AUDITOR GENERAL'S DEPARTMENT
ACTIVITY BASED AUDIT REPORT
OF THE
NATIONAL PUBLIC HEALTH LABORATORY

The Auditor General is appointed by the Governor General and is required by the Constitution, Financial Administration and Audit Act, other sundry acts and letters of engagement, to conduct audits at least once per year of the accounts, financial transactions, operations and financial statements of central government ministries and departments, local government agencies, statutory bodies and government companies.

The Department is headed by the Auditor General, Pamela Monroe Ellis, who submits her reports to the Speaker of the House of Representatives in accordance with Section 122 of the Constitution of Jamaica and Section 29 of the Financial Administration and Audit Act.

This report has been prepared by the Auditor General's Department of Jamaica for presentation to the House of Representatives.

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November 24, 2015

The Honourable Speaker
House of Representatives
Gordon House
81 Duke Street
Kingston
Jamaica

Dear Sir,

In accordance with the provision of Section 29 of the Financial Administration and Audit (FAA) Act, I have the honour to submit my report on the findings and recommendations of the Activity-based Audit on the National Public Health Laboratory for tabling in the House of Representatives.

Yours faithfully,

Pamela Monroe Ellis (Mrs.)
Auditor General

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EXECUTIVE SUMMARY

The National Public Health Laboratory (NPHL) is the apex of the national laboratory network. Its goal is to be the leader in diagnostics and laboratory technology whilst promoting and facilitating access to safe, reliable and appropriate diagnostic technologies and laboratory services. The NPHL plays a central role in the national health infrastructure that includes monitoring conditions of public health importance and national disaster response as well as supporting the diagnosis, care and treatment of patients.

The NPHL provides laboratory services for clinical and public health interventions, as well as support to the Regional Health Authorities (RHAs), particularly the South East Regional Health Authority (SERHA), within which it falls geographically. It provides particular clinical laboratory support to the Kingston Public Hospital and Victoria Jubilee Hospital and other health institutions within the SERHA and the rest of the national public health system, as required.

In keeping with her mandate the Auditor General commissioned an audit of the NPHL to assess its impact on the timely and effective delivery of health care, in particular the adequacy of lab equipment, physical infrastructure and related tools, processes and procedures as well as its level of certification/accreditation. The audit also examined the economy of the NPHL's administrative activities and management's approach to adhering to good corporate governance practices.

The key findings are outlined in paragraphs 1 to 7 below.

Key Findings

NPHL seeks accreditation in the absence of the Health Facilities (Medical Laboratories) Act

1. Despite the passage of the *Health Facilities (Medical Laboratories) Act* and its subsequent assent by the Governor General ten years ago, laboratories in Jamaica continue to operate without a specific regulatory framework because the *Act* was not gazetted and brought into operation. Section 1 of the *Health Facilities (Medical Laboratories) Act* states that the *Act* "*shall come into operation on a day to be appointed by the Minister by notice published in the Gazette."* However, the relevant notice was not published in the Gazette. We were advised that both the *Act* and the draft *Regulations* are currently with the Ministry of Health's Legal Unit for review because based on the issues to be captured in the *Regulations*, the *Health Facilities (Medical Laboratories) Act* would need to be amended before promulgation. The Ministry advised that in the absence of the *Health Facilities (Medical Laboratories) Act*, labs are monitored under the Public Health Act and the Quarantine Act and that its Standards and Regulations unit conducts periodic inspections of both public and private labs to

determine whether certain public health standards are met. Additionally, the MOH indicated that labs are also assessed as part of the process to obtain Health Provider Status.

2. In the absence of the *Health Facilities (Medical Laboratories) Act,* the NPHL applied for accreditation for some of its activities in November, 2013. These include Haematology, Phlebotomy, Clinical Chemistry, Sample Reception, and Emergency Laboratory. However, the local accreditation body, *Jamaica National Agency for Accreditation (JANAAC)*, conducted an initial assessment of the NPHL in December 2014 and identified thirty-one areas across all the departments that were assessed where the NPHL's systems were inadequate and did not conform to the requirements of the relevant international standard (*ISO 15189:2012*). The NPHL subsequently took corrective action to adequately address seven of the *non-conformities* while the other twenty-four were in various stages of reform. We were subsequently advised that another follow-up review was conducted by JANAAC in September 2015 leading to the closure of most of the non-conformities. However, the details could not be verified as the written report from JANAAC was not yet available for audit review. While credit should be given to the NPHL for taking steps to achieve accreditation for some of its activities, the absence of this type of standardization in other areas increased the risk of inadequate and or inconsistent laboratory practices in those areas which may result in decreased reliance on its test results.

NPHL Performance and Efficiency

3. Despite generally attaining its targeted turnaround time for testing in Haematology, Phlebotomy, Clinical Chemistry, Sample Reception, Emergency Laboratory and urgent Histology cases, the NPHL experienced significant challenges in consistently achieving its established turnaround time in Cytology, Microbiology, Serology, Immunology and "*less urgent"* Histology cases. Data analysis for the period January to July 2015 revealed that there were significant backlogs in these departments as shown in ***Table 1***.

Table 1: Backlog Samples

Department	Standard Turnaround Time	Average Actual Turnaround Time	Backlog Samples
Histology	6–12 weeks (less urgent)	6 -16 weeks	630
Cytology (Gynaecological)	8 weeks	12 weeks	6,905
Cytology (Non-Gynaecological)	7-14 days	20 days	17
Micro-Biology (Tuberculosis)	3 - 13 days	*Testing suspended since November 2014 due to non-functioning Air Condition system. Samples being referred to CARPHA.*	
Serology	5 days	10 days	671
Immunology	10 days 10 days (HIV)	41 days 27 days	1,741 789
TOTAL			**10,753**

Source: NPHL

4. This delayed turnaround time increased the risk of delays in diagnosis, treatment and general patient care. The NPHL indicated that the major factors contributing to the delayed turnaround time include inadequate supplies such as reagents, inadequate water supply, inadequate lab coats, inadequate staff, and unreliable cooling equipment such as Air Conditioners and Refrigerators.

5. Despite having a maintenance system in place, the NPHL was not consistently servicing its equipment on a timely basis in accordance with its standard operating procedures. We identified four critical pieces of equipment, *two Chemical Fume Hoods and two Biological Safety Cabinets*, which were not being serviced in keeping with the recommended maintenance frequency. This increased the risk of equipment breakdown which may lead to greater delays in turnaround time.

6. We were advised by the NPHL that of the projected thirteen major strategies for implementation during the period 2013 to 2015, only four were substantially achieved as at August 31, 2015. The NPHL's failure to implement its key strategies will result in a delay in the modernisation of the NPHL and its goal of providing high quality clinical and public health laboratory testing services in accordance with international standards may not be achieved as planned. Management attributed the failure to execute these strategies within the proposed timeline to the inability to secure the requisite resources.

Hazardous Working Conditions

7. We observed that employees in the Histology Department were working under uncomfortable and hazardous conditions. The Department appears to have outgrown its space as samples waiting to be tested were stored on the floor and under tables. We also noted that there was a high risk of exposure to hazardous chemicals and fumes circulating in the air due to the absence of a functioning laboratory fume extraction system. The NPHL reported that their extraction system has not been working for over a year due to reported electrical problems.

Recommendations

The Ministry of Health/NPHL should carefully review the following recommendations with a view to implementing the proposals outlined.

1. The Ministry of Health should fast-track its review of the *Health Facilities (Medical Laboratories) Act* and Regulations with a view to promulgation in the shortest possible time. This will serve to strengthen the policy and legislative framework governing laboratory services within the island.

2. The NPHL should reassess its strategic priorities within the context of the availability of limited resources to determine whether any strategic readjustments are necessary in light of its failure to achieve some of its targets for the period up to 2015.

3. The Ministry of Health/NPHL should fast-track their review of the proposed Organisational Chart and Job Descriptions for the Consultants and Medical Technologists in order to establish clear and consistent reporting relationships, chain of command and job functions within the NPHL.

4. The NPHL should collaborate with the Ministry of Health and other government agencies to improve its supply chain management system, maintenance of its cooling and other equipment, and the supply of other laboratory commodities in order to increase its efficiency and effectiveness.

PART ONE INTRODUCTION

Background

1.1 The National Public Health Laboratory is the largest health laboratory in the English speaking Caribbean offering both public health and clinical laboratory services. It serves as the national reference and referral laboratory for clinical and community health. The efficiency and effectiveness of Jamaica's public health system depends to a large extent on a modern and efficient public laboratory service which can effectively aid in areas such as disease surveillance, vector control, environmental health and food safety. The goals and objectives of the NPHL forms part of the broader national strategy for health in support of the achievement of the Vision 2030 National Outcome of creating "*A Healthy and Stable Population"*.

1.2 The mission of NPHL is *"to provide high-quality, equitable, accessible, affordable clinical and public health diagnostic, reference and referral laboratory services to facilitate disease prevention and control while meeting the needs of all stakeholders and achieving strategic health targets."* The NPHL provides laboratory services that range from routine testing, such as basic blood counts and cholesterol tests, to highly complex tests that assist in diagnosing genetic conditions, cancers, and other rare diseases. These services include Haematology, Clinical Chemistry, Immunology and HIV research, Microbiology, Histopathology, Cytopathology, and Environmental Health and Vector Research.

Audit Objective, Scope and Methodology

1.3 The general objective of the audit was to assess the impact of the NPHL on the timely and effective delivery of health care, in particular the adequacy of lab equipment, physical infrastructure and related tools, processes and procedures as well as its level of certification/accreditation. The audit also examined the economy of the NPHL's administrative activities and management's approach to adhering to good corporate governance practices.

1.4 Our audit was planned and conducted in accordance with the Auditing Standards issued by the International Organization of Supreme Audit Institutions (INTOSAI). The planning process involved obtaining an understanding of the legislative framework, organizational structure and operational processes of the NPHL and developing an issue analysis to guide our audit approach. Our assessment was based on interviews with senior management and staff, review of internal records, statutes and other documents, observations, and analysis of data provided by the NPHL. The audit focused on information relating primarily to the period April 2013 to July 2015.

PART TWO Legal Framework and Accreditation

Medical Laboratories Act passed but not implemented

2.1 Laboratories in Jamaica are currently self-regulated, for the most part, as there is no specific legislative framework that governs their operations. Apart from the NPHL and other public laboratories, there are several private medical laboratories, collection centres and testing sites that are operating in the island without a specific regulatory or administrative machinery to monitor them. The Medical Technologists employed by these laboratories are, however, required to be registered in accordance with the Professions Supplementary to Medicine Act.

2.2 Information from the Ministry of Health (MOH) revealed that in addition to the NPHL, laboratories are located at each public general hospital and select health centres across the island while some health centres serve as collection sites. However, the MOH currently does not maintain a comprehensive database of private laboratories, neither does it provide extensive regulatory oversight of these laboratories. The Ministry indicated that the labs are monitored under the Public Health Act and the Quarantine Act and that its Standards and Regulations unit conducts periodic inspections of both public and private labs to determine whether certain public health standards are met. Additionally, the MOH advised that labs are also assessed as part of the process to obtain Health Provider Status.

2.3 In recognition of the need to regularize, standardize and improve the general management of medical laboratories, Parliament passed the *Health Facilities (Medical Laboratories) Act* in 2005. This initiative was geared towards ensuring quality assurance and standards for medical laboratories, which form an important component of the country's health services and are critical to disease control, prevention, and patient management. The passage of the *Health Facilities (Medical Laboratories) Act* was also aimed at providing for the establishment of a Medical Laboratories Council, which would regulate and control the activities of medical laboratories and collection centres across the island, and establish compulsory standards, which reflect regional and international standards.

2.4 Despite the passage of the *Health Facilities (Medical Laboratories) Act* and its subsequent assent by the Governor General in 2005, the laboratories in Jamaica continue to operate without a specific regulatory framework because the *Act* was not gazetted and brought into operation. Section 1 of the *Health Facilities (Medical Laboratories) Act* states that the *Act* "*shall come into operation on a day to be appointed by the Minister by notice published in the Gazette.*" However, the relevant notice was not published in the Gazette. We were advised that both the *Act* and the draft

Regulations are currently with the Ministry's Legal Unit for review because based on the issues to be captured in the *Regulations*, the *Health Facilities (Medical Laboratories) Act* would need to be amended before promulgation.

2.5 The establishment and implementation of the regulatory framework under the *Health Facilities (Medical Laboratories) Act* would improve the MOH's ability to regulate and monitor the operations of the island's laboratories.

NPHL working towards accreditation

2.6 Medical laboratory services are essential to patient care and accreditation provides reasonable assurance that laboratories meet both the technical competence requirements and the management system requirements that are necessary for them to consistently deliver technically valid results. The general benefits of accreditation include:

- Improved reliance and assurance on test results from accredited laboratories;
- Promotes continuous improvement of systems, processes and procedures in keeping with new technological developments; and
- Facilitates easier identification of anomalies in laboratory systems, processes and procedures.

Additionally, effective management of the laboratory quality system enhances staff discipline and development.

2.7 One of the international benchmarks for laboratory accreditation is *ISO 15189:2012 Medical laboratories – Requirements for quality and competence.* This international standard specifies the requirements for quality and competence in medical laboratories and is used by medical laboratories in developing their quality management systems and assessing their own competence. It is also used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.

2.8 The NPHL applied for accreditation for some of its activities in November, 2013. These include Haematology, Phlebotomy, Clinical Chemistry, Sample Reception, and Emergency Laboratory. The NPHL did not seek accreditation for Histology, Cytology, Immunology and Microbiology as it was deemed impractical as certain known prerequisites were not in place. The local accreditation body, *Jamaica National Agency for Accreditation (JANAAC)*, conducted an initial assessment of the NPHL in December 2014. JANAAC identified thirty-one areas across all the departments that were assessed where the NPHL's systems were inadequate and did not conform to the requirements of

the *ISO 15189:2012*. The NPHL was then given approximately two months to advise JANAAC on the corrective actions taken to address the *non-conformities* that were highlighted following the assessment. Subsequent checks by JANAAC in April 2015 revealed that seven of the *non-conformities* were adequately addressed and therefore closed while fifteen were partially adequate and another seven were deemed not adequate. The status of the other two non-conformities remained unchanged.

2.9 Examples of the *non-conformities* that prevented accreditation include:

- Inadequate system for evaluation and audit;
- Inadequate system for managing verification of examination procedures;
- Inadequate system for communicating responsibility, authority and interrelationships;
- Inadequate system for patient sample collection facilities at Kingston Public Hospital; and
- Ineffective complaints system.

2.10 We were subsequently advised that another follow-up review was conducted by JANAAC in September 2015 leading to the closure of most of the non-conformities. However, the details could not be verified as the written report from JANAAC was not yet available for audit review.

2.11 While credit should be given to the NPHL for taking steps to achieve accreditation for some of its activities, the absence of this type of standardization in other areas increased the risk of inadequate and or inconsistent laboratory practices in those areas, which may result in decreased reliance on its test results.

PART THREE Laboratory Efficiency

NPHL not meeting its established turnaround time

3.1 Laboratory turnaround time is one of the most important indicators of laboratory efficiency. Turnaround time is generally defined as "*elapsed time between two specified points through pre-examination, examination and post-examination processes*"[1]. It is one of the most noticeable signs of laboratory service and is often used as a key performance indicator of laboratory performance. The NPHL established standard turnaround times for each of its examinations and uses a monthly reporting mechanism to monitor its activities.

3.2 Despite generally attaining its targeted turnaround time for testing in Haematology, Phlebotomy, Clinical Chemistry, Sample Reception, Emergency Laboratory, and urgent Histology cases, the NPHL experienced significant challenges in consistently achieving its established turnaround time within the other five of its major specialist areas. Data analysis for the period January to July 2015 revealed that there were significant backlogs in Cytology, Microbiology, Serology, Immunology and "*less urgent*" Histology cases as shown in ***Table 1***.

3.3 This delayed turnaround time leads to delays in diagnosis and treatment and is an impediment to optimal patient care, particularly in high-volume patient care areas. According to the NPHL, the major factors contributing to the delayed turnaround time include inadequate supplies such as reagents, inadequate water supply, inadequate lab coats, inadequate staff, and unreliable cooling equipment such as Air Conditioners and Refrigerators.

3.4 The NPHL has a system in place that requires all laboratory equipment to be cleaned daily after use. The system also requires monthly preventative maintenance and regular maintenance annually or biannually depending on the equipment. However, a review of the laboratory equipment master list and life records/maintenance cards revealed that the NPHL was not consistently servicing the equipment on a timely basis in accordance with its standard operating procedures. We identified four critical pieces of equipment, *two Chemical Fume Hoods and two Biological Safety Cabinets*, which were not being serviced in keeping with the recommended maintenance frequency ***(Table 2)***. This increased the risk of equipment breakdown which may lead to greater delays in turnaround time.

[1] *ISO 15189:2012*

Table 2: Equipment Maintenance

Equipment	Maintenance Frequency	Date Tested
Chemical Fume Hood (69410)	Annual	18/2/2014, 19/9/2012, 22/7/2011
Biological Safety Cabinet (60474)	Annual	18/2/2014
Biological Safety Cabinet (SG400)	Annual	18/2/2014 & 18/6/2012
Chemical Fume Hood (2246301)	Annual	18/2/2014 & 19/9/2012

Source: NPHL

3.5 We also conducted a walk-through exercise of the Histology Department and found that employees were working under uncomfortable and hazardous conditions. The Department appears to have outgrown its space as samples waiting to be tested were stored on the floor and under tables. We noted that there was a high risk of exposure to hazardous chemicals and fumes circulating in the air due to the absence of a functioning laboratory fume extraction system. The NPHL reported that their extraction system has not been working for over a year due to reported electrical problems.

3.6 The MOH/NPHL indicated that efforts are currently being made to improve its efficiency through partnerships with other local and international organisations to among other things, replace obsolete equipment, refurbish its cold rooms and improve its central cooling system, and provide laboratory supplies and specialists to help reduce its backlog.

Weak Supply Chain Management

3.7 Accredited laboratories are required to have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of their service. Suppliers should be selected and approved based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements. Laboratories should establish clear criteria for selection and a list of selected and approved suppliers of equipment, reagents and consumables should be maintained. Additionally, laboratories should monitor the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria[2].

3.8 As part of the process of developing its Strategic Plan, the NPHL conducted a SWOT analysis where it identified a *weak supply chain management system* as one of its significant weaknesses. To overcome this weakness, the NPHL developed as one of its strategic objectives, the establishment of an effective and efficient supply chain management system for laboratory commodities. The plan was to establish a best practice model based on an updated range of tests to be performed, accredited suppliers and service utilization. This would result in the establishment of a unit with an

[2] *ISO 15189:2012(4.6)*

appropriate cadre of qualified and competent personnel as well as the procurement and implementation of appropriate tools for inventory management, commodity utilization, tracking and forecasting within three years (2013-2015).

3.9 At the time of this report this strategic objective was a work-in-progress as the NPHL was still experiencing delays in the procurement of commodities and other laboratory supplies. The NPHL, however, indicated that measures were implemented to improve and strengthen the supply chain management system. These include the assignment of a new Stores Officer and two additional personnel from the Ministry of Health to assist with procurement, the development of a procurement plan, and the introduction of the stock module of the Laboratory Information Management System (LIMS) in October 2015. The MOH/NPHL advised that the approach taken "*was to target the areas which did not require significant resource mobilization but yet could have significant impact*".

PART FOUR Corporate Governance

NPHL not meeting key targets

4.1 The NPHL's Strategic Plan for the period 2013 to 2017 outlined the following three main Goals under which its objectives and strategies were developed:

a. Improved Governance for Effective Leadership, Management and Accountability;

b. Enhanced Laboratory Capacity and Effectiveness; and

c. Equitable Access to High Quality Laboratory Service.

The Plan contained an overall thirty-two strategies and sixty-eight performance indicators that were projected over the five year period with the aim of providing a comprehensive structure for the Modernisation of the NPHL and to facilitate the overall strengthening of the functions carried out by the laboratory in an effective, efficient and economical manner in keeping with the National Strategies of the National Development Plan-Vision 2030.

4.2 We were advised by the NPHL that of the projected thirteen strategies for implementation during the period 2013 to 2015, only four were substantially achieved as at August 31, 2015. These include the acquisition and implementation of a comprehensive integrated Laboratory Information Management System (LIMS), development of a framework for improved laboratory safety, comprehensive assessment of workflow per department per tests, and the alignment of the laboratory accreditation process with national and international best practices. The other nine strategies were not substantially implemented as at August 31, 2015 ***(Table 3)***. Management attributed the failure to execute these strategies within the proposed timeline to the inability to secure the requisite resources. This lack of resources, according to the NPHL, led to the adjustment of its Operational Plans and focus was instead placed on three key areas:

i. Attainment of Accreditation;
ii. Effective Laboratory Information System; and
iii. Development of a National Laboratory Policy.

4.3 Failure to implement the key strategies will result in a delay in the modernisation of the NPHL and its goal of providing high quality clinical and public health laboratory testing services which is highly efficient, effective and in accordance with international standards may not be achieved as planned.

Table 3: Strategies 2013-2015

	STRATEGIES	Projected Implementation Date	Status
1	Establish a governance and management framework in keeping with proposals under the Modernisation Project.	2015	Not Achieved
2	Collaborate with stakeholders to develop strategies for strengthening policy and legislative framework governing laboratory service especially as they relate to patient care, quality and regulation of professional conduct.	2013	Not Achieved
3	Support the development of a national tiered laboratory network structure with clearly defined roles, responsibilities and operating protocols.	2014	Not Achieved
4	Apply health system economic modelling principles and techniques that incorporate patient safety into laboratory service planning.	2014	Not Achieved
5	Develop and implement HR strategy (to include employee career framework development and programmes to improve and maintain staff morale) for recruiting, training and retention of staff.	2015	Not Achieved
6	Ensure standardized credentialing and scope of laboratory practice process are applied	2013	Not Achieved
7	Develop a plan to establish best practice model for SCMS for laboratory commodities based on updated range of test to be performed, accredited suppliers, and service utilization	2015	Not Achieved
8	Develop laboratory capacity to attain Biosafety Level III status	2015	Not Achieved
9	Develop and implement a framework to enhance research	2014	Not Achieved
10	Acquisition and implementation of a comprehensive integrated Laboratory Information Management System (LIMS)	2013	Achieved
11	Development of a framework for improved laboratory safety	2015	Achieved
12	Comprehensive assessment of workflow per department per tests	2013	Achieved
13	Alignment of the laboratory accreditation process with national and international best practices	2013	Achieved

Source: NPHL

Job Functions not clearly defined

4.4 Staff at the NPHL is generally categorized as Consultants, Technical and Administrative/Support personnel. The Consultants provide general oversight and supervision of each department while the technical staff such as Medical Technologists conduct routine and complex analyses of samples. Despite the technical nature of their duties, we found that the revised Job Descriptions for the Consultants and Medical Technologists were not finalized and signed by each member of staff. The NPHL indicated that the Ministry of Health undertook a reclassification exercise of the entire health sector in 2009 and the Job Descriptions for the Consultants and Medical Technologists are still under review. We also found that a revised Organisational Chart, which was approved by the NPHL's Director in December 2014, outlining the reporting relationships for all staff was still being reviewed by the Ministry of Health.

4.5 The absence of an approved updated organisational structure and clear chain of command that reflects the current situation increase the risk of confusion among staff in relation to their job functions and their reporting responsibilities. This risk is high within the NPHL as currently there appears to be no consensus on whether the Medical Technologists should routinely report to the Consultants or to the Supervisory Medical Technologists. Additionally, the accreditation process may be delayed until the Job Descriptions and the Organisational Chart are finalised and are consistent with each other, showing clear reporting relationships.

4.6 The MOH indicated that the existing Job Descriptions and Organisational Chart remain in force until the revised versions are finalised. The Ministry reported that the Medical Technology group objected to the current reporting relationship and hence the Job Descriptions and reporting relationships are being reviewed.