Mariupol City Branch of Donetsk Oblast Laboratory Center of MOH, Laboratory of Especially Dangerous Infections and Laboratory of Virology (GCA) Laboratory Assessment Report

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Acronyms and abbreviations

BSC  Biosafety Cabinet
BSS  Basic Safety Standards
ELISA  Enzyme-linked immunosorbent assay
EDI  Especially Dangerous Infections
EQA  External Quality Assessment
GCA  Government Controlled Area
IQC  Internal Quality Control
ISO  International Organization for Standardization
PCR  Polymerase Chain Reaction
PHC  Public Health Center
PPE  Personal protective equipment
RNA  Ribonucleic acid
RT-PCR  Reverse Transcription Polymerase Chain Reaction
SOP  Standard Operating Procedure/s
UPS  Uninterruptable Power Supply
WHO  World Health Organization
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I. Overview

<table>
<thead>
<tr>
<th></th>
<th>650 000</th>
<th>150</th>
<th>1000</th>
<th>Public health, environmental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated population covered by the Laboratory</td>
<td>650 000</td>
<td>150</td>
<td>1000</td>
<td>type of laboratory</td>
</tr>
<tr>
<td>Average number of specimens tested per day</td>
<td>34%</td>
<td>64%</td>
<td>78%</td>
<td>88%</td>
</tr>
<tr>
<td>Average number of PCR or RT-PCR tests run per week</td>
<td>28%</td>
<td>71%</td>
<td>54%</td>
<td>71%</td>
</tr>
</tbody>
</table>

Key indicators

<table>
<thead>
<tr>
<th>Organization and management</th>
<th>78%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document management</td>
<td>64%</td>
</tr>
<tr>
<td>Specimen collection, handling and transport</td>
<td>72%</td>
</tr>
<tr>
<td>Data and information management</td>
<td>73%</td>
</tr>
<tr>
<td>Consumables and reagents management</td>
<td>71%</td>
</tr>
<tr>
<td>Equipment management</td>
<td>64%</td>
</tr>
<tr>
<td>Facilities</td>
<td>54%</td>
</tr>
<tr>
<td>Human resources</td>
<td>45%</td>
</tr>
<tr>
<td>Biorisk management</td>
<td>44%</td>
</tr>
<tr>
<td>Public health functions</td>
<td>44%</td>
</tr>
<tr>
<td>SARS-CoV-2 testing capacity and capability</td>
<td>44%</td>
</tr>
</tbody>
</table>

Strengths

+ Established equipment management system
+ Strong consumables and reagents management

Weaknesses

- Old building without renovation
- A single and not certified BSC for the whole lab
- Absence of necessary training for staff (i.e. transportation of infectious substances, biosafety, biosecurity, risk assessment, PCR data interpretation and troubleshooting)
- Data safety: absence of back-up of patients’ information
II. Background

With the recent increase spike of COVID 19 cases in Ukraine conflict affected zones, impact on overwhelming of laboratories and testing facilities in Donetsk Oblast (Government Controlled Areas) is more and more concerning. A rapid assessment is urgently needed to assess the functionality of the laboratories, also in terms of quality of the work, to identify strengths and gaps and develop a plan of action. The assessment was carried on by WHO experts under the coordination of Health Cluster based on existing and pre-validated tools.

III. Objective of the assessment

This report is focused on the analysis of the current state of Mariupol City Branch of Donetsk Oblast Laboratory Center of MOH, Laboratory of Especially Dangerous Infections and Laboratory of Virology in Mariupol (GCA). It is the part of rapid assessment, which designated COVID-19 laboratories aims to assess: structure, equipment, quality of the work, HR and training needs, existing plans and protocols, gaps and major areas that require investment and response. The purpose is to produce an evidence-based plan of action.

IV. Methodology

The assessment was conducted using WHO tool designed to assess capacities of existing laboratories which have implemented or aim to implement SARS-CoV-2 testing. Questionnaire is divided 2 parts:

1. Core capacities of the laboratory (which might include but are not limited to SARS-CoV-2 testing)
2. Specificities related to SARS-CoV-2 testing

The direct visit to the laboratory was performed in November 2020.

V. Team composition

The assessment was coordinated by joint efforts of Health Cluster assessment team and WHO. The team was composed of:

- Assessment was conducted by Artem Skrypnyk
- Coordination was supported by WHO and Health Cluster: Emanuele Bruni, Igor Novykov
- Design, analysis & reporting: Iryna Koval and Oleksandra Abrosimova
V. Results

Organization and management

The laboratory normally works 38.5 hours in a week and the time could be extend due to providing emergency services. In terms of external communication: the telephone is absent, while computer (with Internet access) is available. There is a developed organizational structure with responsible laboratory staff and lines of authorities.

The laboratory reported that the salaries are rather small in health sector including labs. The budget for consumables, test, and sample collection kits is not enough to cover all of the needs for period longer than two weeks. There is no adequate budget for purchasing/maintenance of equipment and for surveillance and overall public health activities.

3 years ago WHO provided recommendations to the lab, during the mentoring program for bacteriology laboratory which were partially implemented. The laboratory did not receive a certification or ISO accreditation.

Documents

The laboratory has an archiving system in the form of paper journals, which does not give the guarantee to find all the results if needed.

The manual describing the quality system is absent in the laboratory. The lab also reported that quality system needs updating.

Published standards, specimen handling, testing procedures (RNA extraction, RT-PCR, serology, etc.), and other similar documents are partially available in the laboratory. The procedure of storage of primary specimens, verifications of methods are not in place, as well as the procedure to record incidents and complaints.

Risk assessment related to the lab procedures has not been performed and documented. BSS procedures are partially reflected in the documentation. Biosafety manual is required. Especially such topics as disinfection of contaminated materials, sterilization, storage and destroy hazard sample, laboratory related injury are absent in the manual at all.

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Subjects include next: handwashing, PPE, disinfection of contaminated materials, sterilization, glassware and equipment washing, waste disposal, laboratory cleaning, storage and destroy hazard sample, spillage, laboratory related injury, fire emergency.
Specimen collection, handling and transport

Specific collection procedures used for specimens are partially documented.

Internal system includes minimum patient identification details and standard specimen request form are available.

The laboratory does not have developed criteria for acceptance or rejection of primary specimens. There is no rejections due to political reasons.

Adequate storing conditions as well as procedure for primary specimens are not present in the lab.

The laboratory has appropriate packaging for referring specimens. Transportation system for sample referrals is set-up.

Data and information management

The laboratory observations are recorded. Before releasing, the results are reviewed and authorized.

There is established procedure for the case when sample needs to be referred to another laboratory. There is no immediate notification of physicians when results are critical for patient care, while it exists when results are critical for ministry/surveillance network.

The laboratory could provide statistical data from internal activities (f.e. number of tests ordered, aggregated qualitative/quantitative data, etc.)

The laboratory reported that patients` information is protected, while a back-up procedure is not in place. The lab does not use any software/application for information management system.

\(^2\) Storing in the fridge, -20C freezer, -70C freezer, or other recommended storage conditions.
Consumables and reagents management

There is a person responsible for the procurement who buys consumable and reagents. In the past, the lab mentioned interruptions of supply due to COVID – 19.

There is a program for inventory system. Consumables and reagents are inspected upon receipt; and appropriately stored (with needed temperature, humidity, etc.)

Reagents and kits have clearly written date of opening. All new reagents are verified against old reagents or reference materials before the use, while batch-to-batch verification is not conducted for PCR kits. The laboratory never use expired reagents. Disposable supplies like tips, plastic pipettes, and gloves are never reused. There is a system for the forecasting consumables and reagents in place.

Equipment management

There is equipment inventory with available name of the equipment, contact details of the manufacturer (or local supplier), condition (i.e. new, used) and maintenance activities for some equipment (i.e. pipettes, autoclaves). The laboratory has needed resources to perform nucleic acids extraction (i.e. automatic RNA extraction platform QIAcube (Qiagen), serology, RT-PCR, incubators, dilutor, water bath, microscopes and pH-metres).

There is an assigned person in charge of maintenance management. The equipment is partially maintained in a safe working condition (f.e. autoclaves are old, they are used since 1983 year). There is a daily monitoring and recording of temperatures and airflow in biosafety cabinets. The laboratory does not implement preventive maintenance program. The staff is duly trained and authorized before first using equipment.
Availability of equipment

Available functioning equipment necessary for SARS-CoV-2 testing

<table>
<thead>
<tr>
<th>Available in a single copy</th>
<th>Available in the amount of 2</th>
<th>Available in the amount of 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Biosafety Cabinet class II</td>
<td></td>
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<tr>
<td>- Nucleic acid automated extractor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ELISA equipment (wash/wash/reader)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Thermal cycler (Thermocycler, PCR Machine or DNA Amplifier; Real Time with 4 channels)</td>
<td></td>
<td></td>
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<tr>
<td>- Water distiller</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Autoclave (clean)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Freezer (-20 °C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Microfuge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- PCR working station</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Autoclave (dirty)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Micropipette 10 - 100 µl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Micropipette 20 - 200 µl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Multichannel pipette</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Vortex</td>
<td></td>
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<tr>
<td>Available in the amount 4</td>
<td>Available in the amount of 6</td>
<td></td>
</tr>
<tr>
<td>- Centrifuge (simple)</td>
<td></td>
<td></td>
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<tr>
<td>- Micropipette 0.5 - 10 µl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Micropipette 100-1000 µl</td>
<td></td>
<td></td>
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<tr>
<td>- Printer for laboratory work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Computer for laboratory work</td>
<td></td>
<td></td>
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<tr>
<td>- Refrigerator</td>
<td></td>
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</tr>
</tbody>
</table>

All equipment is registered and maintained. The majority of equipment is certified, besides biosafety cabinet class II and nucleic acid automated extractor.

The laboratory also reported unavailable equipment:
- Freezer (-70 °C)
- Extraction manifold
- Micropipette 20 µl
- Plexiglas screen
- Vacuum pump
Facilities

The lab located in the old building without renovation. The building has no foundation and multiple breaches are visible. Specimens are received and registered by the virology lab located on the second floor of the building. However, PCR is conducted by Especially Dangerous Infections laboratory located in the basement of the same building. Virology laboratory does not have special room to receive samples so the samples are received in the common corridor. There is no BSC in the lab.

Heating, ventilation and air conditioner is not available in the laboratory. It is very cold in premises during winter season. Lighting is not sufficient. Autoclaves are outdated.

The lab reported the absence of emergency electric generator. Only thermocycler has own UPS, while the rest of equipment does not have it.

The laboratory noted having an adequate size for its activities (400 m²). However, there are no separate rooms for mastermixing, addition of nucleic acids, and thermocyclers; all 3 processes are conducted in 1 room.

Human resources

15 people composes laboratory team: 7 senior staff representatives, 5 laboratory technologists and 3 laboratory assistants. There is no quality manager and biosafety officer in the lab.

Staff is competent to perform nucleic acids extraction, serology, RT-PCR and bacteriology. There is a periodical competency assessment of the personnel (i.e. reconfirmation by the reference labs). There is a need on training for biosafety, risk assessment and biosecurity.
Biorisk management

The laboratory reported having biosafety level 2\(^1\). Disinfection and decontamination, as well as waste management procedures are implemented in the laboratory, but there are not enough separate disposals for infectious and non-infectious wastes.

Rooms have different sinks for handwashing only (one per unit). If there is a need for manipulating samples producing potential dangerous aerosols, there is only 1 BSC available at the EDI laboratory, which is not certified. There are biohazard signs indicated on the doors of the rooms where microorganisms are handled. There are door entry locks with security measures that prevent non relevant staff or visitors to enter the laboratory. There are locks on the freezers where primary specimens and aliquots are stored.

Accident/incident and nonconformities related to biorisk are not correctly managed. Lab coats and laboratory linens are washed at the lab.

PPE are available in enough quantities for the work load and number of laboratory personnel. Staff adhere adequate PPE during work (not worn outside lab areas, no eating or drinking within lab, no open-toed footwear etc.). The laboratory has dedicated PPE for each PCR areas (extraction, mastermix, and amplification).

Personnel has access to occupational health services and follows a regular testing for SARS-CoV-2 as health workers.

Public health functions

The lab is not a SARS-CoV-2 national reference laboratory, but it is a part of national surveillance network.

The lab gives advice on specimen collection and transport practices from the field during the investigation of public health emergencies. Virology Lab has a stock of emergency laboratory sampling kits (PPE, sample collection material, transport media, sample transport packaging)

The lab refers specimens or isolates to a Donetsk Oblast Laboratory for public health purpose (e.g. routine surveillance, outbreak investigation).

COVID-19-related reporting to public health authorities is established and implemented. There is a standardized document (in the form of Excel template) to report notifiable diseases or other events. It is filled daily and shared with local health authorities, and further with PHC.
SARS-CoV-2 testing capacity and capability

The lab reported the absence of a particular SOP for COVID-19 sample collection.

Specimen handling and SARS-CoV-2 testing procedures (RNA extraction, RT-PCR, serology, etc.) are written and readily available to staff, as relevant. The testing procedure for SARS-CoV-2 has been verified before starting regular testing. The laboratory use current versions of published standards for SARS-CoV-2 testing.

Risk assessment related to the procedures undertaken for SARS-CoV-2 testing and biosafety management are not in place in the laboratory. Appropriate PPE for the handling and testing of specimens for SARS-CoV-2 are available.

Personnel is trained in running SARS-CoV-2 testing (with the help of such platforms as Quant Studio 5, Thermo).

Part of the staff had previous experience with PCR testing. The equipment used for SARS-CoV-2 testing is adequately maintained. Required reagents for SARS-CoV-2 testing are available, while the necessary consumables for SARS-CoV-2 testing are available only for 2 weeks.

IQC specimens are included when performing SARS-CoV-2 testing, including procedure with corrective actions if needs to be used. The lab participates in EQA for the SARS-CoV-2 test, but the system to record and assess EQA results is absent.

Assessed laboratory does not have arrangements with the SARS-CoV-2 national reference laboratory for referring specimens for confirmation of results, or with a WHO COVID-19 reference laboratory as applicable. Personnel is partially trained in troubleshooting SARS-CoV-2 PCR results and a change in assay performance.
V. Conclusions/Recommendations

The laboratory might implement:

1. Strengthen diagnostics capacities by procurement of two additional BSCs for EDI laboratory and three BSCs for virology laboratory
2. To put in place biosafety manual
3. Implement a back-up procedure for patients’ data to prevent loss of the information
4. BSC needs a mandatory certification
5. Quality and biosafety management systems need to be implemented.

Next steps might be done by partners/WHO:

1. To support on the procurement of the additional equipment
2. To support with reorganization and if it’s possible reconstruction of laboratory premises.
3. To support on the conducting trainings:
   - on national regulations for transportation of infectious goods,
   - biosafety, biosecurity, risk assessment
   - PCR data interpretation and troubleshooting.