

LABORATORY TEST COSTING TOOL

USER MANUAL/TRAINING MANUAL



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Abbreviations

BLBH	Better Labs for Better Health	
ELISA	Enzyme-linked immunosorbent assay	
EQA	External Quality Assessment	
IQC	Internal Quality Control	
HR	Human resources	
IHR	International Health Regulations (2005)	
LFM	Laboratory Financial Minute	
LTCT	Laboratory Test Costing Tool	
PAT	High Threat Pathogens Team	
SOP	Standard Operating Procedure(s)	
QC	Quality Control	
QM	Quality Management	
WHE	World Health Emergency Programme	
WHO	World Health Organization	

Introduction

In alignment with the Maputo Declaration on Strengthening of Laboratory Systems and the Health 2020 European Policy for health and well-being, the WHO Regional Office for Europe launched the Better Labs for Better Health initiative in 2012. This initiative is an intersectoral approach aimed to improve the quality of laboratory services and it is a principal part of WHO's efforts to assist Member States to accomplish their commitment under the IHR core capacity implementation. Better Labs for Better Health builds on the premise that sustainable laboratory services require a rational approach to laboratory system strengthening. A crucial component of an efficient laboratory system is having a comprehensive overview on laboratory expenditures and actual cost of tests.

Better Labs for Better Health advocates for clear organization of laboratory systems at all hierarchical levels within a country, including the development of clear terms of references, tests and methods for each level. To support this, Better Labs for Better Health has developed the laboratory test costing tool (LTCT) to help laboratories evaluate the cost of a specific laboratory test, justify this cost and produce pricelists for laboratory tests.

Purpose

The LTCT is designed to calculate the cost of a specific laboratory test. The LTCT can be used by various professionals including:

- policy-makers;
- health economists and administrators;
- Ministry of Health (MoH) representatives; and
- laboratory directors, coordinators and quality managers.

Presentation of the tool

The LTCT is an MS Excel[™] spreadsheet with six worksheets.

Fig. 1: Worksheets in the LTCT



Altering or renaming worksheet names, cell labels or protected fields can result in calculation errors and possibly compromise the interpretation of the data. Any changes to these parameters should only be made by the Better Labs for Better Health development team.

A language selector allows the tool to be displayed in English, French, Russian and Ukrainian.

The **How to use the tool** section of this guide provides an example of how to enter data in the LTCT.

Data Entry Results worksheet

You use this worksheet to enter all general data and laboratory variables for the calculation of the cost of the test – for example, the currency to be used.

You also use this worksheet to change the language of all the worksheets. English, French, Russian and Ukrainian are currently available.

Fig. 2: Language selection

Select language	English	
	English	দুই
	French	
	Russian	
	Ukrainian	

Click on the yellow language cell to activate the selector arrow to open the drop-down list of languages.

Changing the language does not change the tool's functionality in any way.

Reagents and Consumables worksheet

You use this worksheet to calculate the costs of reagents and consumables, and to gather information concerning procurement (ordering reference) of reagents and supplies used in the laboratory.

This worksheet describes the number of units in one package of reagents and the number of units used for each patient sample. This allows you to calculate the price of reagents and consumables for a patient's test, which will be added to the total costs.

The worksheet also contains information on Quality Control (QC) and Calibrators and estimates the number of tests used to run QCs and calibrations.

The costs of all consumables such as gloves, masks, gowns etc. are entered using this worksheet.

Equipment worksheet

You use this worksheet to specify equipment costs (acquisition price) and status (number of service years (year expected for equipment to be used for testing), its identification and costs of maintenance.

This worksheet is divided into General equipment (e.g. biosafety cabinets, thermostats, automatic pipettes, refrigerators etc.) and test-specific equipment (e.g. PCR machines, various analyzers, microplate washers, microplate readers (spectrophotometer)).

The worksheet automatically calculates the annual amortization value of the equipment, the equipment use price per day and the per laboratory financial minute (LFM).

Personnel worksheet

You use this worksheet to calculate the cost of the total number of personnel involved in performing specific tests and all the related personnel costs.

An additional 20% is added to the total cost of personnel to cover administrative personnel costs, such as:

- Administrative and management personnel
- Quality and biosafety managers
- Laboratory director
- Human resources personnel

In the tool, the percentage can be adjusted. It is up to the users' discretion to add the cost for administrative personnel.

The user can use the actual size and profile of the laboratory and type of organization to adjust estimation.

Facility worksheet

You use this worksheet to calculate costs related to the facility, e.g. rent, maintenance, gas and heating, water, electricity and communications.

Quality Management worksheet

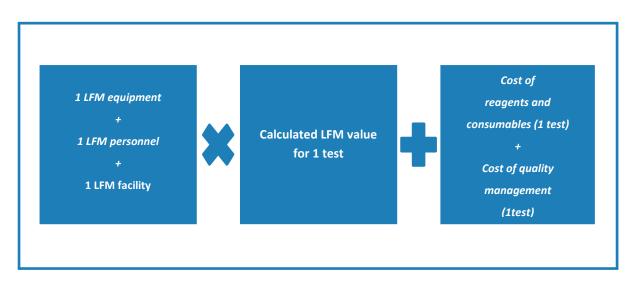
You use this worksheet to calculate the cost of quality management, including costs of proficiency panels and annual audits.

Method used to calculate the cost of a test

The LTCT uses the **Laboratory Financial Minute** (LFM) as a measurable unit to estimate the cost of a test. The tool uses the **Equipment**, **Personnel** and **Facility** worksheets to calculate the **cost of 1 LFM**.

Explanation of Formula: The cost of a single test is estimated as the sum of the Cost of 1 LFM for Equipment, Personnel and Facility, multiplied by the calculated LFM value for the test added to the cost of R&C and QM for the test. See the example of calculations in **How to use the tool**.





The **Reagents and consumables (R&C)** and **Quality management (QM)** worksheets do not use LFM, but calculate the cost of a single test based on the total costs of inputs.

How to use the tool

Table 1 describes the colour-coding of the cells in the LTCT.

Table 1: Colour-coding and content of the LTCT data cells

Tool: Colour legend		
Black	Fixed titles and totals	
White	General information and legends	
Grey	Automated calculations – protected	
Blue	Data to be entered by user	
Green	Reference data to be entered by the user	

Cells coloured in green in the user manual are reference data cells – these cells are for the user to fill in for quality purposes and they will not affect the formulas and calculations but are there for your laboratory to look back to for reference in the future. Although this data is not mandatory to use the tool, this can be used as a reference for quality management reasons.

Data entry and results worksheet

The *Data entry and results* worksheet contains two tables – the **Data entry** and **Results** tables:

- Enter all necessary data and numbers in the **blue** cells in the **Data entry** table.
- The **Results** table contains only **grey** cells, which the user cannot enter data in (they are protected). These cells automatically use the formula described <u>above</u> to calculate the cost of a single test based on the data entered into the worksheets in the LTCT.

Table 2: Entering data in the Data entry table

Data entry table		Helpful Hints and Examples
Name of test		e.g. Brucella
Year	Optional data	
Testing area (scope)	Optional data	
Intended use	Optional data	
Sample type	Optional data	
Method	Optional data	
Commercial (or in house) test kit	Optional data	
Time needed to run one testing batch (minutes)	Enter the time (in minutes) to perform one testing batch (testing run). This is actual working time of the technician and/or specialist. It can be estimated according to the Laboratory Testing User Manual /testing SOP description.	How much time does it take to do the analysis of this test? Remember, if the laboratory is responsible for pre- analytical work, the time it takes to do that is added here, if not, only put the time it takes to do the analytical part of the test. Enter the number in minutes.
Lab Working Hours per day	Enter the number of working hours per day.	How many hours a day is your laboratory open? Enter in hours. Ex: 8
Lab Working Days per year:	Enter the number of working days per calendar year. An accounting/ financial calendar can be used. This can be estimated using the laboratory "opening-hours" profile (e.g. 24/7 duty, Mon-Fri, Mon-Sat).	How many working days is your laboratory open in a whole year? For example: Usually it is 240 days, not accounting for holidays. If the laboratory is open on weekends, account for these days as well.

Lab Working Weeks per year: Testing schedule (times per week)	Enter the number of working weeks (usually 50-52). Enter the number of times you perform the test in the week.	How many working weeks is your laboratory open in a whole year? Divide how many days you are open in a whole year and divide by how many days in the week you are open. For example: 240 (open days a year) / 5 (open days a week) = 48 weeks How many times do you perform test per week?
Number of testing	This cell is automatically	Ex: Twice a day for 5 days = 10 runs The formula for this cell is C17 * C18
batches (runs) per year	calculated.	C17 Lab working weeks multiplied by C18 testing schedule per week For example: 48 weeks * 12 times a week = 576 times that I run this test per
		year Take note that sometimes batches have
		multiple samples. Batch definition: A group of up to 20 samples, sample extracts, or (including QC aliquots) depending on the test, that are analyzed together on the same instrument.
Mean of tests per years	Enter the number of tests per year of this specific test. This can be estimated by taking the mean number of tests for the <u>past three years</u> .	Remember to put the number of tests you get per year for this specific test. For example: My laboratory received Year 1 – 1500 HIV samples Year 2 – 2500 HIV samples Year 3 – 1000 HIV samples My answer would be: 5000 / 3 = 1666.67 On average the mean of tests per years for HIV in my laboratory is 1667
Currency	Enter the local or international currency.	Remember to use this currency for all costs throughout the tool

The LTCT displays the calculated value of the Lab Financial Minutes (LFM)¹ for a single test and the total cost of a single test² in the *Data entry and results* worksheet.

¹ Data Entry & Result Cell C26

² Data Entry & Result Cell C33

Reagents and Consumables worksheet

Table 3: Entering data in the *Reagents and consumables* worksheet

Here we describe how to enter the data in the Reagents and consumables worksheet

Reagents and consumables worksheet			
Category	Enter the category of reagent or the name of the consumable.		
Ordering Reference	Enter the ordering reference for reagent or consumable.		
Name of reagent or consumable	Enter the commercial name/manufacturer.		
Number units per package	Enter the number of units per kit/package/box.	How many units are there per package or box?	
Package price	Enter the price.		
Unit used per patient sample	 Enter the number of reagent units used for a single patient test. Reagent units can be estimated according to the Laboratory Testing User Manual /testing SOP description. Enter the consumable units. These can be estimated according to the testing method/technology, according to laboratory biosafety practices and internal SOPs. 	How many units do you use for a single patient test? For example: For consumables that are not for one time use only. Make sure that you accurately calculate the amount by using the calculation below. If you can use this consumable 2x per patient sample put 0.50 for units used per patient sample. 1 unit / 2 times = .50 units used per patient sample 1 unit / 50 times = .02 units used per patient sample	

QC per 1 batch (run)	Enter the number of QC units used for a single testing batch (run). QC units can be estimated according to the Laboratory Testing User Manual /testing SOP description.	Only enter data here if it is not included in test kits
Calibrators per 1 batch (run)	Enter the number of calibrator units used for a single testing batch (run). Calibrator units can be estimated according to the Laboratory Testing User Manual /testing SOP description.	

Quality Control - the use of control materials to monitor the accuracy and precision of all the processes associated with the examination (analytic) phase of testing³.

Calibrators - are solutions with a specified defined concentration that are used to set or calibrate an instrument, kit, or system before testing is begun. Calibrators are often provided by the manufacturer of an instrument⁴

³https://apps.who.int/iris/bitstream/handle/10665/44665/9789241548274_eng.pdf;jsessionid=400E8 D69C192B279B3C1E954CA48384D?sequence=1(Page 75) ⁴https://apps.who.int/iris/bitstream/handle/10665/44665/9789241548274_eng.pdf;jsessionid=400E8 D69C192B279B3C1E954CA48384D?sequence=1(Page 79)

Equipment worksheet

Table 4: Entering data in the Equipment worksheet

Equipment Worksheet		
Identification	General Equipment: Enter the type of general equipment. This equipment is not test- specific and can be used for different methods. Specific Equipment: Enter the type of test-specific equipment. This equipment is essential for test performance. Information can be taken from	
	the Laboratory Testing User Manual /testing SOP.	
Name/Manufacturer	Enter the commercial name and manufacturer.	
Acquisition price (without tax)	Enter the acquisition price.	Any equipment donated to the laboratory should still have an estimated price to account for amortization for future equipment. Example: If a donated equipment can have a lifetime of 5 years, the price placed here will give the laboratory an opportunity to allocate some cost for purchasing the next equipment after 5 years.
Number of years	Enter the expected lifetime of the equipment. The estimated number of years the equipment will be in use according to national legislation or the manufacturer's description.	How long will you be able to use this equipment for? Indicate number in years.
Maintenance contract cost per year	Enter the cost of maintenance as specified in the contract.	

% of use for method /day	Enter %. This can be estimated according to the number of tests and methods used on the same item of equipment.	Data needed in minutes: A: Time needed to run one testing batch (minutes), this is the data entered in the Data Entry and Results page cell B14. B: Total time used for this equipment for all methods per day. Add the different time need to run one testing batch for ALL methods in this equipment.
	 machine for HIV testing in my la The time needed to run one test (A). I use my ELISA machine for 4 dif HIV – 40 minutes Hepatitis C – 30 minutes 	od per day for method per day for my ELISA boratory. ting batch for HIV is 40 minutes
	 Hepatitis B – 100 minutes E.Coli – 120 minutes The total time used for this equi 40+40+ 100+ 120= 290 minutes 40/290*100 = 13.79% 	

Personnel worksheet

Table 5: Entering data in the *Personnel* worksheet

Personnel worksheet		
Category of laboratory personnel	Enter (list) the personnel involved in testing individually.	Remember to enter salaries that you want to be accounted in the cost of a specific test. Example: If the head of the laboratory is paid by the state, their salary should not be included here.
Personnel identification	Enter the name of the member of personnel.	
Annual salary	Enter the personnel member's annual salary including taxes.	

Facility worksheet

Table 6: Entering data in the Facility worksheet

Facility worksheet		
Monthly Rent cost	Enter	Facility costs should be based on data gathered by the accounting office. Remember to enter facility costs that you want to be accounted in the cost of a specific test. This is up to the user's judgement.
Building maintenance costs/month	Enter	
Gas and heating cost/ month	Enter	
Water cost/ month	Enter	
Electricity cost/ month	Enter	
Internet/telephone	Enter	
Other costs	Enter any other facility costs not specified above.	

Quality Management worksheet

Quality management worksheet	
Quality Management Activities	Enter different quality management activities such as proficiency testing or annual auditing
Price	Enter the price of the activities
# total number of methods being audited	Enter the number of methods that were inspected during the audit.

Table 7: Entering data in the *Quality management* worksheet

Language worksheet

Any modification of the wording in the module's worksheets should ONLY be done in the *Language* worksheet, because the cells in the other worksheets refer to cells in this worksheet. This worksheet is hidden; changes to cell labels etc. can therefore only be done by the Better Labs for Better Health development team.

Note

Your changes and improvements may be of interest to us as this is still a developing project. We kindly ask you to send us your new version or revised version to the following email addresses: <u>eulab@who.int</u>

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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