St. James's Hospital Laboratory Medicine External Users Newsletter

Issue No. 3 *October 2012*

Welcome

This is the 2012 edition of the Laboratory Medicine newsletter aimed at external laboratory users. Its purpose is to bring you information on developments in laboratory medicine at St. James's Hospital. We would be delighted with your feedback on issues you would like us to address in the newsletter. We hope you find it useful. Comments or suggestions can be sent to either e-mail address below:

Mr. John Gibbons, Laboratory Manager. E-mail; jgibbons@stjames.ie
Mr. Brian Kelleher, Quality Manager. E-mail: bkelleher@stjames.ie

Laboratory Medicine Department at St. James's Hospital is a fully Accredited Laboratory Service

All 10 departments within the LabMed Directorate have been inspected this year as part of their accreditation/licence. All retained their status,

An audit of the **Tissue Establishment/Cryobiology** was carried out by the IMB in May 2012. The Tissue Establishment retained its license.

The **Blood Transfusion** department (incorporating haemovigilance) was inspected in April by the Irish National Accreditation Board (INAB). This was the 4th and final surveillance visit of this accreditation cycle. It was a very successful process and the accreditation ISO 15189 certificate is maintained

All Other 8 Clinical Laboratory disciplines have retained their accreditation status to the Clinical Pathology Accreditation (CPA) standards (incorporating ISO 15189) following surveillance inspections in June of this year.

These include the following:
Microbiology laboratory, Irish Mycobacteria Reference Laboratory, National MRSA Reference Laboratory, Biochemistry, Histopathology (incorporating Cytopathology), Immunology, Haematology (incorporating Coagulation) and Cancer Molecular Diagnostics

Some comments from the inspection reports include:
"The department is well managed by an experienced senior management team. There is excellent planning for the service and robust communication systems that are clearly documented".

"Regular interaction with the users of the service feeds directly into objective setting for the department".

"Document control continues to be excellent".

The quality team are *"committed, well motivated and adequately supported to ensure the ongoing maintenance and development of the QMS".*
"……. all members of staff are informed of continual improvement issues. TATs are regularly monitored and are being achieved. Audit programmes are in place and cover the scope of both the QMS system and examination processes"

"Outcomes of audits are well documented and the department was able to demonstrate an improved understanding of remedial, corrective and preventive action and root cause analysis".

"All members of staff should be commended for their team approach to assessment and their continued commitment to conforming to CPA Standards".

Developments in IT infrastructure

New Laboratory Information Management System (LIMS)

St. James's laboratory is part of a group of laboratories involved in a national procurement of a new LIMS system to meet the clinical and future business needs of its service. It will enhance the provision of end-to-end connectivity with the user, benefitting the patient in their journey through primary, secondary and tertiary care. This process has now started and tender document should be issued by end of 2012.

Sample Tracking & Tracing from Referring Laboratories (LIS2LIS)

This project is well underway and will allow the electronic transfer of laboratory requests from a referring laboratory to SJH laboratory as well as the return of reports electronically. Part of this project is a sample tracking system, which facilitates the tracking of samples until delivered to the recipient laboratory. Once received into the laboratory a message is sent to the referring laboratory confirming that step has been achieved successfully.

Benefits for St. James's Hospital

- Manage the sample shipment between the referring laboratory and St. James
  - This will ensure that a complete audit trail is present for each sample being sent for analysis to St. James.
  - The audit trail is present in both St. James and the referring laboratory.
- Automated data entry at request entry will support demographic and sample detail capture using a 2D bar coding.
- Reduction in the number of duplicate external laboratory patients on the LIS.
- Laboratory test/examination reporting of 'Delta' check flags will work more consistently and correctly, simply because all results for the patient are filed together

Benefits for the Referring Laboratory

- Patient demographic data is consistent and correct
- Data quality is much improved due to automated data entry in St. James's
- The result reporting will function much better as all results for the patient will be filed in the Laboratory system correctly.
- Integration of results to external laboratory information system will be streamlined, as demographic data will be consistent.
- Sample tracking advantages, above, will also accrue to external laboratory.

One major hospital laboratory has fully connected in this way and is running very successfully. Four other hospital laboratories are in progress of being linked up and will be fully operational by end of November 2012. It is intended to increase the number of users with this connectivity gradually over the next number of years.

Laboratory User Website

The Laboratory updated its section of the St. James's website in July of this year (www.stjames.ie/labmed) and now includes information on all aspects of the test /examination repertoire carried out in each department. In addition, it has information on contact numbers for advice, and links to other relevant websites also. Information on post mortems/autopsies is also accessible from the hospital website at www.stjames.ie.

Service Developments

Policy on Provision of Laboratory Services

External Agency Pathology / Laboratory Service Provision Policy
Policy Number: SJH: LabMed (P):003 has been updated and is available on the hospital's website. See above.

Departmental Updates

Biochemistry

Single Specimen Type

As part of the automated core laboratory facility, the laboratory is discontinuing the routine use of the **green (Lithium Heparin) tube** and is to be replaced by the current **red capped tube,** which is also in use in the hospital**.** This means we will have one tube type in the laboratory except for glucose and other special tests**.** The transition has not taken place yet on the EPR and reminders will be issued when that happens. There will be one exception, such as, when patients are on heparin therapy, it is best to use the green Li. Heparin tube for routine biochemistry tests.

Reporting of Glucose Results

In line with recent guidelines concerning disorders of glucose homeostasis (both from HSE and from international organisations e.g. ADA, WHO) the department, in conjunction with our consultant diabetologist colleagues, has updated its reporting of plasma glucose results.

Firstly, samples should always be clearly designated as fasting, random, or post-prandial/post oral glucose load, whichever is considered appropriate. Any sample that is not designated as either fasting or post-prandial/post oral glucose load will be automatically labelled as RANDOM.

Secondly, please note that there is no effective reference range for Random plasma glucose. Therefore any random sample will automatically be flagged as abnormal so that any potentially abnormal results are highlighted for the benefit of the service user. All glucose reports will be issued with a specific GUIDE TO INTEPRETATION, which is informed by recent national and international guidelines.

Critical Phone Limits

The Biochemistry service has updated the critical phone limits for abnormal results generated during sample analysis. If abnormal results cannot be phoned to service users during routine office hours then only those results that meet the criteria for critical phoning as determined by the joint Royal College of Pathologist/RCGP guidelines, issued in November 2010, will be considered for further action, particularly outside of routine working hours.

Serum Chemistry	Units	Critical Phone limits – GPs & External Institutions
Sodium	mmol/L	≤125 ≥150
Potassium	mmol/L	≤3.0 ≥6.0
UREA*	mmol/L	>15 mmol/L provided result >8 mmol/L above baseline/preceding result
Creatinine *	μmol/L	>150 μmol/L provided the result > 44 μmol/L above baseline/preceding result
Bicarb	mmol/L	≤12
Corrected Calcium Corrected Ca = Pts Ca + [(40-Pts alb) x 0.02]	mmol/L	≤1.90 ≥3.0
PHOSPHATE	mmol/L	≤ 0.45
Magnesium	mmol/L	≤ 0.40 ≥1.80
Glucose	mmol/L	≤3.5 ≥20.0
Amylase**	IU/L	≥450
CK**	IU/L	≥1000
AST**	IU/L	≥400
ALT**	IU/L	≥350

Notes:

*Urea results above 15 mmol/L will be phoned if there are no recent results (within the last 3 months) available for comparison in LIMS/EPR or if there is a greater than (>) 8 mmol/L increase above the baseline admission result or the immediate preceding

result, whichever is the more recent. Similarly, for Serum Creatinine, any results above 200µmol/L for an in-patient or 150µmol/L for and out-patient/GP patient will be phoned where there are no recent results (within the last 3 months) available for comparison in LIMS/EPR or if there is a greater than (>) 44µmol/L increase in Creatinine above the baseline admission result or the immediate preceding result, whichever is the more recent.

- **Results will be phoned if there are no recent results available for comparison in LIMS/EPR, or if the results are significantly (≥50%) higher than previous levels reported in LIMS/EPR
- If the abnormal results cannot be communicated to the clinical team by phone, despite two attempts by Biochemistry Staff to do so, these results will then be released. Further attempts to contact the clinical team may be undertaken but cannot be guaranteed. If GP or External institution's patient results cannot be phoned then only those results that meet the criteria for critical phoning as determined by the RCPath guidelines Nov 2010 will be considered for further action, particularly outside of routine working hours.
- Please note that abnormal results for hsTroponin T and NT-proBNP will not be phoned under normal circumstances.
- All other results of tests performed in the Biochemistry Department will be released as soon as they have been authorised in the Biochemistry Department.
- **Finally, while the staff in the Biochemistry Department will do their best to adhere to the above guidelines, I remind you that it is the duty of all doctors to follow up, in a timely fashion, on the results of all investigations requested on patients under their care.**

Screening for Cystine in Urine

To date the Biochemistry Dept., St James's Hospital has provided a qualitative urine cystine screen for service users. Any screen positive samples were subsequently forwarded to Biochemistry Department, Children's University Hospital, Temple Street for quantification.

From 1st October 2012 the Biochemistry Dept. St James's Hospital will no longer provide the qualitative cystine screening service. **It is recommended that all service users send samples for urine cystine analysis directly to Biochemistry Department Children's University Hospital Temple St.**

Haematology

Guidelines on Thrombophilia Testing

The National Centre for Hereditary Coagulation Disorders (NCHCD) has introduced guidelines for the laboratory testing of thrombophilia. These guidelines relate to the determination of appropriateness of laboratory testing for thrombophilia. For patients where testing is indicated, interpretation of the results requires integration of clinical, laboratory and family data. Consequently, it is recommended that such patients are referred for Haematology review. In general, testing of patients for laboratory thrombophilia in the setting of General Practice is not recommended.

A summary of the guidelines for testing for heritable thrombophilia and for anti-phospholipid antibodies can be accessed at the following web address:
http://www.stjames.ie/GPsHealthcareProfessionals/LaboratoryPolicesGuidelines/
It is important that all details, as stated in this guideline, including the appropriate clinical information, are completed for each request. Samples received for testing where there is incomplete clinical information or where the reason for the request does not fall within the recommended guidelines will

be held in storage in the laboratory. Additional clinical details will be requested from the requesting clinician prior to testing and/or that the case is discussed with a Consultant Haematologist in the NCHCD. The samples will be discarded after eight weeks if there is no response or if it is determined that testing is not indicated.

These guidelines will apply to the majority of patients. However it is recognised that individual patients may have specific circumstances that warrant testing. Where necessary, such cases may be discussed with the Consultant Haematologist on-call for the NCHCD (contactable at 01-4162141).

Cancer Molecular Diagnostics

Solid Tumour Markers Update

The Cancer Molecular Diagnostics (CMD) laboratory has successfully expanded its test repertoire to include theranostic markers for solid tumours. The markers - KRAS, EGFR, BRAF and ALK - are used to guide treatment decisions for oncology patients.

Numerous recent studies have highlighted that "high-tech" medicines, such as the monoclonal antibody Cetuximab, are only proven effective in specific cohorts of patients. These patient cohorts are identified by their tumour's expression of specific somatic mutations which can impact the drug's efficacy at a molecular level. Molecular testing is used to identify whether a patient sample exhibits these mutations. With this information, oncologists can be confident that those patients who qualify for therapy are likely to benefit from their treatment. This information is particularly relevant when weighing up the benefits of a drug against potentially debilitating side-effects.

The CMD laboratory has been providing molecular diagnostics at a national level for haematological malignancies since 2001. Since the establishment of the service, a close working relationship with the haematology department in St James's Hospital has aided the development of both departments. Building upon this experience, a similar working relationship has been established between CMD and the Histopathology department. This link will allow CMD to develop a service that is continuously optimised to work with "traditional" pathology. This will permit the attainment of quality and turn around time goals that are compatible with international best practice for both internal and external requests.

The CMD department is in a position to offer this service to external users. The laboratory is happy to discuss an SLA with any interested user. Please contact the Laboratory Manager as detailed on page 1.

Editorial Committee: Dr. Brian O'Connell, Mr. John Gibbons, Mr. Brian Kelleher