DEPARTMENT OF PATHOLOGY AND MOLECULAR MEDICINE

ANNUAL REPORT

APRIL 1, 2004 – MARCH 31, 2005

Pathology and Molecular Medicine
KINGSTON GENERAL HOSPITAL
CLINICAL LABORATORY SERVICES

Mission:
"Together, we proudly serve our regional community through the provision of expert laboratory and clinical services, education and research."

Vision:
"We strive to be national leaders in advanced diagnostic services, employee success, student achievement and knowledge discovery."

Values:
"In our pursuit of excellence, we value people by practicing mutual respect, professionalism, teamwork, integrity, trust and accountability."

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1. EXECUTIVE SUMMARY

1.1 PREAMBLE

The Department of Pathology and Molecular Medicine at Kingston General Hospital and at Hotel Dieu Hospital is tightly integrated with KGH Clinical Laboratory Services. The Department is organized into five divisions: Anatomical Pathology, Clinical Chemistry, Clinical Microbiology, Hematopathology, and Genetics. Management and medical direction for the KGH Infection Control Service and the Transfusion Medicine Service are the responsibility of our Department (i.e. within the Division of Clinical Microbiology and affiliated KGH Microbiology/Infection Control Service; and within the Division of Hematopathology and affiliated KGH Blood Bank, respectively). However, those two annual reports are presented separately to the MAC and are not included as part of this departmental report.

In addition to providing clinical service, education and research, several departmental faculty members have significant administrative responsibilities for clinical co-supervision of a large number of technical staff and co-management of operational and capital budgets.

1.2 WORKLOAD AND UTILIZATION TRENDS

Surgical Pathology, which comprises the bulk of day-to-day service work for most Anatomic Pathologists, showed a slight growth in overall case numbers but more importantly, the shift to more complex and work intensive cases has continued. Similar workload trends have been observed by the Hematopathologists. There were dramatic increases in both routine and specialized laboratory testing in the Core Laboratory (particularly in Clinical Chemistry and Immunology) which significantly impacts upon faculty time and energy. In Laboratory Genetics, a severe shortage of technical staff resulted in a very significant backlog of clinical cases requiring drastic actions.

It is worth noting that laboratory physicians have very little control over their own workload or over laboratory test utilization; this is determined by clinicians on the wards, in the clinics, and in the Operating Rooms. External data (e.g. from the HayGroup) has shown that while KGH has one of the most cost-efficient academic hospital laboratories in the province, it also has one of the highest rates of laboratory test utilization. One of our objectives over the upcoming year will be to begin to understand why this is so, by examining utilization rates by clinic, clinical program, etc. Ultimately, however, implementation by the hospitals of tools such as computer-based physician order entry, are essential to properly begin to address the problem.

1.3 QUALITY IMPROVEMENT ACTIVITIES

The Clinical Laboratories at KGH and at HDH each received a full five year accreditation certificate in 2004 from the Ontario Laboratory Accreditation (OLA) program. Preparation for OLA stimulated many new quality initiatives throughout the Department.

One-time capital equipment funding for clinical laboratories in the region instigated extensive collaboration with other community hospitals. Several new state of the art instruments were purchased for KGH and HDH. This will improve our diagnostic and testing capabilities required for a tertiary care centre.

1.4 MULTIDISCIPLINARY COLLABORATION

We continue to support well established regional initiatives (e.g. Lab Outreach Program, KGH Forensic Unit, Genetics Program in Peterborough) and multidisciplinary activities (e.g. Regional Cancer Centre Tumour Boards and Disease Site Groups, Infection Control Program, Transfusion Medicine Service). Some of the new initiatives that are just beginning or about to get underway include:

- Regional Infection Control Program
- Stem Cell Transplant Program
- Hearing Loss Clinic (Genetics, ENT)

1.5 TEACHING AND RESEARCH

The departmental educational mission crosses multiple programs at KGH and Queen's. We are extensively involved in the undergraduate medical curriculum and both intra- and extra-departmental postgraduate programs.

The department has a substantial graduate program which includes 19 MSc students and 13 Ph.D students. There are also approximately 14 postdoctoral research fellows in departmental laboratories. We offer 10 courses in pathology, genetics and molecular medicine within the undergraduate life sciences and graduate programs and also participates in courses within the nursing, rehabilitation medicine and biology programs at Queen's. The department plays a significant role in the supervision and training of general medical laboratory technology students from St. Lawrence College. We also train cytology and laboratory genetics students from the Michener Institute (Toronto). Furthermore, each year, an extremely successful course in the Queen's enrichment program for high school students is coordinated by the department.

We have recently been successful in rebuilding our pathology residency programs. From a nadir of a single resident in our department approximately three years ago, we now have eleven residents in our programs, eight of whom are in Anatomic Pathology, two of whom are in Hematopathology, and one in General Pathology. We will continue to expand our postgraduate training programs during the next several years and we have an objective of achieving a stable program enrollment of fifteen residents. Nearly all of our teaching rounds are accredited for Royal College Maintenance of Certification purposes. We have significant teaching and training responsibilities for residents in other programs, most notably – Hematology, General Surgery, Radiation Oncology, OB/Gyn, Pediatrics, and Radiology.

The department also administers a Postdoctoral Training Program in Clinical and Laboratory Genetics. One fellow is currently enrolled in this program.

The department's biomedical research programs continue to be very successful. In calendar 2004, the total value of research grants and awards to primary appointees approximated $4.4 million. The productivity of the department's research enterprise during that reporting year approximated the following: 85 peer reviewed papers; 15 book chapters; and, 100 abstracts and presentations. Lists of departmental research grants, publication records and scholarly presentations are available upon request.

1.6 STAFFING ISSUES

The Division of Anatomic Pathology began the Spring of 2005 with a nominal staffing level of 14.0 FTE pathologists but an effective strength of only 12.25 FTE's. This short staffing will lead to continuing challenges for the fulfilment of the complete departmental mission (service, teaching, research). This situation is being exacerbated as our residency program in Pathology is growing and is placing an increasing teaching burden on faculty. Similar staffing pressures are being faced within the Division of Hematopathology; the individual recruited to the vacant position did not take up his appointment and the expected relief in service and teaching responsibilities did not materialize. We have, however, significantly strengthened our complement of Ph.D. laboratory scientists within the department (all SEAMO faculty): Dr. Lorne Seargeant replaced Dr. Mike Raymond as Service Chief, Clinical Chemistry. Dr. Robert Liao replaced Dr. Tim Karnauchow as Clinical Microbiologist. Dr. Harriet Feilotter is a Molecular Geneticist in a new faculty position within the Division of Genetics.

For more detailed information about our Department and its activities, please visit our website at: ***http://www.path.queensu.ca***

2. REVIEW OF GOALS & OBJECTIVES FOR THE PAST YEAR

Departmental Strategic Priority 1: People

- Successful recruitment of new Clinical Chemist (Service Chief), Clinical Microbiologist, and Molecular Geneticist
- Successful expansion of our Pathology residency programs from 3 to 11 residents
- Successful recruitment of a new Laboratory Administrative Director and two laboratory managers
- Implementation of a "front line leadership" model amongst the senior technologist staff and laboratory managers

Departmental Strategic Priority 2: Quality

- Full (5 year) Ontario Laboratory Accreditation certificates received for KGH and HDH clinical laboratories; many new quality policies and procedures created, updated or revised in the process
- Autopsy suite/Forensic Unit renovations: ~90% complete
- Acquisition of several new major laboratory instruments and analyzers which will help to improve quality of diagnostic laboratory services
- Introduction of computerized screening of quality control data from high volume chemistry laboratory instruments (replacing manual review of QC)
- Introduction of Process Improvement Teams in the Clinical Laboratories
- On-call system to provide STAT volatile testing service 24/7 for suspected methanol and/or glycol poisoning.
- Revision of multidisciplinary collaborative care plans (e.g. coronary care – to improve turnaround time for indicators of cardiac damage – Troponin)
- Introduction of molecular diagnostic technology into the Microbiology Laboratory

Departmental Strategic Priority 3: Integration and Partnerships

- OCRN Tumour bank: Business case was approved and a plan to begin banking tissues approved for Spring 2005.
- Stem cell transplant program launched with provision of CD34 counting, stem cell re-infusion, and Blood Bank logistical support.
- Anticoagulant Clinic Program approved. The Division was directly involved in the planning and on-going appraisal of Point of Care Testing (POCT) instrumentation.
- Revitalization of the regional laboratory managers' and directors' alliance (E2LA) with unprecedented level of cooperation in the regional diagnostic medical equipment acquisition process

Departmental Strategic Priority 4: Business Process Management

- LIS replacement process initiated (RFI issued in May 2004)
- Network migration project nearly complete within the department (from Queen's Pathnet to KGH Kari-net)

- Review of Laboratory Outreach Program technical fee structure with external help from the Queen's School of Business

3. CURRENT STAFFING ISSUES

Division of Anatomic Pathology

Faculty	Position	FTE in Department		Main Service Responsibilities
		Nominal	Effective	
Boag, Sandy	Service Chief, Anatomic Pathology	1.0	1.0	GU, lung, cytology
Childs, Tim	Attending Staff	1.0	1.0	Gyne, cytology, perinatal
Dexter, David	Medical Dir., Autopsy	1.0	1.0	GI, lymphoma, soft tissue/bone, head/neck, forensics
Hiruki, Tad	Attending Staff	1.0	1.0	GI, breast, cytology
Hurlbut, David	Attending Staff	1.0	1.0	GI, head/neck, forensics
Isotalo, Phil	Attending Staff	1.0	1.0	GU, breast, lung, head/neck
Lebrun, David	Medical Dir., Immunohist.	1.0	1.0	Lymphoma
Ludwin, Sam	Assoc. Dean & V.P. Research	1.0	0.25	Neuropathology
Manley, Paul	Attending Staff	1.0	1.0	GI, head/neck, dermatopath
Rossiter, John	Medical Dir., Neuropathology	1.0	1.0	Neuropathology
Rowlands, Caroline	Medical Dir., Cytology & Dir. Postgrad. Educ.	1.0	1.0	Dermatopath, gyne, breast, cytology
SenGupta, Sandip	Medical Dir., Laboratories	1.0	1.0	Breast, gyne, soft tissue/bone
Young, Iain	Dept. Head & Pathologist in Chief	1.0	1.0	Dermatopath, GU, renal, forensics
Vacant position		*1.0*	*0.0*	
Total FTE		14.0	12.25	

Comments:

1. Dr. Manley returned from an administrative leave on July 1, 2004.
2. Dr. Ludwin remains as 0.25 FTE Neuropathologist as a result of his administrative activities as Vice-President (Research).
3. The new recruit for the vacant position withdrew prior to his planned start date of January 1, 2005. The existing staffing shortfall will persist until the vacant position can be filled.

Division of Haematopathology

Dr. Dilys Rapson	-	Service Chief, Haematopathology
	-	General Hematology, Hemostasis
Dr. Lois Shepherd	-	Director, Blood Bank
	-	General Haematology, Transfusion Medicine
Dr. David Dexter	-	General Haematology, Lymph Node Pathology
Dr. David Lillicrap	-	Regional Haemophilia clinic, Haemostasis
	-	Molecular Genetics of Haemostatic Disorders
Dr. David Lee	-	Clinical Haematology
Dr. John Matthews	-	Clinical Haematology
Dr. Paula James	-	Clinical Hematology

Comments:

1. Drs. Lee, Matthews, and James are cross-appointees from the Department of Medicine.
2. The time commitment to Laboratory Haematology varies amongst the members: Dr. Rapson 1.0 FTE; Dr. Shepherd 0.5 FTE; Dr. Dexter 0.2 FTE; Dr. Lillicrap 0.25 FTE.
3. Workload complexity, many teaching commitments, and very limited technical manpower for developmental work curtail the rate of progress and new initiatives in the Division, including some research productivity.

Division of Clinical Chemistry

Dr. Lorne Seargeant	-	Service Chief, Clinical Chemistry (October 2004)
Dr. Chris Collier	-	Clinical Chemist (and interim Acting Service Chief)
Dr. Mike Raymond	-	Outgoing (Retired) Service Chief

Comments:

1. Dr. Raymond continues to provide Clinical Chemistry consultation to outreach clients (Napanee, Perth/Smiths Falls, Weeneebayko) – post retirement.
2. Dr. Collier provides outreach Clinical Chemistry consultation to QHC – Belleville General.

Division of Clinical Microbiology

Dr. Dick Zoutman	-	Service Chief, Medical Microbiology
	-	Medical Director, Infection Control Service
Dr. Lewis Tomalty	-	Clinical Microbiologist
Dr. Robert Liao	-	Clinical Microbiologist

Comment: Dr. Liao, who began his position in Fiscal 2005, is the lead faculty member in the molecular microbiology program starting with MRSA and CMV.

Division of Genetics

Dr. David Lillicrap	-	Service Chief, Genetics
Dr. Karen Harrison	-	Cytogeneticist
Dr. Sherry Taylor	-	Molecular geneticist
Dr. Harriet Feilotter	-	Molecular geneticist
Dr. Mohamed Khalifa	-	Clinical geneticist
Dr. Jennifer Mackenzie	-	Clinical geneticist (part time appointment)
Dr. Cynthia Forster-Gibson	-	Clinical geneticist (part time appointment)

4. PROFILE OF ACTIVITIES

4.1 DIVISION OF ANATOMIC PATHOLOGY

4.1.1 Surgical Pathology

Activity Indicator	Calendar 2004 Activity	Change in Activity	
		One Year	5 Years
Total Cases	23,605	3.1%	2.2%
Indicator cases, complex			
Cases requiring IHC	2,070	16%	52%
External Consults	1,469	(6.0%)	6.0%
Lymphomas	215	19%	49%
Prostate biopsies	791	10%	23%
Indicator cases, simple			
Bone	791	27%	9.7%
Gallbladder	668	5.0%	(1.0%)
Skin	6,342	4.8%	0.0%
Products of Conception	941	1.4%	13.0%

Comment: Total surgical pathology case count has shown a slight increase but the main trend continues to be the shift to more complex and work-intensive case mix.

4.1.2 Cytopathology

Activity Indicator	Calendar 2004 Activity	Change in Activity	
		One Year	5 Years
Total Cases	17,081	(1.4%)	(31%)
Non-gynecological cases			
Total	7,253	1.0%	5.7%
Fine needle aspirations	1,138	3.3%	29%
Cervical ("pap") smears	9,828	(3.6%)	(4.3%)

Comment: The drop-off in community pap smears coming into the hospital lab continued in 2004, although to a lesser extent than in previous years. However, in terms of actual workload, this was more than compensated for by increases in more technically and professionally demanding non-gynecologic specimens, particularly in the area of fine needle aspiration biopsy material.

4.1.3 Autopsy Service

Activity Indicator	Calendar 2004 Activity	Change in Activity	
		One Year	5 Years
Hospital Cases	99	(2.9%)	(42%)
Coroners' Cases	208	17%	17%
Total Cases	307	8.9%	(12%)

Comment: The major trend historically in the autopsy service has been the shift from hospital consent cases to coroners' medical legal cases. While the increased numbers of the latter are consistent with the regional forensic unit sited at KGH, the drop in hospital cases is a concern from a teaching and hospital quality assurance standpoint.

4.2 DIVISION OF HEMATOPATHOLOGY

Technical Workload Units

	Fiscal 2000	Fiscal 2001	Fiscal 2002	Fiscal 2003	Fiscal 2004	Fiscal 2005
Routine Haematology	1,536,050	1,593,045	1,495,010	1,492,539	1,502,177	1,587,800
Special Haematology	111,003	108,555	108,617	115,789	170,524	182,679
Coagulation	873,360	921,666	957,214	979,571	923,583	922,402
Transfusion Medicine	997,836	1,048,555	1,015,438	1,023,095	1,074,919	1,034,441
Immunology	391,826	405,528	442,861	462,644	470,774	400,742

Comment:
Rising workload units are reflected in diverse areas as illustrated in most examples shown below:

Indicators of Clinical Activity by Test Request in Diverse Areas	Fiscal 2002	Fiscal 2003	Fiscal 2004	Fiscal 2005
Bone Marrow Requests	442	456	424	430
Von Willebrand Antigen	218	239	239	328
Immunophenotyping Interpretation	661	727	747	837
Haemoglobin Electrophoresis	173	249	304	266

4.3 DIVISION OF CLINICAL CHEMISTRY

Technical Workload Units

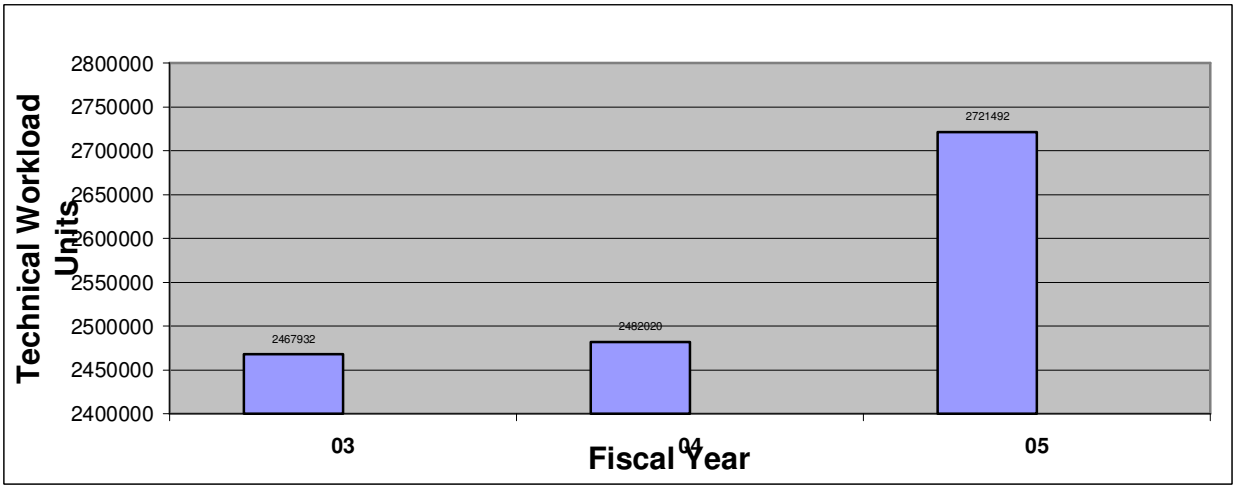
	Fiscal 2001	Fiscal 2002	Fiscal 2003	Fiscal 2004	Fiscal 2005
Routine Chemistry	2,440,937	3,168,462	3,117,846	3,579,453	3,820,077
Urinalysis	151,965	145,209	144,493	139,811	173,941
Therapeutic drug monitoring/ Toxicology	92,618	144,372	158,780	210,083	183,848
Immunoassays	471,216	495,548	521,611	468,548	355,474
Special Chemistry	523,926	445,402	402,790	469,058	517,041
TOTALS	3,680,662	4,398,993	4,345,520	4,866,953	5,050,380

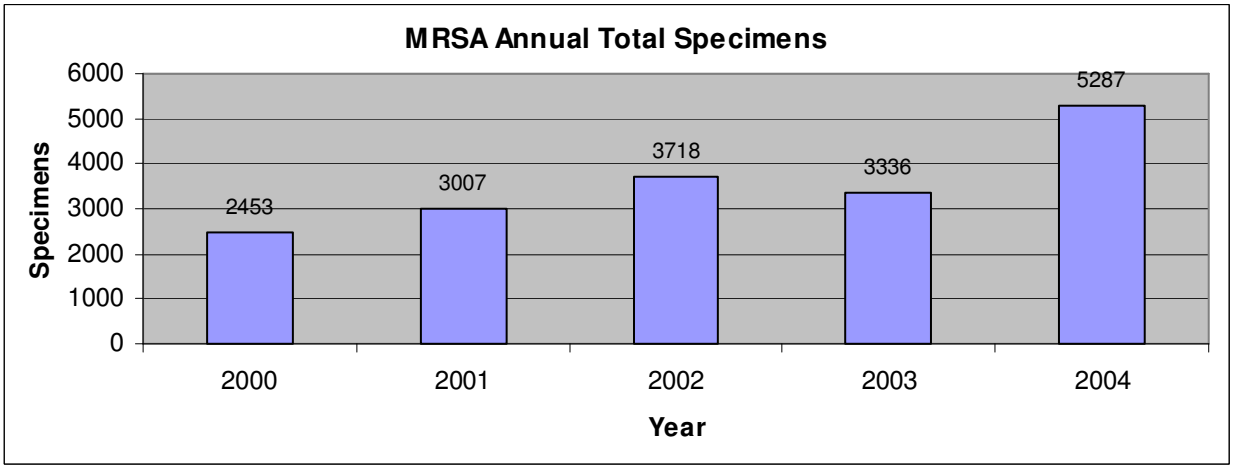
Comment: Most of the increased workload is attributable to routine testing. It is likely that the increase is largely due to a 25% increase in dialysis patients and increased surgery to decrease the backlog of patients requiring knee or hip replacement. In addition, the several bed shortages over the year have placed an increased load on the core laboratory services that are key to decision for discharge of patients.

4.4 DIVISION OF CLINICAL MICROBIOLOGY

Number of Tests Performed for Major Specimen Categories

OHIP Code	Test	Fiscal 2002	Fiscal 2003	Fiscal 2004	Fiscal 2005
L621	Antibiotic Sensitivity	6,080	6,825	6,358	7,581
L624	Blood Culture	17,172	19,197	18,663	19,982
L625	Cervical, Vaginal Culture	4,485	4,108	3,534	4,511
L628	Wound Culture	11,807	13,857	13,238	14,190
L629	Sputum Culture	2,846	2,726	4,207	2,440
L630	Stool Culture	2,182	1,982	2,023	2,059
L634	Urine Culture	18,572	18,999	18,398	22,635
L640	Throat Culture	3,097	2,746	3,963	5,160
L626	Fungal Culture	996	1,259	1,212	1,529
L650	Parasitology concentration	2,107	2,236	2,189	2,113
L654	Parasitology- smear	2,107	2,236	2,189	2,113

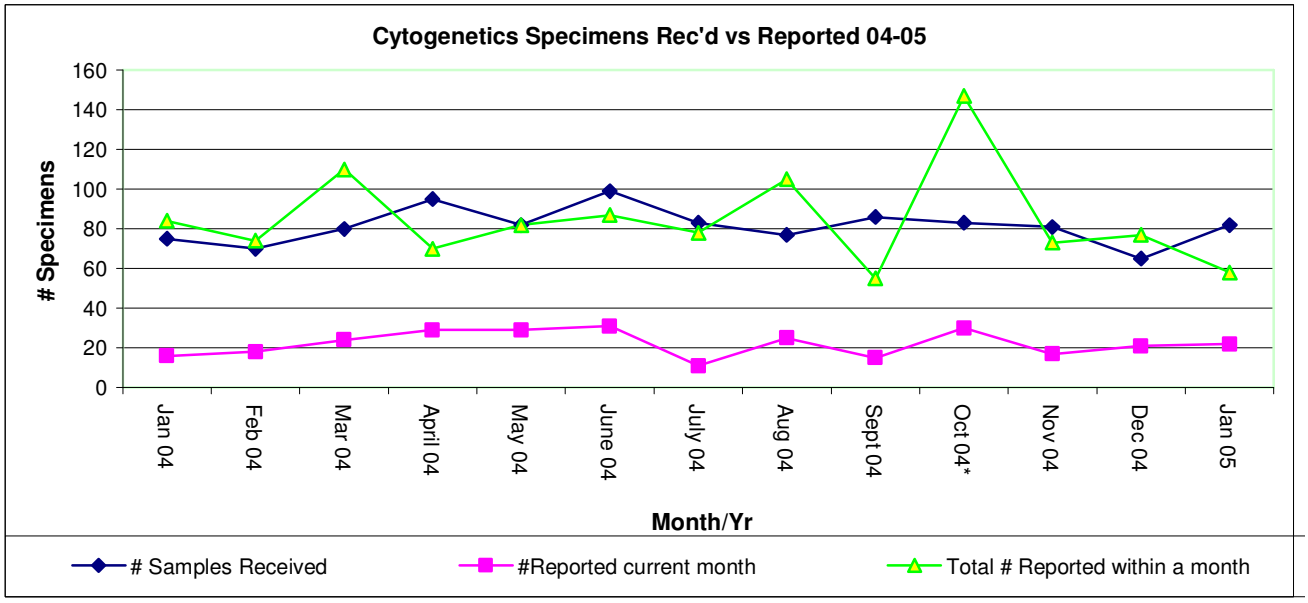




Comment: Microbiology is challenged with increases in MRSA surveillance cultures required to control the spread of MRSA. The proportion of positive cultures is increasing as well. A detailed utilization review of urine cultures in the KGH Emergency Department (E.D.) has been conducted and through feedback with the E.D. staff, we are working towards better utilization of urine cultures in E.D. We have adjusted our reporting protocols for urine cultures and are re-evaluating the impact that this has had.

4.4 DIVISION OF GENETICS

4.5.1 Cytogenetics



Comments: For the past 5 years, the laboratory has been faced with a perpetual backlog of specimens requiring analysis. This has developed due to the lack of technologists available to meet the demands of the increased number of specimens, as well as the increasing complexity of the testing required to complete the cases. The number of specimens received is consistently more than the number of cases reported. The analysis of almost 100 bone marrow specimens received in 2003 was discontinued (after consultation with the referring physicians) in the last quarter of 2004, since the specimens had been backlogged for a year or more. The action plan to address this backlog was as follows:

1. A business case was made to recruit for an additional cytogenetics technologist.
2. A bone marrow triage, coordinated by the hematopathogists and the molecular genetics and cytogenetic labs was implemented. With this triage, all hematological specimens first receive hematopathological evaluation before any cytogenetic testing is initiated. This new algorithm ensures that only clinically appropriate specimens receive laboratory genetic testing. The new algorithm has resulted in a 32% decrease (111/349 cases discontinued) in the number of cytogenetic specimens requiring analysis for hematological cancers (Fiscal 2005).

Increase in Flourescence In Situ Hybridization (FISH) Workload

	Fiscal 2004	**Fiscal 2005**
Prenatal Aneuploidy Screening	31 cases	49 cases
CML patients requiring Gleevac	10 cases	31 cases
Solid tumours (i.e. HER-2/neu amplification or c-myc gene rearrangements)	4 cases	16 cases
Prenatal pregnancy loss chromosome requests	21 cases	34 cases

4.5.2 Molecular Genetics

The changes to technologist staffing in the DNA Diagnostic Laboratory have made it necessary to review the workflow in order to maximize efficiencies. Even so, some turnaround times have lengthened by as much as 30% (familial breast and ovarian cancer testing).

i) Increase in Workload with respect to test and tissue type:

There have been no increases in workload this past year with the exception of a 27% increase in requests for BCR/ABL testing (94 versus 74 specimens annually) The static workload is in part due to the opening of molecular genetic testing facilities in other parts of the province and loss of workload to these facilities. As well, some of our testing which we have been doing for many years, such as Fragile X testing, has reached a steady state with respect to the number of individuals suspected of being affected in the general population. The DNA Diagnostic Laboratory continues to receive requests, both regionally and out of province, to provide services for our current tests or for the development of new tests. With the current limited staffing and with the changes we have experienced it has not been possible this past year to accommodate requests for additional testing. We are updating our current protocols to reflect changes in standards of practice and of knowledge of the genetics of the diseases for which we are providing testing. Included in this are genetic testing in familial breast and ovarian cancer and B and T cell clonality studies in leukemia and lymphoma.

ii) Equipment:

This past year there was the acquisition of a new PCR thermal cycler to replace an older machine, which could no longer be repaired and was unreliable for use in clinical assays.

A business case is in preparation for a Real Time PCR machine to provide quantitative RT PCR assays for BCR/ABL testing in chronic myelogenous leukemia, which is standard of practice, and which we have been unable to offer. This has necessitated the sending out of samples requiring this test to another centre, an option which is not likely to be available to us in the future as other laboratories respond to the regionalization of the provincial genetics program. The acquisition of the Real Time PCR machine would also decrease the workload associated with gel electrophoresis for high volume testing, such as hemochromatosis and tests for deep vein thromboses.

4.5.3 Clinical Genetics

The three clinical geneticists managed 707 patients through the 20 Barrie Street Clinical Genetics Program in Fiscal 2005. This included:

- 223 prenatal cases
- 118 clinical genetics consultations
- 366 patients seen in outpatient clinics

Over the past year, several new clinical genetics initiatives were instituted. A second weekly clinical genetics outpatient clinic was started on Friday afternoons at Fraser Armstrong Patient Centre. A new multidisciplinary hearing loss clinic was initiated on a monthly basis in collaboration with staff in the Ear Nose and Throat Department.

Two senior genetic counselors retired during the year. Recruitment was highly successful; the two new counselors both passed the certification examination set by the Canadian Association of Genetic Counselors. A Nurse Practitioner fills a Genetics Counselor's position in the Familial Oncology program.

5. QUALITY & UTILIZATION IMPROVEMENT ACTIVITIES

Some of the medical quality improvement activities of the Department are highlighted below. The full range of activities is documented in the 2004 – 2005 annual report of the Department's Quality & Utilization Improvement Committee (attached as an Appendix).

5.1 ANATOMIC PATHOLOGY

- Diagnostic biopsy turnaround time (TAT) auditing: 86% reported within 2 working days, within standard of 80% reported in 2 working days
- Frozen section-final diagnosis agreement within expected standards
- Pap smear diagnostic rate (LSIL, HSIL, ASCUS) monitoring: within standards
- Non-gyne cytology TAT rates within standards; gyne TAT rates fell outside 2 week standard due to technologist staffing shortage but corrected through use of part time technical staff
- Hospital autopsy TAT: remains outside 30 day standard to complete 80% of cases (currently 61 days)

5.2 HEMATOPATHOLOGY

- Audit of Protein C & Protein S testing in patients started/established on Warfarin therapy – results suggested triaging these requests will improve utilization and cost effectiveness. This is being implemented.
- STAT turnaround times (TAT's) for STAT differential WBC counts coming from the cancer clinic. The audits demonstrated improvement in TAT's for patients awaiting chemotherapy thus shortening patient waiting times.
- Utility of reflexive immunophenotyping of lymph node biopsies for the diagnosis of lymphoma

5.3 MICROBIOLOGY

- Blood culture positivity and contamination rates: 10% and 1.2% respectively; meets targets; continue to monitor
- CSF cell count turnaround time: 92% within 1 hour
- Positive blood culture rate turnaround time: 79% within 1 hour

5.4 GENETICS

- Redistribution of clinic coverage between clinicians and counselors to decrease patient waiting times
- Revision of laboratory workflow and implementation of a cross training program to ensure that technologists are competent in all procedures
- Development of a PCR based assay for B and T cell clonality studies which will reduce the need for labour intensive Southern blotting procedures
- Improvement and validation of a non-quantitative RT-PCR assay for the detection of BCR/ABL transcript

5.5 CLINICAL CHEMISTRY

- Computerized screening of quality control data from high volume instruments, replacing manual review of 537 quality controls
- Validation of multi-analyte calibrator set points to ensure continued quality performance when new calibrators are implemented
- On-call system to provide STAT volatile testing 24/7 for suspected methanol and/or glycol poisoning
- Addition of new interpretive reports (glucose tolerance testing protocols, etc.)

6. REGIONAL AND MULTIDISCIPLINARY ACTIVITIES

6.1 ONGOING ACTIVITIES

We continue to provide a wide range of regional and trans-regional diagnostic and clinical services, largely through our regional laboratory and clinical genetics outreach programs. Some of these are listed below:

- Diagnostic and medical directorship services and laboratory consultation to Perth, Smiths Falls, Napanee, QHC (Belleville General) and Weeneebayko hospitals. These include weekly or bi-weekly on-site visits (monthly to Moose Factory). The KGH Clinical Laboratories receives referral testing specimens from these sites and several others, including commercial labs and community physicians' offices in the region.
- The Peterborough genetics outreach program is coordinated out of the Peterborough Health Unit and comprises two full time genetic counselors. It is supervised by Dr. Forster-Gibson; she and Dr. Mackenzie visit Peterborough three times each year to provide on-site genetics clinics. Between visits, regular consultations are provided by telephone.
- A regional immunohistochemistry service (e.g. advanced diagnostic workup for solid tumours)
- Regional Cancer Centre secondary pathology review (for cases arriving from community hospitals)
- Regional Forensic Pathology Unit
- Regional Hematopathology service (for blood smear and bone marrow interpretation, including second opinions; consultation for hemostasis problems, blood transfusion issues, etc.)
- Transfusion nurse co-ordinator continues to work with clinical services to improve blood conservation and risk containment
- Multidisciplinary Point of Care Testing Committee – addressing need for new bedside glucose meters and blood gas analyzers outside the main laboratory (eg. O.R.)

6.2 NEW ACTIVITIES

- Regional Diagnostic Medical Equipment fund (MOHLTC) allowed for replacement of several laboratory test analyzers and technical equipment in several of the laboratories (total of $3.48 million for Southeastern Ontario academic and community hospitals)
- Collaboration with Canadian Blood Services (Ottawa) for matters pertaining to Stem Cell Transplant Program
- Collaboration with a working group for POC – INR testing for the planned centralized Anticoagulant Management Program
- Multidisciplinary hearing loss clinic (Genetics, ENT)
- BRAF mutation analysis for Phase 1 study of VEGF receptor AZD2171 – Queen's NCIC Clinical Trials Group Implementation of DHPLC and MLPA for familial breast and ovarian cancer testing

- Assessment of BRCA1 functional status by gene expression profiling – Advisory Research Council, Queen's University

7. GOALS FOR 2005-2006

Each of the following goals relates to one of the four departmental strategic priorities (stated earlier in this report). Each division has prepared its objectives based on these departmental goals. Examples are provided underneath each goal:

1. To recruit and retain a diverse group of highly skilled staff, faculty and students and provide an environment, which will enable them to achieve their highest potentials.
    - Successfully recruit to the vacant Pathologist position.
    - Continue to manage growth of Pathology residency programs

2. To provide clinical and diagnostic services and programs in education and research, which are recognized, nationally for their excellence.
    - Develop interface modification to enable auto-verification of chemistry lab results in order to improve turnaround time.
    - Create a customer service unit for all laboratory inquiries from users.
    - Advocate strongly for new instrumentation in the clinical laboratories to replace aging or obsolete instruments or to improve clinical service and quality.
    - Further integration and expansion of the Familial Oncology Program.
    - Introduce new tests in the clinical laboratories:
        i. Serum beta-hydroxybutyrate (management of diabetic ketoacidosis)
        ii. Enzymic serum creatinine
        iii. Estimated glomerular filtration rate (Egfr) to improve early detection of renal impairment
        iv. Serum transferring isoelectric focusing (detection of congenital defects of glycosylation – for the province of Ontario)
        v. PCR protocols for transplant related viral infections
        vi. HPV detection in Pap smear specimens

3. To lead in the development and optimization of regional laboratory services in Southeastern Ontario.
    - Complete data interfaces to Hospitals-in-Common-Laboratory Inc. as well as to QHC-Belleville and other satellite dialysis units to facilitate electronic transfer of test results.
    - Develop technical policies and procedures to facilitate standardization of testing in hospital laboratories throughout the region.

4. To employ sound business practices, to practice responsible stewardship of our resources, to embrace accountability for high standards of care and resource utilization and to manage resources in a fashion, which allows us to achieve our objectives.
    - Select, purchase and begin implementation of new LIS.
    - Implement the new Shire Genetics clinical patient management system to enable a more integrated system of record keeping and assessment.
    - Develop a new system to track inventory and order reagents and supplies within the clinical laboratories.
    - Develop a business process to enhance and facilitate hospital-based clinical research.
    - Optimize workflow in the Core Laboratory (Chemistry, Hematology) including analysis of instrument test configurations and pre-analytical processing.
    - Develop more robust data processes for tracking laboratory workload and productivity and for utilization management.

8. KEY CHALLENGES

- *IT and LIS Infrastructure*: Current infrastructure is fragmented, non-standardized, and of limited functionality, in comparison with contemporary practices. There is a major risk management issue associated with lack of vendor support for the existing LIS. Must be replaced in Fiscal 2006 – 2007 but considerable resources will be necessary for this enormous undertaking.
- *Equipment*: The lack of sufficient capital funds in previous years has left the Department with considerable outdated equipment, including both major and minor instruments. We lack proper microscopes and centrifuges. We also lack modern instruments capable of high performance liquid chromatography (HPLC), scanning spectrophotometry, fluorometry and mass spectrometry – all essential to meet the expectations of a university hospital.
- *Human resource issues*: More than 25% of our laboratory technologist workforce will be within retirement age over the next 5-10 years. This situation is exacerbated by the insufficient numbers of graduates from training programs and intense competition for these graduates in new disciplines such as molecular diagnostics. Succession planning and increased training of junior staff will be required (handling instruments, computers, data analysis).
- *Increasing demand*: In addition to increased volumes, as technologies change and become more complex, laboratories are also experiencing an escalation in demand for higher quality. An example is the explosion of cancer biomarker predictive testing (eg. HER-2/neu to determine eligibility for Herceptin therapy).
- *Space and Capacity*: Creative efforts are required in order to address the lack of space available in the Clinical Laboratories, most notably in the Chemistry area of the Core lab. The current laboratory requires major renovations in order to accommodate a layout that is commensurate with laboratory operations and provide a suitable working environment. This will necessitate identification of additional space and decanting of appropriate tests, and in addition will allow for development of specialized testing.

- *Research and Development*: Many of our laboratories require evidenced-based data in order to handle the need to recommend new procedures, troubleshoot problem areas, and facilitate wet-lab analysis of great utility to numerous researchers at Queen's, KGH, and HDH. This opportunity would be well received by researchers and it is expected that costs could be offset via purchases of the services. Dedicated staff is urgently required in order to address these requirements.
- *Regional leadership*: The MoHLTC laboratory reform process continues to drive change in the hospital laboratories of Southeastern Ontario. The development of an integrated regional laboratory system will require even greater collaboration than before from all hospital stakeholders so that all may benefit from the value of economies of scale and scope. The role of the Southeast region LHIN in regional laboratory reform is not yet known.

In closing, it is worth noting that there are numerous opportunities for the clinical laboratories to positively impact patient care. The coming year presents challenges that will not only tax our ingenuity and resources, but will also result in improved efficiencies, enhanced services, improved staff morale, and satisfaction for laboratory users.