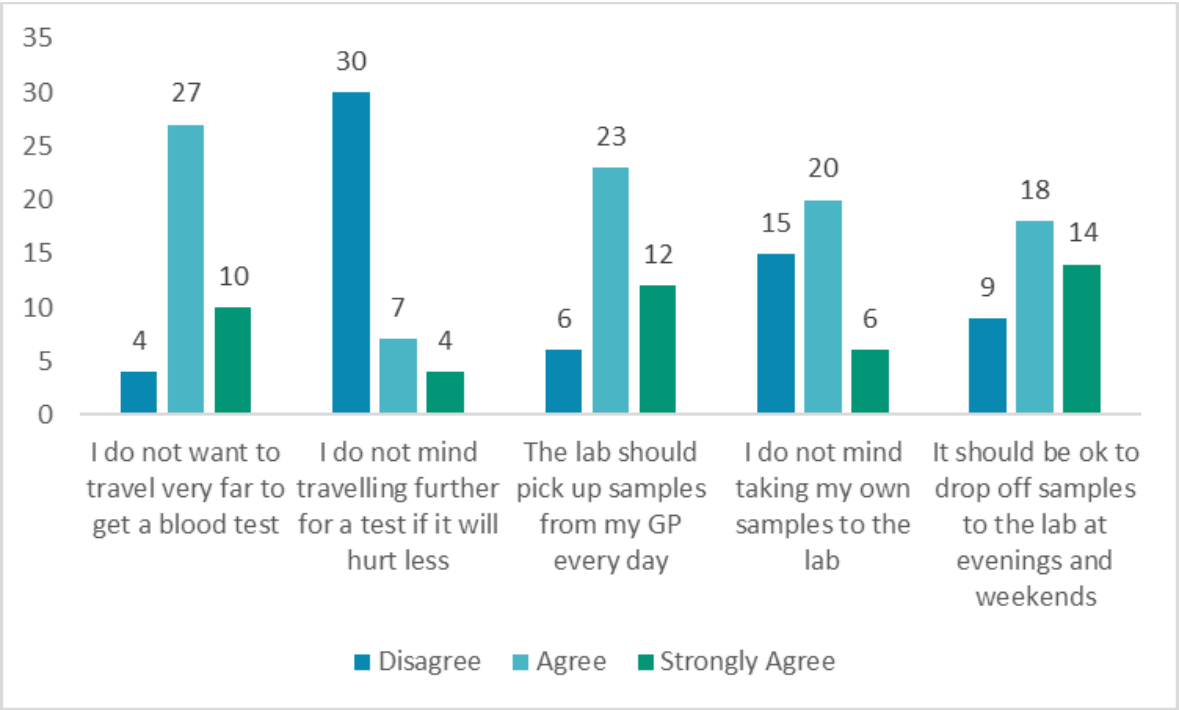
Please indicate your level of agreement with the following statements (cont):



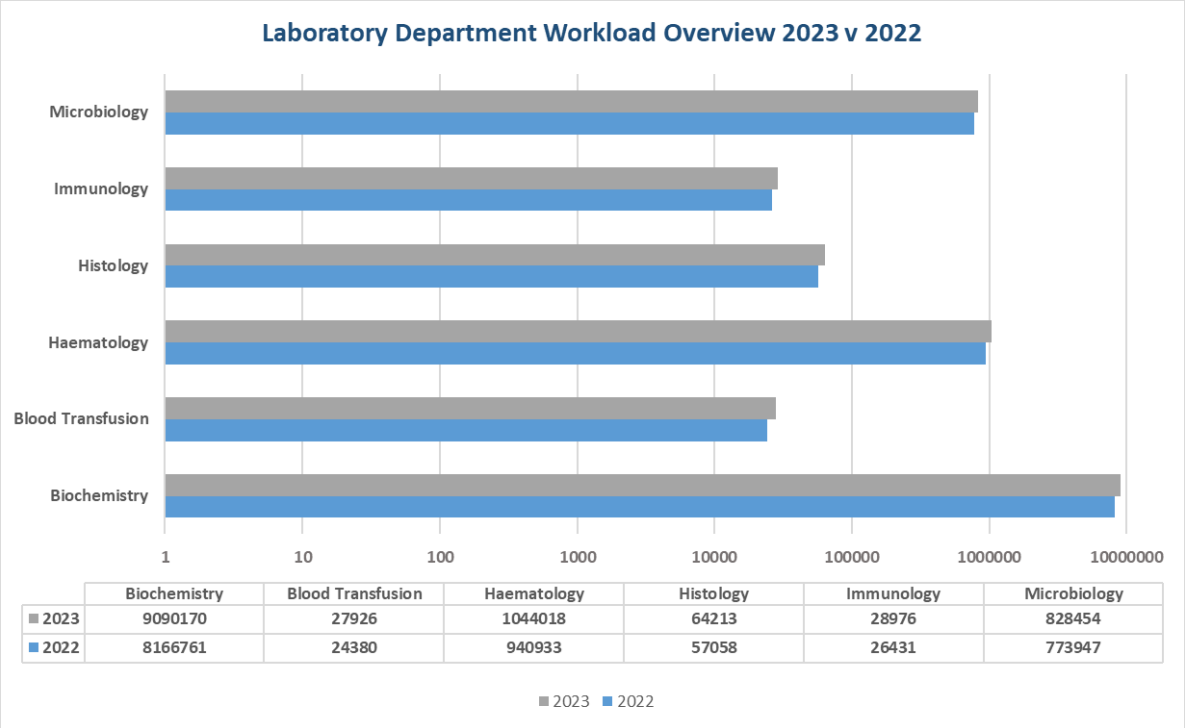


Please indicate your level of agreement with the following statements (cont):

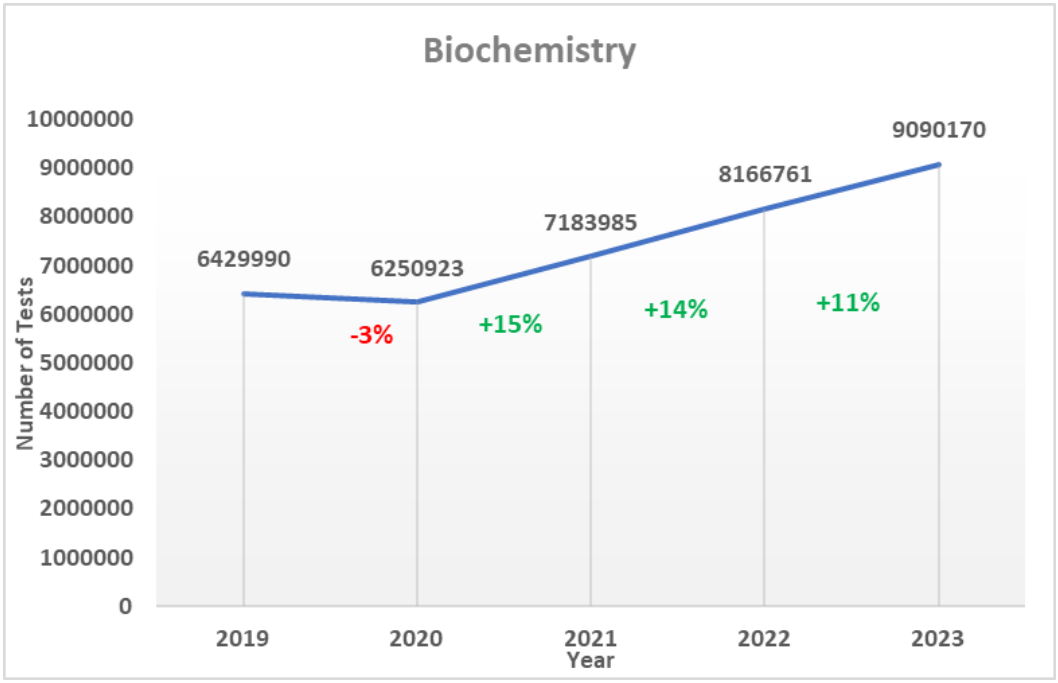


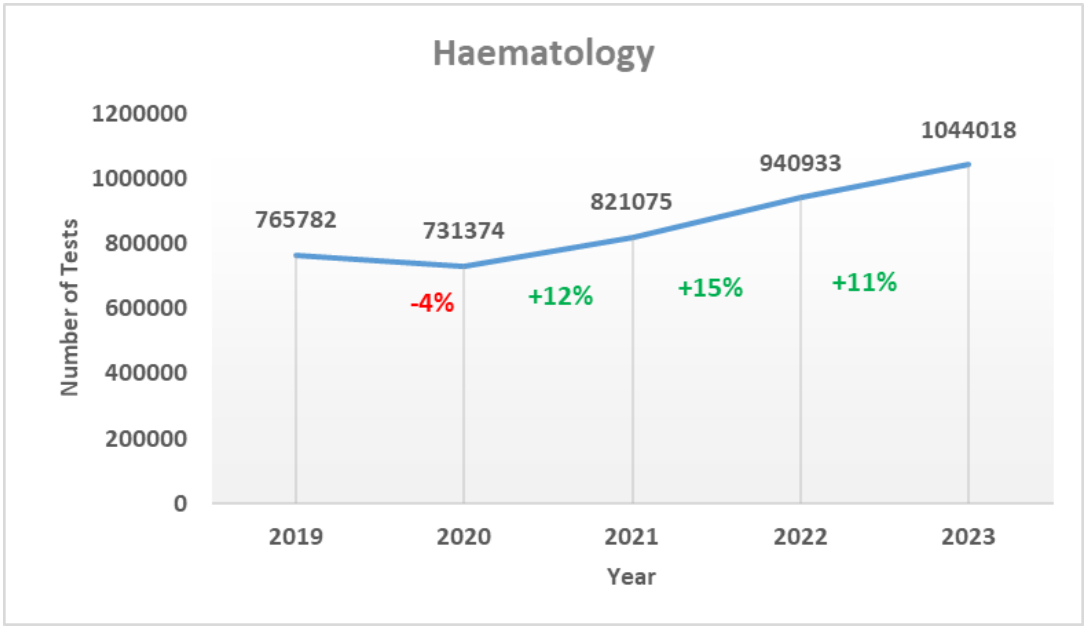


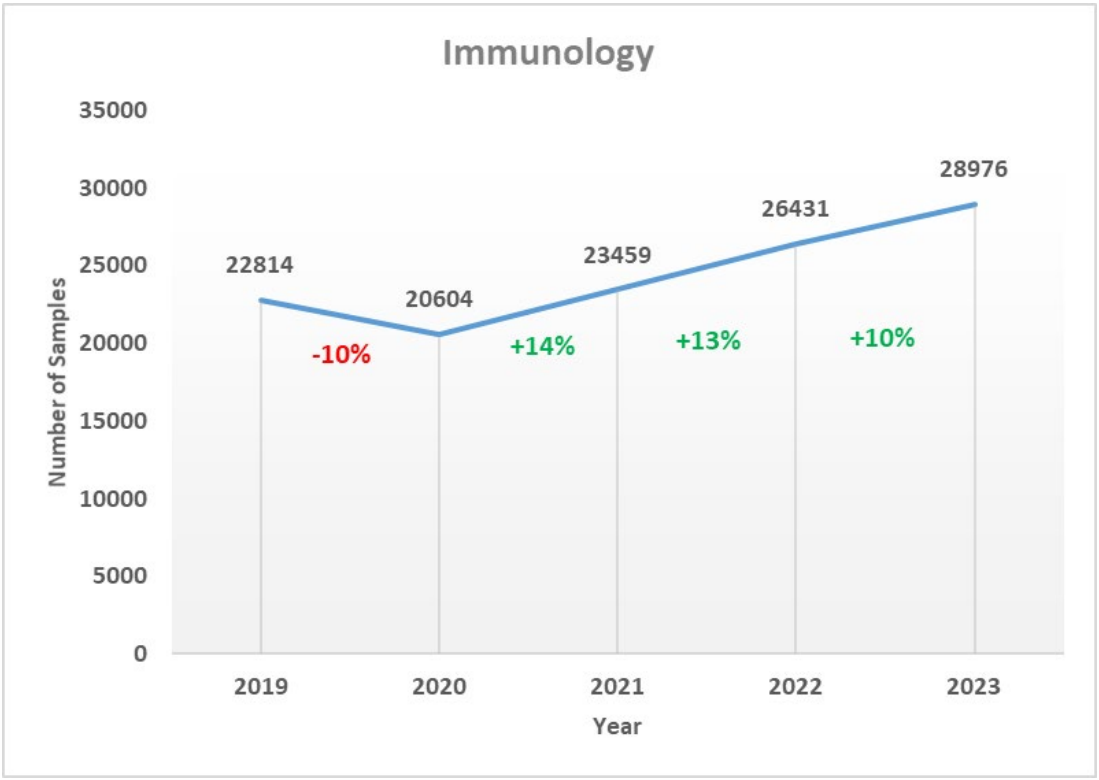
Appendix 4 – Workload Report (University Hospital Waterford)

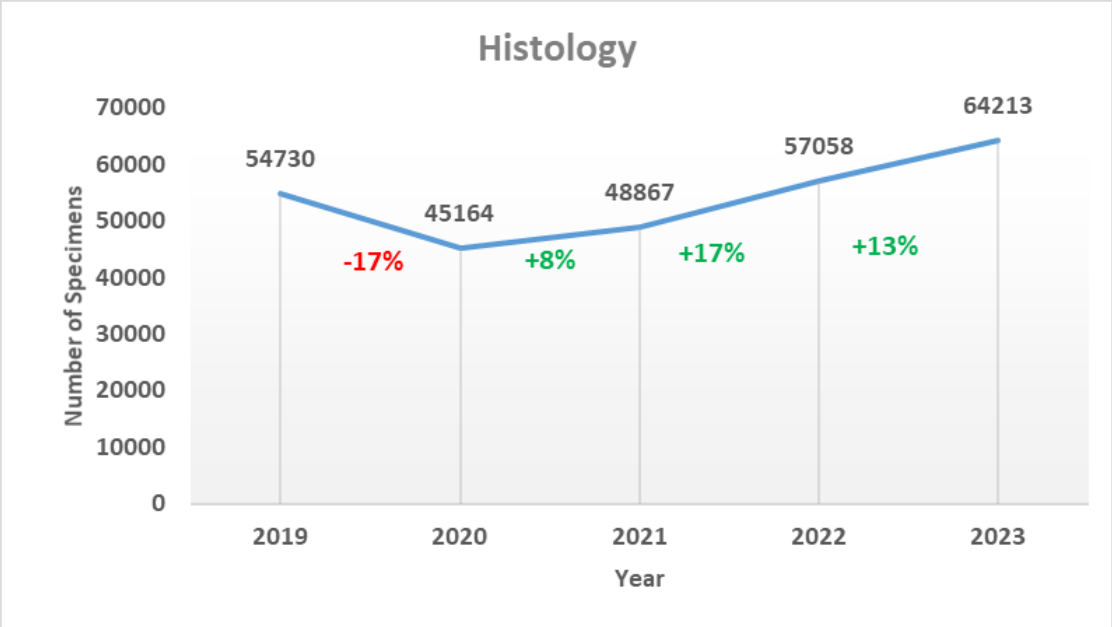


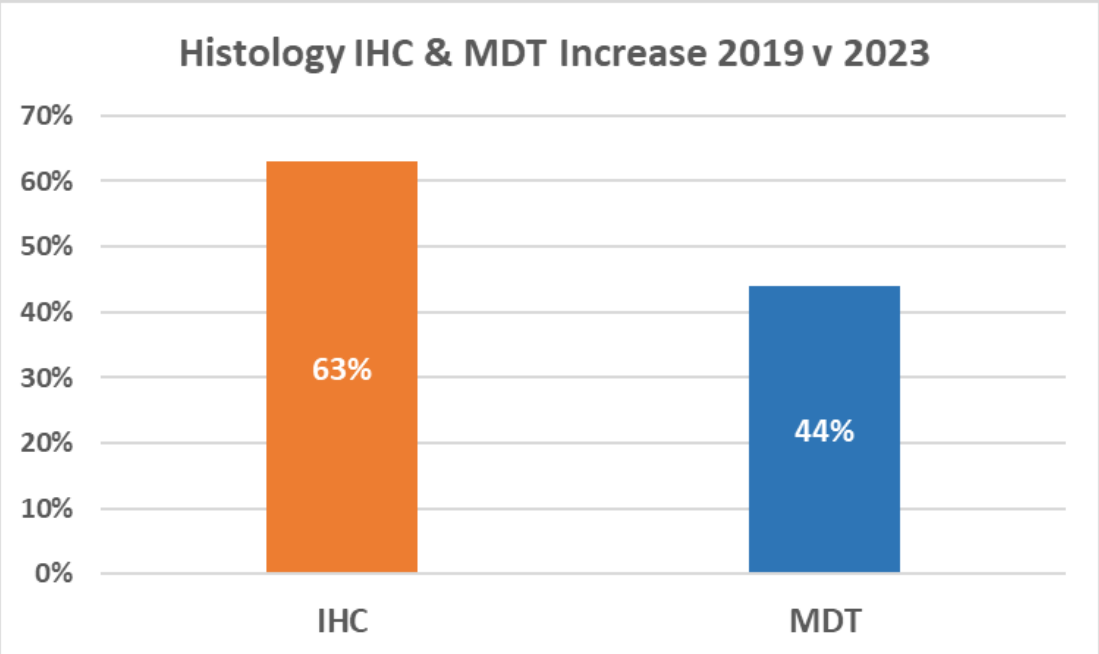
	Biochemistry	Blood Transfusion	Haematology	Histology	Immunology	Microbiology
2023	9090170	27926	1044018	64213	28976	828454
2022	8166761	24380	940933	57058	26431	773947

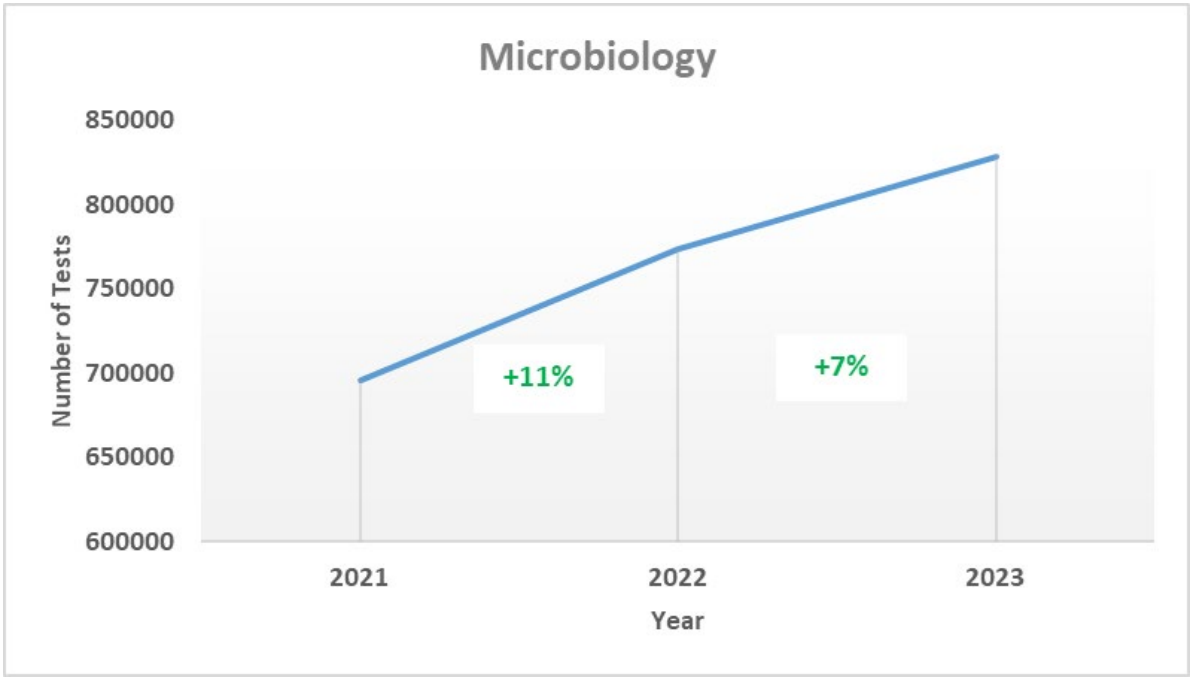


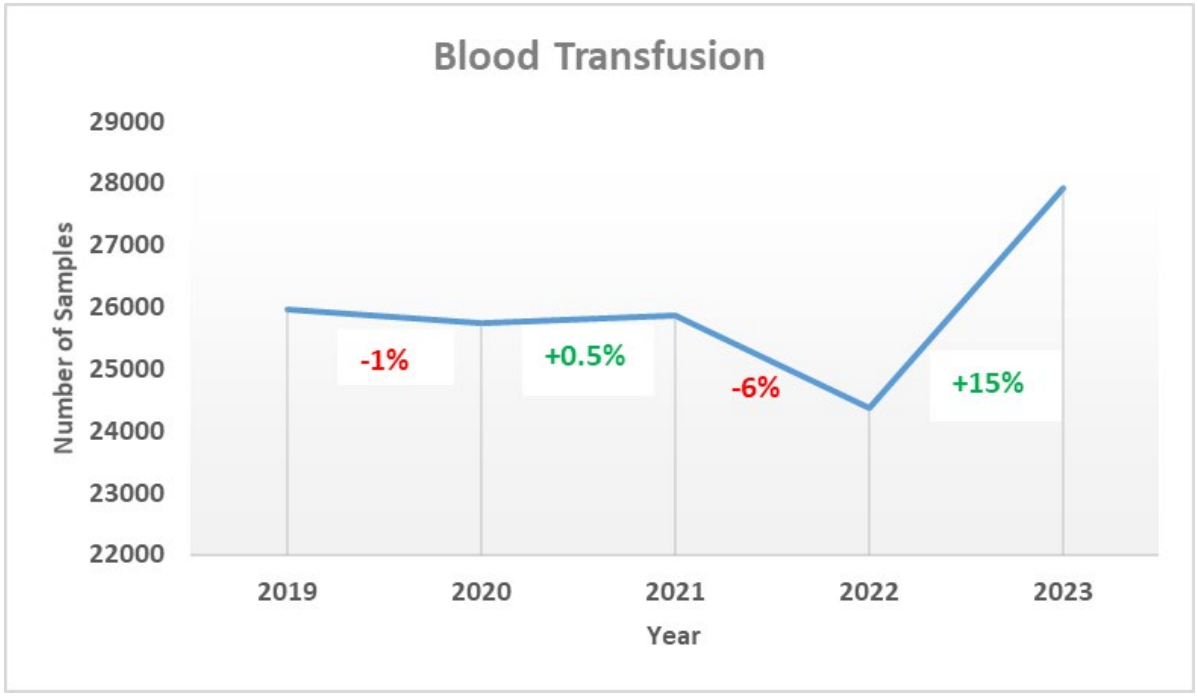

Haematology
1200000
1000000
800000
600000
400000
200000
0
Number of Tests
765782
731374
821075
940933
1044018
-4%
+12%
+15%
+11%
2019
2020
2021
2022
2023
Year

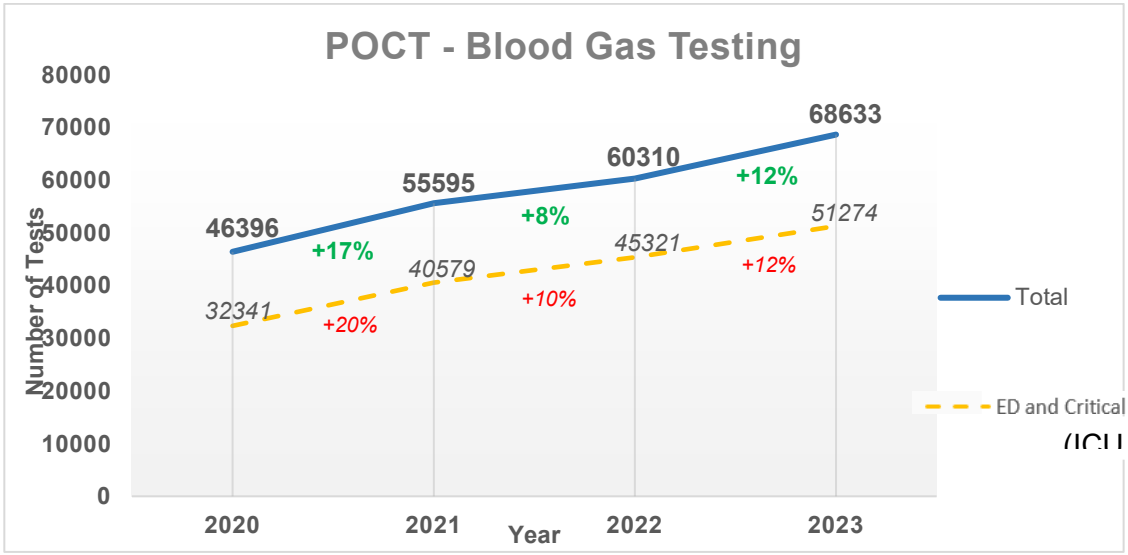

Immunology
35000
30000
25000
20000
15000
10000
5000
0
Number of Samples
22814
20604
23459
26431
28976
-10%
+14%
+13%
+10%
2019
2020
2021
2022
2023
Year


Histology
Number of Specimens
70000
60000
50000
40000
30000
20000
10000
0
54730
45164
48867
57058
64213
-17%
+8%
+17%
+13%
2019
2020
2021
2022
2023
Year

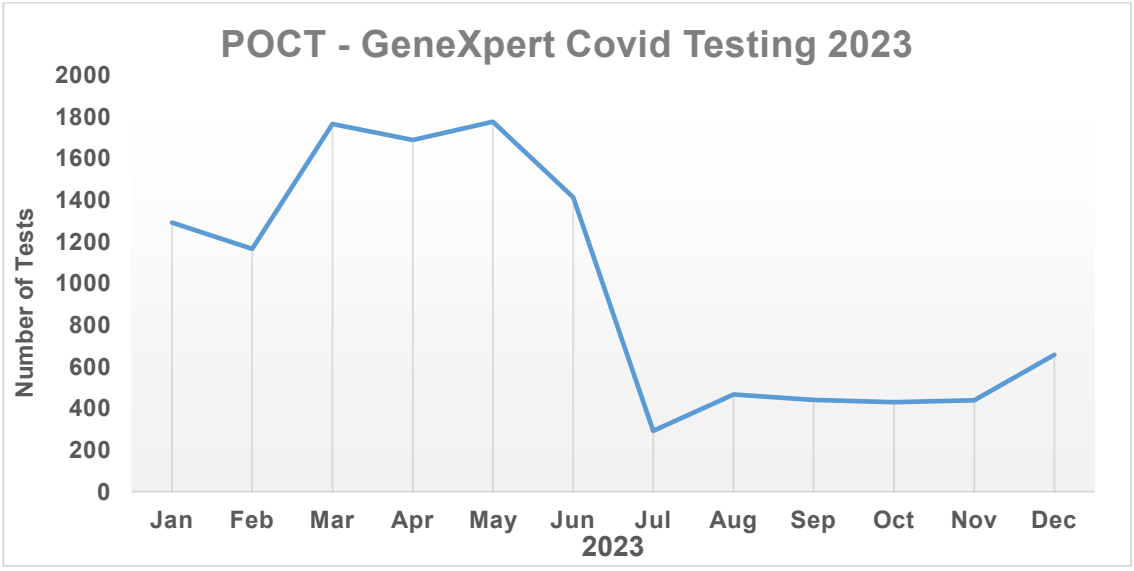

Histology IHC & MDT Increase 2019 v 2023
70%
60%
50%
40%
30%
20%
10%
0%
63%
44%
IHC
MDT


Microbiology
850000
800000
750000
700000
650000
600000
Number of Tests
+11%
+7%
2021
2022
2023
Year


Blood Transfusion
29000
28000
27000
26000
25000
24000
23000
22000
Number of Samples
-1%
+0.5%
-6%
+15%
2019
2020
2021
2022
2023
Year



– Total Blood Gas numbers = **68,633** in 2023, indicating a **12%** increase since 2022, and a **37%** increase since 2019. ED and Critical Care account for biggest increases.



- Total GeneXpert Covid/Flu numbers = **11,830** in 2023.

- Increased activity in the hospital and record numbers being seen in ED due to Wexford hospital closure, and continued COVID, Flu and RSV demands account for the increased workload across Blood Gas and GeneXpert testing.
- All other POCT devices are unconnected – unable to determine estimated workload.