



# Do Laboratory Investigations and Services Add Value ?

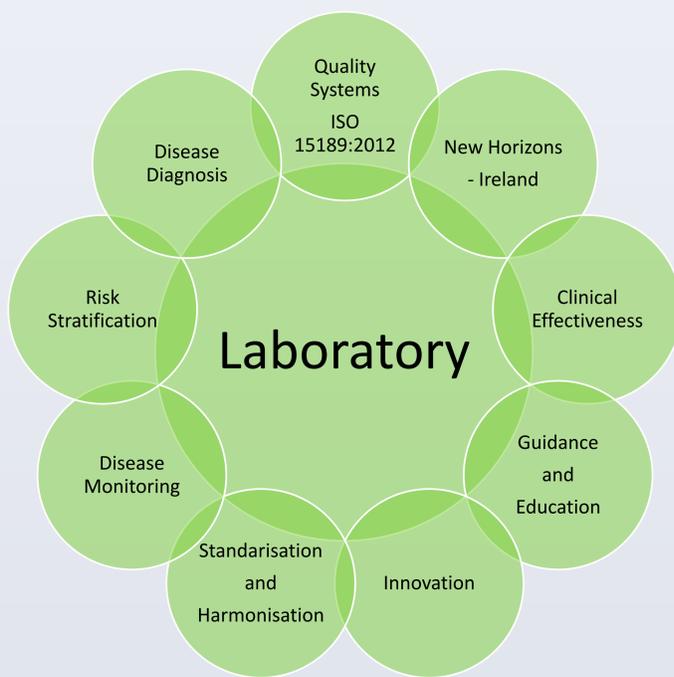


## The Academy of Clinical Science and Laboratory Medicine - Ireland

### Introduction

In 1996, Forsman reported that while Laboratory services represent 3-5% of hospital budgets, 60 -70 % of admission, discharge and medication interventions are based on Laboratory investigations. Clinical diagnosis or exclusion of illness is commonly established or guided by the results of a series of investigations or examinations of major organ pathways such as Renal, Liver, Cardiac, Haemopoetic, Coagulation and Microscopy and Culture of Urine, CSF and Blood. It is necessary for all clinical partners involved in patient care, including Medical Scientists in all disciplines, to understand and interpret test results, in order to achieve correct patient diagnosis, prognosis and therapy (Trenti, 2003). Verified, accurate and timely, best practice investigations are key to cost effective interventions, risk stratification, monitoring and outcomes for patients.

### How Does the Laboratory Add Value?



### Quality Systems - Analysis and Equipment

The Laboratory Professional working within a Quality System and inspected to Laboratory Standard ISO 15189:2012, is required to and can evidence traceability for all parts of the testing process. This requires that all samples conform to identification norms, analyses available under scope of practice have been verified to an acceptable standard, the equipment is regularly maintained, staff have evidential records of training and competency, all reagents are traceable and a system is in place for investigating non conformances and performing root cause analysis for continual improvement. In addition Internal Quality Control (IQC) and External Quality Assurance (EQA) are performed at intervals and required to conform and perform to National/International guidelines. All of the above assist clinicians in evaluating change in results as real change and not attributable to analytical error, interferences in methodology or day to day variances (Beastall, 2013)

### Diagnosis of Disease

While Trenti (2003) outlined the challenge for Laboratory Medicine to demonstrate an evidence base for diagnostics, the centrality of certain profiles such as Renal, Bone and Lipid profiles, Full Blood Count (FBC) and Coagulation to first line investigations is evident. Additional frontline tests such as Troponin in cardiac event diagnostics, glucose in diabetes, Blood Culture and CSF and Urine microscopy in infection and sepsis, cell count and blood film in Leukaemia, blood gas in respiratory disease and infection, CA125 in ovarian cancer, support and guide diagnoses which otherwise would remain suspected. Does abdominal pain become a suspected Appendicitis based on a white cell count (WCC) and C- Reactive Protein (CRP) or Pancreatitis based on an amylase, or a Cholestasis based on bilirubin and liver enzymes or an Ectopic Pregnancy based on a Human Chorionic Gonadotropin (HCG) as these analyses assist with diagnostic stratification?

### Disease Monitoring

Ongoing review of the disease process and response to therapy is provided using many analyses. Renal Profile/Creatinine the progression of renal disease. CRP evidence of response to antibiotic therapy in sepsis. FBC and Haemoglobin the responses to Red cell transfusion and chemotherapy. Prothrombin Time and APTT to anticoagulation support. HbA1c provides ongoing evaluation of treatment targets and future prediction of comorbidities in diabetes. INR provides monitoring of the efficacy of Warfarin therapy. Thyroid function testing the response to thyroid therapies,

Parathyroid Hormone (PTH) the response to parathyroid nodule removal. Blood gas analysis the response to oxygen therapies.

The ability of laboratories to provide complex analyses in response to Dynamic Function Investigations such as a hypoglycaemic challenge, ACTH administration and pathway parameters such as 1:25 Vitamin D, 17 Hydroxy Progesterone, facilitate the elucidation of complex pathways.

### Standardisation and Harmonisation

The development of International standards has facilitated the evaluation of commercial assays such as HCG, Troponin T and I and have driven commercial providers to improve their assay performance and sensitivity of methods. Standardisation of reporting units and a greater understanding of the need for consistent methodologies when monitoring tumour markers such as PSA, to avoid platform to platform variances. Harmonisation of reference ranges, methodologies and investigation profiles have standardised Laboratory services (Smellie, 2012)

### Innovation

While Laboratories are often suspected of reticence, this is in fact a myth as evidenced by the progression from tube technologies to highly automated, integrated, real time technologies, not only in the traditional sites of the Blood Sciences but also in Microbiology for organism identification, antibiotic sensitivity and bench top PCR. Laboratories evaluate and verify new methodologies as fit for purpose, in the absence of clinical usefulness regulation (Walley, 2008)

### Guidance and Education

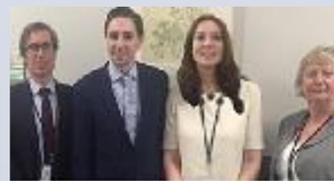
Laboratories evaluate critical results requiring communication to Medical teams, review patient trends through cumulative reporting and delta checking, prevent unnecessary testing or redirect service users to more appropriate investigations. Laboratories are constantly evaluating the literature and clinical practice guidelines e.g. National Institute for Health and Clinical Excellence (NICE), to educate service users and ensure the patient has access to the optimum investigations

### Clinical Effectiveness

Laboratories contain valuable data banks of information which could be better utilised to improve patient care. In the UK where community service users are fund holders, adherence to guidelines and treatment targets is essential for funding. However, greater interrogation of Laboratory data could be used to inform clinicians and prioritise acute/community patients with chronic diseases such as diabetes, Acute Kidney Injury, to rapid access in acute care and improve outcomes. Evaluation of thyroid function and Iron deficiency testing patterns could be used to evaluate adherence to guidelines. Admission to acute care could be prevented by timely and simple outreach screening in community settings such as nursing homes, using verified, accredited Point of Care services and device for commonly acquired infections.

### New Horizons - Ireland

Representations by ACSLM to Ministers for Health, including Simon Harris and the Faculty of Pathology and a future position publication - New Horizons, have achieved support and progression to a Histopathology Dissection Certification programme and a joint working group for Advanced Practice in Medical Science.



### Discussion



Laboratory medicine is central to healthcare delivery and Laboratory Professionals use their expert clinical knowledge to interpret test results, elucidate diagnoses, perform reflective testing, add interpretative comment, communicate critical results and add value.

### References

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