

# **Evaluation of the Logistics System for Transporting Tuberculosis and HIV Samples and Delivering Test Results in the Dominican Republic's Public Health Referral Network**

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August 2014

Translated December 2014

Santo Domingo, Dominican Republic



This report was made possible thanks to the support provided by the United States Agency for International Development (USAID) under the terms of Cooperative Agreement No. AID-OAA-A-11-00021. The contents of the report are the responsibility of Management Sciences for Health and do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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**Supporting agencies:**

United States Agency for International Development (USAID)

Systems for Improved Access to Pharmaceuticals and Services (SIAPS)

**Recommended Citation**

This report may be produced provided that credit is given to the author. Kindly use the following citation:

Moquete E, Tavárez Y, Montoro E, George A, Herrera M, Valdez C, Barillas E. *Evaluation of the Logistics System for Transporting Tuberculosis and HIV Samples and Delivering Test Results in the Dominican Republic's Public Health Referral Network*. Ministerio de Salud Pública de la República Dominicana; SIAPS. Submitted to the US Agency for International Development by Systems for Improved Access to Pharmaceuticals and Services (SIAPS). Arlington, VA: Management Sciences for Health; 2014.

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## ACKNOWLEDGMENTS

Data collection was performed by the following team of field coordinators selected for that purpose: Eider Sánchez, Milagros de la Rosa, José Rodríguez, Aurelino Montero, María Lavandera, and Orquídea Salzuela. Overall coordination of field work and the study itself was the responsibility of Emmanuel Moquete, with support provided by a team from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program. The laboratory coordinators of the Regional Health Services responsible for the laboratories in the service facilities visited and the area representatives in the laboratory serving the HIV and tuberculosis programs and the Directorate General of Epidemiology provided the data for the study.

Dr. Ernesto Montoro provided support to those areas of the study involving biosecurity.

Dr. Yira Tavárez directed the overall framework for the process enabling the study to be carried out.

The Project Implementation Unit, SIAPS personnel, and the technical committee created by the Ministry of Public Health validated the data. SIAPS consultants Alan George, Martha Herrera, Claudia Valdez, and Edgar Barillas performed the final review of the information and prepared this report.

## ACRONYMS AND ABBREVIATIONS

PROVIRAL-DNA	proviral deoxyribonucleic acid (polymerase chain reaction test for early infant detection of HIV-1)
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CD4	cluster of differentiation 4
CEAS	Specialized Health Care Centers ( <i>Centros Especializados de Atención en Salud</i> )
CONAVIHSIDA	National Council on HIV/AIDS Consejo Nacional para el VIH/SIDA
CPN	first-level facilities ( <i>centro de primer nivel</i> )
VL	viral load
DDF/SRS	Directorate for the Development and Strengthening of Regional Health Services ( <i>Dirección de Desarrollo y Fortalecimiento de los Servicios Regionales de Salud</i> )
DIGECITSS	General Directorate for the Control of Sexually Transmitted Infections and AIDS ( <i>Dirección General de Control de Infecciones de Transmisión Sexual y SIDA</i> )
DIGEPI	General Directorate of Epidemiology ( <i>Dirección General de Epidemiología</i> )
DMS	Municipal Health Directorate ( <i>Dirección Municipal de Salud</i> )
DOP	Dominican peso
DPS	Provincial Health Directorate ( <i>Dirección Provincial de Salud</i> )
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
LNSPDD	Dr. Defilló National Public Health Laboratory
MPH	Ministry of Public Health
WHO	World Health Organization
NGO	nongovernmental organization
PNCT	National Tuberculosis Control Program ( <i>Programa Nacional de Control de la Tuberculosis</i> )
PLWHA	people living with HIV/AIDS
SAI	Integrated AIDS Care Center ( <i>Servicio de Atención Integral</i> )
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SRS	Regional Health Service ( <i>Servicio Regional de Salud</i> )
TAT	turnaround time
TB	tuberculosis
URM	Sample Collection Unit ( <i>Unidad Recolectora de Muestras</i> )
USAID	US Agency for International Development
HIV	human immunodeficiency virus



## INTRODUCTION

The Directorate for the Development and Strengthening of Regional Health Services (*Dirección de Desarrollo y Fortalecimiento de los Servicios Regionales de Salud*; DDF/SRS), a unit of the Dominican Republic's Ministry of Public Health (MPH), identified weaknesses in the transportation of laboratory samples and the subsequent reporting of results that directly affect coverage, particularly in certain disease control programs, such as those addressing HIV/AIDS and tuberculosis (TB). The design and implementation of an efficient system is contingent on a situational study that can identify inefficiencies and design intervention alternatives to address them.

In November 2013, the DDF/SRS requested, through the US Agency for International Development (USAID), technical assistance from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program in conducting a baseline study that would generate the evidence necessary for improving the system for transporting samples and delivering results. The work plan prepared by SIAPS and approved by the DDF/SRS in January 2014 includes the methodology proposed for the evaluation and analysis of the study's findings, as well as the next steps for designing and implementing the appropriate logistics system.

This report presents the findings of the evaluation conducted of the logistics system currently used to transport TB and HIV samples, as well as samples for the three pathologies included in the Epidemiological Surveillance Program, based on available technologies and established methods and procedures. The latter three pathologies were included with a view toward identifying and comparing the various logistical flows taking place within the network of health service facilities. The report includes a *Findings* section, which presents the results for HIV, TB, and diseases addressed by the Epidemiological Surveillance Program. It describes the logistical processes and costs involved. The *Analysis* section discusses likely explanations for the problems identified, together with their implications. The report concludes with a section on *Intervention Alternatives* for addressing the problems identified.

## BACKGROUND

Laboratory diagnoses and confirmations, combined with proper management of diagnostic quality, are central to well-focused patient care, as well as to prevention and control activities. The availability of timely and reliable results optimizes prevention-oriented actions at both the primary and secondary levels.

The Dominican Republic has made good strides in the introduction of TB and HIV diagnostic technologies and methods with a view toward aligning its strategies and approaches with those recommended for countries of the region of the Americas by the Pan-American Health Organization and the World Health Organization (WHO). National disease control programs call for universal access to sputum smears, cultures and drug sensitivity testing, rapid HIV tests, viral load (VL) or burden, cluster of differentiation 4 (CD4) counts, and PROVIRAL-DNA (polymerase chain reaction test for early infant detection of HIV-1). Such access is often limited by the lack of availability of reagents, materials, and equipment in the health service facility network. Diagnostic procedures requiring the greatest amount of technological resources and biosafety measures are concentrated in only a few reference laboratories, a situation that leads to considerable dependency on an efficiently operating network for transporting samples and delivering results.

National and international goals agreed upon for the coming years call for an increase in the detection of drug-resistant TB and TB/HIV co-infection, as well as determination of the success of treatment with antiretrovirals.<sup>1,2,3</sup> These requirements will impose additional demands on the system for transporting samples and delivering results.

The transportation of diagnostic samples and etiological agents (infectious substances) must be carried out safely and securely, not only to minimize the risk to humans or the environment, but also to protect the viability of the pathogenic agents themselves.<sup>4,5</sup> The United Nations Committee of Experts for the Transport of Dangerous Goods publishes international regulations governing the safe transport, packaging, and shipment of biological samples and infectious substances. Guidelines for the transport of infectious substances are based on the corresponding

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<sup>1</sup> World Health Organization, WHO End TB Strategy: Global strategy and targets for tuberculosis prevention, care and control after 2015. [http://www.who.int/tb/post2015\\_strategy/en/#](http://www.who.int/tb/post2015_strategy/en/#).

<sup>2</sup> World Health Organization and UNAIDS. *The Treatment 2.0 Framework for Action: Catalysing the Next Phase of Treatment, Care and Support*. Geneva; World Health Organization: 2011. [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110824\\_JC2208\\_outlook\\_treatment2.0\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110824_JC2208_outlook_treatment2.0_en.pdf).

<sup>3</sup> UNAIDS and the Pan-American Health Organization/World Health Organization. New “90-90-90” targets for controlling the HIV/AIDS epidemic in Latin America and the Caribbean. [http://www.paho.org/hq/index.php?option=com\\_content&view=article&id=9655%3Anew-90-90-90-targets-for-controlling-the-hiv-aids-epidemic-in-latin-america-and-the-caribbean&catid=740%3Anews-press-releases&Itemid=1926&lang=en](http://www.paho.org/hq/index.php?option=com_content&view=article&id=9655%3Anew-90-90-90-targets-for-controlling-the-hiv-aids-epidemic-in-latin-america-and-the-caribbean&catid=740%3Anews-press-releases&Itemid=1926&lang=en).

<sup>4</sup> United Nations Economic Commission for Europe, Accord européen relatif au transport international des marchandises dangereuses par route [European Agreement concerning the International Carriage of Dangerous Goods by Road], 2011.

<sup>5</sup> World Health Organization. *Guidance on Regulations for the Transport of Infectious Substances 2013–2014*. Geneva; WHO: 2012. [http://www.who.int/ihr/publications/who\\_hse\\_ihr\\_2012.12/](http://www.who.int/ihr/publications/who_hse_ihr_2012.12/).

Model Regulations, which, in the specific case of ground transportation, are in turn based on the guidelines set forth in the European Agreement concerning the International Carriage of Dangerous Goods by Road (known by its French abbreviation, ADR).<sup>6</sup>

The health sector reform process in the Dominican Republic contemplates the provision of health care services to individuals under the new network-based system, under the direction and responsibility of the Regional Health Services (*Servicios Regionales de Salud*; SRSs).<sup>7,8</sup> The SRSs have a mandate to provide, at a minimum, the health care contained in the Basic Health Plan developed by the Dominican Social Security System and specified in article 25 of the Regulations governing service provision by the Public Health Services Network. These services include diagnostic services and health care for beneficiaries suffering from infections including, among others, TB, HIV/AIDS, and malaria.

The model provides that diagnostic services offered are defined by the various levels of care:

Primary-level laboratory services are to be gradually replaced by the organization of an internal system for collecting clinical samples from peripheral facilities, which must in turn provide for the pickup, transportation, and processing of samples and delivery of results from the points of contact where health care is provided to the general public, to the primary-level structures, whether laboratories designated for the primary level of care or hospital laboratories. In all cases, quality control measures that ensure the reliability and accuracy of results must be in place. In this way, an effort is made to ensure the quality of the analytical results obtained and to avoid the duplication of resources.<sup>9</sup>

Technical reports<sup>10</sup> and non-systematized information<sup>11</sup> have provided evidence of deficiencies in the referral of laboratory samples of TB and HIV/AIDS from the health facilities where the samples are collected to the reference laboratories where they are processed. These logistical problems extend to the delivery of test results to the facilities where patients are cared for and whose treatment is expected to be based on the results of those tests.

To address these deficiencies, in 2012 the MPH created a technical laboratory committee that has analyzed this problem and informed health authorities and cooperation agencies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) of the need to make improvements to the system for transporting samples and delivering results.

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<sup>6</sup> United Nations Expert Committee on the Transport of Dangerous Goods. *Recommendations regarding the transportation of samples of dangerous goods. Model regulations*. Volume 1. New York and Geneva: United Nations; 2011.

<sup>7</sup> Decreto Presidencial N° 635-03. Reglamento de Rectoría y Separación de Funciones Básicas del Sistema Nacional de Salud, publicado el 08 de agosto 2003. Comisión Ejecutiva para la Reforma del Sector Salud (CERSS).

<sup>8</sup> Secretaría de Estado de Salud Pública y Asistencia Social (SESPAS). 2005. Modelo de Red de los Servicios Regionales de Salud: Una guía para el desarrollo de los servicios de salud para la atención a las personas. Disposición 00024; SESPAS, Santo Domingo, República Dominicana.

<sup>9</sup> Ibid.

<sup>10</sup> Consejo Nacional del VIH y del SIDA. 2012. Consultoría para la Red de Transporte de Muestras.

<sup>11</sup> Laboratorio Nacional Dr. Defilló, Departamento de Tuberculosis. Informe técnico sobre evaluación de la red de laboratorio para el diagnóstico de la tuberculosis. 2013. Ministerio de Salud Pública.

## METHODOLOGY

To support this study and the subsequent design of the logistics system for transporting samples, the MPH established a technical committee made up of representatives from the National Tuberculosis Control Program (*Programa Nacional de Control de la Tuberculosis*; PNCT), the General Directorate for the Control of Sexually Transmitted Infections and AIDS (*Dirección General de Control de Infecciones de Transmisión Sexual y SIDA*; DIGECITSS), the National Directorate of Laboratories (*Dirección Nacional de Laboratorios*), the National Council on HIV/AIDS (*Consejo Nacional para el VIH/SIDA*; CONAVIHSIDA), the U.S. Centers for Disease Control and Prevention, the Dr. Defilló National Public Health Laboratory (*Laboratorio Nacional de Salud Pública Dr. Defilló*; LNSPDD), and the DDF/SRS.

The technical committee and the team of SIAPS consultants reached a consensus on the design of an exploratory, descriptive, cross-sectional study. The information-gathering instruments included quantitative-qualitative indicators in four areas:

- Delivery and receipt of samples
- Delivery of results
- Productivity at the central, regional, and local levels
- Costs and expenditures

The sample (name and location of laboratories) was selected based on information provided by the HIV and TB programs, the General Directorate of Epidemiology (*Dirección General de Epidemiología*; DIGEPI), the LNSPDD, and the DDF-SRS.

A non-probabilistic, intentional or selective sample was established, in accordance with the regional networks' within each of the nine SRSs. A convenience-based cluster sampling was conducted, considering the handling of samples (sample collecting units, processing units, and reference laboratories) and their productivity. This provided a broad geographic and functional representation of the country's system for transporting samples. Based on these criteria, the sample included the following facilities:

- Facilities providing primary level of care (*centros de primer nivel de atención*; CPNs), that is, facilities not equipped with a laboratory, that are limited to collecting sputum-smear samples, including high and low levels of productivity, and located in urban areas of the provincial capital where the SRS is located
- Sample-collecting CPNs operating in rural areas
- Municipal, provincial, and regional Specialized Health Care Centers (*Centros Especializados de Atención en Salud*; CEASs) that collect and process samples for sputum smears and cultures (both high and low productivity) and that only send strains for drug-sensitivity testing

- Regional and provincial CEASs and nongovernmental organizations (NGOs) that collect blood samples for CD4 counts, VL, and dried blood spots for polymerase chain reaction tests (PROVIRAL-DNA)<sup>12</sup>
- Municipal, provincial, and regional CEASs that collect samples for dengue, leptospirosis, and cholera testing for the Epidemiological Surveillance Program (high and low productivity)
- The LNSPDD, which receives samples for CD4 counts, VL, PROVIRAL-DNA, sputum cultures, drug sensitivity testing, dengue, leptospirosis, and cholera for processing, and delivers results
- Management bodies: SRSs, Provincial Health Directorates (*Direcciones Provinciales de Salud*; DPSs), and Municipal Health Directorates (*Direcciones Municipales de Salud*; DMSs)

During the fieldwork stage, adjustments were made to the sample, resulting in the elimination of five Integrated AIDS Care Centers (*Servicios de Atención Integral al VIH*; SAIs) in the National District because HIV samples are not transported in the metropolitan SRS, but rather the patients are referred directly to the LNSPDD. Additionally, 5 DMSs were added, for a total of 125 facilities, including the LNSPDD, 9 SRSs, 9 regional CEASs, 21 provincial CEASs, 14 municipal CEASs, 12 DPSs-DMSs, 51 CPNs, 2 prisons, and 6 NGOs.

To collect primary source information, a survey containing both closed and open-ended questions was used;<sup>13</sup> these questions covered topics such as the preparation, packaging, dispatch, and transportation of the sample, and receipt and delivery of results. The types of sample selected for evaluating the various transportation logistics systems were as follows: (a) sputum and extrapulmonary samples for TB diagnosis; (b) clinical/immunological follow-up tests for CD4 and VL; (c) tests for diagnosing HIV in infants (PROVIRAL-DNA); and (d) the most common samples for epidemiological surveillance purposes, such as dengue, leptospirosis, and cholera.

The collection of secondary source information included a review of sample control records and records evidencing the dispatch of results from facilities; reports on sample productivity for TB, HIV, dengue, leptospirosis, and cholera; and budget reports and reports on expenditures incurred in the transportation of samples.

To ensure quality control regarding the data collected, the completed surveys were reviewed in the field, with steps taken to ensure that forms had been collected for all of the health facilities selected and that data had been recorded appropriately. All inconsistencies were corrected through additional visits and/or requests for supporting documentation. Verification of data was

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<sup>12</sup> For HIV, the sample included 51% (39/77) of the SAIs, since these facilities also evaluate samples for TB testing (sputum smear, cultures).

<sup>13</sup> *Protocolo para el diagnóstico de la situación del envío de muestras de laboratorio clínico y remisión de resultados de TB y VIH en la red pública de servicios de salud de República Dominicana*. Marzo 2014. Ministerio de Salud Pública; SIAPS.

carried out by consulting primary records. The results obtained from the database were subjected to a process of review and revalidation of certain information to ensure data quality.

Table 1 shows the processes evaluated in the study and the primary data sources consulted in the facilities and laboratories visited.

**Table 1. Definition of Processes Evaluated and Primary Sources**

<b>Process/scope</b>	<b>Definition</b>	<b>Primary record evaluated</b>
Sample sent	Portion of biological fluid collected in an appropriate container that is sent, under optimal conditions (depending on sample type), to the laboratory operating at the appropriate level for processing	Sample dispatch forms from the TB and HIV programs, Form VF4 from the epidemiology program, and the internal logbook from the laboratory's technical area
Sample received	Portion of biological fluid that reaches the laboratory for processing in an appropriate container in accordance with the receipt accompanying the sample	Laboratory's internal logbook, and epidemiology Form VF4
Sample processed*	Sample that has been subjected to a process of analysis using the required methods and techniques in accordance with the purpose of the diagnosis	Laboratory's internal logbook
Result issued and sent	Notification sent to the appropriate level regarding the numerical data and/or diagnosis obtained based on analysis of the sample	Laboratory's internal logbook, printed results report for HIV (CD4, VL, and PROVIRAL-DNA), copies of the TB bacteriology request form showing results obtained, copies of receipts evidencing the dispatch of commercial transportation documents, and verification of results in the Epidemiological Surveillance System
Result received	Receipt at the requesting facility of the numerical data and/or diagnosis obtained based on analysis of the previously sent sample	Laboratory's internal logbook, printed copies of the forms distributed by the various disease control programs for reporting results (HIV report and TB bacteriology card) at health service facilities, and verification of results in the Epidemiological Surveillance System

\* This study did not include an analysis of the quality of the samples processed. Information was obtained, however, about samples not processed because of deterioration in quality caused by transit time or the time elapsed between the drawing of the sample and receipt by the laboratory.

## FINDINGS

### General

In the Dominican Republic, 1,522 health facilities currently operate in the public health network,<sup>14</sup> including 181 CEASs with varying response capacities and 1,341 CPNs. According to the Regulations governing the National Epidemiological Surveillance System, “*the National Network of Public Health Laboratories is a series of interrelated laboratories, with specific and common interests, which remit samples for the identification of agents of significance in terms of national public health and/or health monitoring.*”<sup>15</sup> The network is made up of 423 clinical laboratories<sup>16</sup> and comprises four levels, each having its own response capacity.<sup>17</sup>

Within the national network, the LNSPDD is the most advanced of all laboratories. It receives samples from less complex laboratories when the latter lack the requisite processing capacity. In addition, it carries out functions involving supervision, advisory assistance, updating, ongoing education, research, and in-service training for laboratory technical personnel, based on the identified needs and priorities of the national health system.<sup>18</sup>

In 2013, the LNSPDD received 65,510 samples for 16 types of clinical diagnosis, including, among others, HIV, TB, dengue, leptospirosis, cholera, influenza, malaria, measles, chickenpox, rotavirus, meningococemia, and food-borne infections (table 2). Eighty-one percent (53,194) of these samples were included in the study; 61% involved HIV and 8% TB.

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<sup>14</sup> Ministerio de Salud Pública. Reporte de Base de Datos de la Red de Establecimientos. Junio 2014.

<sup>15</sup> Decreto no. 309-07, Reglamento del Sistema de Vigilancia Epidemiológica. Santo Domingo, 13 de junio de 2007.

<sup>16</sup> Dirección Nacional de Laboratorios del Ministerio de Salud Pública. 2013. Reporte de Base de Datos Laboratorios Clínicos en RD.

<sup>17</sup> Norma particular de habilitación para la instalación y funcionamiento de los Laboratorios Clínicos y Salud Pública, Marzo 2005.

<sup>18</sup> Ibid.

**Table 2. Total Diagnostic Samples Received at the LNSPDD in 2013**

<b>Type of sample</b>	<b>Total samples received 2013</b>	<b>Percentage of the total number of samples received at the LNSPDD in 2013</b>
BK/cultures	1,462	2
Cultures/sensitivity	3,619	6
CD4	23,489	36
VL	15,562	24
PROVIRAL-DNA	1,067	2
Dengue	6,897	11
Leptospirosis	581	1
Cholera	517	1
Other	12,316	19
Total	65,510	100

### **HIV: CD4 Counts, Viral Load, and PROVIRAL-DNA**

The public network includes 77 SAIs for people living with HIV and AIDS (PLWHA), operating in all nine SRSs. Their functions include ordering samples to be collected for clinical and immunological follow-up of PLWHA, including CD4 counts, VL, and PROVIRAL-DNA.

Two laboratories have been established at the national level for processing samples to determine CD4 count: the LNSPDD in Santo Domingo and PROFAMILIA in Santiago. The bulk of the processing of samples for VL and PROVIRAL-DNA takes place in the LNSPDD. The DDF/SRS has designated regional hubs as intermediate units for receiving samples from collection units, with the purpose of organizing the weekly deliveries to the processing site, using a single designated means of transportation. The study evaluated 39 CEASs possessing a SAI, including public CEASs, NGOs, and prisons.

### ***Preparation, Dispatch, and Receipt of Samples***

In 2013 a total of 33,280 CD4 samples, 15,562 VL samples, and 1,067 PROVIRAL-DNA samples were processed nationally. The LNSPDD received 23,489 (71%) of the samples for CD4 counts and all of the samples for VL and PROVIRAL-DNA. Twenty-nine percent (9,791) of the CD4 samples were received and processed by PROFAMILIA (table 3).

**Table 3. Receipt and Processing of CD4 Samples in 2013**

Facility	CD4	Percentage
LNSPDD	23,489	71
PROFAMILIA (Santiago)	9,791	29
<b>Total</b>	<b>33,280</b>	<b>100</b>

In 2013, 31,650 (79%) of the samples for HIV follow-up and diagnosis received in the LNSPDD were collected directly from PLWHA who were referred from health facilities in SRS 0 (metropolitan region), whereas 8,461 (21%) were samples sent from health facilities in the other SRSs from the interior of the country. Table 4 shows the average monthly volume of samples sent by each SRS and by PLWHA referred by the SAI in SRS 0.

**Table 4. Average Monthly Number of Samples Sent by Each SRS**

Region	SAI	Average monthly number of samples	Percentage
SRS 0	29	2,721 *	64
SRS 1	5	112	3
SRS 2	10	539	13
SRS 3	4	39	1
SRS 4	2	89	2
SRS 5	11	369	9
SRS 6	4	151	4
SRS 7	9	54	2
SRS 8	3	46	2
<b>Total</b>	<b>77</b>	<b>4,241</b>	<b>100</b>

\*This amount refers to PLWHA.

The study made it possible to identify the existence of various routes used for sending HIV samples to the central level. Within SRS 0 in Santo Domingo, no samples are delivered; rather, PLWHA are referred from the SAI to the LNSPDD, where samples are collected directly. As reported by the LNSPDD, 82% of the CD4 samples and 80% of the VL samples processed by that laboratory in 2013 were collected directly from PLWHA. The remaining 18% of CD4 samples and 20% of VL samples were sent by the other SRSs using public or regional means of transportation.

Forty-one percent of the samples for PROVIRAL-DNA testing arrived at the LNSPDD from six CEASs and NGOs located in SRS 0. As an exception to the general rule, the LNSPDD's driver picks up the samples from Robert Reid Cabral Hospital. The remaining 59% of the PROVIRAL-DNA samples come from the other SRSs.

In 92% (36/39) of the facilities surveyed, the dispatch and receipt of CD4, VL, and PROVIRAL-DNA samples flow from the health facilities where the sample is collected to the regional hubs in the SRS. Eight percent (3/39: Taiwan Hospital [SRS 6], Leopoldo Pou Hospital [SRS 3], and Ricardo Limardo Hospital [SRS 2]) send their samples directly to the LNSPDD and/or PROFAMILIA in Santiago without going through the regional hubs (Annex A).

Forty-six percent (18/39) of the facilities evaluated reported that the SRS provides transportation from the health facilities where the samples are collected to the regional hubs. Forty-four percent (17/39) have available resources and means of transportation for sending samples to the regional hubs. In 5% (2/39) of the facilities evaluated, health personnel pay for transportation expenses out of pocket, using their own funds (table 5). All SRSs are responsible for sending samples from the regional hubs to the local commercial public transportation companies, for transportation to the reference laboratories in Santo Domingo and Santiago.

**Table 5. Entities Responsible for Providing Transportation of Samples in the Network**

<b>Transportation provider</b>	<b>Percentage</b>
SRS/Area Management Offices	46
Health facilities	44
None (health staff with personal resources)	5
LNSPDD (PROVIRAL-DNA from Robert Reid Cabral Hospital)	3
Other (unspecified)	2
<b>Total</b>	<b>100</b>

Most of the health facilities with the capacity to collect samples in SRS 1, 4, 5, and 7 collect samples of CD4, VL, and PROVIRAL-DNA from PLWHA once a week—every Tuesday—and send those samples the same or the following day to their respective regional hubs. In those health facilities with the capacity to collect samples and that are located at a considerable distance from regional hubs, samples are refrigerated until sent. For example, the Centro de Salud Verón in Punta Cana (SRS 5) keeps samples refrigerated for approximately two days,<sup>19</sup> until they can be sent to San Pedro de Macorís province, a distance of more than 100 kilometers. The SRSs pick up the samples in the regional hubs no later than one day after their arrival and send them to the LNSPDD by means of public commercial transportation (Caribe Tours and ASTRAPU). Samples from Regions 2, 3, 4, 6, 7, and 8 are picked up every Thursday by the

<sup>19</sup> The guidelines in force in the HIV Program stipulate that a sample may not be retained for more than 48 hours.

LNSPDD in the offices of the public transportation carriers, and on Tuesdays for samples from Region 5. An exception is SRS 1, which uses its own transport and delivers samples directly to the LNSPDD.

Health facilities collecting samples in SRS 2, 3, 6, and 8 do so on Wednesdays. The samples are either picked up or sent to the regional hubs the same or the following day. The SRSs pick them up at the regional hubs within a maximum of two days and send them via public transportation to the LNSPDD in Santo Domingo (for processing VL and PROVIRAL-DNA) and PROFAMILIA in the province of Santiago (for processing CD4), also by means of public transportation.

The study documented that the average time between the collection of samples for CD4 and VL and their dispatch to the LNSPDD is one day (with ranges of between zero and two days), with samples for PROVIRAL-DNA averaging between one and three days.

The study evaluated the use of the triple packaging system recommended by WHO; the use of sealed, leak-proof containers; the use of absorbent material sufficient to absorb all fluid in the case of breakage; appropriate labeling (biological risk symbol, orientation labels to indicate position of closures on the primary receptacles); and the use of gloves for handling samples. The evaluation team agreed to classify failure to adhere to one or more of these criteria as “noncompliance with biosafety standards.” Of the facilities surveyed, 82% (32/39) were determined not to be in compliance with national and international biosafety regulations, despite having properly trained staff.

Eighty percent (31/39) of the facilities reported the availability and use of printed forms provided by each disease control program for sending samples; however, these forms are not standardized and do not come with instructions detailing how they are to be filled out.

The regional coordinators of laboratory services mentioned that they had received a donation of motorcycles from the MPH’s Global Fund/Tuberculosis Project to be used at the local level for picking up TB and HIV samples. These motorcycles have been assigned to the area management offices in most of the SRSs for picking up samples in urban areas or from facilities located a short distance away within the same province. Pickup in remote areas is made with vehicles (pickup trucks) provided by the SRS. Not all area management offices have personnel assigned exclusively to pick up samples. Zone coordinators and drivers from health facilities are used.

### ***Delivery of Test Results***

In 2013, the LNSPDD reported that it received a total of 23,489 samples for CD4, that it processed 100% of these samples, and that it issued a like number of results. A total of 15,566 VL samples were received, of which 14,958 (96%) were processed, and result reports were issued for all samples processed. In the case of PROVIRAL-DNA, a total of 1,067 samples were received, of which 100% were processed, with result reports issued for the full 100%. However, the SRS laboratory service coordinators reported that they do not receive results for all of the samples of CD4 and PROVIRAL-DNA that are sent to the LNSPDD (see table 7).

Four percent (608) of the samples of VL received by the LNSPDD in 2013 could not be processed (and accordingly no results were issued), because, upon receipt, the sample was

deemed to be *unusable* or *in poor condition*. PROFAMILIA reports 68 samples of CD4 that could not be processed because, upon receipt, they were deemed to be *in poor condition* or of *insufficient amount*.

**Table 6. Number of Samples Received and Processed and Results Issued, according to LNSPDD Records**

Type of sample	Total samples received 2013	Total samples processed 2013	Number of results sent in 2013	Percentage
CD4	23,489	23,489	23,489	100.0
VL	15,562	14,958	14,958	96.1
PROVIRAL-DNA	1,067	1,067	1,067	100.0
Total	40,118	39,514	39,514	98.5

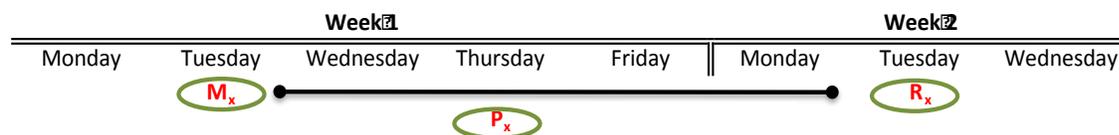
Table 6 shows that results were obtained and reported to the appropriate institutions for 98.5% of the samples processed by the LNSPDD, whereas at the SRS level, results were received for only 67% of the CD4, VL, and PROVIRAL-DNA samples sent in 2013 (table 7). Of the samples sent from the SRSs, results were received for 74% in the case of CD4, 59% for VL, and 71% for PROVIRAL-DNA.

Table 7. Percentage of Results Received as Compared to Samples Sent, Reported by SRS (2013)

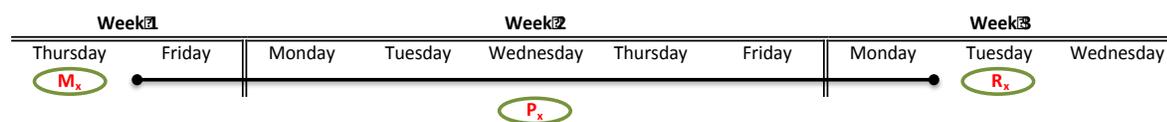
Region	CD4			VL			PROVIRAL-DNA		
	samples sent	CD4 results received	Percentage	samples sent	VL results received	Percentage	samples sent	PROVIRAL-DNA results received	Percentage
SRS 1	878	806	92	479	432	90	32	29	91
SRS 2	3,653	3,174	87	2,758	2,388	87	59	43	73
SRS 3	1,502	656	44	1,040	413	40	56	17	30
SRS 4	455	325	71	75	63	84	32	31	97
SRS 5	4,988	3,676	74	2,984	1,220	41	56	38	68
SRS 6	1,388	904	65	1,348	796	59	40	36	90
SRS 7*	—	—	—	1,516	636	42	21	16	76
SRS 8	645	452	73	571	419	73	30	22	73
<b>Total</b>	<b>13,509</b>	<b>9,993</b>	<b>74</b>	<b>10,771</b>	<b>6,367</b>	<b>59</b>	<b>326</b>	<b>232</b>	<b>71</b>
<b>Grand total CD4, VL, and PROVIRAL-DNA</b>							<b>24,606</b>	<b>16,592</b>	<b>67</b>

\* — data not available in SRS.

The average turnaround time (TAT) time between receipt of the sample at the LNSPDD and issuance of results was 17 days for CD4, 41 days for VL, and 3 days for PROVIRAL-DNA. However, interviews with individuals from the virology department (where HIV tests are processed) revealed that results for all samples that arrive in Santo Domingo via Caribe Tours on Thursdays—sent from SRSs 2, 3, 4, 6, 7, and 8, as well as from the provinces of Puerto Plata, Samaná, and Azua—should be available within a minimum of 8 working days, beginning with their receipt at the LNSPDD. That is, they are received on Thursday of week 1 and results are sent back on Tuesday of week 3.



Results for samples arriving on Tuesdays from SRS 5 via ASTRAPU should be available within a minimum of 5 working days (7 calendar days).



According to records reviewed in the facilities visited, the average TAT from the dispatch of the samples to the LNSPDD to receipt of the results in the health facilities was 19.5 days for CD4 counts, ranging from 6 to 24 days; 28 days for VL, ranging from 9 to 98 days; and 20 days for PROVIRAL-DNA, ranging from 5 to 102 days. The average TAT from dispatch of samples of CD4 to PROFAMILIA to delivery of results is 9 days, ranging from 1 to 20 days.

The LNSPDD does not have a unit dedicated exclusively to receiving samples and issuing results. Each processing area receives its samples directly and carries out its own internal procedures. The immunoserology department delivers HIV results to PLWHA, the SAIs, and the SRSs.

There is no electronic system for delivering HIV results. The LNSPDD sends printed reports via public commercial transportation (and with no prior notification) to SRSs 3, 4, and 6, which forward them on to the requesting SAI. Technical lab personnel interviewed indicated that these deliveries do not follow a regular schedule but rather are based on the availability of funds for transportation.

Results corresponding to SRSs 2, 5, 7, and 8 are sent from the LNSPDD to the regional hubs and from there to the SAI (without going through the administrative offices) by a number of different means: they can be picked up by area management offices or delivered by SRS drivers or CEAS staff members.

Of the 39 facilities visited, 3 SAIs received their results directly from the LNSPDD. Those corresponding to SRS 0 are picked up directly by the patients, while SRS 1 picks up its results at the LNSPDD (Annex B).

## **Tuberculosis: Sputum Smears, Cultures, and Sensitivity**

The PNCT has established the following nomenclature and functions for its network of laboratories:

- Sample Collection Units (*Unidades Recolectoras de Muestras*; URMs) consisting of those facilities that do not have a laboratory and must send sputum-smear samples to laboratories (municipal, provincial, or regional) operating within their geographic area.
- Local (municipal) laboratories with the capacity to carry out sputum-smear testing for the URM in their geographic area and patients consulting in that same health facility. They are required to send their results to the requesting URM and samples for culturing to regional CEASs.
- Intermediate laboratories (municipal and provincial) with the same diagnostic capacity as local laboratories; however, personnel working at this level possess a higher degree of technical training, enabling them to perform quality control for local laboratories. Regional CEASs are responsible for performing cultures within their network and sputum-smear testing for patients consulting in the CEAS and the URMs in their geographical area. They are required to send back results to the intermediate laboratories and the URMs. Regional CEASs send strains requiring drug sensitivity testing to the LNSPDD.
- The LNSPDD is the lead unit at the national level for all other laboratories performing TB diagnostic testing. It is responsible for logistics involving materials and supplies for performing cultures, training, supervision, and evaluation of internal and external quality control for regional laboratories that perform *Mycobacterium tuberculosis* culturing. It conducts tests to identify *Mycobacterium* and sensitivity to first- and second-line TB drugs and enforces compliance with biosafety procedures.

The national TB network currently consists of 1,269 URMs, including CPNs, NGOs, and prisons. A total of 206 municipal, provincial, and regional clinical laboratories have installed capacity for conducting sputum-smear tests. Thirteen regional-level CEASs are lab-equipped to perform cultures. The LNSPDD is responsible for processing drug sensitivity tests.

This study included 81 facilities operating at different levels and covered 50% of the network's sputum-smear processing facilities, 100% of those performing cultures and 5% of all URMs.

### ***Preparation, Dispatch, and Receipt of Samples***

In 2013, 211,361 sputum-smear diagnostic tests, 7,799 cultures, and 428 drug sensitivity tests were performed at the national level. A total of 3,786 samples (3,338 samples for culturing and 458 samples for sensitivity testing) were received by the LNSPDD; 1,462 samples for sputum-smear diagnostic testing were delivered directly by patients.

In 2013, the LNSPDD performed 37% (2,865) of all cultures at the national level and 70% of the cultures requested by the Metropolitan Region (SRS 0). The Santo Socorro, Marcelino Vélez,

Luis E. Aybar, and Robert Reid Cabral metropolitan hospitals have the capacity to perform sputum cultures but send some of their samples to the LNSPDD.

Fifty percent of the samples for culturing and sensitivity testing received at the LNSPDD in 2013 were from regional and provincial CEASs. They were delivered via public transportation using funds provided by the SRSs. The CEASs in SRS 0 send their samples directly to the LNSPDD using their own funds. Thirteen percent of the samples were transported by bioanalysts from metropolitan CEASs, particularly from Robert Reid Cabral and Marcelino Vélez hospitals. Six percent of the samples were taken to the LNSPDD by the DPS/DMS, and 32% were taken directly by patients.

The LNSPDD does not possess a specifically designated unit for receiving and logging in samples, as a result of which the TB lab receives the samples, records them in a logbook, and then proceeds to process them. No standard procedure governs the receipt and handling of samples.

All the SRSs have facilities with the capacity to process sputum-smear samples and perform cultures, with the exception of region 7, which does not have a laboratory with the installed capacity to carry out this type of testing. Samples for culturing in this region are sent for processing to the Cabral y Báez Hospital in SRS 2. Sixty-three percent (4,934) of TB cultures in 2013 were performed in 12 general and regional CEASs. Luis Morillo King Hospital (SRS 8) and Cabral y Báez Hospital (SRS 2) account for the greatest number of cultures performed. One hundred percent of all samples designated for sensitivity testing are sent to the LNSPDD.

Twenty-nine percent of all samples designated for sputum-smear testing were processed in regional CEASs, 28% in provincial CEASs, and 43% in municipal CEASs. Forty-four percent of sputum-smear samples processed by regional CEASs originated in CPNs located outside their catchment area.<sup>20</sup>

**Table 8. Volumes of Samples for Sputum-Smear Testing and Concentration of Processing, by Type of CEAS**

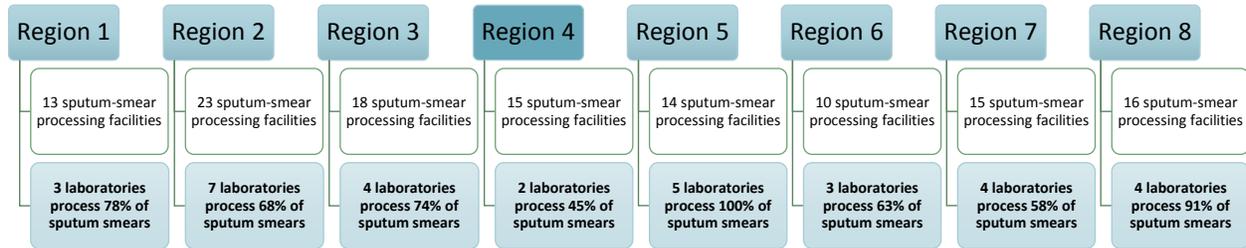
Type of facility	Sputum smear	Percentage
Regional CEAS	60,405	29
Provincial (intermediate) CEAS	60,128	28
Municipal (local/intermediate) CEAS	90,828	43
<b>Total</b>	<b>211,361</b>	<b>100</b>

Figure 1 shows the percentage of sputum-smear sample referral concentration within each SRS. For instance, 13 CEASs have capacity for processing sputum smears in SRS 1, but 78% of the

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<sup>20</sup> An additional report was requested from SRSs 2, 3, and 5, to verify whether the regional hospitals are receiving sputum-smear samples only from the CPN within their catchment area.

sputum-smear tests performed in the region was concentrated in just 3 CEASs. No information was obtained from SRS 0.



**Figure 1. Concentration of sputum-smear samples referred, by SRS**

A total of 15,125 (15%) of samples for sputum-smear testing were not processed, for the following reasons: *spilled sample* (40%), *unusable sample* (19%), and *insufficient amount of sample* (36%) (table 9).

**Table 9. Number of Samples Not Processed by the Study Facilities**

Sputum-smear productivity (samples received vs. processed)	Number
Number of samples received in 2013 (N = 50)	100,862
Number of samples processed in 2013 (N = 50)	85,737
<b>Productivity (%)</b>	<b>85%</b>

In 38% of the facilities visited, the cost of transporting samples is supported by laboratory employees or health personnel. The SRSs provide transportation for samples in 42% of the facilities visited. In 8% of the facilities, samples are picked up by the DPS/DMS.

**Table 10. Entities Responsible for Providing Transportation throughout the Health Services Network**

Transportation provider	Frequency	Percentage
SRS	34	42
Health personnel	30	38
Health facilities	10	12
DPS	7	8
<b>Grand total</b>	<b>81</b>	<b>100</b>

Seventy-five percent (61/81) of the facilities surveyed reported that they use the printed forms provided by the PNCT for sending samples. There are no instructions for filling out these forms. Ninety-six percent (78/81) indicated the existence of one or more staff members responsible for sample preparation and dispatch: the individual responsible for the program in 56% of the cases, and bioanalysts in 41% of the cases. Ninety percent of the facilities use a logbook to record data on sample dispatch and processing.

Ninety-three percent (79/81) of the surveyed facilities were in noncompliance with biosafety criteria established to ensure the proper preservation of samples and the safety of the individuals handling them. The evaluated criteria included the following: use of the triple packaging system recommended by WHO; use of sealed, leak-proof containers; use of absorbent material sufficient to absorb all fluid in the case of breakage; appropriate labeling (biological risk symbol, orientation labels to indicate position of closures on the primary receptacles); and use of gloves for handling samples. Noncompliance with at least one of these five criteria led to a classification of *overall noncompliance*.

### ***Delivery of Test Results***

The LNSPDD received 1,462 samples for sputum-smear diagnosis in 2013. Twenty-four samples (2%) were not processed because of the poor condition of the sample and the lack of a label and/or identification on the primary container; 1,438 samples were processed with results reported.

The LNSPDD received 3,338 samples for culturing, performing cultures on 2,865; it received 458 samples for drug sensitivity testing, processing 428. No results were obtained for 473 (14%) of the culture samples sent or for 30 (7%) of the samples sent for sensitivity testing because of sample contamination and poorly filled out or incomplete forms (table 11).

**Table 11. Number of Samples Received-Processed with Delivery of Results at the LNSPDD**

Type of sample	Total samples received 2013	Total samples processed 2013	Number of results delivered in 2013	Percentage
Sputum smear	1,462	1,438	1,438	98
Culturing	3,338	2,865	2,865	86
Sensitivity	458	428	428	93

The average TAT following receipt of a sputum-smear sample in the LNSPDD was 7 days; for cultures, the average was 60 days, and for sensitivity testing the average was 20 days.<sup>21</sup> Results of sputum-smear, cultures, and sensitivity testing performed at this level are recorded manually by a bioanalyst on the same forms used for requisitioning the tests. No specifically designated unit is responsible for receiving and delivering results. Physical delivery of results in the CEAS follows an irregular pattern, that is, results are delivered indiscriminately, to SRS health area technicians (when the latter go to the laboratory to pick up supplies), to PNCT supervisors, or to DPS/DMS technicians.

Within the health service network, the study revealed that responsibility for delivering results from sample-processing CEASs to health facilities varies in accordance with funds available at the SRS and the health facility. The average TAT is 5 days for sputum-smear tests (ranging from 1 to 107 days) and 95 days for cultures (ranging from 62 to 204 days).

The 54 URMs surveyed during the study sent a total 29,585 sputum-smear samples to processing facilities in 2013. Results were received back at the URMs for only 8,760 of those samples (30%) (table 12). Technical staff interviewed at the facilities indicated that the most common causes for this were *unusable samples*, *spilled samples*, *insufficient samples*, or *samples in poor condition*. Annex C graphically depicts current flows for sending and reception of results.

**Table 12. Sputum-Smear Samples Sent and Results Received**

Results received vs. samples sent for sputum smear	Number
Number of sputum-smear samples sent in 2013 (N = 54)	29,585
Number of sputum-smear results received in 2013 (N = 54)	8,760
<b>Percentage</b>	<b>30%</b>

<sup>21</sup> This time is obtained if the MIDGIT method is used; otherwise, the time increases to six weeks.

## **Others/Epidemiology: Dengue, Cholera, and Leptospirosis**

The established purpose of the National Public Health Network is the identification of agents and the etiological diagnosis of priority illnesses for purposes of disease control. The regulations governing the Epidemiological Surveillance System<sup>22</sup> establish, as part of the National Laboratory Network, the following subnetworks: National Subnetwork of Epidemiological Surveillance Laboratories, National Subnetwork of Environmental Surveillance Laboratories, National Subnetwork of Health Regulation Laboratories, and National Subnetwork of Highly Complex Medical Care.

This set of regulations stipulates that the Integrated Units of the National Subnetwork of Epidemiological Surveillance Laboratories will perform the following functions: (a) diagnosis of diseases with mandatory reporting requirements; (b) surveillance of communicable and noncommunicable diseases; (c) monitoring of bacterial resistance; and (d) definition of tools to be used by the network for carrying out diagnostic testing. The Network of Epidemiological Surveillance Laboratories operates in all 32 provincial CEASs and 14 regional/general CEASs. Each of these facilities contains an epidemiology unit responsible for collecting biological samples for diagnosing diseases with mandatory reporting requirements. The DPSs and DMSs are responsible for transporting the samples from the CEASs to the LNSPDD.

The study included samples for diagnosing dengue, cholera, and leptospirosis to determine how samples are transported and results delivered, and to subsequently contrast these data with similar data for HIV and TB. The facilities selected included the LNSPDD, 6 DPSs/DMSs, and 13 regional and provincial CEASs.

### ***Preparation, Dispatch, and Receipt of Samples***

The LNSPDD receives samples from the 32 provincial CEASs and 14 general/regional CEASs. In 2013, 20,311 samples were received from the Epidemiological Surveillance Program. Thirty-four percent (6,897) of the samples were sent for diagnosis of dengue, 2% (517) for cholera and 3% (581) for leptospirosis. All samples are transported under the responsibility of the DPSs/DMSs, using their funds. An exception to this procedure is the case of the Cabral y Báez Hospital, which processes this type of sample and sends only 12% to the LNSPDD for confirmation using more advanced methods and technologies.

The LNSPDD has a unit responsible for receiving samples for the Epidemiological Surveillance Program; that unit is headed up by bioanalysts appointed by the DIGEPI. Samples are received six days a week and recorded in a logbook before being sent for processing to the laboratory's various internal departments. No automated system exists for recording samples received, samples processed, and results delivered.

Eighty-five percent (11/13) of the facilities visited do not have their own means of transportation for sending samples. The DPSs/DMSs are responsible for the pickup of samples and transportation to the LNSPDD. There is no predetermined schedule for sample pickup. In 69%

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<sup>22</sup> Decreto no. 309-07, Reglamento del Sistema de Vigilancia Epidemiológica. Santo Domingo, 13 de junio de 2007.

(9/13) of the facilities evaluated, samples are picked up three or four times weekly. Fifteen percent reported that they send samples in CEAS vehicles to DPS/DMS administrative offices.

In all of the CEASs evaluated, the staff member responsible for collecting and preparing the samples is the bioanalyst. Responsibility for recording, labeling, and dispatch falls to the epidemiologist.<sup>23</sup> The average time for all samples from collection to the dispatch of the sample to the reference laboratory was two days.

Eighty-five percent of the facilities visited failed to comply with the biosafety and quality assurance criteria being evaluated, despite the fact that 92% (12/13) indicated that they had staff members trained in the handling and preparation of infectious samples.

### ***Delivery of Results***

In 2013, the LNSPDD received approximately 8,300 samples of dengue, leptospirosis, and cholera. The average TAT was 4.1 days for dengue, 2.5 days for cholera, and 3.1 days for leptospirosis.

All results are reported electronically in DIGEPI's Surveillance System, which is installed and networked to the LNSPDD clinical departments and to the epidemiology unit in health facilities. For reporting results electronically from a particular department in the LNSPDD, the bioanalyst in charge locates the patient's file using the code assigned to the sample at the time the epidemiologist entered it into the system. The result is also recorded manually by each clinical area in a logbook and on the VEF-4<sup>a</sup>/2013 form.

**Table 13. Number of Samples Received and Processed and Results Issued by the LNSPDD for the Epidemiological Surveillance Program**

<b>Type of sample</b>	<b>Total samples received 2013</b>	<b>Total samples processed 2013</b>	<b>Number of results delivered in 2013</b>	<b>Percentage</b>
Dengue	6,897	6,540	6,540	95
Leptospirosis	581	553	553	95
Cholera	517	517	517	100
<b>Total</b>	<b>7,995</b>	<b>7,610</b>	<b>7,610</b>	<b>95</b>

### **Costs**

The cost of transporting samples in the Dominican Republic totaled DOP 14.7 million in 2013. Seventy-seven percent (DOP 11 million) of the cost is covered by the MPH, while 8% (DOP 1.5 million) is paid for out of pocket by members of the health staff using their own personal funds, and 13% (DOP 2 million) is covered by the Global Fund, which subsidizes the TB and HIV

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<sup>23</sup> The VEF-4<sup>a</sup>/2013 form is used for sending samples to the LNSPDD when a case is suspected.

programs. Of this amount, 55% (USD 8 million annually) is paid by the SRSs. SRS 0 expenses are covered by the Global Fund. The DPSs report expenditures totaling DOP 2.3 million, while health facilities report a figure of DOP 1.2 million.

The amount for fuel and per diem totals DOP 5.6 million, while payment for private commercial transportation is DOP 2.5 million. Not included in the cost were salary payments made to the staff involved in transporting the samples.

Table 14. Expenditures of the Transport System for HIV, TB, and Epidemiological Surveillance Program Samples in 2013

Facilities	Annual expenditures of sample transportation system, public/direct (DOP)	Annual expenditures of Global Fund/TB projects (DOP)	Annual expenditures of Global Fund/HIV projects (DOP)	Annual total (DOP)	Percentage
SRS 0	nd	371,781	216,000	587,781	4
SRS 1	413,280	142,015	164,329	719,624	5
SRS 2	873,948	100,000	107,903	1,081,851	7
SRS 3	1,151,712	50,000	26,033	1,227,745	8
SRS 4	977,160	50,000	-	1,027,160	7
SRS 5	391,200	100,000	17,950	509,150	3
SRS 6	517,320	202,150	10,368	729,838	5
SRS 7	828,000	117,838	9,350	955,188	7
SRS 8	864,000	150,000	144,000	1,158,000	8
<b>Subtotal SRS</b>	<b>6,016,620</b>	<b>1,283,784</b>	<b>695,933</b>	<b>7,996,337</b>	<b>55</b>
DPS	2,348,112	nd	nd	2,348,112	16
DMS	1,135,536	nd	nd	1,135,536	8
LNSPDD	195,950	nd	nd	195,950	1
DIGEPI	288,000	nd	nd	288,000	2
Health personnel (N = 125)	1,486,728	nd	nd	1,486,728	10
Admin. health facilities (N = 125)	1,219,128	nd	nd	1,219,128	8
Subtotal 2	6,673,454	nd	nd	6,673,454	100
<b>Total</b>	<b>12,690,074</b>	<b>1,283,784</b>	<b>695,933</b>	<b>14,669,791</b>	

nd = no data available.

## ANALYSIS

The creation of integrated networks of health service facilities using the SRS management model requires an increase in response capacity at the primary level of care, including access to diagnostic tests. Technologies and methods for the diagnosis and follow-up of cases of HIV and TB require highly complex laboratories that go beyond the operational and maintenance capacities of facilities at the primary level of care. Laboratory services for the primary level should be gradually replaced by the organization of an internal system for collecting clinical samples from peripheral facilities that allows for pickup, transportation, processing of samples, and delivery of results on a timely basis from the points of health care to the primary-level structures.<sup>24</sup>

According to the results of this study, no organized system under the direct responsibility of the SRSs currently exists for the collection, handling, and transportation of samples between the various levels of care within the network of health service facilities, as stipulated by the health sector reform process. In addition to this institutional/methodological vacuum, the study revealed, among other findings, the absence of operating procedures, a scarcity of instruments and supplies for applying biosafety procedures, and a shortage of financial and human resources.

It was determined that no established procedures are in place for sending samples to the municipal CEASs or criteria governing their transportation to a reference laboratory. In addition, procedures for delivering results from the central level to local levels are not systematized, with evidence of prolonged time lapses between the sending of a sample and receipt of the test results by the health care facility.

The LNSPDD, as the country's primary recipient of samples, does not have a unit specifically designated to receive samples and to assume responsibility for recording their arrival and sending back the results obtained. Despite the significant volume of samples processed, the TB and HIV programs lack an electronic information system to connect the LNSPDD with the regional hubs and CEASs, where information regarding the recording of samples received and result reporting could be available in real time. A similar information system is already being used effectively by the Epidemiological Surveillance Program. Rather, the LNSPDD devotes resources to the collection of samples directly from patients referred by metropolitan health facilities.

A significant percentage of the samples sent by facilities (33% for HIV and 30% for TB) received no results.<sup>25</sup> In the case of TB, the primary cause for lack of results is the dispatch of unusable samples, samples in poor condition or insufficient in amount. This in turn may be attributed to a lack of basic or refresher training for facility personnel. The study also detected a

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<sup>24</sup> Secretaría de Estado de Salud Pública y Asistencia Social (SESPAS). 2005. Modelo de Red de los Servicios Regionales de Salud: Una guía para el desarrollo de los servicios de salud para la atención a las personas. Disposición 00024; SESPAS, Santo Domingo, República Dominicana.

<sup>25</sup> A review was made of the Database for the HIV Social Policies Record (*Ficha de Políticas Sociales para el VIH – FAPPS*) kept by all of the SAIs in the network, from which it was possible to extract all of the results for CD4, VL, and PROVIRAL-DNA tests performed in 2013, together with the date the results were issued by the LNSPDD. These data were linked with information provided by the LNSPDD and PROFAMILIA.

high concentration of work in a small number of processing units. This has significant implications in terms of quality of preparation and the timely dispatch of the sample and warrants a more specific analysis by those responsible for quality control at the PNCT and the LNSPDD.

National and international documents indicate that CD4 results should be available within two days, VL results within seven days, and PROVIRAL-DNA results within three to four days. The study revealed that approximately 4% of all HIV samples sent to the national reference laboratory are not processed because they are deemed unusable or in poor condition; the rest are processed within an average time frame that exceeds processing standards. Due to the lack of a standardized flow with responsible personnel at the network level, the results are delivered to a number of different sites, and consequently many results do not return to the requesting facilities in a timely manner.

The concentration of processing in regional CEASs, as in the case of sputum-smear tests, can be attributed to their convenient geographic location, as well their response capacity. The laboratory network must clearly take the preceding into account in modifying its current organizational structure to increase its efficiency in responding to national demand, by considering the effective decentralization of sputum-smear testing to the primary levels and/or to an established site within the health services network where such an option is warranted.

The study found evidence that a large number of culture samples are concentrated at the LNSPDD, rather than being sent to the metropolitan CEASs that have the appropriate processing infrastructure and technology in place but are not carrying out such tests. Steps should be taken to ensure that the assigned sample flows are enforced to reduce unnecessary workload in the national reference laboratory, limiting its operations to drug sensitivity testing, as is established. This is an issue that should be analyzed in greater depth by the PNCT team and the LNSPDD. In addition, the MPH should reassess the option of building capacity in certain regional CEASs to conduct CD4 counts and VL testing.

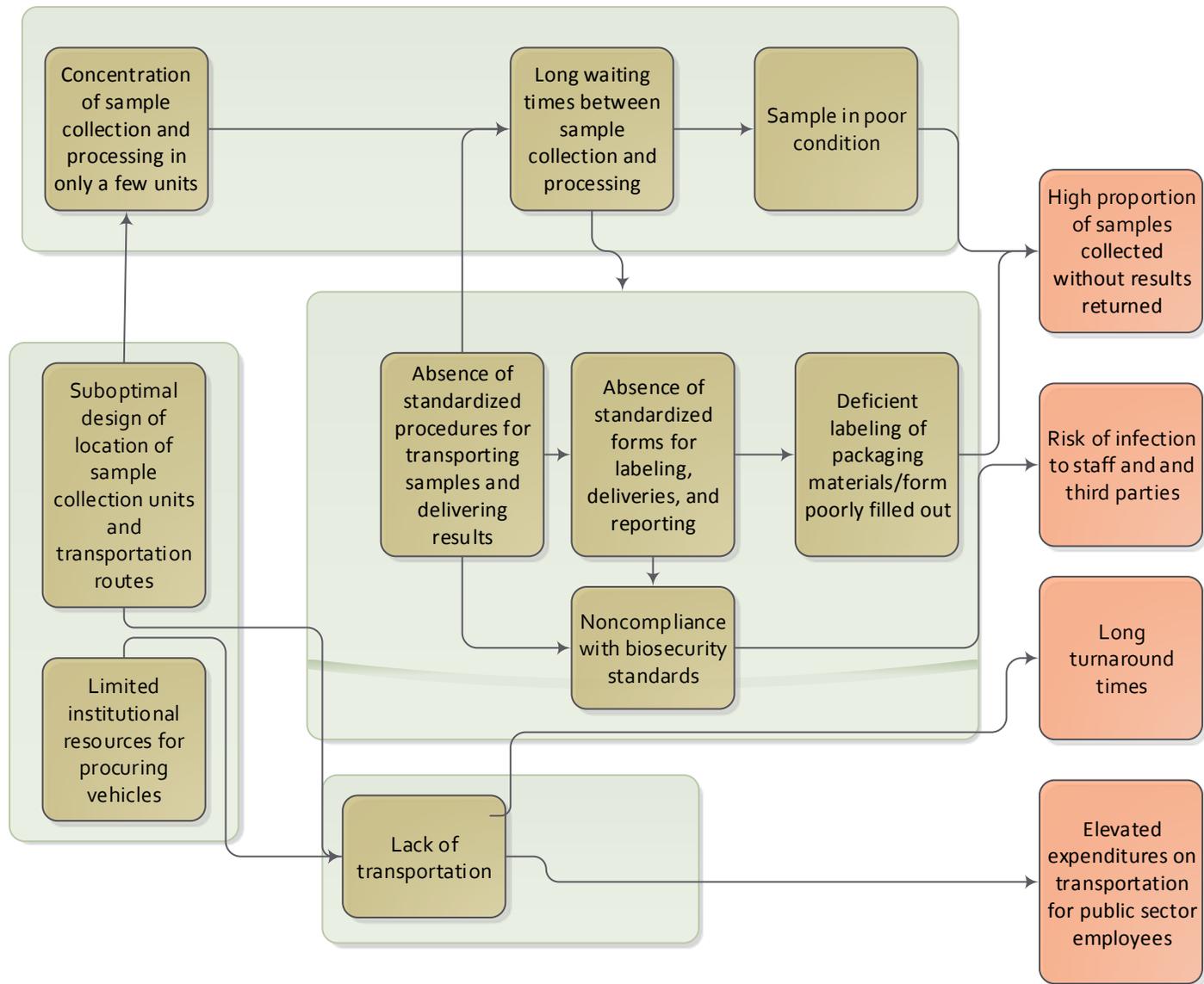
The study was unable to determine whether there would actually be a lack of transportation if available resources were used optimally. At the time the study was conducted, however, a number of issues were evident: long turnaround times, as well as a substantial and unjustifiable out-of-pocket disbursement of funds by health personnel.

At their core, the inefficiencies detected in the system for transporting samples and delivering results (figure 2) directly and negatively affect the detection, diagnosis, and treatment of diseases, with the potential risks that this represents not only for the patient but also for the general public. The ultimate consequence of these inefficiencies is avoidable morbidity and mortality, and high levels of transmission of the diseases involved.

## CONCLUSIONS

- No standard operating procedures exist for the preparation, and delivery of samples within the referral network, from sample collecting facilities to processing laboratories, nor for returning the results obtained.
- An elevated number of basic samples received by third-level (regional) processing laboratories originate in units operating at the primary level of care, a situation that creates bottlenecks and leads to increased processing time and delays in the turnaround times of results.
- A substantial number of HIV and TB samples sent for processing to national reference and network laboratories are rejected because the samples are spilled, unusable, in poor condition, of insufficient quantity, or lack appropriate labeling, and/or because the appropriate requisition form has not been properly filled out. The deficiencies are attributed to incorrect preservation, packaging, and transportation of samples.
- For a high percentage of samples sent for processing, results are not returned to the originating unit on a timely basis or within the time frames established by applicable country standards and/or guidelines established by disease control programs. This is attributed to a lack of human resources and materials available for transportation and the lack of a system for generating electronic reports so that results can be forwarded quickly and easily to the originating facility. Printed results are sent via commercial modes of transportation with no observance of procedures establishing turnaround times and designating the individuals responsible. This in turn contributes to delayed diagnosis and treatment for patients.
- National and international standards of biosafety applicable to the packaging and ground transportation of infectious samples are not observed. The study revealed a lack of basic materials for transporting samples, including a lack of materials for secondary and tertiary packaging, the absence of labels imprinted with symbols or images indicating infectious substances, a lack of general biosafety guidelines for transporting infectious substances, and a lack of awareness on the part of responsible personnel of the proper handling of samples.
- Results are not delivered for substantial number of samples for which processing has been performed because of inaccuracies in the information used to correctly match patients with test results. This is caused in part by a lack of standardized records and by improper completion of the requisitions for diagnostic tests to be performed by reference laboratories.
- Both SRSs and regional and national reference laboratories lack human resources, information systems, and monitoring and evaluation systems, all of which leads to inefficiency in the dispatch of samples and the receipt of test results.

- A portion of the cost of transporting samples from local levels to processing levels (national, regional, and provincial) is paid for by health facilities or by staff members working in those facilities. The cost of returning test results by commercial modes of transportation is often absorbed by the reference laboratory.



**Figure 2. Identification of priority problems**

## INTERVENTION ALTERNATIVES

1. **Review/modification and reinforcement of the national laboratory network:** This study has laid bare a series of deficiencies and weaknesses that point to the need to reorganize the national laboratory network with a focus on strengthening intermediate and local facilities as well as on strengthening the central laboratory to enable the latter to comply with its assigned functions as head of the network and national reference center, all within the context of health sector reform. The laboratory department should officially implement an explicit taxonomy of the entities included in the network, from sample collecting units to central reference laboratories. Also required is an explicit definition of the geographic catchment areas of each and the resources each will require to perform its assigned tasks. Strengthening of the national laboratory network is a requirement for correcting the inefficiencies identified in the transportation of samples and delivery of results, and will contribute to improved quality control, which should be a coordinating element in this effort.
2. **Design of an integrated sample transportation system within the network of health service facilities, with phased-in implementation:**

### Phase 1. System design

- Development of a generic system for transporting samples that takes into account such factors as the introduction of innovative technologies, the reorganization of the network, and the demand for service at individual facilities.
- The above-described unified system for transporting samples will be designed to have the capacity to handle large volumes of samples as additional types of samples and new pickup sites are incorporated.
- The design of this system will incorporate best practices for the carriage of biological materials in accordance with international standards. The delivery of results should incorporate the national experiences of private laboratories.
- Consideration should be given to the facility-based flowchart showing the level of complexity of each facility to avoid increasing implementation costs.

### Phase 2. Standard operating procedures

- **Development of standard operating procedures:** Standard operating procedures should be developed for the preparation, packaging and delivery of samples for testing, as well as for the delivery of results. In addition, monitoring, evaluation, and supervision procedures should be developed. These procedures should consider the integration into a single system of all types of samples collected in health facilities for processing by reference laboratories.

- **Training of staff from the SRSs and DPSs/DMSs:** Procedures should be developed with the active participation of and subsequent validation by the health service network, as well as by DPS/DMS technicians with regard to the monitoring and supervision procedures. Following publication of these procedures, and with the administrative support of the MPH, training should be provided to the technical and administrative personnel responsible for the transportation of samples.

### **Phase 3. Implementation**

Work will proceed gradually in terms of the disease control programs involved, since implementation will take place initially at the regional level (the nine SRSs) and will involve only the transportation of HIV and TB samples and the timely delivery of results. SRS personnel will be given the forms and tools necessary to enable them to proceed immediately with system implementation. This process will need to be supported by the design of transportation routes and the provision or subcontracting of vehicles, as necessary. The SRSs will need to make the necessary budgetary arrangements to cover these expenditures.

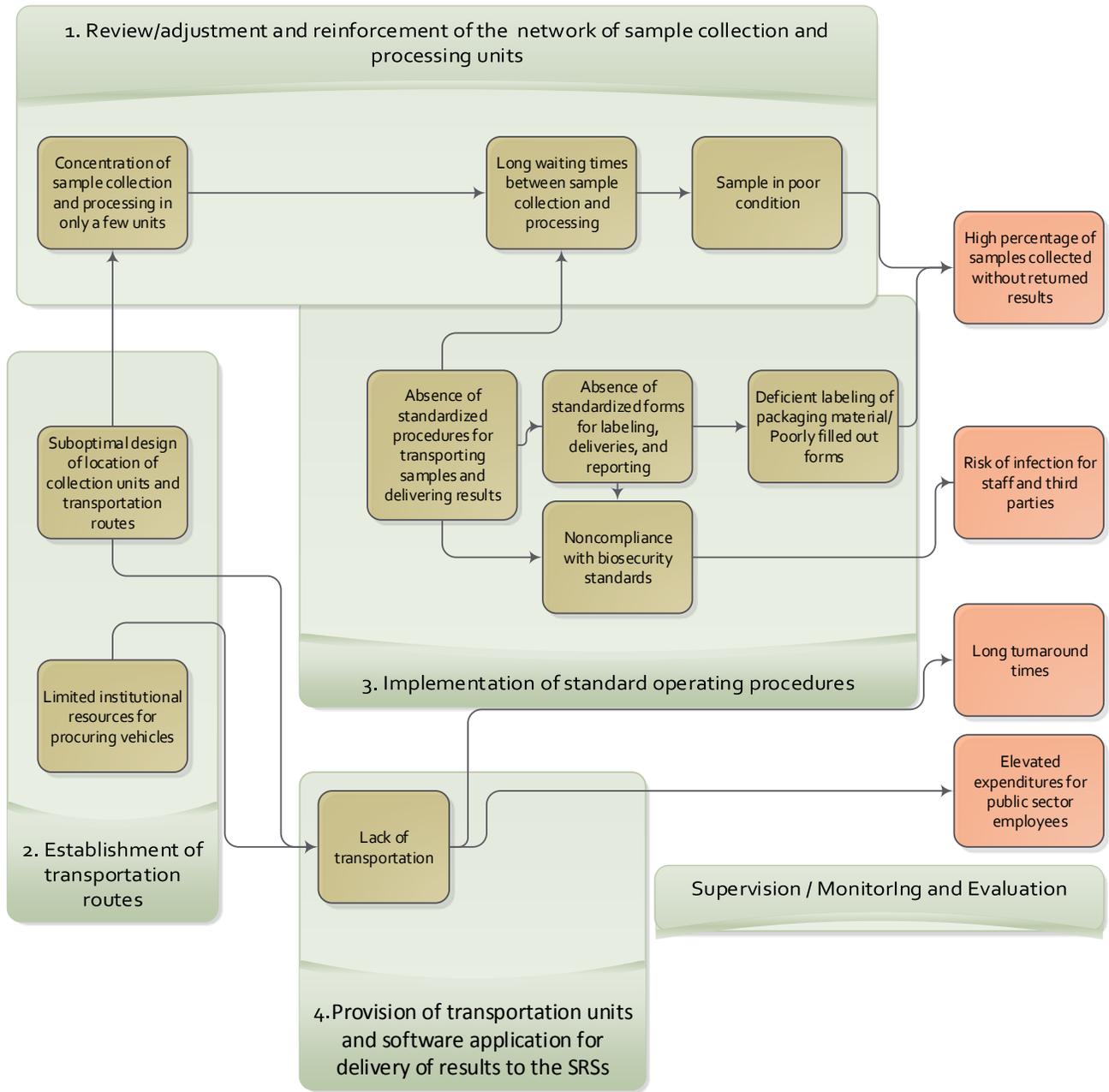
#### **Design of a software application for the receipt of samples and the delivery of results:**

The possibility should be explored of using software applications for logging in and confirming the receipt of samples, and for delivering results to health facilities online. The platform selected should provide for interface with the DIGEPI system to provide a link to the National Epidemiological Surveillance System, as well as with other existing applications.<sup>26</sup> The DIGEPI system could serve as a point of reference for replication and extension, considering the central role played by laboratories in epidemiological surveillance. As with any platform, work should begin with the implementation of a pilot phase that would proceed by stages for specific facilities, such as the LNSPDD, the regional hubs, and the regional CEASs. Inclusion of these facilities would ensure coverage for the delivery of HIV test results (CD4, VL, PROVIRAL-DNA) and TB sensitivity tests from the LNSPDD to the regional hubs and regional CEASs. It is proposed that this be a subject for analysis by teams that possess experience with the introduction of technologies into similar processes. The technical committee should give its backing to this recommendation.

These alternative paths of intervention, and their relationship to the problems identified, are summarized in figure 3.

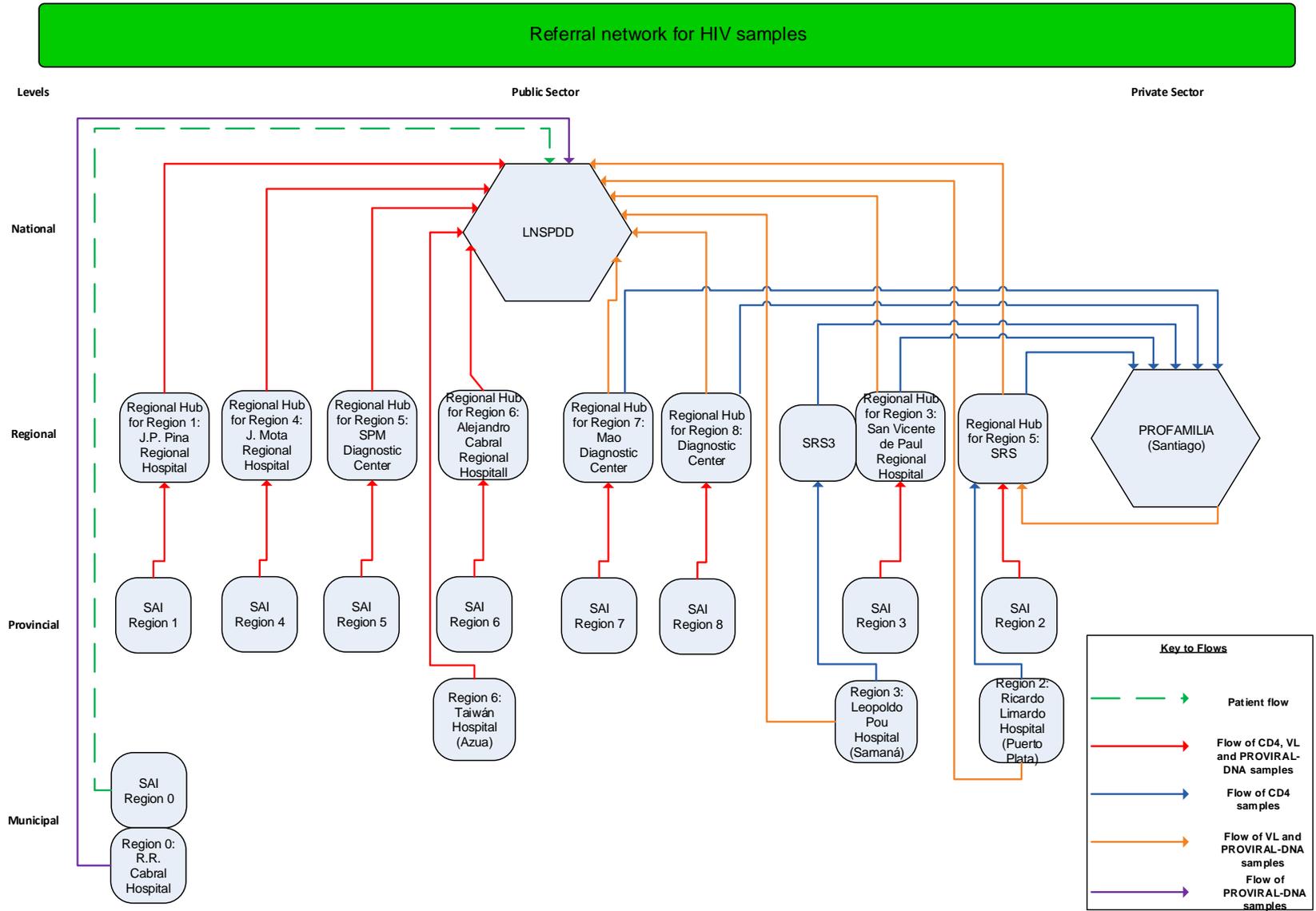
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<sup>26</sup> The PNCT has equipped regional laboratories with computers and Internet access. The SAIs use a software application for following up on patients with HIV.

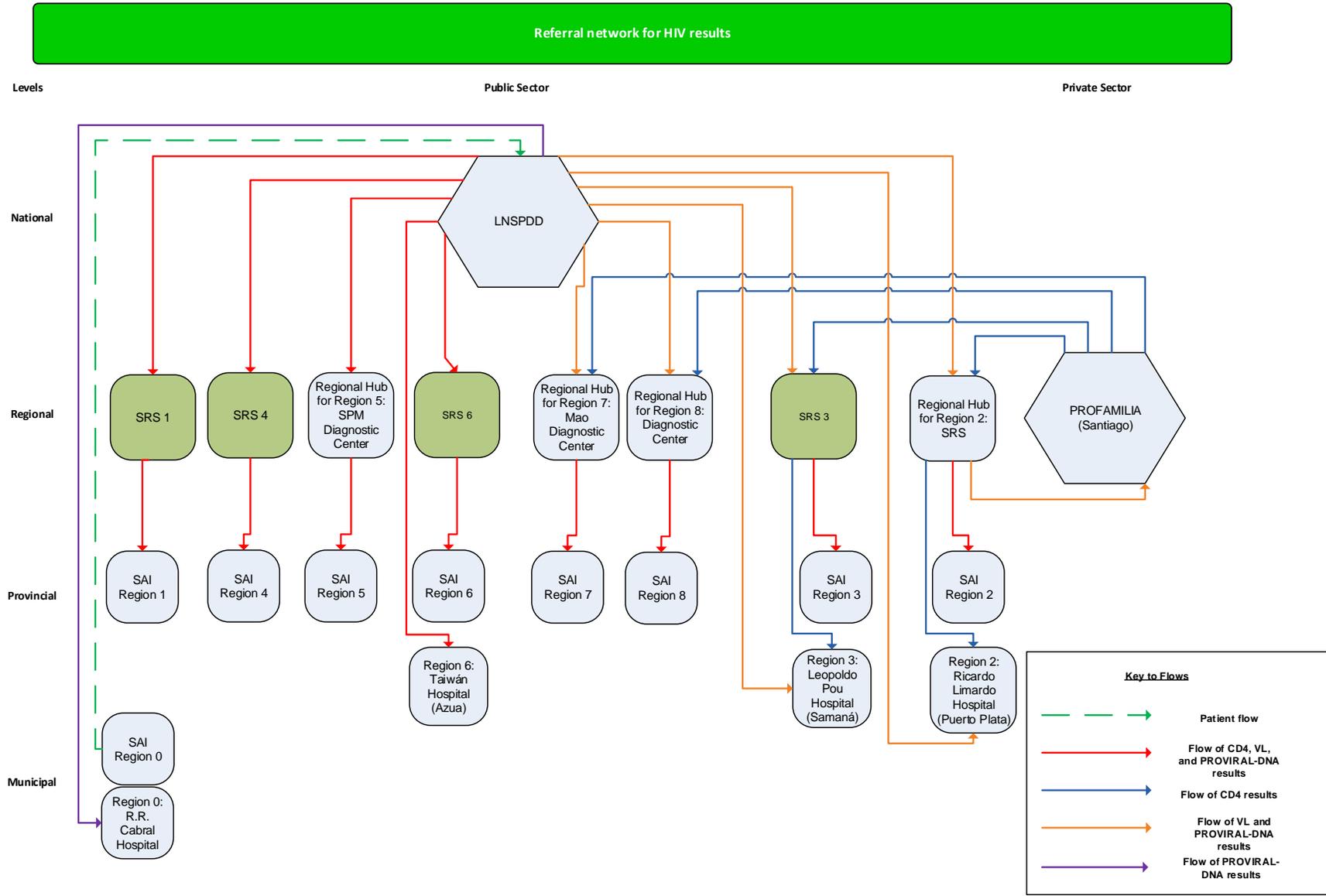


**Figure 3. Intervention alternatives for improving the transportation of samples and the delivery of results**

# ANNEX A. FLOWCHART SHOWING THE NATIONAL DELIVERY-RECEIPT OF HIV SAMPLES



## ANNEX B. FLOWCHART SHOWING NATIONAL DELIVERY OF HIV RESULTS



## ANNEX C. FLOWCHART FOR TB SAMPLES AND RESULTS

