

'CRITICAL VALUES' REPORT

On Ontario's Community Medical Laboratory Services



Ontario Coalition For Lab Reform

December, 2017



CRITICAL VALUES REPORT

-page intentionally left blank-

Summary

Ontarians expect to have the best possible health care and they expect their government and healthcare providers to keep a relentless focus on how to deliver that. Community medical testing, however, has over a long period of time garnered only minimal attention and achieved just a small portion of its potential, with significant negative consequences for Ontario community patients. Many of the people who are most affected are those frequent users too ill to speak for themselves. Finally addressing this overlooked service properly becomes something of a litmus test for the health care system itself. .

- 80 % of medical decisions depend on laboratory tests yet over a million Ontarians face serious problems in getting tested today, including many frail elderly.
- Medical tests are an essential medical service, but over 90% of testing falls under the control of a two very large private companies working together as a legal cartel. Despite good intentions, over time, patient needs have been losing out enormously to the imperatives of these private concerns.
- The Ontario Ministry of Health has been underequipped and, as yet, highly ineffective in its oversight and policy formation, with most initiatives unrealized into patient benefits, whether it is new technology, additional access, or new tests.
- Some six out of ten Ontarians require community medical lab tests each year but very significant imminent changes being developed by the Ministry have been essentially kept secret until now, even from healthcare providers in the province. Unfortunately, several of the measures being contemplated would worsen the quality of testing.

The OCLR has launched a public education campaign called Make Lab Tests Matter, in part to build on last week's Auditor General's report. A much greater level of public awareness about community medical testing is required to ensure that the best choices are made, and a balance is restored in the favour of the needs of individual patients and of the requirements of the health care system as a whole.

It has been in the interests of the large laboratory corporations to claim that the remedies for better, even excellent laboratory testing, are complex and time consuming, as a way of maintaining a status quo has been so long in their favour. In fact, the outlook required is very straightforward. Community medical laboratory services can be markedly improved with three simple and attainable measures:

- 1) **Remove the exception** that supports the privilege of the large laboratory companies. Apply regular commercial law so that the unusual legal laabs cartel or oligopoly is no longer able to function as one.

CRITICAL VALUES REPORT

- 2) **Install active oversight** – appoint a Labs Commissioner to ensure patient needs are constantly the priority, and to provide much needed transparency for the service
- 3) **Establish smart payment rules for fair competition** service. Let payment follow the patient. The right kind of competition provides effective daily protection of patients' and providers' choices of the best possible service. Require volume discounts for those tests with high volumes to save an estimated further \$50 million.

The problems of the provincial community medical laboratory testing services are not the result of any conspiracy but rather a longstanding poorly designed 'non-system', lacking effective checks and balances and therefore subject to exploitation over time.

I. Introduction

In the medical laboratory 'critical values' are those test results which are so much at variance with normal as to be life-threatening, unless something is done promptly and for which some corrective action could be taken. This is the title of our report because its meaning also aptly describes the signals about the condition of the province's community medical laboratory testing eco-system. There is still time and ability to prevent more serious negative outcomes for community patients, but immediate action and a change of course is urgently required.

Critical values of course have another meaning in the public healthcare values that are at stake when it is necessary to act in order to preserve the public interest in conflict with private interests.

By the end of December 2017, the Ministry of Health and Long Term Care (MOHLTC) is expected to finalize significant changes to both the standards and funding system for community medical laboratory testing for the first time in 20 years. There may a few directional improvements but the overall impact threatens to worsen conditions for patients. The purpose of this report is to support the public awareness and debate necessary to realize the much better outcome Ontarians deserve. The report is one step of an overall education campaign, within medical laboratory services and the larger health sector and among the public at large.

This effort was enabled by the Auditor General's report on Laboratory Services in Health Care released last week. The information contained therein allows the public to have an informed discussion and arrive at a sound conclusion. One of the peculiarities of community laboratories is that they have been perhaps the most secretive part of Ontario healthcare with virtually no information available to the public, from payment amounts to inspection reports and all community laboratory service providers sworn to confidentiality.

CRITICAL VALUES REPORT

In Ontario, laboratory tests are still officially viewed as an out-of-sight, out-of-mind, and taken-for-granted service, most often treated as either a 'commodity' to be obtained at the lowest cost in the community or a 'back office expense' in hospitals. Elsewhere, lab tests results are being recognized as a dynamic strategic resource to bring the latest in information technology and medical science advances to health care practitioners and their patients, and personalize the diagnosis, monitoring and treatment of disease.

The Ministry has not yet fulfilled its duty to work with Ontarians to ensure they have the lab services they really need and but it is still about to finalize the first changes in a generation. For example, the Ministry is not seeking "total" quality for labs which is standard in other jurisdictions, linking medical tests to actual patient health outcomes. This would mean better support for test selection and interpretation and the ready availability of expert laboratory advice to frontline clinicians.

LAB FACT: Community medical laboratory tests are the second most used health service in Ontario, after doctor visits. 125 million tests are ordered by physicians, nurse practitioners and mid-wives each year for 7.5 million people. Unique in Canada the service here is provided exclusively by private for-profit laboratory companies, with over 90% from two large mega-labs. Specimens are collected through 380 public patient centres or taken directly in at hundreds of doctors' offices and then picked up by labs for processing and reporting back. Also uniquely, from 1998 until April 1, 2017 the service was conducted mainly through an irregular policy of fixed market shares that prevented competition. A new policy is pending.

I. A Legal Laboratory Services Cartel/Oligopoly

The medical laboratory services sector in Ontario was disconnected from accountability some years ago and has yet to be reconnected. Most people being tested are unaware that their laboratory tests are done by a private company. They assume at the very least it is a closely supervised by the government on their behalf.

Instead, as the Office of the Auditor General report makes clear, the old arrangement allowed certain companies to make severe service reductions at their own discretion in order to increase their profits, restrained neither by competition or public standards to protect patients. It also allowed companies to work uncontested either by explicit or tacit arrangement to create monopolies in 90 Ontario communities.

LAB FACT: A "legal cartel" arose when Ontario's largest laboratories entered into market sharing arrangement by a regulation they proposed to the government in 1998. Such action would otherwise violate the conspiracy provisions of commercial competition laws. The regulatory exemption defense has allowed the largest laboratories to work together, first five, then three and now two in number, even when it may have been against the overall consumer (patient) interest, as the federal competition defers to provincial government acting within their authority.

TABLE 1 – Impact of Weak Ministry Oversight on Largest Laboratory Control Over Conditions of Service

Auditor General Identified Enabling Behaviour by the Ministry	Largest Laboratory Actions Impacting Patients and Healthcare Practitioners
The Ministry cannot assess if the current capacity of community collection centres is sufficient to meet patient needs across the province. (AG 405)	Reduced patient access (specimen collection centres and laboratories) by 47% per capita across the province ⁱ .
No consistent performance measurement and reporting of laboratory services. ...has been a concern in Ontario for more than 20 years, the Ministry has done little to address this concern (AG 407)	Discontinued 69% of healthcare practitioner specimen pick-up services, cutting services to 4,321 physicians and nurse practitioners ⁱⁱ .
The Ministry has not ensured that laboratory services are equally accessible to Ontarians. (AG 406)	Cancelled 97% of home specimen collection services for Ontario’s most frail at home patients, to just a reported 26,100 down from an estimated 770,000 ⁱⁱⁱ .
No assessment of effectiveness and efficiency of different types of laboratories (AG 393)	Gained efficiencies from takeovers and closure of 23 smaller and medium sized laboratories, leaving only five functioning today. Lowered their own costs with new technology by 6% annually ^{iv} ;
The Ministry has not ensured that laboratory services are provided to Ontarians cost effectively . (AG 380)	Accepted an estimated \$1 Billion in overpayments that could have been used to fund other needed health care services from 1998 to 2012 ^v .

As the Auditor General makes abundantly clear and is reflected in Table 1 above, it is the largest laboratories and not the Ministry of Health which are effectively in charge of the terms and conditions and standards of testing services for Ontarians. In the table, the Auditor General’s concerns are matched to factual reductions in laboratory services derived from other sources. As the OAGO report also demonstrates there are no benefits to the public from this unusual self-regulation arrangement.

The Ministry also gave large laboratories in Ontario a unique exclusivity over community medical testing. Ontario became the only province in Canada that does not pay hospitals for

CRITICAL VALUES REPORT

their community laboratory work, and specialty agencies such as In Common Laboratories and mobile lab services were ruled out OHIP work by policy and regulatory decisions of the Ministry. The trade association Ontario Association of Medical Labs (OAML) is controlled by the large laboratories but has often received significant funding directly from the Ministry.

The only improvements in patient service came in the period from 2011 to 2015 when OCLR members were able to convince the Ministry to do pilots of competition combined with performance standards and expectations, resulting in for example, the re-opening of nearly 40 public access centres and 88,000 new hours of service at a lower cost. This significant progress was eroded beginning in 2016 when the Ministry mysteriously reversed course and cancelled the large pilot program, leading to declines in quality and access and leaving the future for quality for community patients in doubt.

Recommendation #1: Restrict harmful 'legal cartel'/oligopoly control over community laboratory services by eliminating their privileged position. Allow the federal Competition Bureau of Canada to re-establish normal jurisdiction over laboratory services by removing the regulatory exemption, or by establishing binding rules through the Minister's regulatory and policy powers.

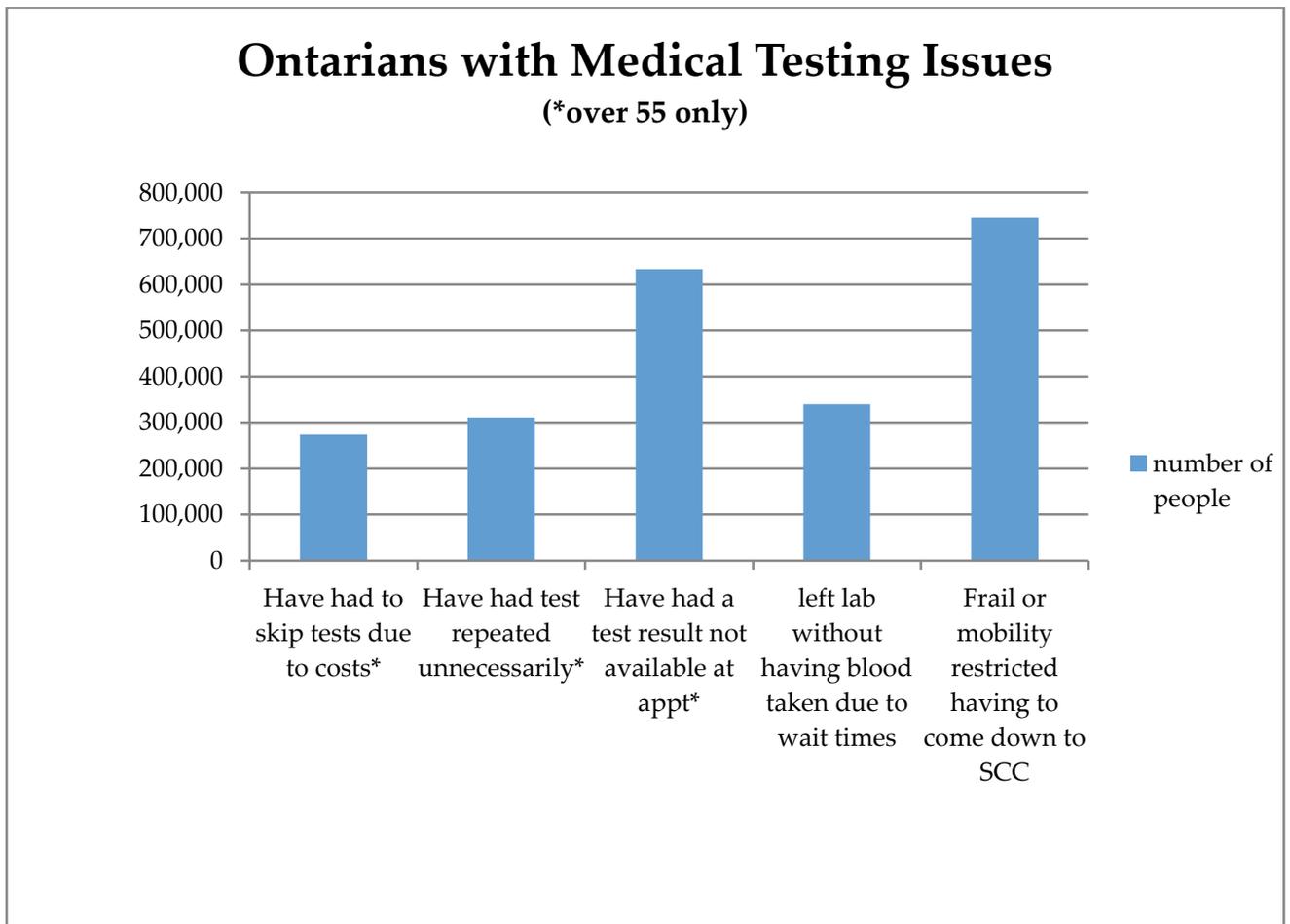
II. Non-Patient Centric Laboratory Services

“For the past 18 years the funding model has been provider centric and volume driven instead of patient outcomes based service delivery. Service quality for patients has been defined by the supplier” (quoting Ministry’s own submission to cabinet, 2016.) (AG 408)

Laboratory staff in all laboratory organizations demonstrate tremendous commitment to the well-being of patients every day. Unfortunately that effort is not sufficient in itself to offset the problems in the design of the “non-system” that is itself not oriented to patients.

A. Consequences for Patients

According to available documentation, **over one million Ontario residents experience serious difficulties in getting their testing completed**, problems that seem to be occurring at a markedly higher rate than elsewhere. (see Graph 1 and Table 2 below)



CRITICAL VALUES REPORT

Table 2- Ontarians over 55 Lab Experiences ^{vii}	Rate	Compared to Canada Avg Rate	11 country average
Have had to skip tests due to associated costs	7.6%	34% higher	40% higher
Have had test repeated unnecessarily	6.1%	20% higher	91% higher
Have had a test result not available at their scheduled appointment with their healthcare practitioner	15.5%	23% higher	

At least **340,000 people per year leave Ontario labs without having their blood taken** due to perceived too lengthy wait times, based on data collected by Ontario’s largest laboratories^{vi}.

“I do blood work at home for my elderly patients and another 200 boarding home residents, but it’s like practicing medicine in a developing country. There are still so many gaps.

When I started practicing medicine labs went into homes to serve patients. But that stopped and people don’t have disposable income to cover the service fees. Home lab tests mean more patients avoid emergency rooms because we prevent more illness.”

Dr. William Etkorn, Community Family Physician, Toronto

Perhaps the most profound health implications are for the large group of Ontarians who have to struggle with their significant mobility or health frailty issues. They are forced to attend public collection centres with assistance of family, friends or community services in order to have tests completed. This is due to the virtual elimination of

home phlebotomy (blood taking) services in recent years. Previously performed free of charge, as they still are in other provinces, they became a difficult to access service with user fees of \$25 to \$60 a visit. Based on previous service levels and other current home care services, between 550,000 and 745,000 of Ontario’s most vulnerable have no choice but to undergo great difficulty or to miss their test altogether, all because of a conflict of their needs with private interests.

“At 94, Mom is blind, suffers from liver disease and arthritis, and needs tests every week or two. Home tests are too costly that often. Yet there are times she is just totally, totally unable to get out.

The round trips to labs every 1-2 weeks can easily take two and a half hours each time; sometimes I call the doctor and say, "Mom just can't go."

Deana Crawley, Waterdown

B. Ontario Patients Face A Patchwork ‘Non-system’ Across the Province

The Auditor General cites public access points per capita for the province are 50% below that of BC or Quebec, and far below Manitoba. Patient problems cited above are exacerbated based on where in the province a community patient happens to live. In the past twenty years the largest private companies were able to reduce public access points, and as the Auditor General makes clear, “community laboratory providers have full discretion to decide where they operate their collection centres” (AC 405). Variation between regions ranged from 20% above to 35% below average in the Auditor General’s data. “ **The underserved areas are not necessarily located in rural and remote northern areas (AG 406)**” but as the Ministry’s own data makes clearer, patients in urban area’s suffer due to choices made by the larger laboratories in closing centres.

Table 3- Ontario population per public patient lab service centre^{viii}

Area	1997	2017	Reduction per capita
Ontario	1: 24,315	1: 35,933	-48%
Toronto	1: 15,903	1:30,017	-89%
Hamilton	1: 18,712	1: 41,301	-121%
Ottawa	1:24,524	1:44,154	-80%

C. Ontario Patients Have Been Denied Access to Any New Medically Necessary Tests for 17 years, while other provinces such as Quebec approved as many as 34 in the last two years alone. The Auditor General lists 16 tests recommended by a consultant but not implemented (AG 396) See appendix 1 for additional medically necessary tests that that are being used in other provinces and not available on OHIP.

The Auditor General also cites 1.1 million tests paid for out of pocket by Ontarians at completely unregulated prices.

Recommendation #2 : Install active oversight – appoint a well- qualified provincial Labs Commissioner with sufficient powers and enough statutory independence to put laboratory medicine and science to work for patients, to ensure higher standards and create the true system Ontarian’s deserve, including a level playing field for hospitals and community laboratories to collaborate together.

III. The Ministry Previously Secret Plan : SOME FUNDAMENTAL CONTRADICTIONS

With 19.5 million patient visits to community medical laboratories a year, the only real way to ensure real time assurance of good service and quality is through a measure of competition. It combines with an Industry Cap or maximum payment limit to protect the government from cost over-runs. Alternatives such a retrospective reporting of standards have been shown to have only limited effects in existing RFPs or contract arrangements. The privilege of private companies providing essential medically necessary services, even in a support mode, brings with it an obligation to put the patient first. Yet the means of ensuring that this is done consistently has to be in keeping the private company form of organization.

Recent public comments by the highest ranking officials would appear to make clear that they agree wholeheartedly with the concept:

THE CLAIM

“..This relates to consumer choice. The choice of which lab they go to, of course, determines which company is going to get paid for the test, so there is an element of competition that has entered in the new arrangement in that previously, labs were capped as to the amount they would receive. What we’re allowing for now is for labs to compete for more business”. The way they would compete... is by offering better service to patients.”- **Deputy Minister Dr. Bob Bell, Deputy Minister, MOHLTC,**

“There came from the laboratory sector itself a desire, by many to have a greater level of competition...for the type, level and nature of the service, to encourage patients, for example, to come to their library site as opposed to a competitors” –

, Hon. Eric Hoskins, Minister of Health and Long Term Care

Estimates Committee, November 15, 2017

THE ACTUAL PROPOSAL(as related in the Auditor General’s Report) *..the funding cap of each community laboratory service provider will be revised annually and funding to each one will increase or decrease based on **changes in the test volumes over the past two years (emphasis added)**, compared to other community laboratory service providers. (AG 409)*

As stated this means that a laboratory willing to provide better service in a new areas would have to **self-fund it themselves for up to 2 and half years**, and take six or seven years to earn a return on the service. At the same time another lab reducing or closing down services would

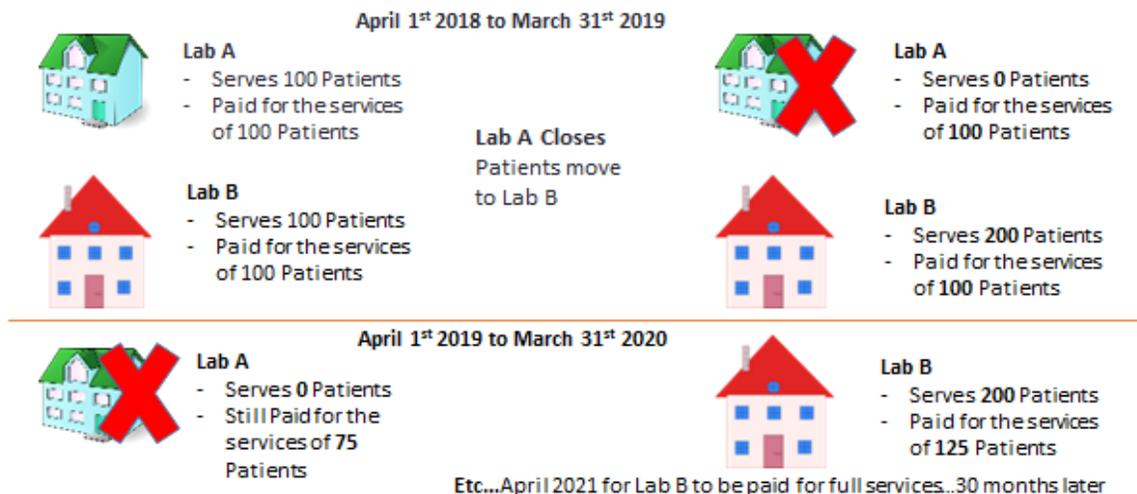
CRITICAL VALUES REPORT

continue to get paid for their discontinued services for the same 30 months period, wasting potentially millions of taxpayer dollar. (Please see Table 4 below)

TABLE 4

Current Ministry Proposal for ‘competition’

1 Year Reset – past two year average – example change halfway through year 1.



This is NOT a transition to meaningful competition, it is perpetuating the broken system

Should this become the Ministry’s final world it would mean enormous favouritism to the largest laboratories as they are the only ones with the deep pockets to afford such economics. It is not clear how such a biased proposal can possibly square with the public remarks made by the Minister and the Deputy Minister.

SME labs would face enormous risk from the unfair advantages by the larger concerns to lose business eventually, perhaps inevitably going out of business. If the longstanding innovative smaller firms that have been advocating for patients cannot persist then patients will be the losers, as they have been so prominently at times of larger laboratory control.

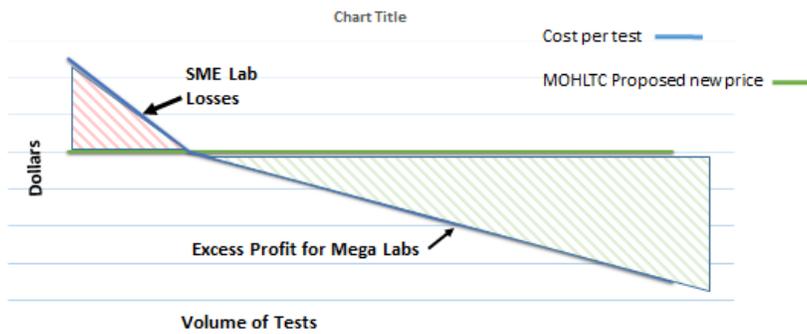
SME labs want to continue to innovate, grow and compete under fair and honest conditions. All of the ten net locations opened in the past two years have come from SME concerns while by contrast enormous market leader Lifelabs has closed a net eight locations.

Recommendation 3A = Smart payment for competition . Let payment actually follow patient. Let patients and providers choose based on best service and quality. Don't pay labs for services they discontinue, as is currently proposed. There is no justification for these delays except to preserve vested interests. If there are additional dollars, pay labs who have been unpaid or underpaid in recent years instead.

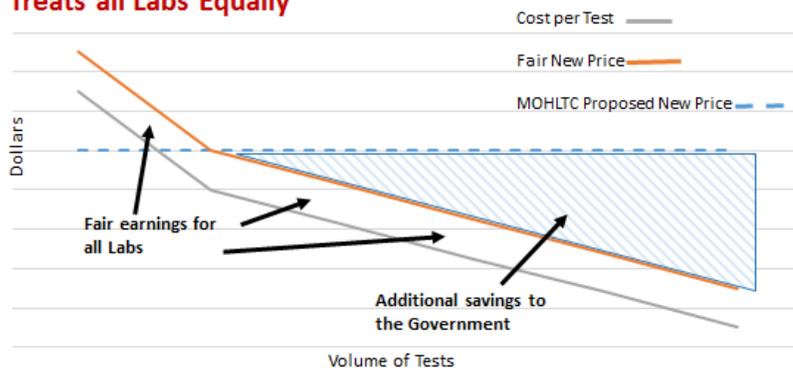
The Ministry is also redoing prices for the first time in nearly 20 years, a necessary task. At the same time, as the Auditor General makes clear this effort in a flawed one. The Ministry has never refuted the microeconomic pricing proposal by the OCLR (see Graph 2) that would not only be much fairer and effective but would also save the Ministry more money.

GRAPH 2

**Ministry Proposed 1 Price Model =
Unlevel Business Environment**
Provides excess profit to mega labs while starving SME labs



**Fair Volume Based Prices = Level Field for Test
Services, & more Government Savings**
Treats all Labs Equally



Recommendation 3B – Smart Payment #2 for competition– Fair Volume Based Prices

Require volume discounts for tests with high volumes and set test prices fairly. Each lab should be paid the same for the same tests at the same volume eg. \$1 each for the first 1000 tests, \$.75 for the next 10,000 and \$.50 for the next 100,000. Taking a **volume price discount** on high volume tests would reflect the real world economics of testing costs. All labs could cover their fixed costs at lower volumes and would earn the same opportunity to grow. Savings to the government would increase overall and could be as much as \$50 million per year



The Ontario Coalition for Lab Reform is a group of longstanding same-owner operated medical laboratories, non-profit laboratory organizations, laboratory professionals, healthcare providers, and allied health services trying to improve the benefit to patients outcomes, value to the healthcare system and confidence among the public of Ontario's medical laboratory system.

Founding Members:

Alpha Laboratories

Bio-test Laboratory

MedEX HealthServices

For more information please contact: (416) 449-2166 ext 1288

www.labreform.ca

info@labreform.ca

All AG reference = Office of the Auditor General of Ontario, Annual Report 2017, Reports on Value for Money Audits Section 3.07 Laboratory Services in the Health Sector pp.375 to 427

APPENDIX 1 – MORE MEDICALLY NECESSARY TESTS NOT AVAILABLE IN ONTARIO

- | | |
|--|---|
| <p>Bioavailable testosterone and Sex Binding Hormone Globulin</p> | <p>Decreased SHBG levels can be seen in obesity, hypothyroidism, androgen use, and nephritic syndrome (a form of kidney disease). Increased levels are seen in cirrhosis, hyperthyroidism, and estrogen use.</p> |
| <ul style="list-style-type: none"> • HPV | <p>Persistence of a cancer-causing type of HPV infection can, over a number of years (10 years or more), slowly cause changes that can lead to cervical cancer unless found and treated.</p> |
| <ul style="list-style-type: none"> • Calprotectin | <p>screening of Organic and Functional Disease and therapy follow up. It is the best Irritable Bowel Disease (IBD) marker as it provides excellent negative predictive value to rule out IBD and supports therapy follow up of IBD patients. It is also of particular interest for pediatric gastroenterology</p> |
| <ul style="list-style-type: none"> • Urea breath test, | <p>Clinical indications for the test are the initial detection and confirmation of eradication of H. pylori infection in adults with dyspepsia</p> |
| <ul style="list-style-type: none"> • Diagnosis of Latent TB Infections (Quantiferon) | <p>Identification and treatment of LTBI can substantially reduce the risk of development of disease and so have the potential to protect the health of the individual as well as the public by reducing the number of possible sources of future transmission</p> |
| <ul style="list-style-type: none"> • BNP and Sex Hormone Binding Globulin | <p>Levels of both BNP and N-terminal pro b-type natriuretic peptide (NT-proBNP) can be measured to help diagnose and monitor patients with heart failure.</p> |
| <ul style="list-style-type: none"> • Celiac Disease | <p>Celiac disease antibody tests are primarily used to help diagnose and monitor celiac disease, an autoimmune disorder caused by an inappropriate immune response to gluten, a protein found in wheat, and related dietary proteins in rye and barley.</p> |

END NOTES

ⁱ Laboratories and Specimen Collectoin Centres in Ontario, Ministry of Health and Long Term Care, Dec 06, 2017 August 05, 1997

ⁱⁱ Assessing the Value of Community Laboratories in Ontario, OAML, 2007, p5, 15

ⁱⁱⁱ Brief on Community Medical Laboratories to Members of Provincial Parliament, MDS Laboratories, 1998, MDS reported 242,000 home visits themselves which extrapolates to 770,000 based on 30.5% markets share.

^{iv} OAML, 2007, p 10

^v OCLR paper based on OAML, Quebec, US and Deloitte consultant estimates of lab efficiency and other methods (available)

^{vi} Report of the Study of Provincial Access to Community Laboratory Phlebotomy Service in Ontario, June, 26, 2012, p.3

^{vii}, Davis, K. et al. *Mirror, Mirror on the Wall: How the Performance of the U.S. Health Care System Compares Internationally*, The Commonwealth Fund, June 2014. special data run, private correspondence Survey n= 1,502

^{viii} Sources: Ministry of Health and Long Term Care Laboratories and Specimen Collection Centres in Ontario , August 05, 1997, and December, 2017, includes 3,000 and 5,000 series licenses open to public, Statistics Canada