Working Paper

Assessment of Public Health Laboratory Capabilities and Role in Surveillance of Vaccine Preventable Disease and Diarrheal Disease in Georgia

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Mission

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- *Implementation of appropriate health system reform.*
- *Generation of new financing for health care, as well as more effective use of existing funds.*
- *Design and implementation of health information systems for disease surveillance.*
- *Delivery of quality services by health workers.*
- *Availability and appropriate use of health commodities.*

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Abstract

Effective laboratories are an important component of any vaccine preventable disease (VPD) surveillance system. This assessment looks at the roles and capabilities of laboratories as they do surveillance and response for VPDs and other priority infectious diseases in Georgia. The paper discusses how standardized World Health Organization laboratory assessment tools were adapted to the Georgian context; gives an overview of the country's laboratory system for diagnosis of VPDs; evaluates operations at central, regional, district, and facility laboratories; and sets out recommendations for laboratory strengthening.

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Acronyms

AFP	Acute Flaccid Paralysis
API	Active Pharmaceutical Ingredient
AST	Antibiotic Susceptibility Testing
ATCC	American Type Culture Collection
CSF	Cerebral Spinal Fluid
CSR	Communicable Disease Surveillance and Response
EQC	External Quality Control
IDS	Integrated Disease Surveillance
IQC	Internal Quality Control
MoLHSA	Ministry of Labor, Health and Social Affairs
NCDC	National Center for Disease Control
NRL	National Reference Laboratory
PHL	Public Health Laboratories
PHR	Public Health Reform
PHR*plus*	Partners for Health Reform*plus* Project
RBM	Roll Back Malaria
QC	Quality Control
SAN EPI	Sanitary Epidemiological Unit
SCL	Structure in Charge of Laboratories
SOP	Standard Operating Procedure
VPD	Vaccine preventable disease
WHO	World Health Organization

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1. Introduction

1.1 Objectives

As part of a broader, comprehensive PHR*plus* assessment of the current surveillance system for vaccine preventable diseases (VPDs) in the Republic of Georgia, this report will focus on the role and capabilities of laboratories as they relate to surveillance and response for VPDs and other priority infectious diseases. The laboratory assessment was designed to address the following issues/products:

- Adapt or modify standardized generic World Health Organization (WHO) laboratory assessment tools to the Georgian context to ensure collection of information as specified below.
- Prepare a descriptive overview of the country's laboratory system for diagnosis of VPDs and other infectious diseases under surveillance including national laboratory policy; description of organizational units and relationships; involvement of the private sector; resources; and the role of laboratory services in the overall surveillance system.
- Evaluate operations of the central, regional, district, and facility laboratories used for the confirmation of cases of VPDs and other priority infectious diseases, specifically:
  - adequacy of space, infrastructure, equipment, and supplies;
  - availability and adequacy of standard operating procedures and protocols;
  - laboratory-based performance indicators, including types of tests performed, validation procedures, and level of quality assurance;
  - field-based performance indicators affecting laboratory performance (e.g., proper specimen collection, storage, and handling);
  - quality of samples received;
  - workload, staffing levels, and adequacy of training;
  - turnaround time, communications between laboratory and health facilities, surveillance and immunization staff; and
  - laboratory and staff safety procedures
- Develop, in consultation with other members of the PHR*plus* assessment team and key stakeholders, a set of recommendations for laboratory strengthening and optimization of operations of laboratory services in Georgia, with an emphasis on VPDs, upon which an action plan could be built.

1.2 Background

The laboratory assessment was carried out for PHR*plus* by a consultant from the WHO Communicable Disease Surveillance and Response, Lyon (WHO/CSR Lyon). WHO/CSR Lyon is currently engaged in activities to strengthen laboratories in a number of countries (including Georgia) in order to improve their contribution to surveillance and response to certain targeted diseases (meningitis, diarrhea, and hemorrhagic fever).

This support will include training Georgian participants specially selected for this purpose over a two-year course. Two Georgian doctors employed by the National Center for Disease Control (NCDC) have already been chosen to attend this course, scheduled for mid October 2002.

Since both programs (PHR*plus* and WHO/CSR Lyon) have similar goals, it is clear that collaboration will be beneficial for improving VPD surveillance. It is anticipated that the participants in the WHO/CSR Lyon course will address the recommendations made during this assessment, both before and after the course begins.

1.3 Laboratories Visited During the Assessment

The assessment of the VPD surveillance systems involved visiting the following laboratories:

- **Tbilisi**
  - NCDC (different sections)
  - Microbiology laboratory, Infectious Disease Hospital
  - Virology laboratory, Infectious Disease Hospital
  - Private laboratory “CITO”
- **Batumi**
  - Adjara Ministry of Health Central Laboratory
  - Infectious Disease Hospital Laboratory
  - Paracels Private Laboratory
- **Rustavi**
  - Sanitary supervision laboratory (two locations)
  - Microbiology laboratory, Infectious Disease Hospital

Figure 1. Map of Georgia

Figure 2. Map of Georgian Regions

2. Laboratory System

2.1 Overview

The description that follows summarizes the *overall* situation with respect to laboratories and their role in VPD surveillance. It is not intended to be descriptive of the situation or operation of all individual laboratories in the country. For descriptive information about the individual laboratories visited, please refer to the detailed lab-specific comments below (Section 2.4).

Adequacy of space, infrastructure, equipment, and supplies

The following inadequacies in the laboratory system were noted:

- The space allocated to the laboratories is generally sufficient, except for private laboratories, which attempt to save money by using smaller spaces or facilities.
- The infrastructure is inadequate and insufficient. Walls and ceilings are in bad condition, especially ceilings, which often have problems of water tightness and infiltration. Walls are rarely tiled. Electric installations are old and not protected near the sink and benches. Autonomous functioning power supplies (in case of electrical failure) are rare. There are no real benches in the laboratories; most specimen handling and analysis is done on wooden desks. Air conditioning is rarely functional in the working areas. With few exceptions, laboratories are not provided with gas. Restricted areas are not clearly defined or marked.
- The equipment is minimally adequate, in terms of both quality and quantity. Existing equipment, though old, is solid, Russian-made equipment, and is almost the same in each laboratory (incubator, microscope, autoclave, spectrophotometer, etc.), which may facilitate maintenance and repair. The worst point concerns microscopes, which are mostly old Russian "Lomo" monocular solar models. Such microscopes are outdated and inadequate and do not allow technicians to perform proper diagnoses. Moreover, in most cases, not enough are available for the workload. There are no real maintenance services in most of the laboratories. The doctor in charge must attempt to fix the equipment himself, without training or specific knowledge in instrument repair and without adequate spare parts.
- Supplies in reagents, small materials, and equipment are very poor, as indicated by the following statements:
  - There is no centralized national supply system that is able to order in large quantities and decrease costs. Individual laboratories are therefore left to identify and order from a wide variety of different suppliers.
  - No fixed percentage of laboratory revenues (generated by patient fees) is devoted to supplies. This is an acute concern with respect to surveillance where certain tests may

not generate fees, therefore requiring cross-subsidization of these tests/analyses by clinical laboratory activities.

- There is little planning and foresight with regard to reordering supplies and reagents; laboratories order supplies on an intermittent, sporadic basis.
- There is little stock management that may help to avoid the expiration of goods.
- There is little local reagent production from raw materials that could potentially help laboratories to avoid shortages and stockouts. The few examples of these cases were for bacteriological media, but with no fabrication date, no logbook, and no batch number. These homemade media are not systematically checked for sterility, and the result of the check is rarely recorded.

In conclusion, regular shortages of reagents and sometimes inadequate or nonfunctional equipment lead to the frequent inability to perform crucial analyses.

Availability and adequacy of standard operating procedures/protocols

There are no comprehensive standard operating procedures (SOPs) currently available for laboratory operations in Georgia. What does exist are old Soviet-era SOPs, at least 10 years old, in Russian, and not adapted to recent improvements in techniques or to the current context/situation in Georgian laboratories.

Some laboratories have attempted to write their own SOPs, or to standardize result and reporting forms (see Annex C). This initiative is encouraging. However, this should be done at a national level, and each public laboratory should use the same SOPs for each sample and analysis and the same reporting form(s) for the result(s). That may allow for a patient to be followed in different laboratories with a good correlation between results.

Laboratory-based performance indicators, including types of tests performed, validation procedures, and level of quality assurance

In general, laboratory-based performance is described as follows:

- Laboratories are often specialized in one or two technical areas (microbiology, biochemistry), which determine the type of tests carried out. However, there is no clear list of performed analysis to which patients and clinicians can refer.
- Except for certain laboratories, neither technical nor biological validation procedures are clear; however, a physician is generally responsible for signing the report forms (always handwritten).
- Quality assurance is extremely limited and inadequate, as evidenced by the following:
  - There is no quality assurance manual, nor SOPs.
  - There is little quality control of the material and reagents received by laboratories.
  - There is almost no external quality control (EQC) (one begun four months ago for biochemistry is sponsored by a reagent manufacturer). In any case, no EQC is available for bacteriology, serology, or parasitology;
  - There is virtually no internal quality control (IQC), especially for bacteriology (no standardized strains to check identification, serotyping, and Antibiotic Susceptibility

Testing (AST)) or serology (a lack of adequate freezers does not allow for the constitution of a serum collection that may be used for control). Even for biochemistry, IQC sera are extremely rare.

- There is almost no IQC for sterilization and disinfections.

Field-based performance indicators affecting laboratory performance

Field-based performance was noted by the following:

- Specimen collection, if performed on site, is generally performed correctly. Except from a biosafety point of view, the handling of samples also appears adequate/correct.

- If the sample is to be stored (due to its collection at the end of the afternoon, night, or weekend) or transported, the quality decreases rapidly, and the chances of it being properly and accurately analyzed, dubious. Once again, there are no SOPs for sampling or sample transportation, and this leads to inaccurate analyses and results.

Quality of samples received

If the laboratory is linked to a clinical service (hospital, clinic, ambulatory), the sampling is generally done by these services, and is received by the laboratory relatively quickly and in good condition. Samples rarely come from outside these services or outside the lab, and most often the patients themselves simply travel to the laboratory where the tests are to be performed. If a sample does arrive from a remote area, it is most often in bad condition because of lack of real SOPs and resources for sampling, preparation, and transportation. Moreover, there is no standardized form to be attached to the sample, which contains data about the patient, the sample, or the clinical details/background.

Workload, staffing levels, adequacy of training

The following were noted regarding workload, staffing, and training:

- The workload varies greatly from one laboratory to another. Some laboratories are overloaded and understaffed, while this is clearly not the case for others. These underutilized laboratories generally also face shortages of reagents and/or consumables, which, in turn, further decreases their workload.

- The work hours for laboratories are generally very short (approximately between 9:30 a.m. and 4:00 p.m.), especially for laboratories linked to an emergency hospital. Night shifts are rare. Clinicians generally call the person in charge during the night if there is need for analysis.

- The adequacy of staffing depends on the laboratory, as shown in these examples:
  - Tbilisi infectious disease hospital (both bacteriology and virology) is understaffed.
  - Rustavi infectious disease hospital bacteriological laboratory is adequately staffed.
  - Rustavi sanitary services laboratory and Batumi Infecious Disease Hospital laboratory are overstaffed.

- The staff working in the laboratories seems to be well trained, especially the senior staff, but the lack of sufficient materials and regents does not allow them to use all their knowledge or

skills. This observation is based on answers to specific questions that were asked of the persons working in the laboratories, but not on the result of a formal/proper EQC process.

- Some EQC materials (gram and blue stain, case studies) have been brought to Georgia, but due to time limitations during the assessment, it was not possible to check the real ability of each staff member. This should be done as soon as possible to have an accurate picture of the training level of each staff and then be able to plan eventual training sessions.

- The continuous/in-service training of the staff seems to be neglected, outside of some specific training performed by international organization (for example, Roll Back Malaria for malaria training).

Turn-around time, communications between laboratory, surveillance, and immunization staff

The communication between laboratory and facilities is very weak. The assessment noted the following:

- There is no communication on a problem with a diagnosis.

- There is no communication to refer a sample to a higher level laboratory.

- There is no communication when facing a shortage in reagents.

- Except NCDC, there is almost no communication with surveillance and immunization staff.

Laboratory and staff safety procedures

Biosafety techniques and procedures are perhaps the weakest points in the Georgian laboratory environment. This is due to the following factors:

- No SOPs are available (regarding hand washing, bench cleaning, use of nondisposable material, disinfection and sterilization, different type of waste, waste disposal).

- Benches are just normal desks made of wood on which both sample handling and report writing are done (no “clean” and “dirty” areas are clearly defined in each laboratory).

- The number of items on benches (tubes, sample, tube carrier, reagents, slides) makes adequate and regular disinfections difficult.

- Lab coats are not used everywhere, and sometime they have to be washed at home.

- Gloves are rare, and protection glasses don’t exist.

- Centrifugation is done on centrifuges without lids, exposing the staff to micro aerosols of contaminated liquids.

2.2 Licensing and Accreditation

The Standardization, Norms and Licensing Department of the Ministry of Labor, Health and Social Affairs (MoLHSA) gives the authorization for all health facilities, including laboratories, to operate in Georgia. Laboratories are divided into different technical areas, based upon the type of services they perform:

- HIV
- Bacteriology
- Cytogenetic
- Biochemistry
- Virology
- Immunology
- Clinical
- Microbiology
- Serology

Two general documents govern the licensing and operation of all health facilities:

- An entrepreneurial law
- Presidential Decree #564 of 01/10/1999, specifically for health licensing

The law on pharmaceutical facilities can also be applied to laboratories, but this is not done officially.

The licensing department does maintain a list of all laboratories operating legally in Georgia. The list can be grouped by name, region, or activity.

There are no minimum requirements to open and operate a public or private laboratory in Georgia. To be licensed, a laboratory must simply provide the department with the following:

- A list of equipment to the department (there is no list of minimum or required equipment);
- Description of the building and/or territory;
- Certificates of professional background of the personnel;
- Description of an organization with indication of roles and responsibilities of the personnel; and
- Certificate on the organization's building consistent with hygienic norms.

The licensing department is actually working to develop a list of minimum requirements that laboratories should fulfill prior to licensure and operation. As an example, the French "GBEA" (Guide for Good Execution of Analysis) has been provided to the department for translation into Georgian to serve as a model. This document details all minimum requirements for French medical laboratories. The head of this licensing department has indicated a desire for increased collaboration with technical partners to assist in writing Georgian-specific minimum requirements.

There are no requirements in terms of quality control for laboratory operation. EQC procedures currently can only be performed by the Center of Genetics and Ecology and not by the MoLHSA directly. The only EQC that has been performed since the collapse of the Soviet Union was done in May 2002, assisted by the Human Laboratory, but only for biochemistry. As part of this procedure, 200 laboratories received samples. To date, only 50 of these laboratories have responded by providing results or responses. The results of the procedure are not currently available.

2.3 Main Georgian Laboratory Supplier

Due to time constraints during the assessment and the unavailability of local suppliers, visits to suppliers were not possible, with the exception of the Cito private laboratory, which is also the official outlet for bioMérieux products. The "Samaia" company, located in Tbilisi, stocks many products, materials, reagents, and equipment, but it was not possible to meet with representatives of the firm during the assessment. As the company representative mentioned later, the company is not limited and is able to supply the laboratory with any material. Price depends on the quantity of ordered goods and prices at the international market.

The Paracels private laboratory also buys reagents at "SABA." The Batumi Infectious disease laboratory buys its reagents at "Area" in Tbilisi.

2.4 Individual Laboratories

2.4.1 National Center for Disease Control

The NCDC was created in 1996 in the Federal Anti-Plague Center and is now assigned responsibility for all epidemiological surveillance activities as formerly assigned under the old Sanitary Epidemiological (SANEPI)[1] system. Environmental inspection responsibilities remain under the SANEPI system in a separate department in the MoLHSA.

The NCDC is located in Tbilisi, and has a branch in Batumi (located in the Adjara Autonomous Republic). The NCDC staff in Tbilisi consists of approximately 180 persons with another 20 in the Batumi branch. About half of the staff are specialists with university education, and about 30 of them have higher scientific degrees.

The NCDC comprises of a number of different laboratories.

[1] The Sanitary Epidemiological system was the Soviet system's approximate equivalent to the current system of Centers of Public Health.

Strain library, plague and natural pesthole infections laboratory

The NCDC collects all the bacteriological strains on which an AST is performed. This unit is located in a restricted access area. The entrance door and the freezers receiving all the strains are properly sealed, but during the assessment it was discovered that it is easy to unseal and then reseal each of them without the original sealing grip. The temperature of the refrigerators and freezers is checked and recorded on a daily basis (perhaps one of the only places within the entire NCDC to perform this necessary action).

Strains are usually stored in a glycerin/beef peptone broth, or directly in a solid media in a tube. Some studies are performed on these strains, but not at NCDC. The total number of strains collected to date is close to 2700.

Located close to this strain library is the high security laboratory for plague and tularemia, which was formally the federal laboratory for these diseases during the Soviet era. A special elevator was built for this purpose, but does not function anymore. Because of a lack of funds, as well as a lack of communication within the country, this laboratory is close to nonfunctional.

Cholera and other enterics unit

The enterics unit covers different types of diarrheas: Cholera, Salmonella, Shigella, Enterococcus. Between 100 and 120 samples are analyzed monthly, half from outbreak investigations, and the other half from clinical laboratories for confirmation of clinical cases (single case or small outbreak). During outbreaks or suspected outbreaks, one person from this unit collects samples. For example, three days prior to the assessment, a small outbreak of diarrhea occurred and staff from the enteric laboratory were called, collected the sample, and obtained the result after two days: Salmonella typhimurium.

Staff use homemade culture media (see photograph in Annex B), prepared on a weekly basis and stored in a refrigerator without temperature chart. There is no name, no batch number, and no expiration date on the various media, which staff recognize based upon their color. The orders for non-homemade reagents are made yearly, via the director of NCDC.

IQC is not regularly performed. Three months before the assessment, an EQC was processed in the unit. The results were acceptable:

- Of the Salmonella strain, 5/8 were serotyped correctly.
- Of the 72 AST results of Salmonella strain, 60 were in total agreement with reference results.
- Two results of E. coli strains were below the expected range.

The details of the EQC and its conclusions can be found in Annex D.

Zooantoponozic and anaerobic infections laboratory (mostly anthrax and botulism)

This laboratory deals with Bacillus anthrasis, Clostridium botulinum, but also with Brucella spp.

In 2002, 50 to 60 cases of botulism and three cases of anthrax were diagnosed. The highest period for anthrax remains between August and September. All the cases of anthrax are registered in a large map of Georgia (see photograph in Annex B).

This laboratory, as with the enterics laboratory, responds directly to requests from the field. Only the town of Kutaisi has a laboratory capable of performing anthrax diagnosis.

Respiratory disease unit

The respiratory disease unit covers a multitude of microorganisms:

- Corynebacterium diphtheriae

  The NCDC is the reference laboratory for diphtheria and is a member of the European group on diphtheria. Since 1996, 1300 cases of C. diphteriae were identified by this unit (including toxinogen and non-toxinogen strains), six were identified in 2001 (four toxinogen), and none in 2002. Last year, an epidemiological survey of 800 children was conducted and three C. diphteriae, including one toxinogen, were found.

  When a suspected case is found in a remote area, the laboratory of the concerned hospital conducting the preliminary analyses (direct examination, gram stain, and culture) notifies the NCDC. A team is sent from the NCDC to the hospital, and takes the first results and the strain back on a slant agar, in a large can. The strain is then identified to confirm the initial diagnosis. The identification is done on the active pharmaceutical ingredient (API) gallery. If positive, AST and research of the toxin are performed. Results have included the following:

  - Staphylococcus spp. (330 S. aureus identified this year);
  - Enterococcus (72 Enterococcus identified this year); and
  - Neisseria meningitidis (follow-up of the contact cases, index cases are followed at the periphery).

  All the contacts investigated were negative.

- Pseudomonas aeruginosa (134 P. aeruginosa identified this year)

  Since the beginning of 2002, this unit has performed 536 AST on positive culture. Samples are provided by the entire country and concern the ORL area, sputum, blood, post surgery, cerebral spinal fluid (CSF), and others.

  The identification is generally performed in tubes, due to the cost of API gallery. A small stock of this gallery is always present at NCDC in order to face any problem occurring during outbreaks and identification. A regular shortage of antisera prevents a proper identification of Neisseria meningitidis, Enterococcus, and Staphyloccocus spp. The unit has some American Type Culture Collection (ATCC) strains for IQC, and collaborates with Minneapolis University. An EQC program for diphtheria was initiated two years ago, but is not functioning now.

Polio and other enteroviruses (polio and nonpolio) and cell culture laboratory

The laboratory is divided into two parts: cell culture and polio diagnosis. Both laboratories are very well equipped, with safety cabinet, CO2 incubator, and a good binocular microscope (see photograph in Annex B). Five cell lines are cultivated in this unit, allowing for direct viral diagnosis.

Currently, the polio laboratory analyzes 15 cases a year. Last year, one child from Azerbaijan was positively diagnosed. A regular IQC is performed every three months for all three polio types, and a yearly proficiency testing program is also performed.

Apart from polio, the unit is also involved in identification of other enteroviruses such as Cox or Echo, especially if there is suspicion of viral meningitis. Based on the equipment present, this laboratory is capable of a variety of other diagnoses, including Herpes viridae (HSV, CMV, EBV) and respiratory viruses.

Molecular biology

This laboratory opened in 1997, and is staffed by five persons. The laboratory is adequately equipped with thermocycler, generator and gel migration tank, and photography system (see photograph in Annex B), and performs a number of different types of analyses:

- Anthrax: search for α plasmides genes, coding for lethal factors (RT-PCR)
- Plague: search for different genetic profiles (RT-PCR)
- Research on drug resistance by PCR: Mycobacterium tuberculosis, Staphylococcus aureus, Enterococcus.

Some activities could be eventually combined/merged with the Infectious Disease Hospital Virology Unit, which is also performing a number of molecular biology tests (see below).

Hospital infections unit

This unit conducts epidemiological and bacterial investigations for hospitals that face an infectious disease problem. Staff go to the hospital to collect samples, except when samples are collected during surgery. The specimens have different origins: blood, sputum, exudates, mucus, nasal, swabs. The specimens are generally collected from patients, but can also be done on medical staff, upon special orders from the hospital direction.

The unit performs the identification of causal microorganisms (see photograph in Appendix 2) and gives the strain to the respiratory unit to perform AST. The unit is also linked with the molecular biology unit for the research of some resistance genes (as MEC-A for Staphylococcus aureus). Studied strains are subsequently catalogued in the strain library unit.

During the first four months of 2002, 500 to 600 samples were studied. However, only bacteriological hospital infections can be studied in this unit. The laboratory does not have the correct media and techniques for fungi identification.

Parasitology unit

The Parasitology unit deals essentially with malaria (reference center for Georgia), and receives significant assistance from the WHO-specific program Roll Back Malaria (RBM). The unit's computer, printer, and photocopy machine were provided through this program.

In 2001, 232 cases were diagnosed (100 percent of Plasmodium vivax), mostly in eastern Georgia. Diagnosis is performed at the facility level and in the Institute of Parasitology in Tbilisi. At NCDC, 100 percent of the positive slides and 10 percent of the negative ones are reread. They use the

Giemsa-staining technique. No immunofluorescence or QBC (Quantitative Buffy Coat) or parasite tests are used.

This Parasitology unit has conducted many training activities for malaria diagnosis, funded by RBM, throughout the entire country.

Stool Parasitology (helminthes and amebiasis) is also performed, using only Willis concentration techniques (no formaldehyde concentration). The research of stool AIDS-linked parasites is not done (Isospora belli, Cryptosporidium parvum, Microsporidia spp, Cyclospora spp).

A specific WHO program for leishmaniosis is also based at the Institute of Parasitology. In 2001, 64 cases of visceral leishmaniosis were diagnosed (bone narrow sample and Giemsa staining). The NCDC Parasitology unit is not involved in leishmaniosis control.

Biosafety

The NCDC has been provided with one incinerator for solid waste disposal. Many other laboratories use this facility to dispose of their waste (Infectious Disease Hospital, Cito private lab). At the NCDC, the individual units (enteric, respiratory, hospital disease, high security) generally disinfect waste before burning it.

Conclusions

The NCDC is probably the best Georgian public laboratory for microbiology. However, the following improvements could be made:

- The regrouping of units, for example, media preparation, stock, cold chain, should not be split among the three main bacteriology services.
- Name, batch number, and date of fabrication should be clearly indicated on each homemade media.
- A computerized centralized stock management should be installed for all NCDC after a general inventory.
- Temperature charts should be generalized to all thermal devices.
- The strain collection should be more secured, and the number of participating laboratories should be increased (including private laboratories).

2.4.2 Tbilisi Infectious Disease Hospital

The Tbilisi Infectious Disease Hospital is a large facility with a dozen buildings. Different laboratories are dealing with analysis: bacteriological laboratory; virology & serology laboratory; sepsis laboratory; and clinical laboratory. The sepsis laboratory mostly deals with blood culture and surgery specimens.

Bacteriology unit

Dr. Macharashvili manages this laboratory. Dr. Macharashvili, who studied one year in Albany, New York, wants to upgrade this unit in order to be able to ensure quality analysis. She works with two technicians and one cleaning person. Almost all analysis performed is clinical analysis.

The laboratory is located on one of the hospital building's floors. The state of the building is not very good, and it has severe ceiling problems (water leakage, infiltration). No generator is available in case of electrical failure.

Sampling is always done in the hospital. All standard bacteriological analysis is performed in the laboratory: stool, swabs samples, urine, CSF, blood, and others. For *Corynebacterium diphteriae*, the laboratory is able to perform the diagnosis, but is sending sample or strains to NCDC in case of suspicion. In 2002, three suspicious cases were analyzed; none was positive. For diarrhea, the laboratory is able to perform identification of all microorganisms, including serotyping; there were 184 diagnoses of *Salmonella spp*. and *Shigella spp*. in 2002.

An estimated 40 AST are performed monthly in the laboratory. These AST are done using standardized methods: Mueller-Hinton two media and regular antibiotic disks. The number of antibiotics tested each time depends on the stock available. A standardized form, written by the doctor, is used for AST results (see Annex C). Results are also kept in the lab (name, sample, strain, diameter, and sensibility profile). All the strains are given to the NCDC strain library.

The laboratory has the same equipment as do other laboratories in the country. However, the laboratory has two binocular microscopes (and two "Lomo" monocular ones). There is no person in charge of the maintenance. The staff deals with all preventive and curative maintenance.

All the culture media are homemade, pouring dehydrated media. A system of stock management on paper is used and focuses on both quantity and expiration date. The laboratory does not use expired media: it is used before the expiration date. Orders are made jointly with the pharmacy, twice a year, mostly to bioMérieux. The laboratory rarely faces shortages, except for antisera. Distillated water is made in the laboratory.

Except for the head of the lab, the technical staff has not been officially trained during the last five years. However, the doctor provides an informal continuous training.

The head of the lab tries to translate into Georgian most of the SOP's used in the United States. The job is almost finished for sampling and sample identification procedures. Some procedures are also written for the weekend: an incubator is present in the clinical part of the hospital, some culture media are also provided there, and a training session for the clinicians was held to let them plate some samples during nights or weekends, in case of emergency. At times the laboratory refers samples to NCDC for confirmation (always for diphtheria) and can participate in outbreak investigation.

Staff provides a monthly written report about all the work performed. The report is divided by analysis, microorganism, and antibiotic tested. Reports on infectious diseases, notifiable or not, are regularly sent to NCDC.

The laboratory is careful about quality control: the head of the lab has some ATCC strains, obtained from American friends. NCDC provides them with *Salmonella* ATCC strains. However, a lack of *Corynebacterium diphteriae* strains is notified. The sterility of all homemade media is checked on each batch. The laboratory is not included in any EQC program, but would like to

perform proficiency testing. The staff always wears labcoats, sometimes gloves, but never protection glasses. The benches are wooden desks.

In conclusion, this laboratory performs a good analysis, and the head of the lab is very much involved in quality assurance: IQC, the writing of SOPs, the quality of reagents, and homemade media. Moreover, this laboratory communicates regularly with clinicians, NCDC, and other laboratories. This laboratory has to take a good place in the Georgian surveillance network.

Virology unit

The virology unit performs various tasks:

- Blood safety

  The laboratory is the head of a large national blood bank network that includes 64 laboratories (there are 66 districts in Georgia). All of these labs are provided with reagents for HIV, B & C hepatitis, and syphilis in order to check donors' blood. Four of these laboratories have ELISA system (Batumi, Kutaisi, Zugdidi and T'elavi). The 60 other labs are using unitary tests. If positive, the sample is brought to the virology laboratory for confirmation. Transportation procedures are not standardized, and transport is generally done using a private car. Sample is received cold if it's less than three days, frozen otherwise.

  Regular QC material is sent to the participating laboratories. The head of the virology lab would like the MoLHSA to be more involved in this program. The laboratory also has training facilities and performs regular training sessions for the members of the network.

- Serology and molecular biology

  Outside of HIV and hepatitis diagnosis, a lot of diagnoses can be performed in this laboratory: *Herpes simplex*, CMV, toxoplasmosis, *Chlamydiae*, Gonococcus, HIV confirmation, EBV, Measles, Rubella, and VZV. Mumps are no longer diagnosed; δ and E hepatitis will soon be diagnosed by PCR. Most of these diagnoses are performed by serology or by PCR.

  Monthly, this laboratory performs 2000 AIDS diagnoses, 400 B and C hepatitis diagnoses, and about 15 measles and rubella serology. Outside specific programs, the analyses are relatively expensive: estimated at US$6 each, US$40 for HIV confirmation (blot), and US$70 for PCR.

- Immunology

- Immunoglobulins, CD4/CD8, and other specific proteins can be analyzed in the laboratory

- Other clinical analysis (hematology and biochemistry)

  This activity is also a way for the laboratory to supply some reagent for public health analysis (different stock than the normal routine activities) using laboratory fees.

  The premises are in a very bad state and are too small, but rehabilitation is planned soon. The staff (10 personnel in total) is well trained and seems to know the job, for both serology and PCR. Regular IQC is performed, generally with the control materials provided in each kit.

EQC was performed formally, linked to a survey on Sexually Transmitted Diseases, and some EQC material (Hepatitis B and C and HIV) are sent from an American laboratory, but on an irregular basis. All the people working in the laboratory would like to get more EQC material in order to check their abilities and improve their techniques.

SOPs are written, but not for everything; all the results are provided with standardized reporting forms. Good contact exists with the bacteriological laboratory and NCDC (a joint project about hepatitis is actually running).

As with the bacteriological laboratory, this virology lab, through the analysis performed, the blood safety network, knowledge in molecular biology and ability for training, should be a strong part of the surveillance network.

2.4.3 Rustavi Public Laboratories

Rustavi is located 35 kilometers south of Tbilisi, and was mostly developed in the 1960s as a result of large industrial Kombinat. At its peak, Rustavi had 140,000 inhabitants, 40,000 of which worked for these Kombinat. After the collapse of the former Soviet Union, all of these industrial complexes collapsed as well. Today, only 7,000 persons are working for the Kombinat, and a large part of the population has emigrated to Tbilisi.

Sanitation services laboratories

The mission of these sanitation services is the control of water, food, air and ground. They have close contacts with veterinarians, but don't perform analysis for them (they have their own laboratory). The sanitation laboratories services are divided in two parts: chemicals and bacteriology. They also declare realizing clinical analysis in bacteriology, because there is no real licensed laboratory.

According to the director of sanitation services, all laboratories of the town are outdated and do not even reach the old Soviet standards. No rehabilitation or investment has been done during the last 20 years.

- Chemical laboratory

  This laboratory checks water for Pb, Cd, As, Sr, Zn, Cu, and Fe. The method used is the polarography. Only one to two analyses are performed monthly, because of a general shortage of reagents, yet 20 analyses should be done monthly (real capacity of 10 analysis daily). The laboratory also searches for chemicals: pesticides, alcohol, methanol, phenol, lactones, cyanides, and others.

- Bacteriology laboratory

  This laboratory is in very bad condition and no longer seems to work. The ceiling allows the rain to enter, the homemade media storage is empty, the straining station is dry, media are close to 10 years beyond their expiration, but the incubator temperature is reported daily in a logbook (when electricity is working, which was not the case during the visit).

The protocols used for water analysis are very old and use a small volume of water, which is not concentrated by filtration. The laboratory is not able to see small water contamination by coliforms. There are very few consumables, no internal or external quality control, and no supervision visit by National Sanitation Services.

Infectious Disease Hospital, bacteriological laboratory

This large hospital has two major units: one for adults and the other for children. Each unit has a clinical laboratory (biochemistry and hematology) and a laboratory for bacteriology. This bacteriological laboratory is composed of four rooms in good standing: plating room, identification and AST room, washing-media preparing room, and stock room. One doctor, one technician, and one person in charge of the washing room are working in the lab. Electricity and water are available, but there is no generator.

The lab can perform all bacteriological analysis, including CSF, diarrhea investigation, and diphtheria. Samples are not made in the lab but in nearby hospitals. Identification and recording of each sample seems to be correct. The equipment is old but functional. An old monocular "Lomo" solar microscope is the only one the laboratory has. No preventive maintenance is performed on equipment, and there is no temperature chart for thermal devices.

The lab also can perform AST (25 monthly), but does so on a homemade media and with homemade antibiotic disks. When performing such AST on a nonstandardized media, the pH, the antibiotic diffusion, the ion strength, and other parameter may change from time to time, and lead to inaccurate results. Moreover, these AST homemade disks are done on a normal blotter paper, using a small perforator. The thickness of these disks is too small and is not the same for each disk. The disks are then home-charged with an antibiotic, are not controlled by a standardized strain, and then are stored at ambient temperature. Antisera for *Salmonella spp*. and *Shigella spp*. identification are also stored at ambient temperature. The results of these AST cannot be used. Strains are then decontaminated and destroyed, and are not sent to the NCDC library.

Upon examining the stock, it was discovered that 75 percent of the reagents are expired and there is no stock management, neither to check the quantity nor the expiration. Some reagents are bought in Tbilisi but irregularly (two to three times yearly), after asking the director of the hospital for money. The staff seems to be inappropriately trained, and is making a lot of mistakes. No refreshing or training session has been offered in the past 10 years. In case of emergency, the doctor can be called at home (although this is rare).

There are no procedures available in the laboratory. No IQC or EQC are performed. The staff doesn't seem very interested in participating in EQC programs. At times the lab sends samples to NCDC for confirmation (always in case of diphtheria suspicion). In case of outbreak, NCDC teams come to conduct the sample and transport it back to Tbilisi. Results are not sent back to the laboratory. Biosafety is incredibly low in the laboratory: no gloves are worn; specimen handling is done on wooden desks; old tubes with blood are placed on the benches; and the benches are very dirty.

Infectious Disease Hospital, clinical laboratory

This clinical laboratory was visited very quickly during the night guard shift. The premises are in good condition, and there is a lot of space. Staff are performing basic biochemistry and hematology analysis, using a small spectrophotometer for biochemistry and manual techniques for hematology (no cell counter). The lab has a lot of nonfunctional equipment, mostly coming from humanitarian

"help" (already broken when it arrives). An ELISA reader is also not functioning. As found everywhere, the biosafety level is low, but knowledge of the staff met seems to be average.

Conclusion

Both bacteriological laboratories should be merged to join equipment and staff (the doctor in charge of the bacteriology laboratory is close to retirement). SOPs and training should be provided in a relatively short time.

2.4.4 Batumi Public Laboratories

MOH Central Laboratory

This laboratory performs only bacteriological analysis. The following different types of analyses are performed:

- Water and food analysis (three samples a day for water)
- Clinical analysis (blood culture, throat, stool, urine, swabs)
- Toxi-infections
- Surgery analysis

Samples can be done in the laboratory (few) or come from hospitals or sanitation services.

A doctor manages the staff, and only 20 persons work in the laboratory. No specific training has been held during the past five years. Some staff have good knowledge in bacteriology, but they need to be trained in modern techniques soon. Moreover, the staff is plethoric, according to the number of analyses performed (especially if one compares this laboratory to the Tbilisi Infectious Disease Hospital Bacteriology laboratory, which performs more analyses with only three technical persons).

The building is in a bad state (see photograph in Annex B) and the lab is also underequipped. For example, only one "Lomo" solar monocular microscope is available for all the laboratories (20 persons). A slide prepared with a Staphylococcus culture and then gram-stained was observed. The observation is possible but requires a lot of attention and leads the observer to a rapid fatigue (monocular). Some incubators are broken, but there are enough incubators functioning to be successful. When there are problems with the equipment, someone from Tbilisi should respond, but this is not very effective.

The lab performs a normal tube identification (no API gallery available) with a certain amount of quality. However, AST are performed on a nonstandardized media (AGV media) that will not give results comparable from one lab to another and that will also not meet the normal diameters for the result. The washing room is very old (see photograph) and not secure (infectious waste is close to noninfectious waste or personal clothes). Lab coats are used but not gloves and glasses. The benches are wooden desks. The level of biosafety is very low.

The reagents are bought in Tbilisi, twice a year. There is no stock management, and more than 50 percent of the reagents used have already expired. The sterility of homemade reagents is not regularly checked. All the analyses performed are written in a large logbook that seems to be well

kept. Communication with NCDC is regular, especially for diphtheria suspicion or for result confirmation. There is no internal or external quality control program. Old Soviet procedures are followed in the laboratory, but seem to be outdated. This laboratory needs to be modernized. Improving equipment, especially microscopes, training sessions, and biosafety measures will allow this laboratory to increase the quality and quantity of analyses performed.

Infectious Disease Hospital

The laboratory is a polyvalent laboratory (biochemistry, hematology, and bacteriology). The actual building is in a very bad state, but new premises are already prepared in the main hospital building (see photograph in Annex B).

Origin of the samples is as follows:

- 70 percent from hospitalized persons
- 20 percent from ambulatory persons
- 10 percent from lab-specific customers

Nine people are working in the laboratory and are managed by a medical doctor (seven persons are always working at the same time). The material isn't very good: only two monocular solar microscopes, old centrifuges without lids, and one incubator works with a petrol burner. However, the staff seem to be well trained and are doing their best with the material, reagents, and equipment available. A workload of 20 patients a day is an average number, including conducting five to seven bacteriological samples. The same "AGV" media is used for AST (see comments for previous lab).

EQC is only performed for biochemistry. No IQC is performed, essentially because of the lack of freezers. Only the sterility and growth potency of each homemade media is checked regularly. SOPs are rare, but are written in Georgian. No one is in charge of maintenance (a lot of equipment no longer functions). The laboratory continuously faces a shortage of reagents and is compelled to use expired reagents. Laboratory fees are not used to restock reagents. Orders are occurring only twice a year. The biosafety level is very low but should be increased when moving into the new laboratory.

Communication with the other laboratories exists, especially regarding NCDC: standardized strain supplying for media control; sample sending for confirmation (informally in that generally the family transports the sample); and training activities, in association with the American International Health Alliance. However, contacts with Batumi Central laboratory are rare.

2.4.5 Private Laboratories

Paracels Private Laboratory (Batumi)

This small, private laboratory is located inside a private clinic. Only the following biochemistry, hematology, and immunology analyses are performed here:

- Blood cell counting, urine cytology
- Classical biochemistry and enzymes; ions are not analyzed

- Chlamydiae, Herpes simplex, CMV, Gardnerella vaginalis, Trichomonas, and toxoplasmosis using ELISA techniques

The lab is located in one room, where all the equipment is present. The equipment is good, and includes a fluorescence microscope, a good ELISA system, two semiautomated spectrophotometers, and centrifuge. Two technicians work in the lab. Their knowledge level seems to be enough for the analysis performed (20 a day). No SOPs are available. The lab uses IQC that was included in the commercial kits. The lab also participates in the biochemistry EQC.

Reagents are bought in Tbilisi but also directly from Moscow. There is no stock management. The laboratory has no special contact with the other laboratories, including NCDC, and doesn't seem to want to have such contacts. The majority of the population will not be able to afford the cost of analysis (US$15 for serology). The biosafety level during specimen handling is better than public laboratories.

Cito Private Laboratory (Tbilisi)

This laboratory, one of the biggest private labs in Georgia, is very similar to a European private laboratory and is opened 24 hours a day, 365 days a year. The lab is connected to seven private clinics and performs all analyses for them; it also has direct customers. The facilities are in very good condition: electricity, water, and gas are available 100 percent (a generator supplies electricity in case of power failure). All laboratory tests can be done in the laboratory: bacteriology, serology, Parasitology, mycology, biochemistry, hematology, hormonology, and immunology.

AST are semiautomatically performed using bioMérieux ATB-expression system. The lab performs 70 AST monthly; each time, 20 ATB are tested and the results are kept in the computer. Cito doesn't participate in the strain library. According to the person in charge, NCDC never asked for it. In microbiology, they are using close to 100 percent bioMérieux products (also for biochemistry, hematology, and serology). Only culture media are homemade, from lyophilized media. Petri dishes are disposable plastic dishes (the only place during the assessment that had these), and the media are poured in a safety cabinet. The lab checks the sterility of each batch. There is no system of stock management, but the consumption is assessed regularly. A distillatory provides distilled water.

Patient information is computerized, and a number is attributed to each specimen. The final result is also computerized and reviewed before signature. The access to patients' history is easy and rapid. Daily and monthly activity reports are available.

Cito receives a lot of samples from other laboratories, especially for bacteriology, CMV serology, and hormones. Six doctors, one lab assistant, two secretaries, and one cleaning person are working in the laboratory (no technician). They are regularly trained informally inside the lab and formally in France at the bioMérieux factory. Staff collect 80 percent of the samples on site (see photograph in Annex B). For bacteriological swabs samples, a specific transport media is given to the clinics (Portagerm media).

The laboratory is well equipped with the following:

- General equipment: four binocular microscopes, two centrifuges, four fridges, four freezers
- Biochemistry: Roche Cobas Mira multichannel analyzer and Corning flame photometer
- Hematology: ABX Micros 60 automated analyzer

- Immuno-analysis: bioMérieux mini-Vidas analyzer
- Bacteriology: two safety cabinet, three incubators

The three incubators have three different incubation temperatures:

- 30°: mycology
- 37°: normal bacteriology
- 42°: Campylobacter spp. Culture

SOPs are written for almost all activities: sample taking; analyzing; transportation; biosafety; preventive maintenance; and validation. Nevertheless, 80 percent of these SOPs are written in English. A logbook is available for each analyzer; a temperature chart is available for each thermal device. An engineer working only for Cito is specifically in charge of the repairing of the equipment and cooling devices.

Quality control is regularly performed:

IQC: Performed using the material provided in the kits and only for media sterility for bacteriology. No real IQC is needed for closed system sold by bioMérieux.

EQC: Cito has a regular EQC provided directly through the Georgian Embassy in Washington. This program covers biochemistry, hematology, and bacteriology. Some problems with transportation are occurring and vials are often broken.

If notifiable diseases are diagnosed, the NCDC is warned officially by courier, but this rarely happens. The biosafety level is good; waste is burned at NCDC after being disinfected locally. Cito is a good laboratory, but its accessibility to the population is very low. Prices are equivalent to prices found in France. In any case, Cito should be incorporated in both surveillance network and strain collection.

Some months ago, Cito became the official reseller of bioMérieux products for all of the Caucasian area, including Georgia, Armenia, and Azerbaijan. Products ordered at Cito (prepaid order) are available within the two weeks following the order, with an increase of 25 percent on the official French prices. This relates to the transportation and taxes.

3. Specific Issues Related to Vaccine Preventable Diseases

Measles

During the assessment, measles serology was only being performed at the Tbilisi Infectious Disease Hospital, where between five to seven measles serology tests (IgM + IgG) are performed monthly. Large, private laboratories in Tbilisi don't perform this serology. Remote health facilities structures rarely refer samples.

Mumps

No visited laboratory performs mumps serology, even the virology laboratory in the Tbilisi Infectious Disease Hospital, which stopped ordering the proper kits after several expired without use. A comprehensive, disease-specific assessment could, among other things, verify/identify the true needs in term of mumps biological diagnosis.

Rubella

During the assessment, both private laboratories and the virology unit at the Tbilisi Infectious Disease Hospital were performing rubella serology tests. The number of tests being performed monthly is the same as the number of measles: between five to seven. Pregnant women should be checked for rubella but, according to a Georgian biologist, clinicians and gynecologists are not aware of the need for testing, and the cost of this serology decreases its accessibility.

Hepatitis B

Hepatitis B diagnosis is part of the blood safety network (64 laboratories). Each blood donor is checked for Hepatitis B & C, AIDS, and syphilis. However, this network is not completely functional and needs to be improved: samples are not transported by a real autonomous system and a private car brings the sample. Sometimes, the patient must travel to the laboratory for required testing. This network could eventually be the beginning of a multi-disease specimen network.

In addition to the blood safety network, private laboratories and some peripheral hospitals currently perform Hepatitis B serology. They should also be part of any network and should send suspicious cases to a central reference laboratory.

Pertussis

No diagnostic analysis for pertussis was in evidence during the assessment. The NCDC respiratory laboratory is capable of performing this culture, but doesn't seem to do it. Serology is not currently available in any of the visited laboratories. Peripheral structures are not sensitized to the disease and rarely refer samples.

Poliomyelitis

A large international WHO rotary-specific program is trying to eradicate this disease. Huge funds and personnel have been allocated to this purpose, and actions taken toward this purpose include re-equipping labs and developing an incredible network for Acute Flaccid Paralysis (AFP) case reporting and sample transportation. As in all the polio laboratories, the NCDC virology laboratory (including the cell lines culture and the enteroviruses laboratory) is well equipped, staff are well trained, and they perform regular proficiency testing programs.

This disease-specific program functions well and doesn't need improvement.

Diphtheria

Diphtheria is one of the only diseases that seems to have a real national surveillance network, evidenced by the following:

- There is a reference laboratory (NCDC respiratory disease unit) that is specialized in the disease.
- This reference laboratory was known in all visited laboratories as a reference for the disease.
- Peripheral laboratories always send strains or sample for diagnosis or confirmation to this lab.
- Diphtheria is followed by epidemiological studies (800 children were randomly checked in 2001).
- The reference laboratory is part of the international network working on diphtheria.

Nevertheless, the quality of samples, the quality of the diagnoses at peripheral levels, and the quality of communication (data and specimens) can be improved.

4. Role of the Laboratories in a Well-functioning Surveillance System

For a laboratory-based disease surveillance system to function well, the following components are required:

- One good national reference laboratory (NRL) performing biological diagnosis, including the following:
  - Premises are adequate, including adequate electricity, water, and benches.
  - Staff is well trained and motivated.
  - Equipment is present, fully functional, and somebody knows how to maintain and fix it.
  - There is no shortage of small material, consumables, and reagents.
  - It is fully linked to the international public health laboratory and proficiency testing networks.
- One good NRL performing biological diagnosis, including the following:
  - Premises are adequate, including adequate electricity, water, and benches.
  - Staff is well trained and motivated.
  - Equipment is present, fully functional, and somebody knows how to maintain and fix it.
  - There is no shortage of small material, consumables, and reagents.
  - It is fully linked to the international public health laboratory and proficiency testing networks.
  - Provide some tools to epidemiologists: AST, serotype, virulence factors
  - Have a good laboratory network that provides samples from remote areas
  - Provide, if necessary, a mobile intervention team that can be displaced to a critical area
- Communication roles of the NRL should be the following:
  - As a disease reporting center, be strongly linked to diseases surveillance authorities
  - Provide data from remote areas
  - Organize and transmit data and comments to surveillance authorities
  - Drive regular supervision, QC activities, and training workshops for the laboratory network

5. Recommendations

The main recommendations that resulted from this assessment are as follows:

1. Improve institutional and organizational frame
    a. Clearly define a structure in charge of laboratories (SCL) for the country. Consider laboratories as only one entity, whatever the type of laboratory (public health lab, clinical lab, blood bank lab, private lab) and the type of analysis performed (microbiology, biochemistry).
    b. Determine an analysis list that should be available at national, regional, and district levels for general and specific purposes. Define the methodology that should be used for each specific diagnosis, including VPDs.
    c. List all laboratories (private, public, research) in the country, send them an assessment tool, and try to draw an accurate map of the country concerning the laboratories.
    d. Review or write the institutional texts concerning the NRL. Include a disease-specific component for all VPDs and other targeted diseases.
    e. Review or write a decree officially creating a laboratory network in the country, eventually based on the network of 64 laboratories currently functioning for blood safety.
    f. For VPDs and other targeted diseases, build the capacity of the NRL to be able to confirm a diagnosis, follow a disease, and sensitize the sample/laboratory-based network.
    g. Review or write the institutional texts concerning the minimum standards required in a laboratory in terms of minimum diploma, minimum equipment, and success in quality control. Check if all laboratories meet these standards, according to data collected in point 1c.
    h. Review or write an institutional text specifying a fixed percentage of laboratory fees that should be directly allotted to laboratories in order to be able to buy reagents and consumables. This fixed amount of money will allow laboratories to begin planning and will allow joint orders that will decrease costs.
    i. Try to decrease as much as possible the taxes and custom fees applied to medical laboratories supplies and reagents in order to decrease the price of analysis and then increase the accessibility.
    j. Try to merge as much as possible similar and close laboratories in order to join staff, equipment, and reagent and then decrease the costs; for example, in Batumi (state lab & infectious disease lab), or in Rustavi (state lab & infectious disease lab), or in NCDC (enteric lab, respiratory disease lab & Nosocomial infection lab).
    k. Following the large assessment of the laboratories targeted on 1c, designate a good laboratory for each of the 10 regions of the country (not including Abkazia), focus on them with a large and precise assessment, including building conditions, detailed

inventory (equipment, material, reagents, consumables, procedures), manpower, and abilities in medical biology (use the material developed in 3d).

2. Write Georgian-specific guidelines, common for all laboratories, in Georgian. These guidelines should include the following (in order of importance):
   a. Sampling and sample handling procedures
   b. Biosafety procedures
   c. Transportation of samples, on a regular basis (don't forget the logistics issues linked with train company, van company, or any other transportation mode)
   d. Reporting and recording procedures, including a lab-specific reporting form
   e. Improvement of existing analysis procedures. Deal first with rewriting the most general ones that will be used by all 10 regional reference laboratories.

3. Communication, control, and training activities of the SCL
   a. Communicate to all interested parties the aim of integrated disease surveillance (IDS) & laboratory strengthening project (MoLHSA regional health authorities, laboratories, international agencies, donors).
   b. Plan a small lecture module that could be dispensed to the university. This module will show the importance of IDS and laboratory strengthening, and present the main procedures for sampling, handling, and transporting the samples. The available list of test and list of regional laboratories could also be distributed; the audience will be the medical doctors, biologists, and lab nurses.
   c. Plan a training session dedicated to the practical implementation of the procedures developed in recommendation #2.
   d. Prepare a set of small kits for EQC that will allow staff to estimate the real abilities of the laboratories for diagnosis. This kit could include slides (gram staining slides, WBC diff. slides, malaria slides, intestinal parasites slides), slides to stain and check staining quality, bacterial strain in conservation media, and some frozen or lyophilized samples. A quiz or any other material also could be used to perform EQC.
   e. According to the obtained results in 3d, plan and prepare the following:
      - △ Training session and supervision visits
      - △ Replacement of equipment in the main national and regional structures.
   f. Plan for the future possibility of implementing a national supply structure that could be in charge of reagents, small material, and consumables for all public laboratories.

Annex A. Persons Contacted

MoLHSA & NCDC

Dr Paata Imnadze	Director of National Center for Disease Control
Pr Akakiy Beridze	Minister of Health of Adjara Autonomous Republic
Pr Guram Kinadze	Head of the Hospital Infection Department at NCDC
Dr Lela Bakanidze	Head of the Department of Bioterrorism threat reduction and international relations, NCDC
Dr Temouri Kuchalashvili	Head of the Anaerobia Department at NCDC
Dr Tsaro Gomelauri	Head of the Respiratory Infection Department at NCDC
Dr Tatjana Shudkova	Head of the Cell Culture Department at NCDC
Dr Tamar Ghaniashvili	Future Lyon course participant
Dr Tamar Zardaisvili	Future Lyon course participant
Ms Ketevan Kavtiashvili	Head of the license department
Mr Kakha Kheladze	In charge of standardization & norms, license department
Dr Ramaz Urushadze	Head of the Public Health Department
Dr Gia Chinakadze	Deputy chief responsible for epidemiological surveillance

Laboratories outside NCDC

Dr Lamara Duruchi	Director of Batumi Public Health Laboratory
Dr Inga Dolidze	Director of Batumi
Ms Tsira Tsivadze	Head of the Paracels Clinical Laboratory (private laboratory)
Dr David Kvezereli	Head of the Inspection of Sanitary supervision, Rustavi
Dr Natela Vardosanidze	Head of the chemical laboratory, sanitary services, Rustavi
Dr Ketavan Abuladze	Head of Rustavi Infectious Disease Hospital Laboratory
Dr Nino Macharashvili	Head of Tbilisi Infectious Disease Hospital Bact. Laboratory
Dr Isa Bodokija	Head of Tbilisi Infectious Disease Hosp. Virology Laboratory

WHO staff

Dr. Rusudan Klimiashvili	WHO liaison officer

Annex B. Photos of Visited Laboratories

NCDC

Anaerobic laboratory

Anthrax cases map

Cell culture laboratory

Cell culture microscope

Enterics fridge

Enterics logbook (in Georgian)

Enterics plating bench

Enterics identification bench

Hosp. Infection bench

Hosp. Infection microscope

Sterilized items (hosp. Infections)

Plague & tularemia animal room

Mol. Biology (gel electrophoresis)

Mol. Biology (thermocycler)

Parasitology laboratory

Plague & tularemia benches

Respiratory disease identification

Right: respiratory disease fridge

Tbilisi Infectious Disease Hospital, bacteriology lab

Identification bench

Microscopy

Autoclaves

Fridge

Staining station

Plating bench

Tbilisi Infectious Disease Hospital, virology lab

Microscopy

Serology room

ELISA system

Laminar flow, material and room for molecular biology

Spectrophotometer

Tbilisi Cito Private Laboratory

Analyzers (Vidas & Micros)

Bacteriology bench

Incubators & safety cabinet

Microscopy

Plating cabinet

Sampling room

Batumi PHL

Fridge

Washing room

Identification

Microscopy

Media storage

Batumi Infectious Disease Hospital

Microscopy (solar)

Distillatory

Petrol burner for incubator

Future laboratory

Bench & incubator

Spectrophotometer

Batumi Paracel Private Laboratory

Specimen handling

ELISA washer

Fluorescence microscopy

Rustavi Sanitation Laboratory, chemical

Safety cabinet & polarograph

Mineralisation bench

Spectrophotometer

Rustavi Sanitation Laboratory, bacteriology

Sampling room ceiling

Water analysis media storage

Water analysis bench

Autoclaves

Rustavi Infectious Disease Hospital, bacteriology lab

The doctor in the plating room

Lomo monocular microscope

Home-made antibiotic disks

Rustavi Infectious Disease Hospital, clinical lab

Main bench

Humanitarian “help”

Old ELISA reader

Annex C. Standardized Form for AST, Infectious Disease Hospital, Tbilisi

ინფექციური პათოლოგიის და კლინიკური იმუნოლოგიის სამეცნიერო პრაქტიკული ცენტრი

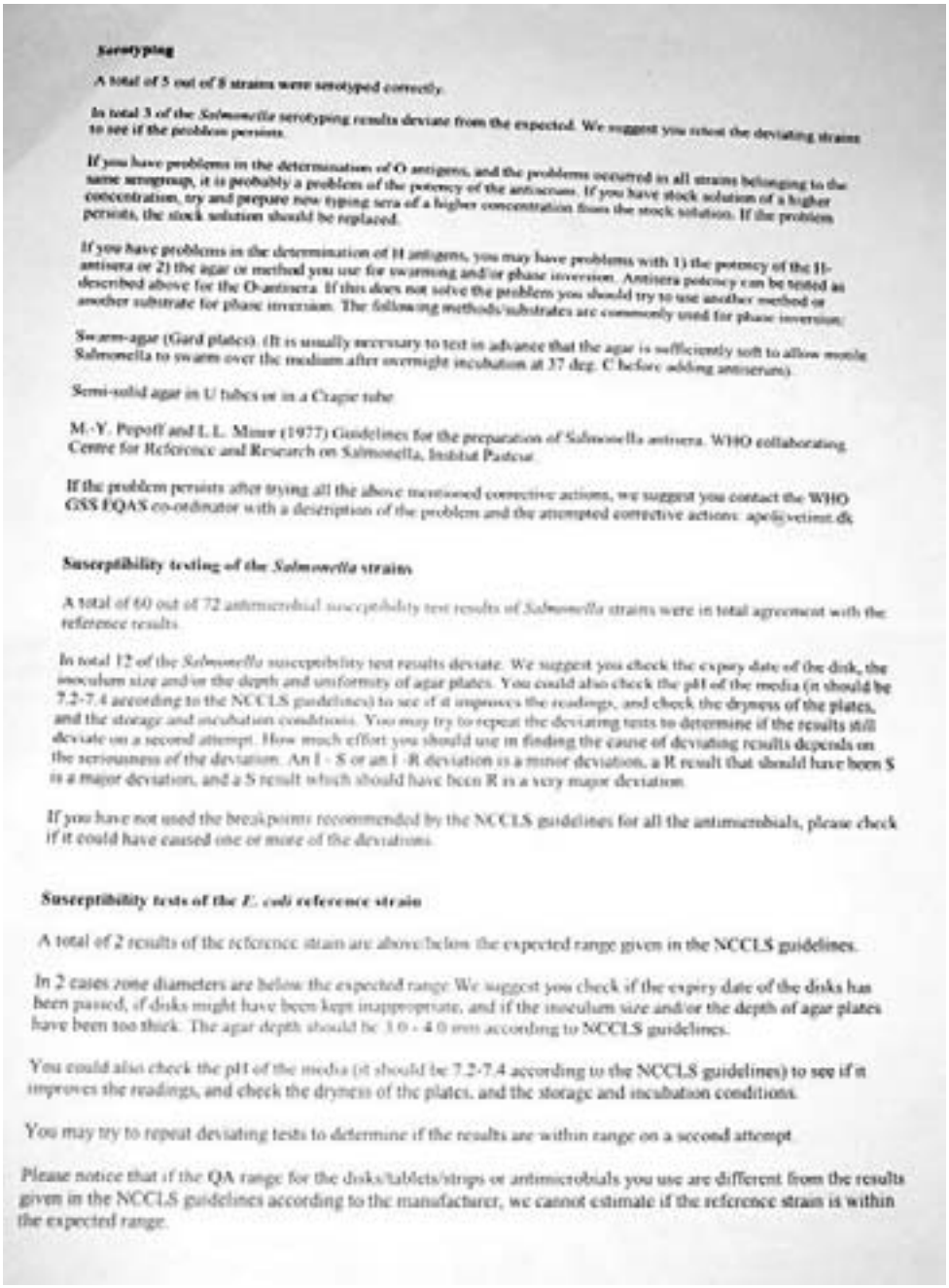
ბაქტერიოლოგიური ლაბორატორია
ანტიბიოტიკებისადმი მგრძნობელობის განსაზღვრა

განმეორებითი მასალის №_____ თარიღი"_____"_____"
სახელი _____ გვარი _____
განყოფილება _____ ქმარი _____
მიკროორგანიზმი _____ MIC

ანტიბიოტიკის დასახელება	კოდი	დისკის პრეპარატი	რეზისტენტობის ზონა	ზომიერად მგრძნობიარე ზონა	მგრძნობიარე ზონა	განმეორებითი მეცნიერის ზონის დადგენა	შენიშვნა
Amikacin	AMK	30 µg	≤14	15-16	≥17		
Amox/Clav.acid	AML	20/10µg	≤13	14-17	≥18		
Ampicillin	AMP	10µg	≤13(≤11)	14-16	≥17(≥14)		
Ampicillin-sulbactam	SAM	10/10µg	≤11	12-14	≥15		
Azithromycin	AZM	15µg	≤13	14-17	≥18		
Carbenicillin	CAR	100µg	≤19	20-22	≥23		
Cefazolin	KZ	30 µg	≤14	15-17	≥18		
Cefepime	FEP	30 µg	≤14	15-17	≥18		
Ceftazidime	CAZ	30 µg	≤14	15-17	≥18		
Ceftibuten	CTB	30 µg	≤17	18-20	≥21		
Ceftriaxone	CRO	30 µg	≤13	14-20	≥21		
Cefuroxime	CXM	30 µg	≤14	15-17	≥18		
Chloramphenicol	C	30 µg	≤12	13-17	≥18		
Ciprofloxacin	CIP	5 µg	≤15	16-20	≥21		
Clarithromycin	CLR	15 µg	≤13	14-17	≥18		
Clindamycin	DA	2 µg	≤14	15-20	≥21		
Doxycycline	DO	30 µg	≤12	13-15	≥16		
Erythromycin	E	15 µg	≤15	16-20	≥21		
Furazidinne	FRN	30 µg	≤14	15-17	≥18		
Gentamicin	CN	10 µg	≤12	13-14	≥15		
Imipenem	IPM	10 µg	≤13	14-15	≥16		
Kanamycin	K	30 µg	≤13	14-17	≥18		
Metronidazole			≤2	3 - 7	≥8		
Netilmicin	NET	30 µg	≤12	13-14	≥15		
Nitrofurantoin	F	300 µg	≤14	15-16	≥17		
Norfloxacin	NOR	10 µg	≤12	13-16	≥17		
Ofloxacin	OFX	5 µg	≤12	13-15	≥16		
Ornidazole			≤2	3 - 7	≥8		
Oxacillin	OX	1 µg	≤10	11-12	≥13		
Penicillin	P	10 U	≤19(≤11)	20-27(12-21)	≥28(≥22)		
Pefloxacin	FLO	5 µg	≤18	19-21	≥22		
Piperacillin	PIL	100 µg	≤17	18-20	≥21		
Piperacillin/Tazobact.	TZP	100/10 µg	≤17 ≤19	18-20 -	≥21 ≥20		
Rifampin	RD	5 µg	≤16	17-19	≥20		
Streptomycin	S	10 µg	≤11	12-14	≥15		
Tetracycline	TE	30 µg	≤18	19-22	≥23		
Tobramycin	TOB	10 µg	≤12	13-14	≥15		
Trimethoprim Sulfamethoxazole	SXT	1.25/23.75µg	≤15	16-18	≥19		
Vancomycin	VA	30 µg	≤14	15-16	≥17		

გამოკვლევა შეასრულა _____

Annex D. Results of EQC, Enterics Laboratory, NCDC



Serotyping

A total of 5 out of 8 strains were serotyped correctly.

In total 3 of the *Salmonella* serotyping results deviate from the expected. We suggest you retest the deviating strains to see if the problem persists.

If you have problems in the determination of O antigens, and the problems occurred in all strains belonging to the same serogroup, it is probably a problem of the potency of the antisera. If you have stock solution of a higher concentration, try and prepare new typing sera of a higher concentration from the stock solution. If the problem persists, the stock solution should be replaced.

If you have problems in the determination of H antigens, you may have problems with 1) the potency of the H-antisera or 2) the agar or method you use for swarming and/or phase inversion. Antisera potency can be tested as described above for the O-antisera. If this does not solve the problem you should try to use another method or another substrate for phase inversion. The following methods/substrates are commonly used for phase inversion:

Swarm-agar (Gard plates). (It is usually necessary to test in advance that the agar is sufficiently soft to allow motile Salmonella to swarm over the medium after overnight incubation at 37 deg. C before adding antiserums).

Semi-solid agar in U tubes or in a Craigie tube

M.-Y. Popoff and L.L. Minor (1977) Guidelines for the preparation of Salmonella antisera. WHO collaborating Centre for Reference and Research on Salmonella, Institut Pasteur.

If the problem persists after trying all the above mentioned corrective actions, we suggest you contact the WHO GSS EQAS co-ordinator with a description of the problem and the attempted corrective actions: apo@svetinst.dk

Susceptibility testing of the *Salmonella* strains

A total of 60 out of 72 antimicrobial susceptibility test results of *Salmonella* strains were in total agreement with the reference results.

In total 12 of the *Salmonella* susceptibility test results deviate. We suggest you check the expiry date of the disk, the inoculum size and/or the depth and uniformity of agar plates. You could also check the pH of the media (it should be 7.2-7.4 according to the NCCLS guidelines) to see if it improves the readings, and check the dryness of the plates, and the storage and incubation conditions. You may try to repeat the deviating tests to determine if the results still deviate on a second attempt. How much effort you should use in finding the cause of deviating results depends on the seriousness of the deviation. An I - S or an I - R deviation is a minor deviation, a R result that should have been S is a major deviation, and a S result which should have been R is a very major deviation.

If you have not used the breakpoints recommended by the NCCLS guidelines for all the antimicrobials, please check if it could have caused one or more of the deviations.

Susceptibility tests of the *E. coli* reference strain

A total of 2 results of the reference strain are above/below the expected range given in the NCCLS guidelines.

In 2 cases zone diameters are below the expected range. We suggest you check if the expiry date of the disks has been passed, if disks might have been kept inappropriate, and if the inoculum size and/or the depth of agar plates have been too thick. The agar depth should be 3.0 - 4.0 mm according to NCCLS guidelines.

You could also check the pH of the media (it should be 7.2-7.4 according to the NCCLS guidelines) to see if it improves the readings, and check the dryness of the plates, and the storage and incubation conditions.

You may try to repeat deviating tests to determine if the results are within range on a second attempt.

Please notice that if the QA range for the disks/tablets/strips or antimicrobials you use are different from the results given in the NCCLS guidelines according to the manufacturer, we cannot estimate if the reference strain is within the expected range.