Lab Practices Committee - Biochemical Genetics Lab Test Turn-Around Time and Sample/Record Retention Survey

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Summary of BGL Survey Performed

The CCMG Biochemical Genetics Survey for the collection of data on current practices for test turn-around times (TAT) and record/sample retention policies was initiated in August 2012, with follow-up email communications through to November 2013. The survey included questions regarding the TATs for common tests performed in most labs (e.g., plasma or bloodspot amino acid analysis), as well as an opportunity to provide data on more esoteric/lower volume metabolite, enzyme or qualitative testing. An effort was made to obtain data for both routine TATs as well as for priority testing such as for the follow-up investigation of a positive newborn screen result.
For sample and record retention, participants were asked to provide statements regarding their current practices, and what existing guidelines they were following.

The results of the participant data was compiled in November 2013 and summarized in the following tables. Table #1 summarizes the number of labs that participated in the survey; out of the 14 Canadian Biochemical Genetic Labs identified, 13 (or ~93%) of the labs submitted complete or partial data.

Table #1

Participation	# labs	%
1. surveys sent out	14	100%
2. responses back from survey	13	92.9%

Results for Routine and Priority Test Turn-Around Times (TATs)

The data in Table #2 summarizes the TATs for common and esoteric biochemical genetics tests. For common tests, the range in routine turn-around times was quite variable across the labs (from 2 days to a month). In at least one case, a significant contributing factor to prolonged routine TATs was instrument capacity (i.e., a single amino acid analyser that limits the number of samples that can be run in a day) versus current volumes. The range of responses for priority testing for the common tests was considerably tighter; from the test being performed on the same day to within 4 days for amino acids and acylcarnitines, and 1-10 days for urine organic acids.

For the esoteric/lower volume tests, the range in routine TATs were also variable but did suggest batching practices. For the single/specific metabolite(s) tests, they appeared to be performed on a weekly or biweekly basis, with likely lower volume tests being performed even less frequently (e.g., total homocysteine and 7-dehydrocholesterol) on roughly a monthly basis in some labs. However, similar to the common tests, priority testing for these esoteric/lower volume tests in the labs that responded was still being accomplished within days to approximately a week in all cases. For enzyme testing, the range in routine TATs was even more variable than the common metabolic testing, with enzyme testing being performed daily to monthly, or even almost bimonthly in some cases. Priority enzyme testing, similar to the previous categories, was reported to be within days to a week in all labs that responded.

Lastly, for qualitative testing, routine TATs were again mostly variable with the exception of electrophoretic tests being conducted largely monthly (only two respondents). For thin layer chromatography and especially for screen-type tests, variation in responses from daily to monthly was reported.

Overall, the findings provide insight into current testing practices of Canadian Biochemical Genetics labs. Although not specifically provided, it is likely that resources limitations (i.e., instrument, personnel, etc.) are a major driver of current routine TAT practices for both common and esoteric/low volume tests. However, labs appear to be able to respond to priority requests within time intervals that are equivalent or approach the quickest routine TATs reported, indicated that priority testing is more likely being influenced by methodological limitations of sample preparation and test performance than resource limitations.

Table #2

	Routine Testing				Priority (e.g., NBS Follow-Up)			
TATs (days)	*# labs*	*mean (d)*	*median (d)*	*range (d)*	*# labs*	*mean (d)*	*median (d)*	*range (d)*
1. amino acids, plasma/bs	13	10.15	7	2-40	11	1.66	1	0.5-4
2. amino acids, urine	13	11.31	7	2-40	8	1.91	1	0.5-4
3. Phe & Tyr monitoring, plasma/bs	12	7.00	7	2-30	N/A	N/A	N/A	N/A
4. acylcarnitines, plasma/bs	8	9.38	7	2-30	6	1.92	1	1-4
5. organic acids, urine	12	13.25	8.5	2-40	10	2.35	2	1-10
6. single/specific metabolite(s) (all)	17	15.94	14	7-45	8	2.25	1	1-10
methylmalonic acid	4	8.75	7	7-14	3	1.33	1	1-2
total and free carnitine	3	11.67	14	7-14	1	1.00	1	1
orotic acid	3	14.00	14	7-21	2	1.00	1	1
total homocysteine	4	14.00	10.5	5-30	1	1.00	1	1
7-dehydrocholesterol	3	34.33	30	28-45	1	10.00	10	10
7. enzyme assay (all)	21	20.71	14	1-49	9	4.11	1.5	1-7
enzyme assay (plasma/serum/bs)	7	22.43	21	2-45	3	4.67	5	3-7
enzyme assay (RBC)	4	19.50	21	1-40	2	3.00	3	1-5
enzyme assay (lymphocyte)	7	14.57	10	5-40	3	4.00	5	1-7
enzyme assay (tissue)	3	32.67	35	14-49	1	5.00	5	5
8. electrophoresis	2	37.50	37.5	30-45	N/A	N/A	N/A	N/A
9. TLC	3	12.67	10	7-21	1	2	2	2
10. screen	8	8.69	7	1-40	N/A	N/A	N/A	N/A

d, days; bs, blood spot; NBS, newborn screen; RBC, red blood cell; TAT, turn-around time.

Results for Sample Retention

The labs were asked to provide a statement that described their current sample retention policy, and whether they were following specific guidelines (Table #3). Of the participants that responded, the responses ranged from samples being disposed of on same day as receipt, to being held onto indefinitely. A dichotomy was indicated by some labs in that regular samples may be disposed of on a routine basis, but that specific material or samples representing positive diagnoses were being held on to for specific purposes (e.g., test development, quality controls, etc.) for a different time length. Given the nature of some of the responses (i.e., indefinite), a mean value could not be determined for either general practice or samples that fell into the exceptions category. Lastly, Most labs did not indicate what sample retention guidelines they

were following, but a subset of labs did indicate that they were following either their provincial College of Physicians and Surgeons recommendations (as part of their accreditation process), or guidelines put out by certain national associations.

Table #3

Sample Retention (months)	Current Practices/Guidelines Followed			
	# labs	*mean (m)*	*median (m)*	*range (m)*
1. general practice	9	N/D	2.5	0.5 - ∞
2. exceptions (specific material, positive samples)	4	N/D	∞	12 - ∞
3. Guidelines followed	None indicated (9), Provincial guidelines (CPS, accreditation; 4), CAP/AALA/NPAAC (1)			

AALA, American Association of Laboratory Accreditation; CAP, College of American Pathologists; CPS, College of Physicians and Surgeons of their respective province; N/D, not determinable; NPAAC, National Pathology Accreditation Advisory Council.

Results for Record Retention

Similar to sample retention practices, the labs were asked to provide a statement that described their current record retention policy, and whether they were following specific guidelines (Table #4). Given that there was little direction provided as to specific aspects of record retention, the responses were varied in terms of detail provided. Of the responses received, there as clear differences in the time patient requisitions and reports were retained, while there was relatively more consistency with the retention of records related to test performance (e.g., worksheets, QC records, instrument validation and monitoring). For some categories, given the nature of the responses (e.g., "life" or "termination"), a mean and in some cases a median value could not be assigned.

Also similar to sample retention policies, most labs did not indicate what guidelines they were following regarding record retention, but a subset of labs did indicate that they were following either their provincial College of Physicians and Surgeons recommendations (as part of their accreditation process), or guidelines put out by certain national associations.

Table #4

Record Retention (months)	Current Practices/Guidelines Followed			
	# labs	*mean (m)*	*median (m)*	*range (m)*
1. requisitions	5	11	3	1-24
2. lab data (worksheets, accession logs, etc.)	5	19.2	24	12-24
3. patient reports	8	84	78	24-180
4. QC records	5	45.6	60	24-60
5. QMS records	2	60	60	60
6. accreditation records (responses, etc.)	2	132	132	132
7. LIS records	3	N/D	N/D	24-"database life+36"
8. test/instrument validations	4	"Life+30"	"Life+30"	"test/instrument life"+24-36
9. equipment monitoring	3	48	60	24-60
10. equipment servicing	3	"Life+132"	"Life+132"	"instrument life"+24-132
11. staff records	3	N/D	N/D	120-"termination+132"
12. safety records	2	36	36	36
13. guidelines followed	None indicated (9), Provincial guidelines (CPS, accreditation; 4), CAP/AALA/NPAAC (1)			

AALA, American Association of Laboratory Accreditation; CAP, College of American Pathologists; CPS, College of Physicians and Surgeons of their respective province; N/D, not determinable; NPAAC, National Pathology Accreditation Advisory Council.

Overall Findings and Implications

Prior to conducting the CCMG Biochemical Genetics Lab survey, it was clear that there were little to no existing recommendations put out by associations or societies that were specific to Biochemical Genetics labs. Following completion and compiling of the data for the survey, the

results reinforced that labs were likely performing testing with TATs that are influenced by local demand and being balanced with limit resources, and they as are trying to follow guidelines for sample and record retention that they feel are most appropriate to them. For record retention, institutional and provincial guidelines should likely be followed wherever possible, as legal requirements for documentation and evidence in cases of medical malpractice suits could have serious implications if not properly followed. For sample retention, the lack of Biochemical Genetics lab guidelines has resulted in some labs following general chemistry guidelines, although with the recognition that positive samples do represent rare and important resources in our specific area. For test TATs, the lack of established TATs for Biochemical Genetic lab tests was evidence by the range of responses, but it was also encouraging to see that all labs indicated that they respond to priority requests similarly. And although the results of this survey are unlikely to lead to the establishment of guidelines for Biochemical Genetics labs, use of either the median or mean routine TATs could serve as a reasonable target for labs to strive to achieve in the future.

Original email communication:

Dear BG colleagues,

As part of the Canadian Ccollege of Medical Geneticists (CCMG) Laboratory Practice committee, I have been tasked at investigating current Biochemical Genetic (BG) lab practices pertaining to test turn-around times (TATs) as well as sample/record retention, with the goal towards informing the committee whether CCMG guidelines for one or more of these practices is warranted/beneficial/required for BG labs. Let me state up front that I am excluding all testing directly connected to newborn screening, as recommendations for these issues mostly already exist (in the literature and/or jurisdictionally).

As a first foray into my investigation, I thought that I would ask each BG lab in Canada to complete a survey to see 1) whether there are any provincial regulatory or accreditation requirements/recommendations regarding TATs or sample/record retention that people are already following, and 2) what are people's current practices regarding test TATs and sample/record retention.

If I could please ask you to spend a few minutes answering the following questions (in bold) and fill out the survey, I would greatly appreciate your input. Also, if I have inadvertantly missed a lab or contact of a person that is currently overseeing some aspect of BG testing, please let me know.

Test Turn-Around Times:

As a starting point, my cursory searches into existing recommendations for TATs specifically in the area of Biochemical Genetics haven't uncovered much. The ACMG has the following statement on-line:

American College of Medical Genetics and Genomics
STANDARDS AND GUIDELINES FOR CLINICAL GENETICS LABORATORIES
2008 Edition, Revised 02/2007

F CLINICAL BIOCHEMICAL GENETICS

F7.2 Turnaround Times: Turnaround times should be established and monitored for each test performed by the laboratory. Laboratory procedures utilized in clinical practice must be capable of providing rapid results when appropriate, particularly in cases of prenatal diagnosis or when the patient is acutely ill. If a rapid result cannot be produced in such circumstances, or if the expected turnaround time cannot be met in a situation that may negatively impact patient care, the referring physician or facility must be notified so as to permit consideration of, and plans for, alternative testing.

It's obviously that TATs are test-specific, as well as dependent on routine versus STAT/urgent testing which would include the follow-up of positive newborn screen results. Other factors that may also influence achievable TATs may include test demand, instrument capacity, staffing, etc. Given the breadth of testing in our field, and the lab-specific nature of certain types of testing, I would propose to take a macro view of our testing and simply touch on standard tests and generalized categories.

Please refer to the attached survey (PDF) to answer questions regarding TATs for standard tests or generalized categories. If you perform more than one or more tests within a given generalized category, please provide a representative TAT example(s). If you do not perform a specified test, or test within a general category, than simply skip that test/category. I have also indicated on the form to try, when ever possible, to given examples of tests within generalized categories that are higher volume tests in your lab and/or are utility for the follow-up of a positive newborn screen. In the latter case, this will help to understand if TATs for that test differ between routine and NBS follow-up testing.

Sample Retention:

Again, my searching on the web for existing recommendations on sample retention specific for Biochemical Genetics labs also hasn't turn up much. Although I did find a number of recommendations for general chemistry sample retention in different provinces, it is unclear to me whether Biochemical Genetics labs in those provinces are necessarily following those guidelines (and I'm not necessarily endorsing that you would follow such guidelines).

Obviously our field differs in a number of respects to general chemistry labs, and not just in test volume and complexity. As an example, it is not uncommon for our lab either to add tests to recent samples on a patient (because of insufficient current sample for example), or conduct investigations on older samples in light of new clinical or disease information. In Alberta, the College of Physicians of Surgeons of Alberta (our current accreditation body) has actually stipulated in their guidelines that Biochemical Genetics specimens are to be retained indefinitely. Although this has allowed us to maintain any sample we have received in the past, this has never been challenged legally so I am not certain as to the weight such guidelines actually hold.

Please provide a brief statement of your current sample retention practices and whether you are following any existing recommendations/requirements in your province.

Record Retention:

Finally, although I haven't found specific recommendations for Biochemical Genetics labs in regards to record retention, I have found general guidelines regarding record retention for clinical laboratories in different provinces. And as records are probably the most generalized aspect across different lab disciplines, I would think that these guidelines may actually serve as a template for many of the Canadian Biochemical Genetics labs.

Please provide a brief statement of your current record retention practices and whether you are following established provincial guidelines for clinical laboratories in your province.

CANADIAN COLLEGE OF MEDICAL GENETICISTS
COLLÈGE CANADIEN DE GÉNÉTICIENS MÉDICAUX

CCMG Laboratory Practices Committee

Survey of Biochemical Genetics Test Turn-Around Times (TATs)

Biochemical Geneticist/Clinical Biochemist: _____

Laboratory: _____

If a specific test within a given category has not been indicated, please choose a test(s) performed in your lab with a representative TAT; preferably a higher volume test and/or a test utilized for the follow-up of a positive newborn screen

	routine (d)	*NBS FU (d)*
Metabolite Profiles		
Amino Acid Analysis, Plasma/BS	_____	_____
Amino Acid Analysis, Urine	_____	_____
Phe & Tyr Monitoring, Plasma/BS	_____	n/a
Acylcarnitines, Plasma/BS	_____	_____
Organic Acids, Urine	_____	_____
Single Metabolite/Specific Metabolites		
_____	_____	_____
_____	_____	_____
_____	_____	_____
Enzyme Activity		
Plasma/Serum/BS_____	_____	_____
RBC_____	_____	_____
Lymphocyte_____	_____	_____
Tissue _____	_____	_____

"TAT" is defined as the amount of time, in days (d), that your lab would be expected to take to report ≥90% of results for a given test; from sample receipt to final report.

Qualitative Testing

Electrophoresis			n/a
TLC			
screen			n/a

"TAT" is defined as the amount of time, in days (d), that your lab would be expected to take to report ≥90% of results for a given test; from sample receipt to final report.