

## **HSE Strategy for Laboratory Services 2025-2029 [Outline Draft Recommendations]**

### **Pathology – Partnership in Patient Care**

#### **Context**

This strategy builds on the foundation of the work captured in the “Review to Inform the Strategic Direction of Laboratory Medicine” published in January 2024. That document presents a comprehensive description of the status, opportunities and challenges for HSE and HSE funded laboratory medicine services from the perspective of the professions working in those services. In addition this strategy 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. As the detailed background for most HSE laboratory services are described in those documents, this document is a concise document focusing on recommendations for the future of laboratory services. The detail of current services, opportunities and issues addressed in the documents referred to above are not repeated in detail here.

The approach to developing this strategy was to focus on the kind of service that can be expected to deliver the best clinical and value for money service for patients and the public. There is considerable scope to improve patient services within the envelope of existing resources through elimination of duplication, improved organization and innovative approaches. It is possible to achieve improved equity of access, reduce environmental impact and ensure a service that is more resilient in the face of challenge such as public health emergencies or cyberattack. The changes required to achieve this will provide a more rewarding working environment and greater professional opportunity for those who will implement the change and deliver the service. Realising the gains available from better organization, leaner working and advances in science, automation and information technology requires investment in buildings technology and in people.

Change brings challenges and concerns as well as opportunities. Some changes proposed in this strategy ask stakeholders in the laboratory services to consider significant change in established roles and work practices. The strategy will require ongoing engagement with all stakeholders to develop and deliver an implementation plan that can deliver on the recommendations.

## **Brief background to HSE and HSE Funded Laboratory Services**

The HSE and HSE funded laboratory services include clinical diagnostic laboratory services, screening services, reference laboratory services, public health microbiology laboratories (incorporating the Official Food Microbiology Laboratories/OFMLs) and Public Analyst Laboratories (PALs).

Clinical diagnostic laboratory services are provided from 42 hospital-based laboratories. The current pattern of service organisation largely represents organic development to support local hospital and community needs. The laboratories vary in size from fewer than 10 staff to hundreds of staff with great variation in the scope and hours of services provided. Most laboratories operate to the ISO15189 (clinical) or ISO17025 (non-clinical) quality standards. Laboratory services are provided by multidisciplinary teams including Administrative Staff, Biochemists, Clinical Scientists, Medical Scientists, Pathologists, Phlebotomists, Public Analysts and Technicians and Surveillance Scientists. These multidisciplinary teams have consistently delivered on service to patients and service modernisation over many years and showed commitment and resilience in the face of the recent pandemic and cyberattack.

The process of sample collection is important to patient comfort and welfare. In some cases, the collection of samples can be a cause of considerable distress for example if repeated attempts are taken to collect a blood sample. The quality of the sample received by the laboratory is fundamental to the quality of the laboratory service. Sample collection, including phlebotomy, is performed by a wide range of health care workers including medical and nursing staff and Phlebotomists. In some cases, the healthcare worker collecting the sample may have limited skills and experience in collection of particular sample types resulting in avoidable discomfort and inadequate samples. The HSE has a cadre of skilled phlebotomists who are expert in collection blood samples of suitable quantity with the minimum of patient discomfort. Building capacity of and broadening access to an expert phlebotomy service offers an opportunity to support medical and nursing staff by reassignment of tasks, to improve patient welfare and the quality of laboratory services. The opportunity to broaden the sample collection service to other sample types should also be considered.

A key aspect of the quality of laboratory services for patients and laboratory users is the time between sample collection and reporting of the results of tests performed (turn-around time/TAT). The TAT required differs by the test requested and the context in which it is requested. For example, the TAT required for serum potassium level may be minutes for some patients in a critical care setting whereas the required TAT for the same test in other contexts may be 24 hours.

There are many opportunities for HSE laboratory services over the coming years. There are scientific and technical advances that provide opportunities to improve detection and management of disease, to stimulate the interest of those currently working the service and attract the next generation. Enhancements of automation and information technology, including digital pathology and artificial intelligence, have the potential to transform service delivery. Organizational change, in particular the move to integration of care in the new Health Regions offers the opportunity to redesign service delivery. 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.

The HSE laboratory services also face many challenges now and over the next five years. Recruitment and retention of staff with the mix of skills required to deliver the service is a key challenge. There is wide variation in clinical laboratory facilities with many services operating from buildings that are not configured and cannot be configured to support modern laboratory services. Laboratories operate laboratory information systems with variations in the systems in use. In many cases, the limits of the laboratory information systems and order communications systems constrain the ability to streamline services, eliminate duplication and make better use of data for planning and policy and health protection. For historical reasons almost all clinical laboratory services are funded and operated primarily as units within an acute hospital although the demands on them for service from the community are often as great or greater than the demands of the hospital in which they are based.

HSE laboratory services also include important structured screening programmes such as the long established newborn infant screening programme, screening for cancer of the uterine cervix and colon cancer. It is likely that emerging technologies will provide additional opportunities for evidenced based structured screening programmes that will improve the health and life expectancy of the population and potentially reduce healthcare costs. On the other hand, managing expectations related to ad hoc “screening” practices that are not part of established evidence-based screening programmes represents a significant challenge. Laboratory testing of healthy people in the absence of evidence that the criteria for an effective screening programme are fulfilled diverts resources from other services and has potential to do harm rather than good.

The term Reference Laboratory Services is somewhat difficult to define. Essentially a reference laboratory provides services primarily related to samples referred from other laboratories as distinct from samples referred directly by laboratory users. There are a limited number of formally established reference laboratory services in Ireland, mostly in the discipline 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. There are several discrete services for individual pathogens distributed over several sites. There are also significant reference laboratory services within Ireland for domains other than microbiology where clinical laboratory services have developed specialised capacity, for example in human genomics, and have agreed to undertake work for other laboratories. However, these services have often not been recognised and funded as national services. In addition to reference laboratory services provided within Ireland, there is significant dependence on specialised testing in other countries. For historical reasons relationships with the United Kingdom are particularly important in this regard. At present, there is also a critical dependence on capacity in the USA for the national cervical cancer-screening programme although work to grow capacity in Ireland is progressing. It is worth noting that certain provisions of the in vitro Diagnostic Medical Devices Regulation may increase the impetus to reduce dependence on service providers outside of the EU.

There are seven public health food and water microbiology laboratories. These laboratories serve a key function in delivering on the OFML obligations of the HSE contract with the Food Safety Authority of Ireland. The OFMLs are essential to support the FSAI in protecting the population of Ireland from food borne infection and in protecting the reputation of food produced in Ireland abroad. In addition to testing food samples in their capacity as OFMLs the public health food and water microbiology laboratories also, provide testing of water samples to support compliance with the EU bathing water directives and to monitor the safety of water supplies in health care settings. For historical reasons, these services function in most cases as units within or associated with hospital based clinical microbiology departments.

There are three Public Analyst Laboratories 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 and medicinal products. These services help to assess compliance with EU requirements and to identify non-compliance. The PALs are based in Cork, Dublin and Galway and have functioned within community services in the former HSE structures. 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.

### **Non HSE Laboratory Services and related services**

There are a large number of private laboratory service providers in Ireland providing clinical and non-clinical laboratory services. Services are provided 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 specialised testing. These arrangements for service with private providers tend to be based on agreements at individual laboratory level taking in the context of local circumstances and capacity. There is little coordination or oversight of arrangements with private providers at regional or national level.

The HSE laboratory services are also critically dependent on private services for logistics of sample transport between HSE and HSE funded laboratories and to private providers.

### **Some Terms used in this report**

**Hospital Laboratory Service** refers to a laboratory based on a hospital or other health service campus and managed as part of that hospital to serve that hospital. It may also provide community, regional or national services by agreement with the Health Region or national service. Hospital laboratory services will encompass near patient testing in that hospital.

**Health Region Laboratories** refers to laboratory services designated as such by the Health Region to support care in the hospital and community for that region. A Health Region Laboratory Service may be delivered by agreement with a Hospital Laboratory or from separate Laboratory Building. The Health Region Laboratory Service may provide reference laboratory services (that are not provided at national level) for that region and should provide governance and support for community based near patient testing that is delivered as part of the regional plan for laboratory services.

**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. A National Reference Laboratory Service (NRLS) may be delivered by agreement with a Hospital Laboratory or Regional Laboratory Building or from a future HSE Central Laboratory. 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.

### **Key principles guiding the HSE Laboratory Strategy**

1. HSE Laboratory services should adapt on an ongoing basis to support and to drive the agenda of healthcare reform to provide integrated care and support the function of the Health Regions.
2. HSE should continue to provide clinical and non-clinical laboratory services to support decision making in patient care, screening for disease, surveillance, public health purposes and policy formulation

3. HSE considers laboratory services as a core health service function that should be delivered by HSE operated services to the greatest extent that is practical taking account of service quality, turn-around-time and cost.
4. HSE considers that laboratory services should generally be provided by services that are integrated in a manner that links with where the person is cared from and across the patient journey in primary, community and residential/hospital/hospice care. Service quality, integration and sustainability are key elements in decisions regarding the degree of centralisation versus decentralisation of services. Centralisation is not an end in itself.
5. HSE provides 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 comprehensive services to General Practice is a key part of the service.
6. Access to HSE clinical laboratory services is based on need and clinical or public health priority and not on ability to pay. Laboratory services may be provided to private healthcare providers under contract/service level agreement provided this does not limit access or impact on turn-around times for HSE, HSE affiliated and other publicly funded services.
7. The goal is to provide equitable access to essential laboratory services that are quality assured, are delivered when and where needed and in an environmentally and financially sustainable way. This approach reflects the value proposition of the strategy.
8. The HSE seek to discourage inappropriate and unnecessary testing as this can be harmful to people tested and is contrary to the goal of a sustainable health service.
9. Effective use of information and communications technology is fundamental to the delivery of an effective and sustainable laboratory service and to support surveillance of communicable and non-communicable disease.
10. Given the sensitivity of much of the data, managed laboratory services must comply with legal obligations with respect to data protection
11. Samples such as tissue and body fluids collected from people should be transported, stored, processed and disposed of in a manner that is respectful and consistent with good practice.
12. Where consolidation or centralisation is required to improve patient services it is expected that this can be achieved in a manner that avoids or minimises relocation of staff through use of remote working from an existing base and relocation of posts (and associated workload) as posts fall vacant.

## Recommendations

### 1. Quality

- a. All HSE laboratories and near patient testing services should operate a quality management system consistent with appropriate standard such as the EN ISO 15189 (2022) or EN ISO 17025 standard.
- b. Clinical laboratory services on a single site should operate a single quality management system for all disciplines provided on that site. In addition, it is appropriate for smaller laboratories that operate within a laboratory network/unit to be included in a network wide quality management system whenever practical do so.
- c. Achievable, context specific, HSE target turn-around-times (TATs) should be specified for common and critical laboratory services. These targets should be defined by clinical requirements rather than current capacity. HSE laboratories should measure their performance against those targets and report their performance to users of laboratory services.
- d. Context specific retesting intervals for tests should be defined where appropriate.

### 2. Workload management

- a. The HSE laboratory service should provide services to those healthcare practitioners registered to practice in the jurisdiction of Ireland who are eligible to request HSE laboratory services. Those healthcare practitioners for whom registration is not currently available should also have access to HSE laboratory services within their scope of practice if they are working within the HSE or other public services (cite here the HSE Guidance on Access to Laboratory Services that will be published soon Draft in Appendix 1).
- b. Each laboratory service unit (one site or multisite) should have a Clinical Director and laboratory manager to manage the overall service.
- c. Within the laboratory service unit each major clinical laboratory discipline (such as clinical biochemistry, haematology, histopathology, immunology, microbiology, transfusion) should have an appropriately qualified person identified as clinical lead for that discipline with the authority and responsibility to manage that element of the service and to account for it to the clinical director. The discipline clinical lead will be a Consultant Pathologist or Scientist with appropriate training and competence in the discipline concerned. The discipline lead should account to the Clinical Director for range of services provided taking account of relevant national guidance and practice norms.

- d. The Clinical Director of the laboratory unit, in consultation with the laboratory manager, discipline clinical leads, laboratory users and senior managers and taking account of relevant guidance should determine the requirements (sample type, clinical details) for access to testing including limitations on access and criteria for sample rejection.
- e. The Clinical Director, Laboratory Manager and discipline clinical lead should ensure that information on the range of services provided, requirements for tests and target TATs for key tests are readily accessible to users of laboratory services.
- f. Laboratory services to General Practitioners registered to practice in Ireland should be provided as provided for in the 1970 health act.
- g. All users of laboratory services practising outside of HSE or HSE associated facilities 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 (cite document on Access to Laboratory Services).
- h. Services that are provided by HSE laboratory services 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.
- i. Where demand exceeds service capacity the Clinical Director of the laboratory unit in consultation with the Laboratory Manager and discipline leads should have the responsibility and authority to identify to users of laboratory services which services must be curtailed to ensure that the quality of the service is not compromised by the volume of samples submitted.
- j. If service restrictions are necessary they should be communicated in the first instance to relevant senior management and then to laboratory users. Service restrictions should be based primarily on clinical need and take account of relevant national standards and guidance. Service restrictions should not be based on prioritisation of one hospital over others or prioritisation of one geographical area served by the laboratory over other hospitals or areas served. Prioritisation cannot be based on an assumption that tests submitted from the community are of lower priority than samples submitted from the hospital setting.

### **3. Sample Collection Services**

- a. Laboratory services should develop or extend phlebotomy services for hospitals as part of the laboratory service and within the laboratory governance.



b. Blood sample collection should be performed by phlebotomists with requisite skills in communication with the patient regarding the process and the collection of high quality samples with minimum discomfort for the patient.

c. Laboratories 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.

d. Laboratory services should provide access to phlebotomy services for patients referred by their GP service on the basis that it is particularly difficult to collect adequate blood samples from the patient.

#### **4. Organisation**

##### **4.1 Services to support care in the community**

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

b. Laboratory services for people cared for in primary and community care should have the same priority as laboratory services for people cared for in hospital. Although the clinically required turn-around-time is context and test specific, services for people cared for in primary and community care should be recognised as equal in priority with services provided to people cared for in hospital.

c. Laboratory services for people cared for in primary and community care 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 people cared for in primary and community care should be provided in a way that ensures that all laboratory requests can be made electronically (order communications). Results should be reported electronically and be accessible to the healthcare worker and be comparable whether the person is being cared in the community or the hospital.

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

f. Laboratory services for people cared for in primary and community care should include effective logistics for safe, efficient and timely collection and transportation of samples taken in the community to the laboratory.

g. Laboratory services for patients cared for in primary and community care should be provided by a laboratory in a conveniently located hospital laboratory where the community service provided in this location meets the needs of people cared for in the community. This approach supports integrated service delivery across patient journeys.

h. Laboratory services for patients cared for in primary and community care should be provided by a laboratory service that is separate from the nearby hospital (for example from a Health Region laboratory) if the nearby hospital laboratory does not meet the needs of the service, for example if it cannot achieve appropriate TATs.

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

#### **4.2 Services to support care in the hospital**

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 accessed and delivered.

b. The planning and delivery of laboratory services for patients in hospital should take account of 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 impact of the range of services and turn-around-time on patient flow through Emergency Departments and facilitation of patient transfer and discharge.

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.

#### **4.3 Services to support Clinical Programmes**

The HSE has a growing number of national clinical programmes that provide for integrated care of patients. The planning of care by these national integrated programmes with regard to their use of clinical diagnostic laboratory services should ensure that the laboratory capacity to meet the demands of the integrated care service can be met.

### **5. Clinical Laboratories including Reference Laboratories**

a. Clinical laboratory services should normally be delivered as an integral part of the HSE. Outsourcing should be considered as 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. In that case, 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 must be adhered to.

b. The HSE Laboratory Services should be structured in three levels (1) hospital level, (2) Health Region level and (3) National level.

### **5.1 Hospital Level Laboratory Services**

a. A menu of laboratory services defined as core for that hospital in the context of the services provided at the hospital should normally be delivered by an on-site hospital level laboratory or near patient testing service. This is to support rapid turn-around time and to ensure that the core laboratory service team are integrated as partners in delivery of care. Other services should be delivered from a Health Region or national service if this meets clinical requirements in a cost-effective and sustainable manner.

b. Efficient arrangements for exchange of information (electronic) and transport of samples between laboratories should be in place to achieve effective integrated function of hospital level, Health Region and National services as a network.

c. Small scale hospital laboratory services providing services that must be provided at hospital level to achieve clinically acceptable turn-around time should be managed and governed as spokes of a laboratory service unit based on a larger hub laboratory service unit. The hub laboratory may be a larger hospital laboratory or the Health Region laboratory. (For this purpose, laboratories with about 50 staff or less are considered small scale).

d. Centralisation of testing at national and regional level from hospital laboratories is appropriate where it supports the delivery of the quality and turn-around-time required with significant benefits in terms of efficiency and cost or reduced environmental impact.

e. Centralisation of laboratory services at regional or national level from hospital laboratories should not compromise quality of preparation and processing of samples, discipline specific medical and scientific interpretation of results, the generation of an integrated report or the role of laboratory services and teams as an integral element of patient care.

### **5.2 Health Region Laboratory Services**

a. Each Health Region should have an identified Medical (Consultant Pathologist) and Scientific (Laboratory Manager) Lead for laboratory services in the Health Region to coordinate the work of all the laboratory service units in the Health Region.

b. Health Region laboratory service units should have robust systems for liaison with Regional Departments of Public Health to support use of laboratory data in surveillance of communicable and non-communicable disease.

c. The Health Region will determine the number of sites at which each laboratory service should be delivered. This should take account of the advice of the Medical and Scientific leads regarding clinically required 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.

d. Health Regions should identify which laboratory services should be delivered at by a single regional service. 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.

e. 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 and where the service has not been designated for national service provision. 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 duplication.

### **5.3 National Laboratory Services**

a. An integrated National Reference Laboratory Service (NRLS) should be established to manage and deliver specified laboratory services in all laboratory disciplines (not limited to infection) as an integrated national service for all HSE and HSE associated services.

b. National Reference Laboratory services should encompass all laboratory disciplines and should provide clinical, technical and IT support for Health Region services, hospital laboratories and Public Health in addition to sample processing. 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.

c. The NRLS should be directed by a Consultant Pathologist working with a multidisciplinary medical and scientific team and reporting to the National Director of Public Health as an integral element of Public Health capacity for surveillance of all hazards, planning and emergency response.

d. The NRLS should be funded and managed at a national level as an integrated service designed to meet the needs of the Health Protection and emergency planning and response functions.

e. A multidisciplinary HSE Central Laboratory should be developed. This should be located to support road and rail and public transport links with all areas of the country and therefore is likely to be in the greater Dublin area.

f. The HSE Central laboratory should provide a base for the National Reference Laboratory Service (above), for the National Genetics and Genomics services and other key national services. The HSE central laboratory should also accommodate other laboratory services in the East Coast area for example the Dublin Public Analyst Laboratory and laboratory services currently delivered from the Cherry Orchard campus. Some NRL services may be provided by agreement between the NRLS and one or more Health Region laboratories or Public Analyst Laboratory Services.

g. In addition to confirmatory services for other laboratories, the HSE Central Laboratory should provide a hub for high throughput automated processing of certain sample types and of data to provide services and or surge capacity for Institutional and Regional Laboratories with processing of material and generation of data. This should include capacity to generate images for digital pathology and files of sequence data for further analysis. h. The HSE Central Laboratory should work closely with other 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.

i. Health Regions and hospital laboratories may provide national reference services if this is governed by a service level agreement with the HSE NRLS. Laboratories may not self-designate as national services.

j. Laboratory services for delivery by the NRLS should be designated by the office of the CCO based on medical and scientific advice from the relevant National Clinical Programmes and other clinical strategies/programmes such as the National Cancer Clinical Programme and the National Women’s and Infant’s Programme. This should be reviewed regularly to take account of changing needs and technology.

k. In general, laboratory services should be considered suitable for delivery by the NRLS if the clinically required 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 (2) the total volume of service required at Health Region level is low to moderate (3) there is a significant quality or cost benefit associated with centralised provision.

l. Specialised services required from other jurisdictions should be organised and procured at national level with access through the national laboratory services. With roll out of the Individual Health Identifier number, this will help minimise redundancy in testing and with appropriate IT and logistics this should not compromise turn-around-times.

m. Under governance of the Director of the NRLS, the HSE NRLS and Health Region Laboratories will 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.

## **6. Non Clinical HSE Laboratories and Non HSE Public Laboratories**

a. In keeping with the report “HSE Microbiology Reference Laboratories and HSE Food and Water Microbiology and Virology Reference Laboratories Review” of February 2022 unified governance should be provided for these services as soon as is practical. In the context of this strategy, the governance for that integrated service should be expanded to include the Public Analyst Laboratories. This will provide a nidus for development of the comprehensive National Laboratory Service recommended in this strategy.

b. The integrated National Public Analyst Laboratory service including the Official Food and Water Microbiology services should be managed by a National Lead Public Analyst at Assistant National Director Level.

c. Over the 5 years of this strategy the food and water microbiology laboratory service should be incrementally consolidated to three sites associated with the three public analyst laboratories in Dublin, Cork and Galway by the unified governance group referred to in 5a. Environmental testing (water, air and surfaces) required for monitoring in HSE healthcare facilities should be included in the remit of these laboratories with agreed context specific turnaround times.

d. The food and water microbiology laboratory service and PAS laboratory service should liaise closely with relevant hospital and clinical services regarding laboratory services required for monitoring the environment (for example water, clean rooms, air) in HSE healthcare facilities.

e. With respect to laboratory services not managed as a National service (for example testing of hospital water samples from washer-disinfector units), each site providing non-clinical analytical services should provide services for the Health Region in which they are based and

one other adjoining Health Region. Health Regions will agree on the mechanisms to share associated costs.

f. Non-clinical analytical services should be delivered at a single site where this has significant practical or cost benefits. Health Regions will agree on the mechanisms to share associated costs.

g. HSE should work with other state funded laboratory services related to testing of human samples (for example the State Laboratory, Toxicology Laboratory) to ensure that services support each other and minimise duplication of service provision and embed a “One-Health” approach in their work.

## **7. Infrastructure**

a. Hospital Laboratories should be based in secure permanent building that are designed and built with flexibility to facilitate install and operate high throughput automated systems and multidisciplinary working of teams. The building should address needs for security, rest and refreshment for staff working unsocial hours.

b. Hospital Laboratories should include a space within the laboratory proper or in the adjoining hospital where tests related to different disciplines can be provided as “stat-lab” services in particular out of hours. This will support team based delivery of critical services required on a 24/7 basis and will reduce personal security concerns associated people working alone for extended periods in isolated facilities overnight and at weekends.

c. Design of new or refurbished buildings for delivery of patient care services, in particular Emergency Departments and Critical Care Units should take account of the potential of near patient testing/”stat-lab”.

d. The HSE should develop at least one Health Region Laboratory in each of six Health Regions to provide those services that are designated by the Health Regions for provision at regional level. The Health Region Laboratories should be designed with surge capacity and ease of expansion to support the HSE Central Laboratory in response to a public health emergency

e. The HSE Health Region Laboratories should be co-located with a hospital site to preserve a clinical ethos and partnership in-patient care.

- f. The HSE Health Region 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.
- g. The HSE Central Laboratory and Health Region Laboratories 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.
- h. Public Analyst Laboratory infrastructure should be developed or extended as required to accommodate the broader service remit outlined in this strategy.
- i. The multidisciplinary HSE Central Laboratory should 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.
- j. The HSE Central Laboratory should be designed to provide capacity to redeploy space and expand footprint rapidly in the event of a public health emergency.
- k. The HSE Central Laboratory 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.
- l. The HSE Central Laboratory should accommodate NRLS other than any that may be agreed for delivery under SLA by Health Regions.

#### **8. Information Communication Technology for safe and efficient laboratory service delivery**

- a. All enhancements and changes to the digital environment within which laboratories operate should be carefully planned to ensure security and continuity of services
- b. Rollout of the national laboratory information system for clinical laboratories should proceed to all HSE laboratories. This should be achieved in three to five years depending on resource allocations
- c. Pending the full implementation of the national laboratory information system, laboratory information systems in Health Regions, should continue incremental progress. Where order communications technology is not present early rollout of the national system should be considered.



d. During the roll out period, any systems deployed in laboratories as interim measures, should be interoperable with the national laboratory information system to achieve the goals of access to patient results wherever the patient attends for care and use of laboratory generated data for health surveillance, planning and management including crisis response

e. The HSE will be deploying Electronic Health Care Records (EHR) in the future. Laboratory diagnostics should be integrated within the EHR for a patient. 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

## **9. Information Governance**

a. Information governance should be strengthened to 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 and appropriate mechanisms to deliver on this principle should be established so that the laboratory records can be readily accessible to the patient's chosen healthcare provider

b. Information governance arrangements should be established to ensure non-patient identifying laboratory information is efficiently shared between HSE and HSE funded healthcare service providers and with Irish or EU public health agencies to support surveillance and policy development.

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## **10. Automation and new technologies**

a. Automation offers potential 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

b. Automation of all stages of sample preparation and processing should be enhanced in all disciplines facilitated by developments in infrastructure, robotics and IT.

c. The opportunities to enhance automation of processes afforded by the use of digital pathology and artificial intelligence should be developed.

d. Managed service contracts for facilities and equipment have practical advantages and should be used as appropriate.

e. Opportunities to improve patient services and reduce cost through automated systems should not be constrained by traditional laboratory discipline boundaries. .

## **11. Staffing**

a. Consultant Pathologists and appropriately qualified scientists in each discipline should function as part of sub-regional or regional teams as appropriate to support the service. This should provide more equitable access to expertise, more resilient service to patients and more equitable and sustainable rotas for out of hours work. With appropriate IT and harmonisation of practice multi-site team service should not require frequent travel between sites.

b. The productivity of existing Consultant Pathologists and Specialist Registrars should be maximised by reassignment of tasks as appropriate. International experience has examples of success of enhancing skill of non-medical staff to take on tasks in sample processing, interpretation and reporting traditionally limited to medical staff. This aligns with general measures to review productivity across healthcare.

c. There should be equity of access to training and pathways for advancement for all scientists working in the laboratories. This should be supported by consolidating staff training structures and career pathways, grades and pay scales into one professional cadre/scale with differentiated levels that are applied consistently across the HSE and HSE funded services to reflect the skills, role and responsibility associated with the position.

d. At entry level scientific staff recruitment should include a mix of Medical Scientists (multidisciplinary training) and laboratory scientists (including but not limited to Biochemists) graduating from others honours level courses relevant to specific disciplines such as bioinformatics, clinical biochemistry, epidemiology, haematology, histopathology, immunology, microbiology, molecular biology and transfusion science.

e. Advancement from entry level Medical Scientist/Biochemist/Scientist to senior grades should, as at present, require a higher degree and specified experience and be based on a competitive process.

f. Advancement from senior grades to higher grades should be provided for Medical Scientists/Biochemists/Scientists in all laboratory disciplines and should be based on three pathways clinical, scientific and management (see section 12).

g. Advancement 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) with support for training programmes and costs.

- h. The HSE should define an expanded range of tasks that may be performed by Laboratory Aide staff subject to demonstrated competence. As at present, these post should not require an honours science degree in a relevant discipline for entry. This should assist in ensuring that the available Medical Scientists/Biochemists/Scientists can focus on tasks that require their existing skills and provide opportunities to develop new skills.
- i. With the exception of final review and authorisation, the range of task potentially assigned to Laboratory Aides (pre-processing and processing) should only be restricted by the requirement that they have demonstrated competency in accordance with EN ISO 15189 and that there is appropriate scientific or medical supervision of their work.
- j. Career progression for Laboratory Aides should be facilitated by competitive access to defined numbered training posts that support them in acquiring the qualifications that make them eligible to compete for entry to Scientist grade posts.
- k. HSE Laboratory services should develop a cadre of Engineers, Information Technologists and Administrative Support staff specialising in the optimal costing and delivery of laboratory services and working within the laboratory governance system to support the efficient operation and maintenance of the Central and Health Region Laboratories.
- l. HSE laboratory services should recruit and retain a sufficient cadre of permanent phlebotomy staff to provide the core service over an extended working day and weekends and to ensure supervision of temporary staff recruited to support the service.
- m. All HSE laboratory staff (medical, scientific and laboratory aide) working in a service that delivers an out of hours service should be required, as appropriate to the needs of the service and their competence, to contribute to the out of hours service as a matter of obligation. To ensure that the full range of essential services required is available 24/7 adequately staffed shifts should be established on a similar basis to other healthcare workers who provide essential 24/7 services.
- n. The staffing structures in Public Analyst Laboratories that are currently in place remains generally fit for purpose in the context of the broader remit of the PALs outline in this strategy.
- o. Public Health Food and Water Microbiology Laboratories should primarily recruit technical staff with education and skills that prepare them to work in food and water microbiology rather than Medical Scientists or other Scientists with education and skills that prepare them for work in Clinical Laboratory services.

p. Opportunities for training and development should be provided for staff of Public Analyst Laboratories and Food and Water Microbiology Laboratories similar to those provided for laboratory staff in clinical laboratories.

## **12. Education and training**

a. HSE laboratories should maintain and develop partnerships with third level institutions and professional bodies to support undergraduate and postgraduate education and training through contributions to the teaching programme and student placements

b. 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 Consultant Pathologist appointments.

c. Expanded opportunities for training to advanced practice for scientists within the HSE laboratory services should be provided consistent with the Health and Social Care Professions Advanced Practice Framework 2023. The opportunity to progress to autonomous practice, currently limited to Biochemists, should be available to all scientific disciplines. Scientists at this level will have gained competence to engage in unsupervised clinical scientific practice including independent scientific direction of laboratory services where this meets the requirements of the service.

d. The scientific training programmes for scientists in clinical laboratories and technical staff in non-clinical laboratories (Food and Water and Public Analyst) should make full use of EU funded training opportunities and should support training to doctorate level in specific scientific and data analysis skills relevant to the development and delivery of laboratory services.

e. The managerial training programmes for scientists in clinical laboratories and for technical staff in non-clinical laboratories should provide training including relevant qualification in health services management.

f. Participation in educational activities with partner institutions should be recognised as a part of the work of all laboratory staff. Staff should have protected time to participate in these activities assigned to them.

g. Given the importance of life-long learning, continued professional education is essential and should be supported for all laboratory staff.

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

i. 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.

### **13. Research, Innovation, Development and Audit**

a. Research, innovation, development and audit should be considered an integral part of HSE laboratory service delivery as essential to support improvement of service

b. All staff should be supported to participate in research, innovation development and audit as part of their work

c. HSE laboratories should develop partnerships with third level institutes, regulators and industry to support research, innovation and development.

d. With appropriate consent and controls, the HSE central and regional laboratories should consider the practicality of developing and maintaining a bank of material (biobank) for use in research and development

### **14. Financing of laboratory services**

a. HSE laboratory services should be financed by a laboratory services revenue budget clearly defined within the overall institution /governance unit that hosts the laboratory service unit. In most cases, the host institution will be a hospital or a group of hospitals that function as a laboratory service unit within a Health Region. The revenue budget should cover human resources, laboratory supplies, cost per unit managed service contracts and other laboratory specific services. This will support greater transparency in relation to costs of provision of laboratory services and ensure that service demand is managed within a defined resource.

b. HSE laboratory service units should have defined capital funding for acquisition of laboratory equipment based on the laboratory service priorities. This will support greater transparency in relation to costs of provision of laboratory services and ensure that service demand is managed within a defined resource.

c. Reimbursement on a fee for service model of diagnostic laboratory should not generally be adopted, as it tends to incentivise overuse of testing, undermine diagnostic stewardship, to and to detract from the view of laboratory services as partners in care as distinct from simply test providers.

- d. All new service developments proposed by the laboratory service unit or other clinical services should include a defined financial provision for each Health Region and laboratory service unit supporting the new service that becomes part of the budget for the laboratory providing that service. This should address revenue and capital funding requirements
- e. HSE laboratories should not seek to fund their operation by competing with private providers to provide diagnostic laboratory services to actors external to HSE and HSE affiliated services.
- f. HSE laboratories should provide diagnostic or analytical services to private healthcare providers on request in particular where they can offer specific services that are not otherwise readily accessible. The private provided should cover the full cost of the service with fees generated should be used to support the laboratory service.
- g. 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.
- h. HSE laboratories that are designated and funded as national reference laboratory service providers should not charge fees to for the reference laboratory services they are have been designated to provide. Fee per service for reference laboratory services deters laboratories from submitting samples to reference laboratories and therefore undermines the public health function of reference laboratories.
- 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 from other HSE laboratories is explored and that the HSE fully uses the volume of service it procures to leverage best value for money.

## **1 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





# The Laboratory Services Reform Programme

Incorporating  
The National Clinical Programme for Pathology



PATHOLOGY

FINAL DRAFT

**General recommendations for managing access to HSE and HSE funded Laboratory Services**

DRAFT

The Laboratory Services Reform Programme makes the following recommendations to **HSE and HSE funded clinical laboratories**:

The term “laboratories” is used in this document to refer to these HSE and HSE funded clinical laboratories.

This is general guidance. It should be considered and applied in the context of what is practical at a given time in the individual laboratory setting and consultation with laboratory users.

### **1.1 Who is eligible to access services?**

Within the limits specified by the service, eligible healthcare practitioners registered to practice in Ireland <sup>Note 1</sup> may access services in the laboratory that serves their area subject to the requirements in this document.

### **1.2 What services are provided?**

As per the “Scope of the Public Hospital Medical Testing Laboratory Network” 2019 *“The pathologist plays a key role in diagnostic stewardship, which includes determining what tests should be done in what clinical scenarios and how they should be interpreted.”*

### **1.3 Requirements for Laboratory Users**

General Practitioners and other registered healthcare practitioners who practice outside of the HSE and HSE affiliated facilities and who are entitled to use HSE laboratory facilities should provide the laboratory with a contact number(s) that they, or an appropriately qualified deputy, can be contacted 24 hours per day 7 days per week. This is required to allow the laboratory to alert a person able to take responsibility for care of the patient in the event that sample analysis generates a potentially critical result including when these results are obtained outside normal practice hours.

The laboratory user requesting services is responsible for ensuring that the correct samples for testing are collected and stored appropriately and for verifying that the patient from whom the samples are taken are correctly and comprehensively identified on the sample and accompanying request (paper or electronic).

Test requests should be related to the scope of practice and expertise of the laboratory user.

The laboratory user should use the form of request (electronic or paper form) specified by the laboratory as required and complete all required fields.

Requests for laboratory services must provide all relevant patient details and clinical details as required by the laboratory. Providing a phone number for the patient may facilitate management of unexpected critical results if the healthcare practitioner cannot be contacted promptly.

Requests for laboratory services must clearly indicate the family name and registration number of the healthcare practitioner making the request.

Laboratory users are responsible for timely review of laboratory results and for acting on the result in a timely manner or bringing the result to the attention of a team member who can act on the result in a timely manner.

Laboratory user requests should normally be made on the basis of a hospital or practice protocol, their own professional judgement, on behalf of the healthcare team within which they practice or within the context of a collaborative care arrangement with a HSE or HSE affiliated facility <sup>Note 2</sup>.

In relation to testing of healthy people with no specific clinical indication for testing, HSE laboratory services should be used only in accordance with recommended national guidance on screening for disease. HSE laboratory services should not be used to support testing of healthy people for disease based on recommendations or opinion other than authoritative national guidance on screening. They should not be used to support employer's "screening" requirements outside of recommended national guidance from the Department of Health or the HSE.

Laboratory users should not normally request laboratory services on behalf of healthcare professionals outside of the HSE or HSE affiliated facilities who are providing remote or in person consultation independent of the HSE or other publicly funded health and social care services. Such services are expected to have their own arrangements for laboratory services in place.

Requests for laboratory services to support research projects require advance agreement with the laboratory and are subject to ethical approval.

#### **1.4 Advice for Laboratories.**

1. Laboratories should define as clearly as is reasonably practical their catchment area in terms of hospitals and other clinical services, including doctors engaged in General Practice. In defining this catchment, laboratories should collaborate to ensure that all doctors engaged in General Practice have access to a laboratory service.
2. Laboratories should implement a process to ensure, in so far as practical, that requests for clinical laboratory tests are accepted only from healthcare practitioners eligible to use services (as outlined above).
3. For healthcare practitioners practicing outside of HSE or HSE affiliated services the laboratory should maintain a record of practice, specialty and contact details for all those for whom it provides services. This primarily relates to doctors engaged in General Practice. Non HSE affiliated healthcare services other than General Practice should normally have their own arrangements in place to provide laboratory services.
4. Laboratories may decline to provide services to users who are not able to meet requirements in particular related to obligations to accept and manage critical results at whatever time these may be generated.
5. Electronic systems for requesting tests should be implemented where practical to do so as they are an efficient way to limit requests to those authorised to access the electronic requesting system. They also support submission of the correct sample, clarity regarding the test requested and provision of relevant clinical details. As electronic systems for requesting are not currently available to many laboratories, laboratories should continue to adapt and refine paper based alternatives to achieve the objectives to the greatest degree practical.
6. In the absence of order communications laboratories should require that paper based requests include a clearly legible family name of the requesting healthcare practitioner **and** their registration number (Medical Council, NMBI, CORU or other).
7. To make provision for healthcare practitioners within HSE and associated services who do not have a registration number because there is no register for their profession, the laboratory should maintain a record of those non-registered healthcare practitioners eligible to access services.
8. Samples accompanied by request forms that do not have a clearly identifiable healthcare practitioner should generally be discarded without processing (rejected). This is applicable to samples from within as well as from outside of HSE and HSE associated facilities. Exceptions are appropriate if there is reason to believe that there is urgency in processing the sample or because the sample is likely to be difficult to

- replace (for examples blood samples from small children, tissue samples and certain body fluids). Laboratories should have a standard operating procedure for specimen acceptance and rejection including specification of who is authorised to reject samples.
9. As diagnostic stewardship is an important function of laboratory services, laboratories should decline to perform specific requested tests on correctly identified samples where the requests are not adequately supported by necessary clinical details.
  10. When samples are rejected or when specific test requests are declined the laboratory should issue a report in a timely manner with a comment to the effect that the sample was not processed/test was not performed and the reason for this decision. Where practical to do so the sample should be stored for a period of time to allow the requestor to contact the laboratory to discuss the declined request.
  11. If samples that are likely to be difficult or impossible to replace are not processed they should be stored appropriately and a report issued in a timely manner with a comment to the effect that the sample was not processed and the reason it was not processed. The report should indicate that the sample has been stored for a period of time and may be processed if the required information is provided. If the sample is not processed because the requesting practitioner is not identifiable the report may be generated and may be accessible but it may not be possible to direct it to the relevant practitioner.
  12. It is appropriate that healthcare practitioners who work within laboratory services modify or add to requests for services within their scope of expertise and in accordance with the laboratory Standard Operating Procedures.

## **2 Background**

The Health Service Executive and HSE associated agencies provide an extensive range of clinical laboratory services from more than 40 clinical laboratories throughout Ireland. These services are very valuable in providing support to healthcare practitioners in delivering care to people.

The HSE has a responsibility to ensure that access to these services is appropriately managed for a number of reasons. The primary reason to control access to services is that laboratory test results must be interpreted and applied by healthcare practitioners in the context of other relevant clinical information therefore laboratory tests should be requested by qualified personnel for a specific purpose. Inappropriate use of testing services can result in unnecessary venepuncture or other sample collection and generate anxiety about minor variation in the value of measured parameters. Testing outside the correct clinical context or authorised national screening guidance can also lead directly to clinically irrelevant results, initiation of an inappropriate diagnostic cascade, increased healthcare utilisation and inappropriate onward referral. Inappropriate testing also impedes the laboratory from efficient processing of necessary testing and generates significant avoidable waste and CO<sub>2</sub> emissions.

General consideration on the provision of laboratory services are addressed in the document “Scope of the Public Hospital Medical Testing Laboratory Network” included as part of the Laboratory Handbook (2019). Laboratories are intended to provide services primarily to HSE and HSE affiliated health and social care services in hospital and community and to doctors engaged in General Practice in Ireland. Services are also provided under service level agreements to certain other healthcare providers. In recent years some laboratories have received requests from other sources including healthcare practitioners providing specialist

services other than General Practice in a private capacity, from alternative healthcare providers and from healthcare practitioners based outside of Ireland and engaging remotely with patients in Ireland. This document is intended to provide clearer definition regarding who can access HSE and HSE funded laboratory services and to define key terms that apply to those accessing those services. Some laboratory services may not be accessible to all laboratory users. Access to certain services may be limited to healthcare practitioners with specific expertise or they may require that specific additional details are provided or that the cases is discussed with a pathologist. The laboratory should make information on sample type and other requirements available to laboratory users.

**Note 1.** Services to healthcare practitioners who are not registered to practice in Ireland should be provided to healthcare practitioners in disciplines for which registration is not available when they are working in the HSE or HSE affiliated organisations.

**Note 2.** Laboratory users should not normally act as proxies for healthcare practitioners practising independently of HSE or a HSE affiliated facility by collecting samples and making requests on their behalf. Independent healthcare services are expected to provide their own laboratory services or enter into service level agreements with HSE laboratories if required.

**Authors:** Developed by the Laboratory Services Reform Programme Incorporating The National Clinical Pathology Programme.

**Approved By:** Martin Cormican

The “Scope of the Public Hospital Medical Testing Laboratory Network” document is available at

<https://www.hse.ie/eng/about/who/cspd/ncps/pathology/resources/scope-of-the-public-hospital-laboratory-network.pdf>

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