

Management of Laboratory Reagent Supplies in the Dominican Republic Ministry of Health

Background

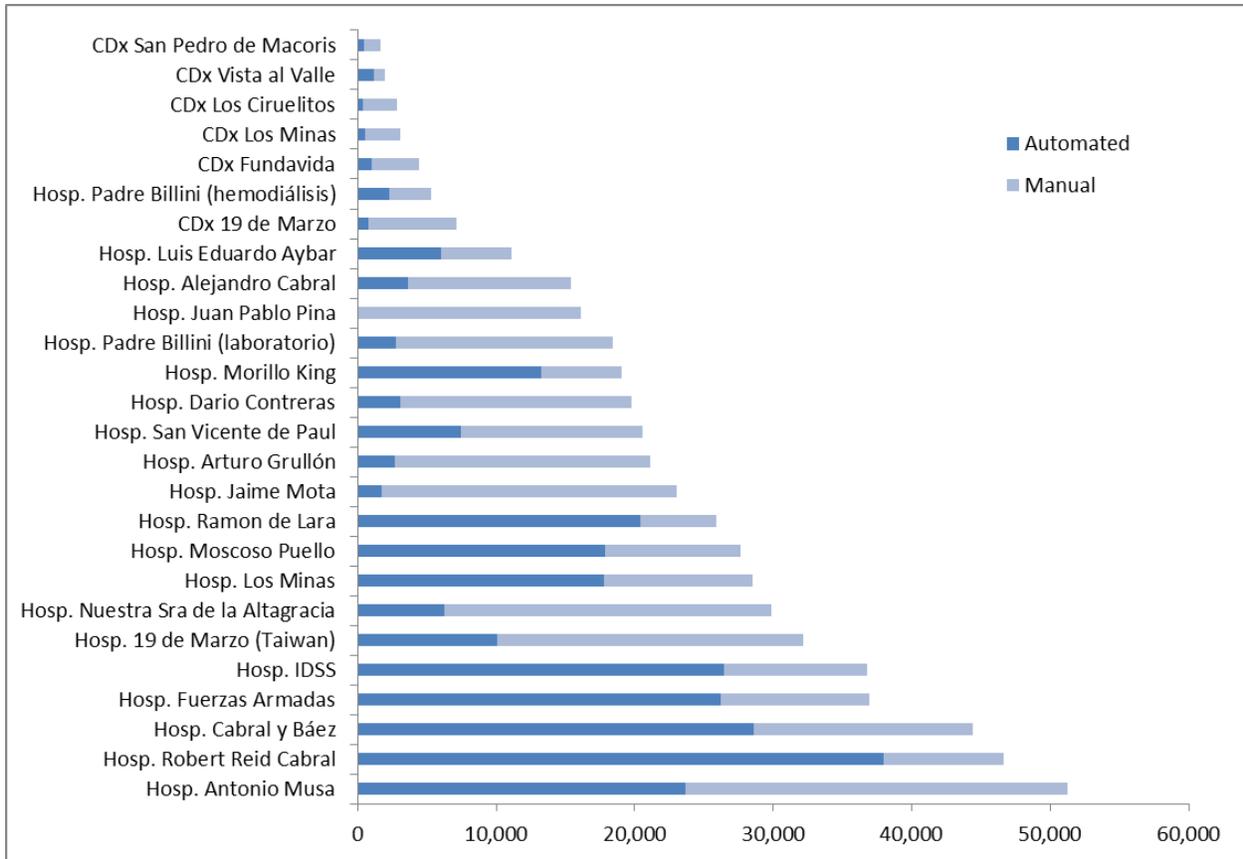
In 2012, to optimize the use of public resources, the president of the Dominican Republic issued an Executive Decree in which he instructed government public agencies to consolidate their requisitions of medicines, pharmaceutical supplies, and laboratory reagents so that the Essential Medicines Program/Center for Logistical Support (Programa de Medicamentos Esenciales/Centro de Apoyo Logístico, PROMESE/CAL) could establish a joint purchasing system. The Ministry of Health's National Pharmaceutical Management Unit (Unidad Nacional de Gestión de Medicamentos, UNGM), with support from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, provided technical coordination to the process of estimating needs and programming the joint purchase for 2013/14. Participating in the exercise were the Ministry of Health's Public Service Network, the Armed Forces, the National Police, the Dominican Social Security Institute, and the Office of the President's Social Plan. Reagents for clinical laboratory tests could not be included in this estimate because the multiplicity of products available and the lack of standardized technical specifications impeded the consolidation of requirements.

During the second half of 2013, the UNGM, with support from SIAPS, conducted a rapid study to determine the availability and consumption of laboratory reagents, so they could be included in future programming for the joint national purchase. The sample included 26 clinical laboratories: 11 located in national referral specialized care centers (*centros especializados de atención, CEAs*), 9 in regional and provincial CEAs, and 6 in diagnostic centers operating in primary health care facilities. A total of 99 types of tests, both manual and automated, were studied, in seven diagnostic areas.¹

Availability, Consumption, and Supply Status

The laboratories included in the study perform 2,353,208 tests per month. Of these, 88 percent are conducted manually while 12 percent use automated methods (figure 1). In the area of hematology, all complete blood count tests are performed using automated methods (figure 2).

¹ These areas are clinical chemistry, hematology, immunoserology (includes blood bank and virology tests), parasitology, special tests (includes tests from different areas), and microbiology.



Note: CDx = diagnostic center; Hosp. = hospital.

Figure 1. Average number of laboratory tests conducted monthly

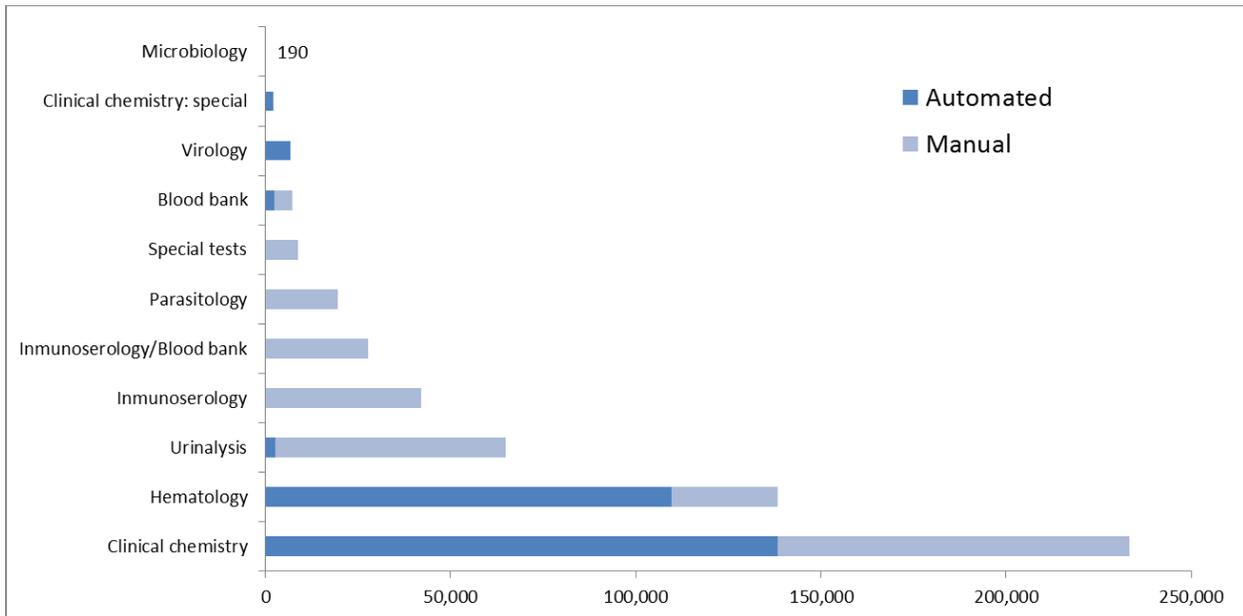


Figure 2. Average number of laboratory tests conducted monthly, by clinical area

CEAs conduct 93 tests using manual methods, and these tests involve 180 different analytical methods (table 1). The reagents for these tests are provided by a number of different commercial suppliers (even in the case of a single analytical method). Blood glucose reagents, for example, are marketed in different presentations and concentrations by six different providers. PROMESE/CAL provides reagents for only 23 of the 93 tests conducted using manual methods; the remainder are procured by direct purchase from private sector providers.

Table 1. Laboratory Tests Available, by Manual Analytical Methods Used

Area	Number of tests	Methods used
Hematology	13	15
Immunoserology/Blood bank	20	46
Parasitology (includes confirmatory tests)	8	11
Special tests	13	13
Clinical chemistry	27	80
Urinalysis (includes confirmatory tests)	12	15
Total	93	180

At the time of the study, 9 percent of manual tests were not being performed because of a lack of reagents. The principal causes of this shortage were the lack of availability of the required product at PROMESE/CAL and the inability to purchase on credit from private suppliers because of accumulated debt. Of the laboratories evaluated, 31 percent were forced to stop conducting some of the manual tests during the three months preceding the study because of a lack of reagents.

All of the laboratories evaluated had autoanalysis equipment available at the time of the interview. This equipment is used primarily in the areas of hematology and clinical chemistry (table 2). A total of 107 pieces of equipment were identified, including 55 different models (series and brand names).

Table 2. Autoanalysis Equipment Available, by Clinical Area

Area	Number of pieces of autoanalysis equipment
Hematology	54
Clinical chemistry and special clinical chemistry tests	37
Immunoematology: blood bank, virology	13
Urinalysis	2
Microbiology	1
Total	107

In 14 (54 percent) of the 26 laboratories evaluated, at least one piece of autoanalysis equipment was out of order, as a result of which the tests conducted using those machines had to be suspended for an average of seven days during the three months prior to the study.

Autoanalysis equipment uses cleaning, calibrating, and diagnostic reagents that are exclusive for each brand and model of equipment. Some 28 percent of all reagents were out of stock at the time the study was conducted for a number of different reasons, primarily their high procurement cost.

Analysis of Results and Intervention Alternatives

The high cost of laboratory reagents and accumulated indebtedness are the primary causes of shortages and stock-outs. The lack of availability of these products limits timely diagnosis and treatment in public health facilities. Public resources available for reagent procurement could be optimized through the use of centralized purchasing by virtue of the economies of scale it would create. The resulting reduction in unit prices would make procurement of larger amounts possible within existing budget ceilings. This strategy cannot be implemented immediately, however, since the multiplicity of equipment and reagents prevents the consolidation of requirements. The intervention alternatives presented below include an initial phase in which PROMESE/CAL would procure only those reagents that are most frequently used and shared, followed by a second phase in which the standardization of analytical methods and regulations to govern the incorporation of new diagnostic technology would make increased joint purchase volume possible:

- **Centralized purchase of the most frequently used reagents:** PROMESE/CAL should procure all reagents and supplies required for manual methods in 2014. These items account for more than 90 percent of requirements in both value and number of units (Annex 1). For autoanalysis equipment, PROMESE/CAL can procure reagents for the five equipment models in greatest use (Annex 2). The remaining reagents should be procured on a decentralized basis, since the centralized purchase of these products would not provide any economies of scale.
- **Preparation of a catalog of reagents and supplies:** The UNGM will prepare a national catalog of reagents for both manual methods and the most frequently used autoanalysis equipment, to guide and organize the programming of purchases in 2015.
- **Incorporation of the supply of laboratory reagents and other supplies into the Integrated System for Medicine and Supply Management (Sistema Único de Gestión de Medicamentos e Insumos, SUGEMI):** To ensure improved management of supplies, both reports on consumption and stock on hand and reports on amounts requisitioned and dispatched should be prepared on standardized SUGEMI forms. The information generated will help guide the next round of programming exercises and form the basis for a policy to govern the implementation of new technologies.
- **Prepare and implement a technology inclusion policy:** This alternative should consider current national diagnostic and treatment protocols as international recommendations, the current demand for diagnostic tests and their correlation with clinical results, and the cost and productivity of both manual and automated methods. This policy should lead to norms and procedures that will regulate the inclusion of new technologies and ensure the uninterrupted supply of reagents and other materials for the operation and maintenance of those technologies.

Annex 1: Requirements for Manual Laboratory Tests for 2014

Name of method/test	Total monthly requirement, 2014	Total annual requirement, 2014	Percentage of total	Cumulative %
Chemical urine tests	232,277	2,787,324	11.11	11.11
Blood panel: Immersion oil for blood smear	213,451	2,561,412	10.21	21.32
HIV: Rapid screening test	133,389	1,600,668	6.38	27.70
Blood glucose (glycemia)	119,530	1,434,360	5.72	33.42
Total proteins	103,750	1,245,000	4.96	38.38
Serum albumin	102,888	1,234,656	4.92	43.30
Total cholesterol	89,307	1,071,684	4.27	47.57
Blood panel: Stain for blood smear	82,738	992,856	3.96	51.53
Urea	77,615	931,380	3.71	55.24
Rapid test for hepatitis C	77,596	931,152	3.71	58.95
Creatinine (serum, urine, and endogenous)	77,581	930,972	3.71	62.66
Triglycerides	73,055	876,660	3.49	66.16
Coprological (egg detection)	66,859	802,308	3.20	69.35
Hepatitis B Australian antigen (HBsAg)	49,275	591,300	2.36	71.71
Test for syphilis (VDRL)	49,250	591,000	2.36	74.07
Pregnancy test, serum (UCG) / urine	46,918	563,016	2.24	76.31
Typings	46,028	552,336	2.20	78.51
Coprological (detection of occult blood)	43,843	526,116	2.10	80.61
Toxoplasmosis	37,904	454,848	1.81	82.42
HIV: Rapid confirmatory test	36,986	443,832	1.77	84.19
HDL cholesterol	28,505	342,060	1.36	85.55

Annex 2: Most frequently used/most productive autoanalysis equipment

Autoanalysis equipment	Clinical area	Number of tests per year
A25 - BIOSYSTEM	Clinical chemistry	772,025
SYSMEX KX 21-N	Hematology	401,612
ABX MICROS 60	Hematology	370,588
URIT 2900	Hematology	283,608
DIMENSION X PAD	Clinical chemistry	266,352
DIMENSION	Clinical chemistry	259,200
ABX PENTRA 80	Hematology	180,000
MINDRAY BS 200	Clinical chemistry	119,616
STAT-FAX	Clinical chemistry	50,796
BC 3000 PLUS	Hematology	48,000
STRIP ANALYSER 500	Virology	48,000
BIO-RAD MODELO 1575	Clinical chemistry	36,960
HORIBA ABX 400	Clinical chemistry	36,120
DIALAB STRIPT ANALYSER 500	Clinical chemistry	36,000
MINDRAY BC 5300	Hematology	32,112
DISTINCT U500	Urinalysis	32,112
MINIVIDAS	Virology	24,000
MINIVIDAS	Clinical chemistry: special	4,992
IRMA TRUPOINT	Clinical chemistry	24,960
RAYTO RT-3100	Clinical chemistry: special	20,412
ELECSYS 2010 ROCHET	Clinical chemistry	16,500
LENA	Clinical chemistry	13,800
TECAN	Virology	10,560
LECTOR	Clinical chemistry	9,600
BIOTEC	Blood bank	9,600
ELX800	Blood bank	7,680
HORIBA ABX 200	Clinical chemistry	7,200
OPTI LION	Clinical chemistry	6,000
ACCESS 2	Blood bank	5,760
RAYTO RT-7600	Clinical chemistry	4,800
LX800	Blood bank	4,800
BACT/ALERT 3D 60	Microbiology	2,280
QUICK COAG 4000	Hematology	1,680
GEMPREMIUN 3000	Clinical chemistry	1,320