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ASSESSMENT REPORT ON THE KYRGYZ REPUBLIC LABORATORY FOR VIROLOGIC AND MOLECULAR GENETIC STUDIES

Local Health System Sustainability Project

Task Order 1, USAID Integrated Health Systems IDIQ

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Local Health System Sustainability Project

The Local Health System Sustainability Project under the USAID Integrated Health Systems IDIQ helps low- and middle-income countries transition to sustainable, self-financed health systems as a means to support access to universal health coverage. The project works with partner countries and local stakeholders to reduce financial barriers to care and treatment, ensure equitable access to essential health services for all people, and improve the quality of health services. Led by Abt Associates, the five-year, $209 million project will build local capacity to sustain strong health system performance, supporting countries on their journey to self-reliance and prosperity.

Submitted to:

Scott Stewart, Contracting Officer's Representative
Office of Health Systems
Bureau for Global Health

Mary de Boer
Health & Education Office Director
USAID/Kyrgyz Republic

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Abt Associates
6130 Executive Boulevard | Rockville, Maryland 20853
T: 301.347.5000 | F: 301 652.3916 | www.abtassociates.com

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Acknowledgements

From August 23-25, 2021, an evaluation team visited the Laboratory for Virologic and Molecular Genetic Studies of the Kyrgyz Republic's Department of Disease Prevention and State Sanitary and Epidemiological Surveillance (DDP&SSES), a part of the Ministry of Health, to assess conditions for the installation of GeneXpert. The assessment was conducted using the GeneXpert checklist.

Assessment Leader

Baarinisa Iskanova	Laboratory Specialist of the Republican AIDS Center

Evaluation Participants

Damira Ashyalieva	Head of Laboratory for Virologic and Molecular Genetic Studies, Department of Disease Prevention and State Sanitary and Epidemiological Surveillance (DDP&SSES)
Kalila Zhumalieva	Head of Virologic Laboratory at DDP&SSES

Local Health System Sustainability Project (LHSS) Team Members

Cholpn Asambaeva	Country Director, LHSS in Kyrgz Republic
Aizhan Dooreonbekova	Data and Surveillance Specialist, LHSS in Kyrgz Republic
Zamira Baidulloeva	Regional Laboratory Specialist, LHSS Project

Assessment Approved By

Sultan Abdyldaevich Abdykadyrov	Director, Department of Disease Prevention and State Sanitary and Epidemiological Surveillance (DDP&SSES)
Kalila Zhumalieva	Head of Virologic Laboratory at DDP&SSES

Acronyms

DDP&SSES	Department of Disease Prevention and State Sanitary and Epidemiological Surveillance
LDMIS	Laboratory Data Management Information System
LHSS	Local Health System Sustainability Project
PCR	Polymerase Chain Reaction
SOP	Standard Operating Procedure
WHO	World Health Organization

Visit to Assess Readiness for GeneXpert and Other Testing Methods

The USAID Local Health System Sustainability Project (LHSS) visited the Laboratory for Virologic and Molecular Genetic Studies of the Kyrgyz Republic's Department of Disease Prevention and State Sanitary and Epidemiological Surveillance (DDP&SSES), a part of the Ministry of Health, to assess conditions for the installation of the GeneXpert platform. The assessment was conducted in August 2021 using the GeneXpert checklist.

Objectives of Visit

The objective of the visit was to evaluate the laboratory's readiness to conduct testing using molecular genetic methods such as GeneXpert by assessing:

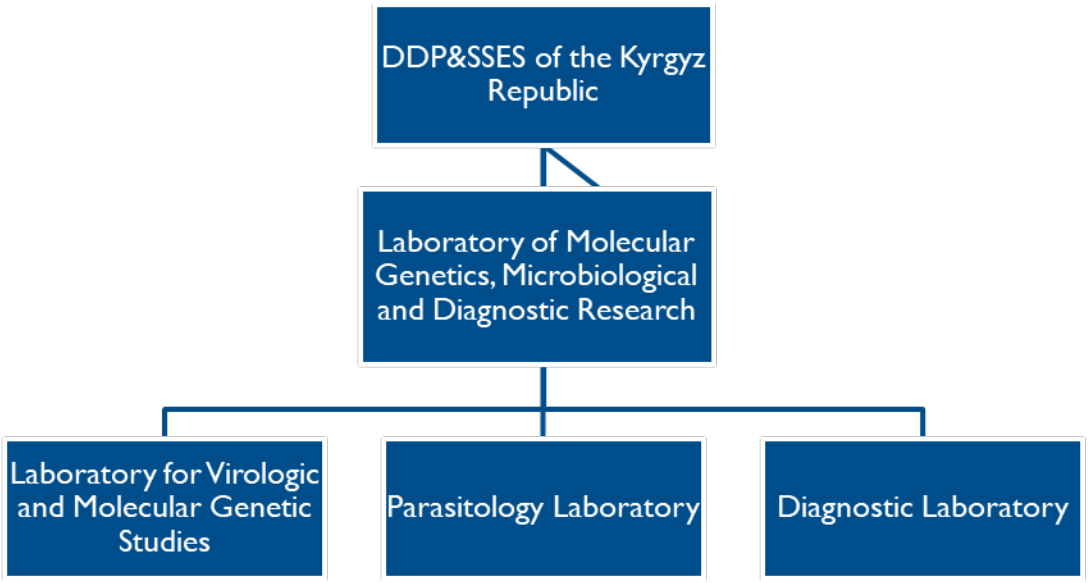
- The level of biosafety and biosecurity of the laboratory
- The available equipment, consumables, and laboratory environment

Organizational Structure of Laboratory System

The Laboratory for Virologic and Molecular Genetic Studies, which was the focus of this assessment, is one of the three subdivisions of the Laboratory for Molecular Genetic, Microbiological and Diagnostic Studies, which is part of the Laboratory Testing Center of DDP&SSES.

Structure of the Laboratory Test Center

The following diagram illustrates the structure of the Laboratory for Molecular Genetic, Microbiological and Diagnostic Studies.



Personnel

Laboratory staff are selected based on their professional education (confirmed by a diploma) and by their specific work experience necessary to perform the required work (confirmed by records in employment documents).

The Laboratory for Virologic and Molecular Genetic Studies has six specialists with higher education and one specialist with post-secondary education; see Table 1. Four employees perform laboratory diagnosis of coronavirus using the polymerase chain reaction test (PCR) method.

Three laboratory specialists received basic on-the-job training in the use of the GeneXpert 4-module platform, which was temporarily borrowed from the Republican AIDS Center for this purpose. This training focused specifically on interpreting results and carrying out laboratory diagnosis using the PCR method with reverse transcription, which was performed using Xpert Xpress SARS-CoV test systems.

Table 1: List of Employees of the Laboratory for Virologic and Molecular Genetic Studies

Occupation	Quantity	Education	COVID-19 Diagnostic and Biosafety Training: Year, Place	Onsite Training on the Use of the GeneXpert 4-Module Platform
Head of Laboratory; virologist	1	Higher medical education	-	-
Head of Laboratory; virologist	1	Higher biologic education	-	1
Microbiologist	3	1 biology—higher 2 medical—higher	-	1
Physician virologist	1	Higher biologic education	2020; theoretical instruction online, and field practice on the basics of PCR testing, provided by CDC/ICAP	-
Laboratory Technician	1	Biotechnical bachelor's degree	-	1

Strengths and Weaknesses

Each employee has a personnel file, and job descriptions have been developed. Each staff member is familiar with their job description. One staff member involved in real-time PCR was trained in coronavirus diagnosis in 2020, with support from CDC/ICAP.

A competency assessment of specialists was not done through the assessment. Three staff involved in real-time PCR testing have not been trained in coronavirus infection diagnosis and biosafety. At this point, staff in the virology and molecular genetics laboratory can operate the GeneXpert 4-module platform at the user level only, and cannot perform preventive maintenance processes on the platform.

Recommendations

1. For the safety of laboratory staff and to ensure diagnostic quality, all staff should be trained in laboratory diagnosis of coronavirus infection and biosafety.

2. Additionally, staff need training in the operation and maintenance of GeneXpert platforms and in diagnosis and the collection and transport of samples.
3. Training sessions should be conducted on a regular basis. They should provide an opportunity for employees to update their knowledge and learn about new developments and advances in laboratory diagnostics. Training is also important for providing opportunities for discussion and networking among staff as well as strengthening the capacity staff. Staff would benefit from training and advice on biosafety for existing and new laboratories in accordance with international standards.

Laboratory Activities

The workload of the virology laboratory in the diagnosis of coronavirus infection is currently high. Five specialists perform PCR tests, and the average workload per employee is 160 samples per day (Table 2). For the diagnosis of coronavirus infection, PCR with reverse transcription is used, with real-time detection, using test systems from different manufacturers (Table 3).

Table 2: Workload per Laboratory Specialist for PCR Testing

Number of Tests Performed per Day on Average	Number of Laboratory Staff	Number of PCR Tests per Specialist	% Daily Appropriate Workload per Specialist	Number of Tests per Specialist per Day According to the Load Norm
800	5	160	533	30

Table 3: PCR Test Systems Used

Test System Name	Manufacturer
AmpliSense Cov-Bat-FI	AmpliSense, Russia
RealBest RNA SARS-CoV-2	Vector Best, Russia
ArtBioTech	ArtBioTech, Belarus
Real-Q 2019-nCoV Detection Kit	BioSewoom, South Korea
Bio-Speedy Direct RT-qPCR SARS-CoV-2	Bioeksen, Turkey
Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Sansure, China
Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2	BGI, China
LightMix SarbecoV E-gene plus EAV	TIB MOLBIOL, Germany
SARS-CoV-2/SARS-CoV	DNA Technology, Russia

Between June 18, 2021, and August 31, 2021, the virology lab performed 186 nasopharyngeal swab tests on the GeneXpert platform, of which 48 positive results and nine errors were detected. The data analyses showed that the errors were mainly due to power outages and to a lesser extent to insufficient sample volume (Table 4). The tests were from patients from the National Institute of Cardiology Research and the National Hospital, and members of the Government of the Kyrgyz Republic.

Table 4: Number of Tests and Errors on the Platform 4-Module GeneXpert for June 18 to August 31, 2021

Name	Quantity
Number of tests	186
Number of positive tests	48
Number of errors	9
Errors due to a power outage	7
Errors due to insufficient sample volume	2
Approximate cost per cartridge in soms	1,550

Strengths

The laboratory uses appropriate methods that are generally recognized and standard. It has undergone two external quality assurance reviews, with satisfactory results. The laboratory has developed 21 standard operating procedures (SOPs):

- Preanalytical phase—8
- Biosafety—6
- Analytical phase—6
- Customer information form (customer—1)

Weaknesses

- The high workload has created staff turnover over the past two years.
- The workload per specialist is approximately five times higher than the norm.
- Power failures and to a lesser extent insufficient sample volumes have caused a high number of errors occur with the use of the GeneXpert platform.
- Laboratory technicians are not trained on how to interpret results or to perform maintenance on the GeneXpert machine.
- Although the laboratory is using GeneXpert, no basic SOPs have been developed for that use, or for the interpretation of results or maintenance of the GeneXpert platform, both of which are necessary to ensure the quality of work.
- The cost per test on the GeneXpert platform is approximately 1,550 soms ($15.00 USD). In case of power failure during operation of the 4-module platform, the financial loss will be 6,200 soms (approximately $60.00 USD). This would be far worse with the 16-module platform, with a cost of about 24,800 soms (approximately $240.00 USD). Repeated failures of the16-module platform will cause much more economic loss (Table 5).

Table 5: Losses Caused by Errors or Malfunctions of GeneXpert Platform

Type GeneXpert Platform	Number of Samples	Cost per Cartridge in Soms	Total Cost of a Single Analysis in Soms	Total Cost of a Single Analysis in USD
4-module	4	1,550	6,200	$60.26
16-module	16	1,550	24,800	$241.04

Recommendations for DDP&SSES

1. To reduce the workload on the laboratory specialist, it is necessary to revise the staffing units at the laboratory. That may partially solve the problem of staff turnover.
2. All laboratory equipment needs to be protected with an uninterruptible power supply or battery with capacity to provide backup for more than four hours.
3. To improve the quality of diagnostics it is necessary to train laboratory professionals in the proper use of GeneXpert and the proper collection, storage, and transportation of samples.
4. SOPs for use, maintenance, reporting, and interpretation of COVID-19 assays using Xpert Xpress SARS-CoV-2 tests should be developed.

Equipment, Test Systems, and Consumables

The virology and molecular genetics laboratory is equipped with PCR equipment and refrigerators, with class II biological safety cabinets and other necessary equipment, as indicated in Table 6.

Currently procurement of equipment, test systems, and consumables for laboratory diagnosis of coronavirus infection is under a special account of the DDP&SSES and partially at the expense of international organizations (CDC-ICAP).

Free tests are mainly provided by test systems and consumables purchased with funding from external international organizations.

Table 6: Laboratory Equipment Used in the Laboratory of Virologic and Molecular Genetics

№	Equipment	Quantity (pcs)
1	Class II Biological Safety Box	7
2	Refrigerator	14
3	Freezer -20°C	9
4	Freezer -40°C	1
5	Freezer -70°C	3
6	Thermostat	6
7	Centrifuge	2
8	Centrifuge amplifier (DTprime, Rotor Gene)	4
9	Biosafety cabinet	5
10	Autoclave	3
11	Aquadistiller	1
12	Dry-heat chamber	1
13	Analytical scales	1
14	Tablet washer	1
15	Microplate photometer (analyzer)	1

Strengths

- For PCR amplifiers, except for the GeneXpert platform used in the laboratory, SOPs have been developed, and there is a maintenance logbook and an approved preventive maintenance plan.
- At the DDP&SSES, maintenance and repair issues are handled by a metrology engineer, as well as a quality control manager.

- The equipment used to diagnose coronavirus infection is maintained and repaired as needed with financial support from donor organizations.

Weaknesses

- Not all equipment is provided with an uninterrupted power supply.
- No SOP has been developed for the GeneXpert platform.

Recommendations

1. Provide equipment with an uninterruptible power supply.
2. Develop missing SOPs for the proper use of the equipment.

Documents, Records, and Information Management

Documents and records are kept in accordance with the following regulatory documents:

- Kyrgyz Republic Government Decree No. 346 of December 31, 2010, "List of standard management documents generated in the activities of institutions, organizations, enterprises, with an indication of storage periods"
- Ministry of Health Order No. 588, dated August 10, 2009, "On Approval of the List of Documents Generated by Health Care Institutions of the Kyrgyz Republic with an Indication of Retention Times"
- Kyrgyz Republic Government Decree No. 160 of March 18, 2014, "On Approval of exemplary regulations on the archive of the state body, local government and other legal entities, on the Central Expert Commission and on the expert commission of the state body, local government and other legal entities" (National Lab Standard for Competency and Quality Requirements for Medical Laboratories 15189:2016)

Strengths:

- The laboratory uses forms of journals and referrals recommended by the World Health Organization (WHO) and approved by the Ministry of Health and Social Development of the Kyrgyz Republic, Order No. 254 as of 25.04.2020.
- There is also a unified Laboratory Data Management Information System (LDMIS) for input of laboratory data.
- Standard approved forms are used in the development of SOPs.

Weaknesses

- SOPs for operation and maintenance of the GeneXpert platform, and for reporting and interpretation of test results on COVID-19 using Xpert Xpress SARS-CoV-2 tests, have not been developed.
- The GeneXpert machine is not connected to LDMIS, which creates challenges in obtaing results on time.

Recommendations

1. The GeneXpert platform should be integrated into LDMIS to obtain timely results.
2. Develop SOPs for all laboratory equipment in the laboratory.

Biosafety and Handling of Biosamples

When handling samples taken for PCR diagnosis of COVID-19, the chlorine-containing agent DP-2 is used for disinfection. Decontamination and disposal is performed by autoclaving at 120° and recorded in the disposal log. Laboratory personnel work in personal protective equipment. Transportation or transfer of samples taken within the department is carried out in special transportation bags, and personnel are fully responsible for them. Samples are labeled and records are kept. Facilities are available for both long-term and short-term storage of samples.

Strengths

- An SOP for handling and disposing of biohazardous waste has been developed. Autoclaving is carried out by personnel with a certificate of completion of special courses. Safety warning signs are displayed in the laboratory.

Weaknesses

- Other than two PCR staging personnel, staff have not received biosafety training.

Recommendations

- Training in biosafety and sample collection and transport when using Cepheid test systems, consumables, and platforms is recommended.

Infrastructure and Safety

The Laboratory for Virological and Molecular Genetic Studies is located on the first and second floors of the DDP&SSES building and is equipped with the necessary equipment to carry out laboratory activities (Table 7).

Table 7: Laboratory Space and Equipment

№	Name of the room	Quantity	Equipment
1	Doctor's room	2	Furniture, computer, handwashing sink, air conditioning
2	Serological testing rooms	1	Refrigerator, set of enzyme-linked immunoassay equipment, laboratory furniture that can be disinfected, sink for washing hands, air conditioning, bactericidal lamp
3	PCR test rooms	4 (with pre-boxers, which are closed and isolated rooms for laboratory tests)	Class II biological safety cabinet, biological safety box, refrigerator (one has a freezer), air conditioning, bactericidal lamp
4	Storage room	2	Equipped with shelving, air conditioning
5	Bathroom and shower	2 on every floor	
6	Sampling and reception room	1, separate from the virology laboratory in another part of the building	Furniture, refrigerator, freezer -20, air conditioning, bactericidal lamp

Strengths

- The organization has a separate entrance for patient/client intake and specimen collection (for COVID-19 diagnostics) near the front door; the lab itself is in another part of the building.
- Access to the laboratory is restricted. Employees have a special chip pass. The laboratory is divided into clean and dirty areas. The lighting is adequate, the windows are insulated, and there are iron bars on the outside. Laboratory and storage rooms are equipped with an exhaust system, and also have air conditioning. Laboratory and storage conditions comply with sanitary requirements. The temperature regime of the laboratory and the warehouse is monitored.

Weaknesses

- The front door on the first floor where the purchased GeneXpert platform is planned to be installed is plastic and does not have an iron grille for security.

Recommendations:

- An iron grille should be installed on the front door for security.

Quality Control

The virology laboratory of the DDP&SSES is preparing for accreditation by the national accreditation body certifying its compliance with the requirements of GOST P ISO15189:2016. Basic documents of the quality management system are being developed.

Strengths

- With WHO support, the laboratory participated twice in an international external quality assessment on the diagnosis of coronavirus infection, with a result of 100 percent, confirmed by a certificate. Under the external quality assessment program, WHO/Europe sends blind samples to the lab to validate their testing processes and accuracy.
- Currently, the lab is expecting a new batch of blind samples for COVID-19 from the external quality assessment program.
- Patient samples positive for COVID-19, confirmed by the laboratory, have also been sent for retesting and phylogenetic studies to the WHO referral laboratory. The last shipment of samples was in June 2021. According to the results of the latest phylogenetic studies, 86 percent of the cases (out of 30 samples) in the Kyrgyz Republic are delta strains.

Weaknesses

- No samples are used for internal quality control for COVID-19.

Recommendations

- Ensure quality control of laboratory tests for COVID-19; purchase control materials.

Conclusions

Below are the evaluation team's main takeaways from this assessment:

1. Laboratory personnel need regular training on:
    - Biosafety and biosecurity regulations.
    - Modern laboratory diagnostics
    - Instructions for safe handling of laboratory specimens
    - Proper specimen collection, storage, and transport
2. GeneXpert is not connected to an uninterruptible power supply.
3. GeneXpert is not integrated into the existing LDMIS, which creates barriers to obtaining timely test results for emergency response during a pandemic.
4. Staff have a high workload and a high rate of staff turnover, which leads to staff shortages. Staffing levels need to be revised upwards.
    - The budget line does not provide for the purchase of additional consumables, such as cartridges and an uninterruptible power supply, nor to fund timely maintenance.

Recommendations

Below are the evaluation team's main recommendations for DDP&SSES from this assessment.

1. Provide regular training for laboratory staff on:
    - Implementation of real-time PCR molecular diagnostics using GeneXpert
    - Maintenance of GeneXpert platforms
    - Safe use of existing equipment, as well as the use of new, modern equipment
    - Proper collection, storage, and transport of samples
    - The requirements of the quality management system as described in National Lab Standard for Competency and Quality Requirements for Medical Laboratories15189:2016
2. Strengthen the equipment of the laboratory
    - It is necessary to connect all equipment in the laboratory to an uninterruptible power supply to reduce the number of errors and financial losses due to wastage of cartridges.
    - Review the budget line for purchasing cartridges and consumables, as well as for providing maintenance of laboratory equipment, etc.
3. To establish timely information transfer and strengthen communication and improve integration between laboratory professionals, physicians, and the public:
    - Integrate the GeneXpert apparatus into the existing Laboratory Data Management Information System.
    - Develop SOPs for the operation and maintenance of the GeneXpert platform.
    - Develop SOPs for diagnostics, interpretation of results, and gathering and transport of samples, for the testing systems used in the GeneXpert platform.
4. To improve laboratory activities and for safety purposes, it is necessary to do the following:
    - Review laboratory staffing, for proper workload distribution.
    - Install an iron grille on the entrance door of the laboratory for safety in the laboratory.