



# International Influenza Laboratory Capacity Review Tool (Version 3, June 2012)

## Guidance Document

### Background

The International Influenza Laboratory Capacity Review Tool (hereafter referred to as the ‘Laboratory Capacity Review Tool’ or the ‘Tool’) was developed in 2009 through a collaboration between the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL). It is a data gathering tool designed for assessing the capabilities and capacities of national influenza laboratories, with an emphasis on influenza diagnostics. Information collected through this tool can be used to identify a laboratory’s strengths as well as opportunities for improvement across a wide variety of functions. Assessments are offered to countries with which CDC has cooperative agreements. Participation by partner countries is voluntary.

In 2012, version 2 (v2) of the Laboratory Capacity Review Tool was updated, as follows:

- Individual questions were edited for clarity.
- Some questions were removed to avoid duplication of content.
- New questions were added to address gaps in the tool.

In addition, the Tool was restructured to improve usability (e.g. all items on equipment are now in one section.) As such, the June 2012 version 3 (v3) of the Tool consists of nine modular sections:

- Laboratory Contact Information
- General Laboratory
- Specimen Handling, Collection, and Reporting
- Virology Laboratory
- Molecular Biology Laboratory
- Laboratory Safety and Biosafety
- Quality Assurance/Quality Control
- Equipment
- Training

It also includes the following:

- Background
- Capacity Report Template
- Acronyms
- Appendix A: A list of links to online influenza resources such as WHO materials.
- Appendix B: A list of suggested reagents and supplies.

## Quantitative analysis

A new analytic framework can now be applied to data collected through version 3 (v3) of the Laboratory Capacity Review Tool. The purpose of performing a quantitative analysis of the data is to be able to present the results of assessments visually and thereby readily identify the strengths and opportunities for improvement in influenza laboratory capacity by country or region. It also provides a standardized approach to tracking changes in laboratory capacity over time. Questions have been selected from the Tool for assessing laboratory capacity in eight categories:

- **National Influenza Center Criteria:** Questions in this category evaluate a laboratory's capacity against NIC criteria as defined in the WHO National Influenza Centre (NIC) Terms of Reference\*, for example, participation in the WHO External Quality Assessment Project.
- **Laboratory Management:** Questions in this category assess capacity in laboratory management systems and procedures, for example, maintaining supply of laboratory consumables.
- **Biosafety:** Questions in this category assess capacity in laboratory security and safety, in particular, the safe handling and containment of infectious microorganisms and hazardous biological materials, for example, the provision of appropriate personal protective equipment (PPE).
- **Quality Assurance & Quality Control:** Questions in this category assess capacity in the systems and methods a laboratory employs to minimize errors and measure the accuracy of influenza test results, for example, inclusion of controls.
- **Molecular Biology:** Questions in this category assess capacity in the molecular biology procedures and techniques used in the influenza laboratory, for example, application of a uni-directional workflow for PCR.
- **Virology:** Questions in this category assess capacity in the virological procedures and techniques used in the influenza laboratory, for example, application of the haemglutination inhibition test.
- **Specimen Handling, Collection and Reporting:** Questions in this category assess capacity of influenza specimen handling, collection and reporting by laboratories, for example, storage conditions of specimens prior to testing.
- **Equipment:** Questions in this category assess capacity of equipment and reagents used for performing influenza testing, for example, calibration of pipettes.
- **BMBL:** Questions in this category assess capacity in BSL-2 laboratory safety and security as defined by the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual.

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\* WHO National Influenza Centres: *Terms of Reference related to work with Pandemic Influenza Preparedness Biological Materials*



Each question in a category is worth one point: the points are summed and divided by the total points possible for each category. The raw scores are converted into percentages and can be displayed on a chart.

## **Assessment Process**

Assessments are conducted by CDC or APHL representatives from U.S. public health laboratories. These representatives have significant experience in: virology (specifically influenza); molecular biology; influenza diagnostics; training laboratory staff; and real time RT-PCR.

Assessors receive training in the use of the tool prior to in-country assessments. Assessments take place on-site over three to five days and include meeting relevant government representatives and influenza laboratory staff as well as direct observation of laboratory operations, allowing assessors the opportunity to provide real-time technical assistance if required. The modular design of the tool allows for its implementation by multiple assessors in the case where a team is completing the review.

Following a review, the assessor/s prepare and submit a detailed report to CDC and APHL. The report identifies the laboratory's strengths and provides recommendations for improvement and is shared with the laboratory for comment before being finalized. From 2013, countries assessed will receive a summary report with the quantitative analysis of laboratory capacity included, as described above. Data collected through the tool and presented in the final report is confidential. For the purposes of external reporting, all data is de-identified by CDC and APHL or used in aggregate so that individual country results are not shared.

The Laboratory Capacity Review Tool may also be used by influenza laboratories to conduct self-assessments.

## **Modular Sections of Version 3, June 2012**

### **Laboratory Contact Information**

The purpose of this module is to capture all high level information regarding the function of the laboratory as well as gather information on the relevant contact points for the laboratory including: the Laboratory Director, key staff, and key contacts in the Ministry of Health.

### **General Laboratory**

This module is intended to capture daily laboratory practices and operations to assess the overall functionality of the laboratory. This module includes a number of questions to be answered following interviews with relevant laboratory staff and questions that can be answered by observation alone. More specifically, question 11 may be answered with brief statements which describe general activities and expectations of the influenza laboratory staff. Additionally, the reviewer should request a schematic outline of the laboratory's algorithm for questions 36 and 38.



## **Specimen Handling, Collection, & Reporting**

This module is intended to document all procedures and practices used by the laboratory in specimen handling, collection, and reporting. The reviewer should document details relating to reporting such as whether or not results are reported electronically, and the length of time from specimen receipt to reporting of results. The specimen table, located at the end of the section, should be completed by the reviewer and laboratory staff. The assessor should calculate the frequency and percentage of specimens being shipped by the laboratory, and provide recommendations for improvement if applicable.

## **Virology Laboratory**

The purpose of the Virology Laboratory module is to document basic virological techniques the laboratory performs including virus culture and isolation practices. The reviewer should note whether influenza isolation rates are similar to what would be expected during a typical influenza season and report and discuss any discrepancies between culture and PCR results. The virus isolation table, located at the end of the section, should be completed by the reviewer and laboratory staff. The assessor should determine the frequency and percentage of specimens isolated by the laboratory, and provide recommendations for improvement if applicable.

## **Molecular Biology Laboratory**

The Molecular Biology Laboratory module is intended to document specific practices and procedures the laboratory employs for molecular diagnostics. For example, the reviewer should observe whether there is a uni-directional workflow for PCR in the laboratory (question six). If the laboratory reports (question 12) that they do not have a reliable source for real-time PCR reagents and supplies, the reviewer should identify the supply-chain barriers and provide recommendations for overcoming these, for example, identify an alternate in-country or regional distributor.

## **Laboratory Safety and Biosafety**

The Laboratory Safety and Biosafety module is intended to identify safe laboratory practices employed in the laboratory as well as basic assessments of laboratory security. For example, if the laboratory operates under multiple biosafety levels (BSL), please identify the approximate laboratory area dedicated each biosafety level, as requested in question 16. For example, the laboratory has BSL-2 and BSL-3 facilities, but ninety percent of the space is dedicated to BSL-2 with the remainder for BSL-3 practices. Questions 17 and 18 ask the reviewer to identify which biosafety practices are maintained from a list of recommended practices (by BSL) documented in the 5<sup>th</sup> edition of 'Biosafety in Microbiological and Biomedical Laboratories.'<sup>†</sup>

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<sup>†</sup> Biosafety in Microbiological and Biomedical Laboratories, 5<sup>th</sup> Edition available at: [www.cdc.gov/biosafety/publications/bmb15/BMBL5\\_introduction.pdf](http://www.cdc.gov/biosafety/publications/bmb15/BMBL5_introduction.pdf)



## **Quality Assurance / Quality Control**

This module is designed to capture all quality assurance (QA) and quality control (QC) procedures and practices instituted in the laboratory. The QA and QC module may be adapted, at the discretion of the reviewer, to capture site-specific information reflecting current strengths and opportunities for improvement in QA and QC policies. For example, the use of a National Institute of Standards and Technologies (NIST) certified thermometer for monitoring temperature readings, policies to establish and maintain freezer temperature logs, and frequently monitor temperature trends.

## **Equipment**

The equipment tables are intended to identify various equipment and instruments needed to perform Real-Time RT-PCR and other influenza diagnostic techniques. Please document whether equipment is in working order and whether or not there is a procedure for preventative maintenance.

## **Training**

The training table is intended to capture all training that laboratory staff undergo prior to beginning work in the laboratory as well as any annual or refresher training provided by the institution. Training topics include: general, specimen handling, collection, and reporting, influenza, virology, molecular biology, laboratory safety and biosafety, etc. The reviewer is requested to identify the name of each training course, who provides the training (e.g. laboratory staff, the principal investigator (PI), WHO, CDC, etc.), the format of training (e.g. lecture, webinar, wet workshop, etc.), the frequency of training (e.g. annual, semi-annual, etc.), and where the training is conducted (e.g. on-site, off-site, classroom, etc.). Additionally the reviewer should identify who is trained (e.g. all staff, new staff, etc.), whether or not refresher courses are offered, if training is documented (e.g. electronically, written records, etc.) and include if the training records are updated regularly. Other matters to consider for the general comments area include: whether the reviewer or laboratory staff feel there are unmet training needs, and whether there are specific training requests.