

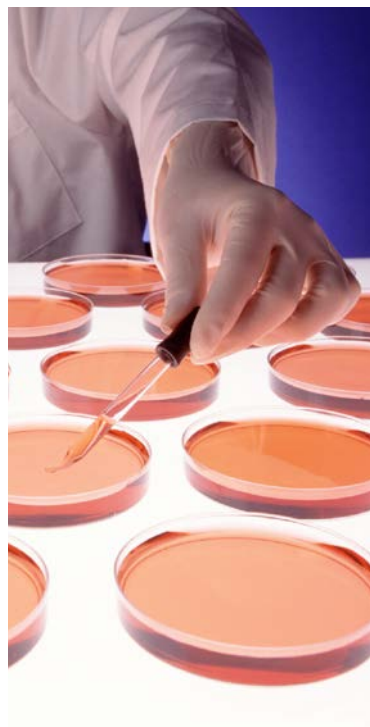
PVS Laboratory Mission Manual

PVS Laboratory Tool

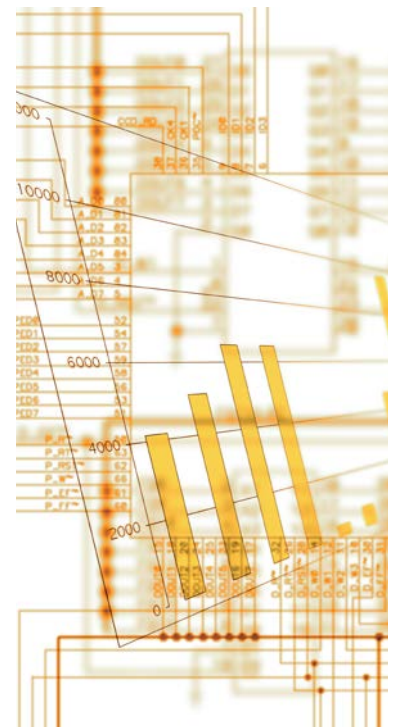
Laboratory function and
analysis
of the demand



Organising, managing
and financing the
laboratory function
of Veterinary Services



Budgeting
of the veterinary
laboratory network
and functions



2013

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Acronyms and Abbreviations

Agg	Agglutination
AGID	Agar Gel Immunodiffusion
AH	Animal Health
BBAT	Buffered Brucella antigen test
CC	Critical Competency (of the OIE PVS Tool)
CEC	Cost Estimation Card (of a CC in the PVS Gap Analysis)
CF	Complement fixation
CIF	Cost, Insurance and Freight (Incoterm)
ELISA	Enzyme-linked immunosorbent assay
FOB	Free On Board (Incoterm)
GC	Gas Chromatography
HPLC	High Performance Liquid Chromatography
IHA	Immuno-hemagglutination
MAT	Microscopic Agglutination Test
OIE	World Organisation for Animal Health
PVS	OIE Tool for evaluation of the Performance of Veterinary Services (OIE PVS Tool)
PCR	Polymerase Chain Reaction
Rt-PCR	Real-time Polymerase Chain Reaction
VS	Veterinary Services

NB: In order to avoid the multiplication of acronyms, please limit them as much as possible in Final Reports to what is strictly necessary or frequently used in the country.

Glossary

Analytical line	All equipment necessary excluding consumables and reagents to conduct any given test.
Client	All persons or institutions that request laboratory analysis results. In the first instance, it may be the Veterinary Services themselves for the purpose of official programmes, or in the second instance, other public or private institutions, private veterinarians, farmers, donor projects, etc.
Cost	The amount of money necessary for the laboratory to purchase or maintain any consumable (e.g., reagents, sampling kits, etc.), service (e.g., local transport, international transport, etc.), utilities (e.g., electricity, water, etc.), salaries, equipment and other physical resources (e.g., buildings).
Demand	Includes two facets depending on the context: <ul style="list-style-type: none">– more broadly, the Veterinary Services' expectations for laboratory analysis related to national programmes, including type of analysis, geographic location and volume;– and more specifically, every request that is submitted to the laboratory by a client. It may include several samples and several tests.
Laboratory	A physical entity carrying out all or part of the laboratory function.
Laboratory function	Defined in relation to the service rendered and is distinguished from the term 'laboratory'.
Price/Tariff	The fee charged by a laboratory to conduct a test of a sample.
Reference Price	The price of a laboratory service on the free market, often charged by a private laboratory in the country or by international reference laboratory, that has taken into account the global cost of analysis due to its interest in profitability.
Sample	Any biological product, organ or dead animal sent to the laboratory, irrespective of the tests to be conducted.
Strategy	Logical and consistent actions in order to implement objectives.
Supply	Includes those laboratory tests and services that are currently offered by the national laboratory network or accessed through an international laboratory network. This term also refers to what laboratory tests and services the national laboratory network in question is able to offer the market, or efficiently access on the international market.
Test/Analysis	Laboratory-specific method to be conducted on any sample.

PART I: Introduction to the PVS Pathway Laboratory Mission Methodology

1. Objectives, approach, outputs and outcomes of the PVS Pathway Laboratory Mission

Objective

The purpose of many laboratory-related expert technical evaluation missions is to assess or evaluate technical capacity and suggest improvements. As these missions are generally restrained by the context and terms of reference, they often do not allow for the in-depth examination of substantive systemic or strategic issues. The most frequent outcome of these kinds of missions is at best partial examination of structures and systems, to the detriment of an overarching or strategic view. Often this leads to simple technical recommendations and over-investment in structures that are systematically unable to implement them properly.

The OIE PVS Evaluation missions and PVS Gap Analysis missions allow for the evaluation of Veterinary Services¹⁹ official need for laboratory analysis as well as their availability and cost but do not allow an in-depth analysis of the pertinence and efficiency of the national laboratory network. In particular, the heavy cost of a national laboratory network is not considered in terms of Veterinary Services' official need for laboratory analysis.

The objective of the PVS Pathway Laboratory Mission is therefore not only to determine the resources needed by the national veterinary laboratory network but also to evaluate the pertinence of its structure and its viability in the national context in order to present elements needed for strategic decision making to the Veterinary Services. This approach also allows the national laboratory network's relationships with all other service providers to be analysed.

Approach

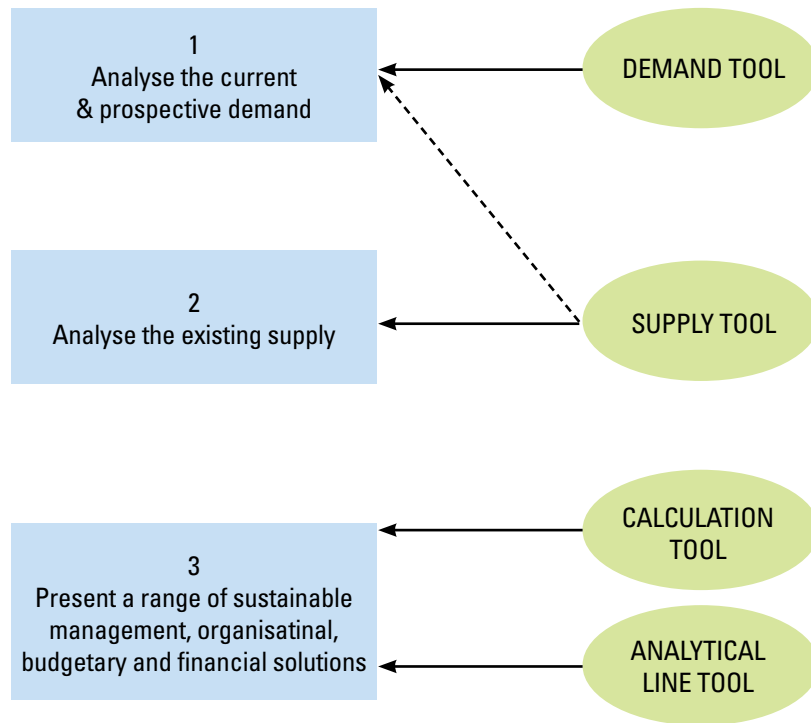
Based on established procedures and practices of the OIE PVS Pathway, a Laboratory Mission will be implemented in the country after preliminary data collection to:

- Analyse the current and prospective demand for veterinary laboratory analysis, mainly defined through current laboratory activity, the PVS Gap Analysis and described official programmes, as well as from other partners and/or from prospective demand, including a global estimate of the number of samples and the nature of tests, of the geographical distribution of demand, and of the cost of analysis (including the cost of consumables, sampling kits, transport and reagents);
- Analyse the existing offer, or 'supply', of veterinary laboratory analysis at the national level, mainly delivered by the national veterinary laboratory infrastructure, as well as by other laboratories²⁰, including their existing capacity and their potential to break into new markets to make the laboratory function a more coherent investment;
- Present a range of sustainable management, organisational, budgetary and financial solutions, with different options and their costs, in order to assist decision making related to the structure and management of the national laboratory network, including options such as official delegation to the private sector or to international Reference Laboratories.

19 As defined by the OIE *Terrestrial Animal Health Code*.

20 Other public institutions or the private sector.

Diagram 1:
PVS Pathway Laboratory Mission Approach and Tools



Outputs

The Veterinary Services will receive a Final Report including:

- an estimate of the demand for laboratory analyses for the next five years, including an evaluation of the total cost of analyses,
- an estimate of the current supply of laboratory function, including future prospects for potential new markets,
- proposals of sustainable management and organisational solutions of the national veterinary network,
- estimates of human, physical and financial resources needed for the implementation of the best solutions adapted to the national veterinary network,
- an evaluation of the total cost of the national laboratory network, compared to known resources and budget allocations.

Outcomes

The Veterinary Services' decision makers should have a better understanding of:

- the current and prospective demand for laboratory analysis in their country,
- the total cost of the national laboratory network and laboratory analyses,
- sustainable ways to organise the veterinary laboratory network to make the laboratory function a more coherent investment,
- how to better allocate or advocate for sufficient resources to support accurate and timely diagnosis of priority animal diseases and veterinary public health issues.

2. Context and limitations of the PVS Pathway Laboratory Mission

Relation of the Laboratory Mission to the PVS Pathway

The Laboratory Missions described here are part of the PVS Pathway. The objective of the PVS Pathway, in accordance with the OIE *Terrestrial Code* as it concerns laboratories, is to ensure that the national laboratory infrastructure²¹ meets the needs of the Veterinary Services, is sustainable and is regularly audited²². When a Mission is deemed appropriate, in chronological order it should always follow the PVS Evaluation ('diagnosis') and PVS Gap Analysis ('prescription'), as a part of the specific technical expertise that the OIE can provide to support compliance ('treatment') of the quality of Veterinary Services with international standards as defined in the OIE *Terrestrial Code*.

The PVS Pathway Laboratory Mission and the PVS Gap Analysis Mission

The starting point of a PVS Pathway Laboratory Mission is based on the national priorities of the Veterinary Services as defined in the PVS Gap Analysis Report. Those priorities are related to livestock development, veterinary public health, animal health and organisation of the Veterinary Services. To fulfil these priorities, the Veterinary Services often need access to laboratories in order to obtain accurate and timely results. The national laboratory network is considered a tool that should be adequately sized and scoped to achieve these priorities. As such, the national laboratory network cannot be considered as a priority in a PVS Gap Analysis and a PVS Pathway Laboratory Mission should not aim to dramatically change these national priorities.

Within the PVS Gap Analysis, Pillar 4 provides elements for the laboratory analysis needs of the Veterinary Services. The principle is that an analysis of the laboratories' resources and requirements is based on the needs²³ arising from the priorities defined in the previous pillars²⁴.

Determining the need for laboratory services presupposes that the strategies and laboratory analysis requirements for national programmes described in the activities by Critical Competency or by pillar have already been determined. The laboratory chapter is therefore the last technical element to be dealt with.

It is important to determine the necessary quantity of laboratory analyses and the techniques to be used for each national programme so as to be able to estimate the means required, especially with regard to:

- early detection and epidemiological surveillance (active and passive);
- inspection of food products²⁵;
- surveillance of residues in food products;
- border inspection;
- quality control of veterinary medicines and biologicals; and
- post-vaccination serological controls.

21 If existent.

22 Level 5 of CC.II.1.B of OIE PVS Tool, 2013.

23 Number and types of analyses.

24 'Trade', 'Veterinary public health' and 'Animal health'.

25 Including internal quality control i.e., samples from industry sent for laboratory analysis.

The choice of techniques to be used has a profound effect on the total cost and is based on the OIE *Terrestrial Animal Health Code*, 'Chapter 1.3: Prescribed and alternative diagnostic tests for OIE listed diseases'. Further information on these tests is provided in the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. However, the choice of diagnostic technique may differ according to the intended purpose, for example routine surveillance, diagnosis, or certification. It is up to the PVS Gap Analysis Experts to adopt the appropriate solution taking into account the costs as calculated by the tools provided in the PVS Gap Analysis intended to characterise the demand for laboratory analysis. This approach allows the determination of the demand for laboratory services generated by the Veterinary Services. If the national laboratory network is housed within the Veterinary Services, the budget must be calculated in order to allow the national laboratory network to exist and operate in the case where the official Veterinary Services' needs don't cover these operational costs.

Justification for a PVS Pathway Laboratory Mission

The scope of the PVS Gap Analysis is not a detailed and specialised study of each laboratory, nor a fine analysis of the relevance or sustainability of a national laboratory network. Time allocated to veterinary laboratory analyses during a PVS Gap Analysis Mission is limited. Below are presented three possible situations encountered during the PVS Gap Analysis Mission that could justify a request of the PVS Gap Analysis Experts in the PVS Gap Analysis Report for a laboratory-specific mission:

- The national laboratory network is considered unsuited to support the needs of the Veterinary Services²⁶. The PVS Gap Analysis Experts have only costed laboratory analysis on the international market in the 'consumables' cost line of CEC II-1. This cost is in any case sufficient for the Veterinary Services to obtain accurate laboratory analyses. The PVS Gap Analysis Experts did not consider any other resources (e.g., human, physical, reagents, quality, etc.) for the laboratory network and request a specific mission for an in-depth follow-up mission examining the national laboratory network.
- The national laboratory network is considered partially suited to support the needs of the Veterinary Services²⁷. This would be usually noted as Level 3 or 4 of the CC II.1.B 'Suitability of national laboratory infrastructures' in the OIE PVS Tool, 2013 edition. The PVS Gap Analysis Experts have costed consumables for laboratory analysis locally including reagents, sampling kits, and local transport in relevant cost lines of CEC II-1. They have also costed the relevant human and physical resources in CEC II-1 and relevant cost for quality assurance in CEC II-2, based on the PVS Gap Analysis guidelines and/or data given by the Veterinary Services and national laboratories. In addition, the PVS Gap Analysis Experts have requested a specific mission for an in-depth assessment of the overall national laboratory network, taking into account all the laboratories that have not been considered in the PVS Gap Analysis Report. This mission is usually costed in CEC II-1 on cost line 'international expertise'.
- The national laboratory network needs to expand on one or several activities to meet the goals of the Veterinary Services as proposed in the PVS Gap Analysis Report²⁸. This is usually Level 4 of CC II-1.B 'Suitability of national laboratory infrastructures' in the OIE PVS Tool, 2013 edition. The PVS Gap Analysis Experts have costed the new laboratory analyses according to the cost on the international market, and they have requested a specific laboratory mission on this issue²⁹.

26 This would be usually noted as Level 1 or 2 of the CC II-1.B 'Suitability of national laboratory infrastructures' in the OIE PVS Tool, 2013.

27 For instance, one or several laboratories are reasonably justified on a professional or political basis.

28 For instance, on specific techniques, residue testing, veterinary medicine, quality control, food safety, etc.

29 Costed in CEC II-1 on cost line 'international expertise'.

Limitations of the PVS Pathway Laboratory Mission

This laboratory mission is not intended to evaluate, assess or develop plans to improve technical components of the central veterinary laboratory or of the national laboratory network. For example, if technical assistance is requested only to develop or improve quality assurance, this is not within the scope of a PVS Pathway Laboratory Mission. Rather, this kind of capacity building should be delivered through mechanisms –potentially by other partners– and through OIE Laboratory Twinning Projects. However, quality assurance development would be considered during a PVS Pathway Laboratory Mission in the definition of the proposed strategies and budget needed to improve compliance with international standards for laboratory quality assurance.

3. Overall description of the PVS Pathway Laboratory Mission and main components

The main mission components are described below:

- Set goals by analysing the demand for laboratory analysis, extracted from PVS Gap Analysis Report, other sources, data collection sent by the country prior to the mission, etc., using the Demand Tool,
- Compare the required human, physical and financial resources to meet goals with the current resources, using data collected in the Supply Tool,
- Propose different options, and optimisation of such options, and to explain their advantages and disadvantages including national policy, donor contributions, existence of infrastructure, etc., using the Analytical Line and Calculation Tools,
- Propose an optimal budget taking into account all constraints, using the '1. Current & Proposed Budget' Sheet in the Calculation Tool.

PART II:

Guidelines for a PVS Pathway Laboratory Mission

1. Typical organisation of a PVS Pathway Laboratory Mission

The mission has three main phases and is organised around nine distinct steps (see Table 1 of this Manual):

- Before the mission, as described in Steps 1-5, the mission should be organised and existing data should be gathered.
- As described in Step 6, the technical expertise is given during the mission.
- After the mission, the Final Report must be finalised by the PVS Pathway Laboratory Expert Team (Step 7) and sent to the country by the OIE for validation, as described in Steps 7-9.

Table 1 is an overview of the main steps of the organisation, preparation, and implementation of a PVS Pathway Laboratory Mission and the preparation, finalisation, validation and use of a Country PVS Pathway Laboratory Mission Report. The objective of Table 1 below is to clarify who is in charge of each key step of the mission and to explain the use and purpose of the different tools, models, and documents provided to the Experts but is strictly indicative and can the process can be modified as and where needed.

2. Process of the PVS Pathway Laboratory Mission

The following table summarises (see next page, Table 1) the main steps of the process.

- Preparation phase (Steps 1-5), composed of the country mission request, data collection, missions procedures and confirmation : 3-5 months
- Mission (Step 6) : 2 weeks maximum
- After the mission (Steps 7-9) composed of report redaction, validation by OIE HQ, peer review, and validation by the OIE Delegate : 3 months

Taking into account the weekend, it is thus expected that the country mission will last between 1 and 2 weeks depending mainly on the complexity of the national laboratory network.

Table 1: Table of PVS Pathway Laboratory Mission

	Person in Charge	Documents	Time Schedule	Working Days
BEFORE THE MISSION				
Step 1 / Mission request by the country Should include reference to PVS Evaluation and PVS Gap Analysis Reports, the nomination of a focal point and clarification of other authorities to be invited	OIE Delegate		Day 1	
Step 2 / Analysis of the request and acceptance of the mission				
– Selection of a Team Leader	OIE HQ		2 weeks	
– Analysis of the request	OIE HQ + Team Leader			
– Acceptance of the request	OIE HQ		1 week	
Step 3 / Preparation of a mission budget		Template Budget (Note de Service PVS Pathway Missions)		
– Draft budget sent to Team Leader and Expert Team	OIE HQ			1 day
– Possible comments and proposed modifications	Team Leader			1 day
– Finalisation of the indicative mission budget	OIE HQ		< 1 week	
Step 4 / Preliminary data collection – Supply Tool sent to country for data collection – Supply Tool data received from country – Determine and justify if field visits will be necessary during the mission	Team Leader	PVS Pathway Laboratory Mission Explanatory Note and	3 months maximum	4 days
Step 5 / Confirmation of the mission – Confirmation if essential data are available or not – Proposal of Expert Team, dates and schedule of mission – Organisation of flight booking, visa applications, etc. – Advance payments to experts	Team Leader + OIE HQ		1 month	
DURING THE MISSION (Step 6)				
Step 6 / The mission				
– Courtesy visit – Description of the mission process	Political authority Experts + national partners			1 day
– Analysis of the demand for laboratory analysis	Experts + national partners	Demand Tool		1 day
– Field visit (if determined necessary)	Experts + relevant lab staff	Supply Tool		1 – 3 days
– Analysis of the supply of current and potential laboratory analysis	Experts + national partners			1 day
– Strategies, management and financing brainstorming	Experts + national partners	Analytical Line Tool, Calculation Tool		1 day
– Development of costing & financing solutions	Experts			1 day
– Validation of costing & financing solutions	Experts + national partners			1 day
– Closing meeting	Experts + national partners	Report Template		1 day
AFTER THE MISSION				
Step 7 / Writing of the Mission Report and internal check	Team Leader and OIE HQ	Report Template	1 month	7-10 days
Step 8 / Validation and transmission of the Mission Report	OIE HQ and OIE Delegate		2 months	
Step 9 / Final payments to experts	OIE HQ		< 1 week	

3. Steps of the process

Before the mission

Step 1: Mission request by the country

The OIE Delegate should request a specific PVS Pathway Laboratory Mission to the OIE, mentioning who would be the national focal point for this mission, and making a link to the PVS Gap Analysis Report. The request should also clearly establish the relevant level of authority requesting the mission, especially if it goes beyond the Veterinary Services authority, to take into account other laboratories which are under the authority of other institutions or Ministries.

Step 2: Analysis of the request and acceptance of the PVS Pathway Laboratory Mission

Once the country has sent the request for a PVS Pathway Laboratory Mission to the OIE and after initial review, a Team Leader and Expert Team, who would eventually conduct the mission itself, is nominated by OIE HQ.

In the first phase of this Step, the Team Leader should thoroughly study the PVS Evaluation and PVS Gap Analysis Reports and track all elements related to the laboratory analysis needs of the Veterinary Services and to the current or expected national laboratory network. The Team Leader should also note relevant information related to laboratories such as general objectives, priorities and expert recommendations. The Team Leader should identify any weaknesses, lack of information, or possible inconsistencies. If necessary, s/he should list the archived documents or data listed in the annexes of the PVS Pathway Reports, in order to obtain necessary quantitative data, either from the PVS Pathway Mission archives or from the country. Special attention should be given to the relevance of laboratory analysis to the official programmes mentioned in the PVS Gap Analysis Report.

It is not the purpose of the PVS Pathway Laboratory Mission to modify or renegotiate significantly national priorities and official programmes, but it may be necessary to detail some technical aspects of relevant laboratory analysis for those national programmes where sufficient detail was not originally provided. For instance, changing the type or number of laboratory analyses for an official disease programme on a more scientific basis, taking into account that not all PVS Gap Analysis Experts are specialists in this field, is acceptable. It is important to ensure that the types of analysis¹⁹ as well as the number of samples²⁰ are well-adapted to the country's context.

Changing the aim of the programme, and therefore changing the number and type of laboratory analyses, may not be appropriate²¹. However, changes in priorities and official programmes since the PVS Gap Analysis was conducted may be evoked or future trends or potential new markets may emerge in the course of the mission and therefore should be noted in the Final Report.

The Team Leader should also take into account the context of the laboratory components within the PVS Gap Analysis Report, and in particular should pay attention to the findings related to the veterinary field network. If the findings were such that the Veterinary Services field network staff (public or private) is not able to initiate, collect and provide samples to the laboratory network to implement official programmes of the Veterinary Services, this fact may make the strengthening of a national laboratory network difficult.

¹⁹ Either on the basis of the standards stated in the OIE Terrestrial or Aquatic Animal Health Codes, or for other reasons such as routine tests available in country or prohibitive testing costs.

²⁰ Based on scientific elements such as target population, estimated prevalence, confidence levels, etc.

²¹ For instance, changing from a simple survey to active surveillance or active surveillance based on random sampling to a comprehensive passive surveillance of an entire population.

The Team Leader should also take into account the current activity of the national laboratory network, which may include other laboratories that do not fall under the Veterinary Services, but which may represent prospective demand for laboratory services that had not been included in the PVS Gap Analysis (e.g., research programmes, donor projects, etc.).

The Team Leader will then introduce as much as possible all available data into the DemandTool, in order to estimate the number and type of laboratory analyses, cost of analyses on the international market, and cost of reagents. If there is insufficient information to conduct this step before the mission, it could be deferred until a later stage.

The 'demand' includes those laboratory analyses and services that the Veterinary Services require to support official programmes²², and additional laboratory services that may be requested (e.g., diagnosis, outbreak response, etc.). As already mentioned, the PVS Pathway Laboratory Mission should not be used to modify priorities of the Veterinary Services established during the PVS Gap Analysis. If they appear unrealistic, a new PVS Follow-up Evaluation Mission or PVS Gap Analysis Mission could be considered, especially if the previous missions were conducted more than five years prior.

A letter of acceptance of the mission proposal is then sent by the OIE to the country, with the contact information of the Team Leader. In this communication, the OIE explains that the principle of a PVS Pathway Laboratory Mission is accepted, but that the implementation of the mission itself is dependent on appropriate data collection to be provided prior to the confirmation of mission dates.

Step 3: Preparation of a mission budget

Once the request acceptance letter is sent to the requesting country by the OIE, the World Fund Coordination Unit will prepare the draft mission budget according to the OIE administrative procedure outlined for the PVS Pathway. This draft budget will be sent to the Team Leader for comment, possible modification, and validation. The remaining members of the Expert Team will also be given the opportunity to comment on the draft budget.

Step 4: Data collection and analysis prior to the mission

This work is under the responsibility of the Team Leader and should be finalised within a maximum period of three months after acceptance of the mission or two weeks after the Team Leader acknowledges receipt of all necessary information. This activity should take no more than four days of pre-mission work. At the end of this step, the Team Leader will either confirm dates for the implementation of the mission or recommend deferral of the PVS Pathway Laboratory Mission to the OIE in the case that the necessary data has not been received.

The Team Leader will send the Supply Tool (see Part III.1 'Use of the Supply Tool'), which includes the necessary pre-mission data collection, to the designated mission focal point in the country. Included in the letter on the organisation of the mission (see Annex 1: PVS Pathway Laboratory Mission Explanatory Note and Supply Tool Guidelines) will be an explanatory note and clear guidance about the use of the Supply Tool and how to collect the data requested. The data collection step is intended to further define the supply and demand for laboratory services needed by the Veterinary Services in the country. If necessary, the Team Leader could be in direct contact by telephone or email with the country focal point.

²² Current or planned, which should have been defined in the PVS Gap Analysis, but may need updating or further detailing prior to or during the PVS Pathway Laboratory Mission.

The 'supply' includes what laboratory tests and services are currently offered or able to be provided by the national laboratory network or accessed through an international laboratory network. This step aims to collect data that are not available in other documents, including data related to additional partners, for the 'demand' and 'supply' components of laboratory analysis (e.g., other institutions, private sector, etc.). It should also allow the Team Leader and country focal point to decide on whom to invite to participate in all meetings during the mission itself.

Taking into account available Reports and collected data, the Team Leader will confirm the mission dates and Expert Team and provide a schedule for the mission to the OIE. The PVS Pathway Laboratory Mission is intended as a central level mission—being conducted at/or in association with the main veterinary laboratory should one exist—similar to the procedures for a PVS Gap Analysis mission. A short visit (1-2 hours) to the central veterinary laboratory will allow the Experts to ensure a common understanding of concepts²³. Additional documentation (e.g., photos, documents or assessments of the laboratories) are welcomed by the Team Leader in order to avoid unnecessary and long travel during the mission.

If more field visits are desired by the Team Leader, they must be justified in writing by the Team Leader and approved by the OIE in advance of the mission. In limited and specific circumstances, visits to key partners or external laboratories may also be desired during the mission. Visits of this nature shall not delay the implementation of the mission nor should it prolong the mission and incur additional costs to the OIE without prior written approval. In all cases field visits should be proposed by the Team Leader and approved by the OIE in writing prior to departure if they involve additional days added onto the mission and are essential for conducting thorough expertise.

It should be made clear to the Veterinary Services and the Expert Team that such visits are not an evaluation or an assessment of technical capacity of the laboratory, and they should be clearly described as having the goal of providing a common understanding between the experts and the national partners regarding the critical components of the national laboratory network. When necessary, these visits should target only specific and relevant laboratories or sections of special interest, or a 'sample' of different kinds of laboratories (e.g., regional, provincial, local, etc.) to obtain an appropriate and clear vision of the situation when existing documentation available to the Expert Team (e.g., photos or documented procedures) are deemed inadequate or are unavailable. When approved in advance, such field visits should occupy a maximum of two days (including travel) of the mission, should be done separately by the experts when possible, and should occur whenever possible outside of scheduled mission meetings.

Step 5: Confirmation of the mission

In part based on the recommendations of the Team Leader, the OIE will confirm the mission request to the country, including mission dates and two to three additional technical experts to accompany the Team Leader.

The mission should be implemented within a maximum period of three months of this confirmation. The logistics should be arranged according to the OIE administrative procedures of the PVS Pathway.

23 E.g., hygiene, biosecurity, quality, quantity, competency, procedures, etc.

During the mission

Step 6: Implementation of the PVS Laboratory Pathway Mission

Each day of the mission is briefly described below, with more in-depth sections following in Part III. The length of a PVS Pathway Laboratory Mission can vary, but should not exceed ten working days. Below an example of a PVS Pathway Laboratory Mission schedule is presented.

Day 1: Courtesy visit and presentation of the PVS Pathway Laboratory Mission process

The Expert Team will begin the mission on the first half day with relevant courtesy visits and a description of the mission's aims and process with *all* participants of the mission meetings. Each laboratory of the national laboratory network should be represented to the extent possible, especially those not under the authority of Veterinary Services.

Many basic concepts that are discussed throughout the PVS Pathway Laboratory Mission may be new concepts for laboratory personnel and thus need to be explained and discussed in order to ensure a common foundation for the PVS Pathway Laboratory Mission from Day 1. In addition, these terms may have specific definitions within the framework of this mission or may not often be used or well known by laboratory personnel. These concepts, presented in the Glossary, should be reiterated and reviewed when the different tools are presented throughout the mission. The Team Leader should present these concepts in a clear and simple way, integrating the concepts into the presentation of the objectives, method, and outputs of the PVS Pathway Laboratory Mission.

Days 2, 3 & 4: Analysis of the Supply and the Demand

Analysis of the supply and demand may take from 1 to 3 days, depending on whether field visits have been planned and the extent of data gathered prior to the mission. It is advisable to keep 2 days to work on refining the information gathered in the Supply Tool and preparing it for use in the subsequent tools, as it is expected that new information will arise about laboratories from other institutions that were not included in the PVS Gap Analysis process.

The aims of the Supply Tool are:

- To better understand the current equipment and activities of the national laboratory network, and therefore the services that it could potentially offer to respond to market demand.
- To gather an optimal amount of information about each laboratory in the national laboratory network that is essential for good laboratory management and strategic planning
- To ensure a holistic view of the national laboratory network and its components

Additionally, more in-depth discussion and potentially new data collection to further refine the Supply Tool for the national laboratory network, including available resources, costs, capacities and possibilities, may be necessary if additional stakeholders intend to participate in the meeting.

During this time, the Supply Tool should be used to:

- Present the results of the analysis of the supply filled in by the Veterinary Services prior to the PVS Pathway Laboratory Mission
- Finalise data entry with data collected during earlier meetings, and if applicable during field visits

- Discuss and collect data concerning additional supply coming from other sources (e.g., private sector, other laboratories, human health sector, etc.).

At least one day will be necessary to complete the analysis of the demand for laboratory analysis and services. Once again, it is not intended to change the priorities and programmes of the Veterinary Services established during the PVS Gap Analysis.

The aims of the Demand Tool are:

- To validate, detail and/or calculate the official Veterinary Services' needs for laboratory analysis and,
- To assess additional demand that may come from other sectors not taken into consideration during the PVS Gap Analysis (e.g., private sector, other institutions, etc.). This step is essential to clarify the structure and size of the national laboratory network, even if it is not entirely under the authority of the Veterinary Services; an undersized network may be inefficient and an oversized network may need subsidisation.

During this time, the Demand Tool should be used to:

- Present the results of the analysis of the demand for laboratory analysis based on the official programmes as described in the PVS Gap Analysis Report prior to the PVS Pathway Laboratory Mission
- Include data concerning potential additional demand from the Supply Tool (sheets 5a.-5d. 'Activities' sheets) filled in by the Veterinary Services
- Discuss additional demand for laboratory analysis coming from other sources (e.g., human health sector, private sector)
- Finalise the Demand Tool to be included in the Final Report

Day 5: Strategy, management and financing brainstorming session

One participatory meeting should be organised for one full day with all relevant partners²⁴, in order to propose and discuss possible strategies and existing constraints. The experts will explain the different models (see Part III.2 'Strategic elements for organising, managing and financing the veterinary laboratory function of Veterinary Services' of this Manual) and discuss relevant possibilities in the country. It may be advisable to keep enough flexibility in the agenda to allow separate meetings or visits with selected partners that were not scheduled in the previous days.

The aim of this meeting is:

- to reach a consensus on the different possible options and strategies, based on strengths, weaknesses or limitations identified in the previous meetings, that are feasible and that the experts should include in the costing exercise and present in the next meeting 'Day 7: Validation of costing and financing proposals'.

During this time, the experts will use the information in Part III.2 of this Manual entitled 'Strategic elements for organising, managing and financing the veterinary laboratory function of Veterinary Services' to discuss different options with partners and specific constraints (i.e., political decisions).

Day 6 & 7: Development of costing and financing solutions

The experts will need one to two days of independent work apart from the country team to develop and establish costing and financing proposals based on the outcomes of Day 5. Optimally, Days 6 and 7 would be scheduled over the weekend.

²⁴ Identified before the beginning of the mission, but at the latest during the first day of the mission.

Day 8: Validation of costing and financing proposals

A second meeting with all partners should be held to select, rank and validate costing proposals developed in support of the model(s) chosen by consensus (using the '1. Current & Proposed Budget' sheet in the Calculation Tool and (Part III.2 'Financing and funding arrangements' of this Manual). During this session, the experts may use all available tools and project them with an LCD projector, in order to show live simulations and to tailor proposals to the discussion with partners.

Day 9: Wrap-up and Closing meeting

The closing meeting must at least include the OIE Delegate and all Veterinary Services' and Veterinary Laboratories' senior management involved in the mission. The presence of the responsible Minister(s) or political authority is desirable, although a separate, short meeting is usually more appropriate. The aim of the meeting is to validate the PVS Pathway Laboratory Mission's process and proposals and discuss the country's implementation strategy. Experts may use the Report Template and relevant Tools accordingly during the closing meeting.

After the mission

Step 7: Writing the Mission Report and peer review

The Mission Report is written by the Team Leader²⁵ with inputs and approval requested by the members of the Team. The Team Leader should use the PVS Pathway Laboratory Mission Report Template and send the Report to the OIE within one month of the end of the mission. The OIE is responsible for peer review of the document.

Step 8: Validation and transmission of the Mission Report to the country

Once this Step 7 is complete, the OIE will send the preliminary Report to the OIE Delegate for validation. If the laboratory is not under the same Competent Authority as the Veterinary Services, the OIE Delegate will be encouraged to seek the input of the Director of Laboratory Services or equivalent for this validation. Any comments are sent to the OIE and forwarded to the Team Leader who revises the preliminary Report accordingly, in close collaboration with the Expert Team and the OIE. The Final Report is officially sent to the OIE Delegate by OIE headquarters. If the country agrees to share its PVS Pathway Laboratory Report with Donors and Partners, the Final Report is sent to the relevant agencies.

Step 9: Final payment to experts

Once the preliminary PVS Pathway Laboratory Report has been reviewed and validated by OIE headquarters and sent to the OIE Delegate of the country in question, the OIE will proceed to the final payment of the PVS Experts.

²⁵ Up to the equivalent number of working days as the mission.

PART III:

The technical components of the PVS Pathway Laboratory Mission

Unlike various technical assessments which seek to assess a specific and well-defined area or problem, PVS Gap Analysis and subsequent PVS Pathway Laboratory Missions are strategic in scope: the aim is to propose a system that meets the needs of Veterinary Services, not to quantify the construction of a turn-key laboratory whose financial and strategic future is uncertain within its context.

Accordingly, the PVS Pathway Laboratory Mission focuses on the overall objectives of Veterinary Services in relation to the laboratory function rather than on the technical inner workings of the laboratory itself.

1. Description of the laboratory function and analysis of the demand

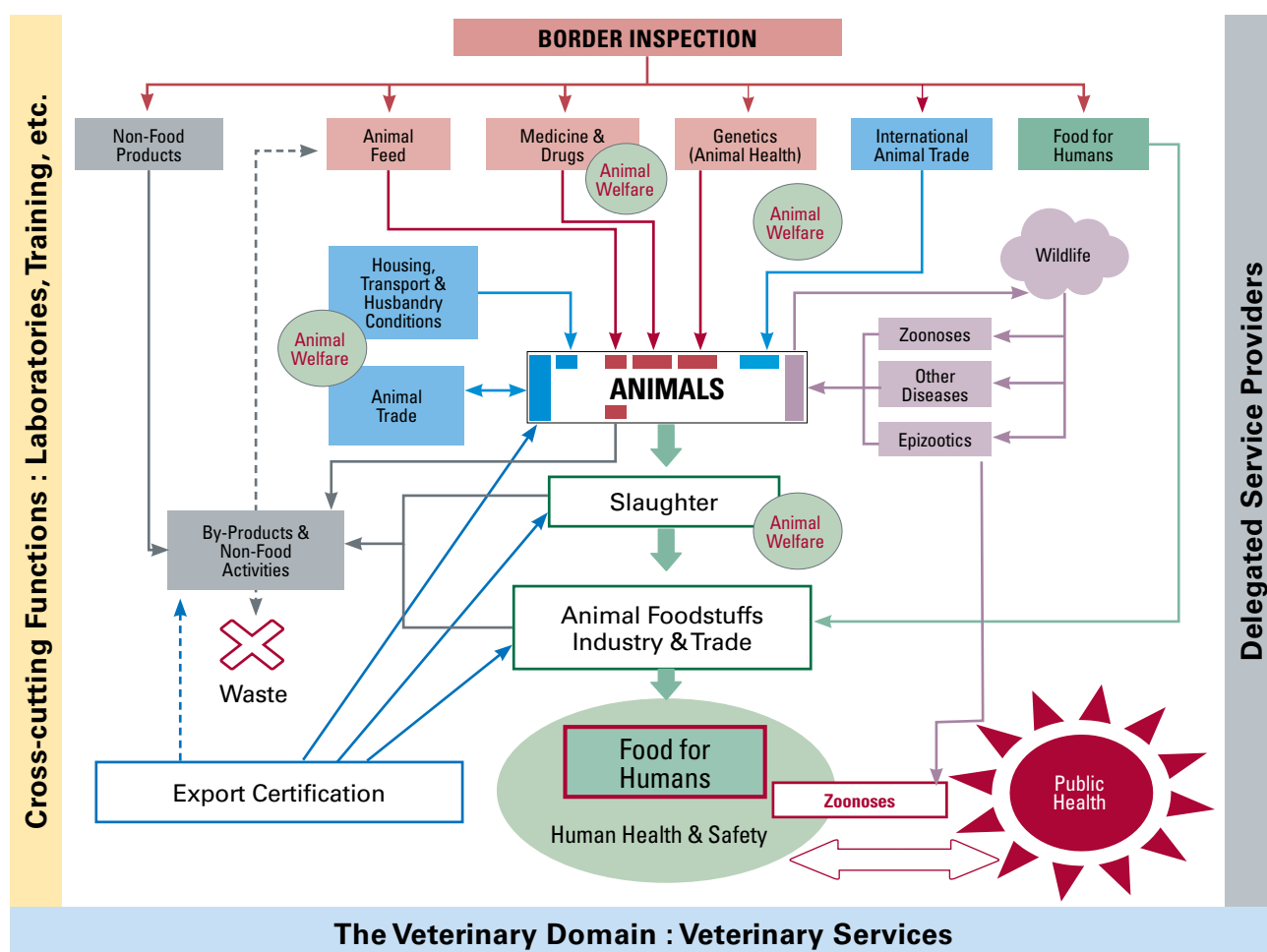
The laboratory function

The term 'laboratory function', which is defined in relation to the service rendered, is distinguished from the term 'laboratory', which refers to a physical entity carrying out all or part of the laboratory function. Its objectives must be clearly described and specific, measurable, attainable, realistic and time-bound. As a reminder, the veterinary domain is defined as all the activities that are directly or indirectly related to animals, their products and by-products, which help to protect, maintain and improve the health and welfare of humans, including by means of the protection of animal health and welfare, and food safety (see Diagram 2 on the next page).

The laboratory function is one which, by the implementation of laboratory techniques, provides the scientific basis for decision-making by the various clients concerned¹⁹. This definition precludes neither the affiliation nor distribution of the laboratory function, which are in fact part of the field of expertise. The organisation of the laboratory function can vary widely within or outside of the Veterinary Services and is not necessarily attached to any of the clients. Its organisation should not be considered as intangible or abstract, but should be rationalised and coherent with demand.

¹⁹ Veterinary Services or others.

Diagram 2: The Veterinary Domain



The laboratory function must provide Veterinary Services with all the technical elements they need for decision-making²⁰. The function covers:

- The laboratory diagnosis, study and surveillance of animal diseases, consisting of all the techniques used for research, characterisation and identification, direct or indirect, of pathogens of all kinds, as well as the measurement of animal biological parameters,
- The measurement of health and qualitative parameters of animal products, food of animal origin and by-products²¹ including, where appropriate, drug residues and contaminants,
- The measurement of health and qualitative parameters concerning:
 - environmental conditions of livestock farming or production, in particular the quality of water
 - inputs for animal production, such as water and feed, as well as medicines and additives.

These measurements can be carried out as part of official inspections or surveys, internal quality control, or for the needs of industry, farmers and individuals. These points cover the entire veterinary domain, including fish products and water quality²². This aspect of the laboratory function is independent of the client and hence of the division and distribution of the veterinary domain among different administrations.

²⁰ This excludes research that does not lead directly to a decision but to the improvement of knowledge.

²¹ In the sense of 'inedible' and 'waste'.

²² As vaccine and drug production are industrial processes, they are a priori excluded from the veterinary domain thus defined.

Definition of the scope of the veterinary laboratory function in the country

A major challenge is to avoid reducing the veterinary laboratory function to the capacity of laboratories controlled by the client²³, but instead to ensure as complete as possible an array of services. As laboratory techniques are not specifically or exclusively 'veterinarian', veterinary laboratories may process industrial and human samples as may other laboratories likewise process animal samples. These assumptions must be explored for inclusion in the array of services offered by the laboratory. Considering all possibilities, context and needs, the first stage of the PVS Pathway Laboratory Mission will therefore be to determine which national laboratory network objectives should be retained given the demand for specific laboratory analyses in the country.

Quantification of the demand for the veterinary laboratory function

Many failures of capacity building and development projects stem from adopting an exclusively qualitative approach leading to the establishment of or over-investment in structures that are non-viable and ruinously expensive because they fail to generate or achieve a sufficient level of activity in the country's context. It is not enough to simply announce the intention to conduct epidemiological surveillance, for example; it is also necessary to specify at a minimum how many samples, for which analyses, and for how long. Experience has shown that the activities of many laboratories, or even national networks of laboratories, occupy only a portion of their workforce's time and a much smaller portion of their theoretical technical capacity.

A market assessment of the laboratory function is a prerequisite to any evaluation or discussion of veterinary laboratories or networks of laboratories, and a quantitative –rather than qualitative– approach to related objectives is mandatory. A quantitative approach is necessary not only to assess the viability of laboratories, but also from a technical standpoint to determine its appropriate size and array of services. Attention needs to be paid not only to the current market, which is possibly biased by the operating conditions of laboratories, but also to the potential or future market.

This PVS Pathway Laboratory Mission, however, is not designed to determine a laboratory's appropriateness strictly in terms of profitability, but to make clear to decision-makers and stakeholders the total cost of analysis—the total amount of money required by the laboratory to conduct its work, including human resources, infrastructure, utilities, maintenance, operations, etc. beyond just the costs associated with sample collection and laboratory analysis (consumables, reagents, sampling kits, and local transport). Additionally, the PVS Pathway Laboratory Mission aims to identify and examine political choices related to laboratories, as well as the need for a coherent array of services to be offered. Each country is free to develop laboratory facilities which operate at a loss if they believe them to serve a political purpose, to be affordable, and to be useful; however making informed decisions may allow decision makers to adjust their focus in Veterinary Services' strategy concerning laboratories.

23 Usually the official Veterinary Services.

Use of the Demand Tool

The Laboratory Analysis Demand Tool, the first tool used during a PVS Pathway Laboratory Mission, elaborates further the estimation made during the PVS Gap Analysis Mission of the cost of laboratory analyses on the international market²⁴ and in the national laboratory network²⁵. During this portion of the mission, the current demand, the PVS Gap Analysis demand, and the possible prospective demand for veterinary laboratory analyses is examined with the country team, as well as the limiting factors and opportunities related to demand for laboratory services.

The Demand Tool can be used:

- to analyse the demand as noted in the PVS Gap Analysis Report
- to refine the information related to the tests conducted for official programmes and other needs of Veterinary Services²⁶ for the national laboratory network,
- to examine and include the demand of other clients, sectors or external partners of the Veterinary Services (e.g., water quality testing, food testing, quality control) that can support the laboratory itself by providing financial self-sufficiency,
- to estimate prospective demand for the next 5 years in order to optimise the services offered by the laboratory function to its clients

As the reference price for international laboratory analysis normally reflects the true cost of analysis (e.g., human resources, infrastructure, utilities, maintenance, operations, consumables, reagents, sampling kits, and local transport, as well as profit) at the international level, one can quickly deduce the maximum reasonable theoretical amount to be assigned by the Veterinary Services to the national laboratory network to ensure payment of the needed analyses.

In addition to quantifying the demand for (number and types) laboratory tests, the main result of the Demand Tool is to enable a comparison between the costs calculated on the basis of international reference prices and the current budget assigned to laboratories at the national level.

A clear breakdown of the actual resources of the laboratory should help to analyse its current sustainability and efficiency. This is possible by adding cell **AB152**²⁷ 'Total Cost: Consumables for National Laboratory' in the Demand Tool, to the cost lines for human and physical resources of the national laboratory network, in the '1. Current & Proposed Budget' sheet of the Calculation Tool (see also III.2 'Use of the Calculation Tool' of this Manual). Taking these costs into account, the national tariff for laboratory tests will later be calculated in the Calculation Tool and compared to the reference price. The difference in cost may be justified by specific political decisions related to national autonomy, decentralisation, or other reasons. However, it provides an initial indication of challenges related to sustainability.

The Demand Tool is the same tool used by experts during the PVS Gap Analysis. If PVS Gap Analysis experts believe that the national laboratory network is relevant for the country and doesn't need major reform, they will copy the results in 'Total Cost: Consumables for National Laboratory' (**AB152** in the original format), into the cost line 'Reagents' of the Cost Estimation Card II-1.B of the PVS Gap Analysis Costing Tool. They will also include salaries in the same Cost Estimation Card as well as other relevant cost lines related to the national laboratory network.

If the PVS Gap Analysis experts believe that the national laboratory network is not able to respond to national needs and that there is a need for PVS Pathway Laboratory Mission, they could input the amount in 'Total Cost: International Laboratory Analysis' into the cost line 'Reagents' of the Cost Estimation Card II-1.A of the PVS Gap Analysis.

²⁴ Including cost of analyses, sample kits, local and international shipment.

²⁵ Including cost of consumables, reagents, sampling kits and local transport.

²⁶ Not already included under the official programmes.

²⁷ This cell reference will vary if the experts delete lines from the final Demand Tool.

Practical tips for use:

- The Demand Tool calculates cost (on the international market and to be conducted in the country) on the basis of ONE TEST = ONE SAMPLE. At this time, the tool is unable to simulate the possibility where ONE SAMPLE is used to conduct SEVERAL TESTS, in which case the sampling costs would be much lower.
 - Consequently, the unit cost for one test automatically includes ONE SAMPLING KIT and ONE TRANSPORT unit cost. For example, if one blood sample is collected to conduct brucellosis/leucosis/IBR tests, the sampling costs calculated using the Demand Tool will be three times that of the true sampling costs, thus largely overestimated.
 - In the countries where a PVS Pathway Laboratory Mission is likely to occur, the national programmes won't usually be of a large enough scale to make a difference on these costs. However, if the experts wish to describe a Scenario that would include millions of samples on which several tests will be run, the Expert should account for and withdraw the overestimated sample collection costs calculated in the Demand Tool from the total cost.
- All prices and costs indicated in all four Tools of the PVS Pathway Laboratory Mission are in EUROS (€) and are strictly indicative. If the Expert Team has more accurate prices available, they are encouraged to insert them in the appropriate fields.
- The Demand Tool is protected by default. Protection should not be removed until data are saved, except if the expert wants to modify the cost of reagents or reference prices.
- For the purposes of this part of the mission, only one Demand Tool should be included in the Final Report for the entire national laboratory network. The Experts should only create and insert additional tables IF it is directly relevant and adds clarification to the report, according to current and prospective demand. It should also be noted in this case that special attention to data entry should be paid in all cases to avoid errors.
 - However, the Demand Tool may be used at several other points in the mission, and several tables can be created as needed, especially to compare different Scenarios of demand (e.g., influence of new disease control programs on future demand) as with the Calculation Tool. This work is prepared by the experts separately, presented to the country team, and then discussed, modified, and validated by the whole group together.
- The following colors, while strictly indicative and not obligatory, will help to guide the Expert Team to the OIE prescribed and alternative tests for each OIE listed disease (if applicable), as described in the *OIE Manual for Diagnostic Tests and Vaccines* as of May 2012.
 - Green: OIE Prescribed Tests
 - Grey: OIE Alternative Tests
 - Pink: Other tests as described in the OIE Manual
 - White: Other Tests
 - Shaded: Not Applicable

How to use the Demand Tool

- Remember the four types of demand included in the PVS Pathway Laboratory Analysis:
 1. Demand related to official programmes of the Veterinary Services described in the PVS Gap Analysis Report,
 2. Demand related to official programmes of the Veterinary Services refined during the Mission,
 3. Demand related to other clients, sectors, or external partners,
 4. Prospective demand for the next 5 years.
- Cost of local transport and international shipping for a parcel of 2 kg should be input into cells **C7** and **C8**, respectively. The results of row 9 of the Demand Tool will provide the inputs for column **(II)** 'Cost of sampling kits and local transport' of each test to be inserted into the '2. Tariff Estimation' sheet of the Calculation Tool.
- The number of tests should be entered into relevant cells for each OIE listed disease, other diseases, food safety, and chemistry.
- The cost by programme (disease) is automatically calculated in columns **(a,b)** and **(a,c)** for consumables and international analysis, respectively.
- The table presents cost of consumables if the analyses are conducted within the national laboratory network **(AB152)** and the cost of international analysis **(cell AC153)** for all programmes and all tests.
- The results appearing in cell **(AB154)** will be used in the '1. Current & Proposed Budget' sheet of the Calculation Tool.
- Row **(n)** 'Total Number of Tests' will provide the data for column **(v)** 'Number of Tests' of the '3. Estimated Cost of Analysis' sheet of the Calculation Tool.
- Data should be saved in a first file with another name, in order to keep a back-up file.
- A copy of the first file should be created and saved with another name in order to make the table presentable for the Final Report to remove unused/not applicable lines.
 - First remove protection of the sheet,
 - Delete all unused lines,
 - Then reset protection.
- This final table will be incorporated into the Final Report (see Report Template). Please provide the original Demand Tool spreadsheet (before modification for insertion into the Final Report), as well as all original Tools, with the Final Report to the OIE for quality control purposes.

Use of the Supply Tool

Before the mission, the Team Leader should send the Supply Tool to the Delegate and the country focal point of the mission with an explanatory note and clear guidance on how to collect data and fill in the Tool (see Annex 1: PVS Pathway Laboratory Mission Explanatory Note and Supply Tool Guidelines for detailed instructions). The purpose of the Supply Tool is to collect all relevant data related to each of the veterinary laboratories in the national laboratory network related to human resources, equipment, infrastructure, quality assurance, and transport, as well as the full array and number of veterinary laboratory analyses that are offered by the national laboratory network.

The Supply Tool includes several sheets: general information, human resources, equipment inventory, equipment management, transport, premises, quality assurance, activities (demand, samples, tests and prospects), and budget information. The last sheet, 'Lists', is protected by a password and should not be filled in, modified or erased as it conducts all internal calculations and distributions and ensures the correct functioning of the Supply Tool.

This Tool establishes automatic ratios for human, physical and financial resources. It assesses if the laboratory analyses offered by the laboratory function meet the demand. Most of the tables (sheets) will be annexed in the Final Report to support findings and proposals described (see Report Template).

Every public veterinary laboratory of the country, being at national or lower levels, regardless of the Competent Authority under which it falls, as well as every private laboratory providing diagnostic or quality control services within the Veterinary Domain, should fill in a copy of this file. Laboratory directors or managers should fill these sheets with the information and data that they have or can collate. The experts will then collect each 'Supply Tool' filled in by each laboratory and analyse and collate the relevant information about the national laboratory network.

2. Strategic elements for organising, managing and financing the veterinary laboratory function of Veterinary Services

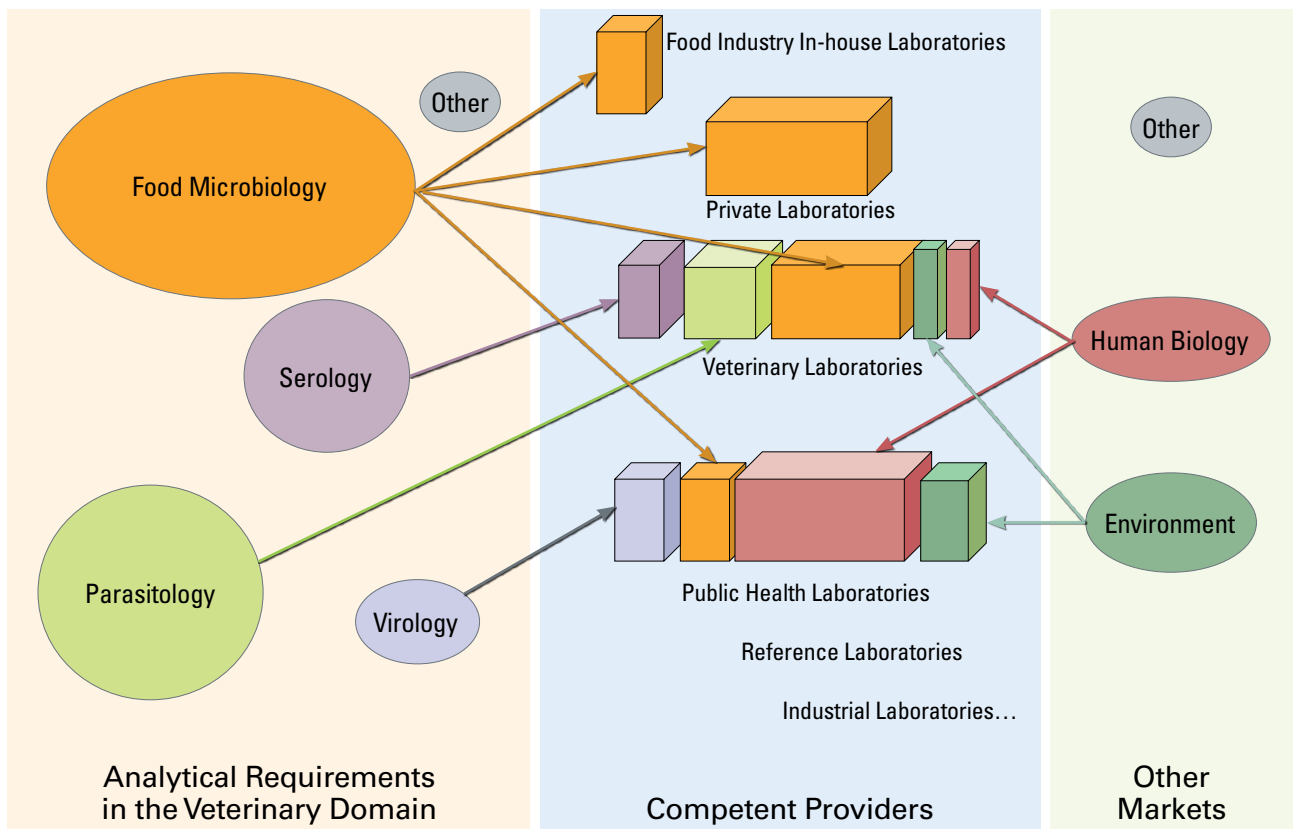
After having analysed the demand for and the current supply of laboratory analyses using the Demand and Supply Tools, the next step of the mission is to build a proposal for a sustainable national veterinary laboratory network that would take into account its constraints and needs. This should be discussed during a brainstorming session with national partners.

Many options are possible. In order to organise the brainstorming session, three main aspects should be taken into consideration: distribution, management and financing options for the laboratory function.

Distribution of the laboratory function

To achieve the objectives of the laboratory function in terms of the Veterinary Services and other demand calls for a wide variety of competencies (e.g., microbiology, chemistry, epidemiology, etc.) and the use of many laboratory techniques. In addition, analyses must meet the client's time-bound needs, meaning that laboratories must be geographically accessible. The problem can be analysed using a three-dimensional matrix, outlined in Diagram 3. Each part of the matrix must be addressed iteratively based on the other two parts through discussion with the country team.

Diagram 3: Providers of the laboratory function in the Veterinary Domain



Functional and technical distribution

Each specialty requires technical facilities, particular competencies and specific methods. At the level of a technical assessment, there is no a priori need to tackle them as a whole or as intangible sets tied to existing structures. The technical units (e.g., serology, virology, etc.) needed to cover all identified demand must therefore be considered on a case-by-case basis. The size of each unit will need to be assessed in accordance with the demand and the volume of activity generated by the clients.

Depending on their size, and hence their potential for autonomy, these units may be distributed as:

- several specialist laboratories;
- a central service or local service of a larger laboratory, **regardless of whether it is an animal health laboratory**; or
- a single activity in a technical unit of a laboratory.

These options are not mutually exclusive. Here we see that the main deciding factor is the **volume of activity** and hence indirectly the size of the market share and the existence of providers, and not the mere fact of being a 'veterinary' laboratory. Any competent laboratory can absorb a veterinary activity: this is common with environmental analyses (e.g., water, waste water, etc.) or analyses to measure the quality of products (e.g., food controls, residues, etc.).

Conversely, a veterinary laboratory can absorb non-veterinary analyses, such as plant pathology or human samples. It follows that veterinary domain needs can be covered by different laboratories belonging to separate and often independent entities about which an external donor or technical organisation conducting an expert evaluation of the veterinary laboratory may have little knowledge, interest, or control. Such competitive situations should not be underestimated or understudied.

Geographical distribution

This approach to the market makes sense only if the laboratory is accessible to the client. Clients need contact with the laboratory and only have access to a local laboratory and in some cases, have little or no access to a central laboratory. Similarly, some samples are not easy to transport, such as animal carcasses. In such situations, the geographic location of laboratory analysis providers should be adapted by reproducing the above rationale as many times as necessary (but only as many times as rational), based on parameters such as accessibility of the laboratory and transportability of samples.

These parameters vary widely depending on transport infrastructure, client mobility, and type of samples, among others. They must be addressed in a PVS Pathway Laboratory Mission because of their impact on the number of laboratories required and the breadth of the national laboratory network, their inter-relatedness and the total cost of the implementation plan. Moreover, in many cases it is unnecessary to radically multiply the number of fully-functioning laboratories and sometimes more sensible to keep only specimen collection centres in the field, which are associated with a small number of specialist laboratories at district or provincial level.

However, it should not be forgotten that difficulty in accessing the laboratory is a major cause of loss of epidemiological information, which represents a risk to accurate and timely diagnosis and analysis. The assessment of this risk may warrant investment in mobile laboratories or maintaining low-activity facilities operating at a loss for monitoring purposes only.

Political constraints

Apart from the above technical elements, political choices can have a large impact on the two previous points. They influence both the distribution of competencies within laboratories and their geographical distribution.

All combinations are possible between the following two Scenarios:

1. the veterinary laboratory function is in the public domain;
2. the laboratory function can be carried out by any competent provider.

In Scenario 1, public Veterinary Services develop their own laboratories and, where appropriate, can provide services outside the regulated sphere. Choices regarding the geographic distribution and distribution of competencies are not usually based on an economic study but on a qualitative approach transposed into regulations. This is the case with regional laboratory networks, for instance. These choices constitute a constraint on any expert evaluation because the issue is not so much to establish a rational strategy as to support what already exists.

In Scenario 2, official Veterinary Services are only interested in test results as decision-making elements and can procure laboratory services from any accredited provider. Except in special cases, they do not develop public veterinary laboratories. In this situation, it is the market that dictates the geographic distribution and distribution of competencies.

Between the two Scenarios, all solutions are possible and may be discussed with the expert providing the most comprehensive and objective analysis possible. Again, these Scenarios should not be regarded as an indivisible body of 'veterinary analyses' but on a subject-by-subject basis: for example, the position taken for food safety analysis may differ from that for animal health.

Nonetheless –and this is a strategic issue– the choice should be clear in the Final Report. A response regarding the optimal national laboratory network is a priority in the PVS Pathway Laboratory Mission.

Laboratory management

An evolving market

The market has a major influence on any system, but the market itself is sensitive to different parameters. When an action or an animal health standard is encouraged or made mandatory, the market adapts.

For example:

- choosing enzyme-linked immunosorbent assay (ELISA) over the buffered antigen test (BAT) as the method for brucellosis screening changes the cost of the operation by a factor of around 1 to 5;
- introducing mandatory microbiological quality control of food creates a market for quality control commensurate with the regulatory requirements and leads to the emergence of private laboratories and the development of in-house company laboratories;
- developing residue control plans creates a specific demand;
- establishing regulations for accreditation for the execution of public procurement contracts focuses competencies on laboratories capable of complying with the rules.

These types of actions should be envisaged as strategic instruments because they modulate the market and hence the potential for supply of and demand for the laboratory function and its activities. They

enable laboratories to exist and in exchange provide monitoring or diagnostic functions that would be financially unsustainable in isolation.

Public/private distribution

The status of laboratories has an impact on meeting demand for laboratory analysis because it determines how the supply of services is organised. The political choice regarding the public/private balance (see III.2 'Political Constraints') is very important for both the distribution of laboratories and the efficiency of public laboratories.

In an essentially public system, only the demand corresponding to the laboratory development policy can be met. There is 'top-down' control, where the administration decides what is available to actors. Where the quality or availability of such laboratories is poor, demand is unmet and this hampers actors in the veterinary domain. The budgetary problems of many of these laboratories greatly reduce their activity and create a vicious cycle:

reduced appropriations → deteriorating supply → reduced demand

This cycle can be exacerbated by administrative management methods based on budget accounting rather than the pursuit of economic efficiency.

In an essentially private system, it is the cost-effectiveness of an analysis that governs its availability. There is little room for public-interest monitoring or diagnostic functions (e.g., rabies, foot and mouth disease, etc.).

The PVS Pathway Laboratory Mission must therefore help to determine the public/private balance and distribution that best meets the requirements of the veterinary domain, whether or not they are financially viable, including requirements relating to epidemiological surveillance functions.

Management

Private laboratories are free to choose their own management method, based on profitability.

Influencing factors are compliance with rules and standards, competition, and access to both public procurement and the creation of markets (e.g., quality control, certification, etc.) arising from legal obligations.

With public laboratories, the management method is a key factor. There are three main types²⁸:

1. Unit in an administration

The laboratory is part of the organisational chart of a Ministry or department. It is subject to hierarchical control and common budgetary rules and does not usually have its own budget. This is a very 'comfortable' situation in times of budgetary ease because the main objective is expertise and there is little need to pursue efficiency.

However, the situation is paralysing in times of budget cuts because there is no room for manoeuvre. Budget cuts affecting the consistency of analytical lines, consumables and maintenance, in particular, are the starting point of the vicious cycle described in Section III.2 'Public/private distribution'. This system is useful for small laboratories focusing on public procurement because it is economical in terms of administrative services.

²⁸ Terms may vary from one country to another.

2. Public institution

The principle is that, while subject to government supervision, the structure enjoys management autonomy. Within its mandate, it can take initiatives and develop activities. There are different types of public institutions (i.e., administrative or commercial) with different types of resources and rules for using them.

Administrative institutions operate on a state budget and are subject to public accounting rules –including the transfer of revenues to the Treasury– even if they help to balance the budget. This status is quite satisfactory for research, for example, and does not require ‘profitability’ because any deficit is covered by the state budget.

Commercial institutions use private accounting. Public participation is pre-determined and the budget must be balanced for each activity. Employees are not necessarily civil servants. Although this status is more dynamic, it requires a management system determined predominantly by financial efficiency.

While public institutions that confer a degree of autonomy are more likely to be dynamic, they generate major overheads that are justified only by significant volumes of activity. There are instances where such institutions may be less productive than units in a public administration, with 95% overheads and 5% productive expenditure, although is often the fault of oversizing rather than the fault of the system itself.

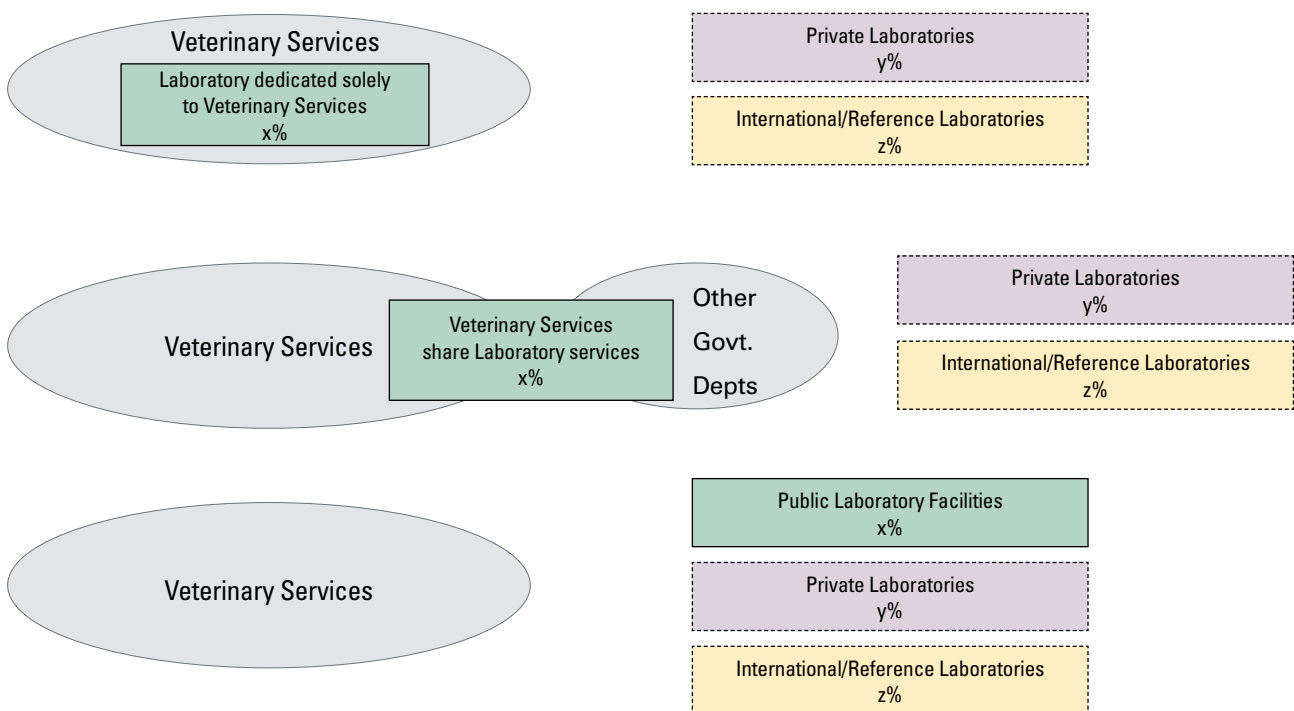
3. Semi-public company

These are companies obeying market rules in which the state has a shareholding. They have an obligation of financial balance and may be interested in profitability, but the corporate objective may be public service. Few laboratories are semi-public companies.

Implications

The above-mentioned choices can lead the laboratory function to be positioned in a variety of ways.

Diagram 4: Range of options for positioning the veterinary laboratory function



Each option represents a compromise between the availability of an analysis and its quality/price ratio. There is no single solution and the PVS Pathway Laboratory Mission expertise is also intended to provide guidelines that should take into account the parameters described earlier in the country's context. In any event, the management method is very important and, wherever the volume of activity permits, precedence should be given to technical autonomy.

If the private network makes available all services at any location in the country, in theory it would be possible to address the problem through a public service delegation. As this is rarely the case, public structures need to develop a sufficient volume of activity reserved for the veterinary national laboratory network to keep them in operation.

Examples

A multipurpose public central veterinary laboratory

This type of laboratory handles all requests from the various sectors including food safety and animal health. There are no private laboratories and no market sharing of expertise with other laboratories. It restricts demand, which has no other alternative. This is an option for a small country with a limited market for laboratory analysis.

A public central veterinary laboratory divided into regional laboratories

This is the same as the above system but for a larger territory and market, warranting the creation of regional units.

- The central laboratory is multipurpose and acts as a reference laboratory. The regional units reproduce the central organisation. This is a highly administrative solution that is intended to demonstrate regional equality (i.e., political choice), but fails to take into account the geographic variability of markets and often results in duplication, inappropriate sizing and local structures operating at a heavy loss.
- Under another mode of organisation, regional units are created not to 'reproduce' small central laboratories but to meet the specific requirements of the local market. They are more appropriately sized and may be specialised. This is closer to a network operation controlled by the central laboratory. Where appropriate, specialist regional units may act as reference laboratories.

A group of accredited laboratories

In integrated public systems, the client, contracted party and comptroller come under the same authority. Formalisation of rules is not usually a priority; however, when third parties need to be involved, it becomes essential and requires accreditation systems to be established. To be able to fulfil a request, a laboratory must meet predetermined mandatory requirements. These requirements, such as accreditation, apply equally to private and public laboratories to avoid distorting competition. Under this scheme there is no longer a public monopoly and private laboratories are free to develop in areas where demand is sufficient. Provided they have adequate autonomy and meet accreditation requirements, veterinary public laboratories can coexist with other public laboratories²⁹ and with the private sector.

This situation does not fully meet the objective of controlling the veterinary domain because of fragmentation of results, although legislation can be enacted that requires the transmission of results of priority diseases to the Veterinary Services and ensures implementation as is evoked in the next example.

²⁹ Such as in a decentralised system where laboratories are independent and accredited.

A network of accredited laboratories

By supplementing the previous scheme in the conditions for accreditation for example with legal obligations regarding communication and data transmission to the Competent Authority, and legal obligations regarding the coordination of certain work, it is possible to meet sovereign objectives.

Financing and funding arrangements

The cost of analyses depends on the choice of facilities (i.e., number and distribution of laboratories), management models (e.g., administration, public institution, private, etc.) and their effectiveness. When related to the planned activity, these parameters make it possible to estimate the total cost of analyses and to verify the feasibility and viability of a proposal.

While it is up to the experts not to overlook this point, it is not critical to the final choice. Indeed, financial returns are not the main objective in the case of sovereign duties, and the choice of analytical landscape will be based primarily on economic efficiency and political choices. Nevertheless, **knowledge of the true cost of analysis is important because it enables consistent and effective capital and operating budgets to be determined.**

Consistency is paramount: for example, a capital investment from external donor projects without operating resources will inevitably lead to loss of equipment and expertise or collapse of the host structure.

It is necessary to know these real costs in order to ensure that they are fully covered. For public laboratories, this coverage is provided by:

- the public budget, composed of:
 - property,
 - human resources and staffing,
 - utilities, in some cases shared (e.g., energy, water, telephone, gas, etc.),
 - the structure's regular budget allocated to budget headings or covered by a global grant,
 - exceptional investments, such as construction or renovation.
- revenues from activities
- external investments (e.g., projects, donors, etc.)

The three sources must replenish the budget while maintaining consistency and, in particular, **care must be taken to ensure that high-volume external investments do not drain the operating budgets by diverting resources to the special interests, external priorities, or maintenance of expensive equipment and infrastructure that are ill-adapted to market demand.**

The public budget should be covered by setting adequate prices for analysis and, where this is not possible, by establishing subsidies for the end product to which the laboratory analysis contributes (e.g., animal health inspection fee, fee per ton of meat or milk produced, etc.).

In all cases, the level of funding and the way in which it is covered must be determined when making strategic choices.

Use of the Calculation Tool

The Calculation Tool should be used to simulate the different Scenarios and options depending on the distribution of the budget (see Sections III.2 'Political Constraints' and III.3 'Costing of the veterinary laboratory network and functions' of this Manual). It highlights the total cost of analysis, possible profits or loss, and required subsidies. It also helps to establish the tariff and to calculate the staff numbers necessary to carry out the laboratory analyses. This tool includes four sheets described in detail below. The four sheets should be filled in one by one in the order presented.

Current and Proposed Budget: This sheet should be filled in first. It allows an examination of the current and proposed budgets for the national laboratory network (see III.3 'Use of the Current and Proposed Budget sheet of the Calculation Tool' of this Manual for detailed instructions).

Tariff estimation: The second sheet allows a calculation and estimation of national proposed tariffs for laboratory analyses.

The estimation of a national tariff could be done in two ways:

1. By introducing elements of the total cost of analysis based on known local costs from invoices or other documentation:
 - a. of laboratory staff compared with a reference/developed country
 - b. of equipment comparing FOB and CIF values from invoices or usual known cost of transport and insurance of freight
 - c. of reagents from invoices, or enter one approximate cost of reagents. This will signify that the calculation should be based on this approximate cost for all tests.
2. By introducing tariffs of other laboratories³⁰ in the country. If the tariffs are from a private laboratory, they will have taken into account the real costs of analysis (e.g., staff, equipment, reagents, sampling kits, local transport, consumables, etc.).

Both methods can be applied –by filling in all pale blue cells– to conduct the most complete market analysis of the optimal tariff for each test. However, if not all information is available, the Expert Team should decide, given the information that they are provided and its quality, which method to use for the estimation of the proposed tariff for laboratory analysis.

³⁰ For instance human medicine, preferably private.

Practical tips for use

- All prices and costs indicated in all four Tools of the PVS Pathway Laboratory Mission are in EUROS (€).
- This sheet estimates a national tariff for the major tests offered by the national laboratory network, calculated in column **(p)** for method #1 or column **(r)** for method #2. The Expert Team, in discussion with the country team, should take into account the market constraints in order to advise the country team on the optimal tariffs to choose for each test, entered into column **(s)**.
- As this sheet estimates tariffs for only a small sampling of major analyses that any laboratory network can offer, the laboratory leadership could and should use this exercise and expertise as a starting point for a larger undertaking and analysis of its price list for the entirety of its services and analyses.
- The Calculation tool will produce an error if a decimal point is used instead of a comma to indicate a fraction of a whole number. The expert must enter a comma instead of decimal point in order for the equations to work correctly. For example, the expert should enter '1,43' instead of '1.43' in cell **(c)**.
- Free on Board (FOB) refers to the cost of shipping when the seller pays for transportation of goods to the port of shipment plus the loading costs. It doesn't include the cost of marine freight transportation, insurance, unloading and transportation costs from the arrival port to final destination.
- Cost, insurance and freight (CIF) refers to the cost of shipping when the seller pays the costs, insurance and freight to bring the goods to the port of destination.
- During Days 6 and 7, the Expert Team uses the Calculation Tool to develop the different Scenarios and options to present to the country team on Day 8. The Calculation Tool is then modified actively during discussions with the country team of each scenario and option to provide real-time answers and possibilities. This work is prepared by the experts separately, presented to the country team and then discussed, modified, and validated by the whole group together.
- For the purposes of this mission, only the final Calculation Tool spreadsheet should be retained for the Final Report. Additional tables should only be included if it is directly relevant and necessary to the Final Report.

Table 3: Tariff Estimation (Sheet n°2) of Calculation Tool

2. Tariff Estimation for Analysis in the National Veterinary Laboratory															
Type of Analysis	Proposed Standard Relative Value in points (f)	Proposed International Reference Price in € (g)	Proposed Standard Reagent Cost in € (h)	Proposed Standard Share of Reagents Cost: (i)	Proposed Standard Share of Cost: Equipment (j)	Proposed Standard Share of Cost: Staff (k)	Costs of Sampling Kits & Local Transport (l)	Total Estimated International Reference Price in € (m) = g + i	Examples of Reagent Costs in the country in € (n)	Estimated Reagent Cost in the country in € (o)	Proposed Tariff in € (p)	Examples of Tariffs in other Laboratories in € or points (q)	Proposed Tariff in € (r)	Chosen National Tariff for Tests in € (s)	National Tariff to apply in national or chosen currency (t) = c * s
	(a) Monthly salary of laboratory staff in a reference country in €	3 000					(c) Exchange rate of 1 € to national or chosen currency		2 000					100	
	(b) Monthly salary of similar laboratory staff in the country in €	1 400												115	
Agent Identification															
Parasitology	2,5	15	2	0,20	0,10	0,70	1,40	16,40	2,00	2	11,03		0,00	11,00	22 000,00
Bacteriology	15	25	18	0,30	0,20	0,50	1,40	26,40	18,00	18	20,48		0,00	20,50	41 000,00
Virology	25	50	30	0,30	0,25	0,45	1,40	51,40		30	41,28		0,00	41,50	83 000,00
PCR or RTPCR	15	35	20	0,40	0,40	0,20	1,40	36,40		20	34,77		0,00	35,00	70 000,00
Serology															
VN	10	50	30	0,30	0,25	0,45	1,00	51,00		30	40,88		0,00	41,00	82 000,00
IPMA	5	6	4	0,50	0,20	0,30	1,00	7,00		4	6,22		0,00	6,50	13 000,00
ELISA	5	6	4	0,50	0,20	0,30	1,00	7,00		4	6,22		0,00	6,50	13 000,00
CF	2,5	6	3	0,30	0,10	0,60	1,00	7,00		3	5,17		0,00	5,50	11 000,00
AGID	2	4	2	0,30	0,10	0,60	1,00	5,00		2	3,78		0,00	4,00	8 000,00
IFA	5	10	6	0,30	0,20	0,50	1,00	11,00		6	8,63		0,00	9,00	18 000,00
BBAT	0,3	1	0,6	0,30	0,10	0,60	1,00	2,00		0,6	1,70		0,00	1,70	3 400,00
Agg	1	2	1,2	0,30	0,10	0,60	1,00	3,00		1,2	2,39		0,00	2,50	5 000,00
PRN/CAT	1	2	1,2	0,30	0,10	0,60	1,00	3,00		1,2	2,39		0,00	2,50	5 000,00
HI	1,5	6	3,6	0,30	0,10	0,60	1,00	7,00		3,6	5,17		0,00	5,50	11 000,00
MAT	15	20	15	0,60	0,20	0,20	1,00	21,00		15	19,47		0,00	20,00	40 000,00
FPA	5	5	3	0,30	0,20	0,50	1,00	6,00		3	4,82		0,00	5,00	10 000,00
NPLA	5	6	3,6	0,50	0,20	0,30	1,00	7,00		3,6	6,22		0,00	6,50	13 000,00
gamma interferon test	10	10	6	0,60	0,20	0,20	1,00	11,00		6	10,23		0,00	10,50	21 000,00
Other Tests															
Anatomical Pathology	10	35	4	0,10	0,10	0,80	3,50	38,50		4	24,09		0,00	24,50	49 000,00
HP/LC	35	40	16	0,40	0,30	0,30	3,50	43,50		16	38,90		0,00	39,00	78 000,00
CPG	35	55	22	0,40	0,30	0,30	3,50	58,50		22	52,18		0,00	52,50	105 000,00
Spectrophotometry	30	30	12	0,10	0,60	0,30	3,50	33,50		12	31,40		0,00	31,50	63 000,00
Food Microbiology Standard 5 Parameters	40	40	24	0,30	0,10	0,60	3,50	43,50		24	31,30		0,00	31,50	63 000,00

How to use the Tariff Estimation sheet of the Calculation Tool

To calculate the tariff using method #1:

- Please fill in the monthly salary plus fringe benefits of laboratory staff in a reference country of the expert's choice in euros in **(a)**. Then, fill in the monthly salary plus fringe benefits of similar laboratory staff in the country in euros in **(b)**.
- Please fill in the exchange rate for one euro to the national or other reference currency in **(c)**.
- Please fill in the **(d)** FOB and **(e)** CIF costs in the 'Example of comparative cost of laboratory equipment' field. These values could be found on the invoices of large laboratory equipment (e.g., PCR machine).
- The information provided in columns **(f-k)** are hypothetical proposals based on experience and expertise. The figures are protected and therefore cannot be modified in the table.
 - Column **(f)**, 'Proposed standard relative value in points', indicates the relative value of the main veterinary analyses in terms of a number of points per test. Knowing the price of one of them is sufficient to calculate the value of one point and therefore the value of all other tests and is used to calculate costs in the case of incomplete information.
 - Column **(g)**, 'Proposed international reference price in euros', indicates the cost if the country were to ask an international laboratory to test the sample.
 - Column **(h)**, 'Proposed standard reagents cost in euros', indicates the cost if the country were to test the sample itself.
 - Columns **(i-k)**, 'Proposed standard reagent [column **(i)**], equipment [column **(j)**], and staff [column **(k)**], indicate the share (percentage) of the international reference price of analysis, respectively.
- Row 9 of the DemandTool provides the inputs for column **(l)** 'Cost of sampling kits and local transport' of each test.
- Column **(m)** automatically calculates the Total Estimated International Reference Price by adding **(g)** and **(l)**.
- Column **(n)** must contain a value in order for the automatic calculations in columns **(o)** and **(p)** to function correctly.
 - If no specific information is available, copy the first cell of column **(h)** into column **(n)**. It will automatically establish the local price based on the international reference price.
 - Or, choose one approximate cost of reagents for one test. The automatic calculations will determine more accurate figures for the cost of reagents for other tests using relative values and the proposed cost in column **(h)**.
- Column **(o)** automatically calculates the cost of reagents in the country for all tests, even if information for only one test is entered, using relative values of the cost entered in column **(n)** and the proposed cost in column **(h)**.
- Column **(p)** calculates the proposed tariff by test based on the information provided during the PVS Pathway Laboratory Mission.
- Column **(s)** is the final tariff in euros retained by the country team based on the calculations conducted, the expertise of the Expert Team, and external market and political factors.
- Column **(t)** provides the final tariff in local or another reference currency.

To calculate the tariff using method #2:

- Please fill in the exchange rate for one euro to the national or other reference currency in **(c)**.
- The information provided in columns **(f-k)** are hypothetical proposals based on experience and expertise. The figures are protected and therefore cannot be modified in the table.
 - Column **(f)**, 'Proposed standard relative value in points', indicates the relative value of the main veterinary analyses in terms of a number of points per test. Knowing the price of one of them is sufficient to calculate the value of one point and therefore the value of all other tests and is used to calculate cost in the case of incomplete information.
 - Column **(g)**, 'Proposed international reference price in euros', indicates the cost if the country were to ask an international laboratory to test the sample.
 - Column **(h)**, 'Proposed standard reagents cost in euros', indicates the cost if the country were to test the sample itself.
 - Columns **(i-k)**, 'Proposed standard reagent [column **(i)**], equipment [column **(j)**], and staff (column **(k)**), indicate the share (percentage) of the international reference price of analysis, respectively.
- Row 9 of the DemandTool provides the inputs for column **(l)** 'Cost of sampling kits and local transport' of each test.
- Column **(m)** automatically calculates the Total Estimated International Reference Price by adding **(g)** and **(l)**.
- Please enter the tariff of a particular test in the country in column **(q)**, as this information will help to calculate the tariffs of all tests in column **(r)** using relative values.
 - In column **(q)**, the Expert Team is requested to insert examples of tariffs used in other labs in the country (in either currency or points). It is important to note that the tariff for a laboratory test charged to the Veterinary Services is often subsidised and therefore underestimated. The Expert Team should first verify that the tariff given by the country team reflect the actual price of the analysis.
- Column **(s)** is the final tariff in euros retained by the country team based on the calculations conducted, the expertise of the Expert Team, and external market and political factors.
- Column **(t)** provides the final tariff in local or another reference currency.

Estimated Cost of Analysis: The third sheet allows an estimation of the real cost of analysis taking into account the volume of activity, capital, staff and operating costs of the laboratory. A smaller volume of activity for a test means that each test will cost more to conduct based on the true costs of the national laboratory network and inversely, larger volume will decrease the cost of each test.

Table 4: Estimation of Cost (Sheet n°3) of Calculation Tool

3. Estimated Cost of Veterinary Laboratory Analysis										
Capital Investment 236 525										
Staff 1 318 000										
Other Costs (Excluding Reagents & External Services) 469 500										
Annual Budget (Excluding Reagents & External Services) 2 024 025										
Value of 1 Point (Excluding Reagents) 4,39										
Type of Analysis	Proposed Standard Relative Value in points (f)	Estimated Reagent Cost in the country in € (o)	Cost of Sampling Kits & Local Transport in € (l)	Total Estimated Reference International Price in € (m)	Number of Tests (v)	Number of Points (w) = v * f	Estimated Test Cost in € (x) = o + l + (f * u)	Possible Income Generated under Full Recovery (y) = v * x	% of Economic Activity	% of Volume of Activity
Agent Identification										
Parasitology	2,5	2	1,40	16,40	300	750	14,37	4 311	0,16%	0,16%
Bacteriology	15	18	1,40	26,40	1 200	18 000	85,22	102 266	3,86%	3,90%
Virology	25	30	1,40	51,40	3 000	75 000	141,10	423 310	15,99%	16,26%
PCR or RTPCR	15	20	1,40	36,40	19 000	285 000	87,22	1 657 217	62,58%	61,79%
Serology										
VN	10	30	1,00	51,00	500	5 000	74,88	37 441	1,41%	1,08%
IPMA	5	4	1,00	7,00		0	26,94	-	0,00%	0,00%
ELISA	5	4	1,00	7,00	13 000	65 000	26,94	350 228	13,23%	14,09%
CF	2,5	3	1,00	7,00	300	750	14,97	4 491	0,17%	0,16%
AGID	2	2	1,00	5,00	1 000	2 000	11,78	11 776	0,44%	0,43%
IFA	5	6	1,00	11,00	1 200	6 000	28,94	34 729	1,31%	1,30%
BBAT	0,3	0,6	1,00	2,00	2 000	600	2,92	5 833	0,22%	0,13%
Agg	1	1,2	1,00	3,00		0	6,59	-	0,00%	0,00%
PRN/CAT	1	1,2	1,00	3,00		0	6,59	-	0,00%	0,00%
HI	1,5	3,6	1,00	7,00	100	150	11,18	1 118	0,04%	0,03%
MAT	15	15	1,00	21,00		0	81,82	-	0,00%	0,00%
FPA	5	3	1,00	6,00		0	25,94	-	0,00%	0,00%
NPLA	5	3,6	1,00	7,00		0	26,54	-	0,00%	0,00%
gamma interferon test	10	6	1,00	11,00	300	3 000	50,88	15 264	0,58%	0,65%
Other Tests										
Anatomical Pathology	10	4	3,50	38,50		0	51,38	-	0,00%	0,00%
HPPLC	35	16	3,50	43,50		0	173,08	-	0,00%	0,00%
CPG	35	22	3,50	58,50		0	179,08	-	0,00%	0,00%
Spectrophotometry	30	12	3,50	33,50		0	147,14	-	0,00%	0,00%
Food Microbiology Standard 5 Parameters	40	24	3,50	43,50		0	203,03	-	0,00%	0,00%
Totals					41 900	461 250		2 647 985	100,00%	100,00%

Practical tips for use

- All prices and costs indicated in all four Tools of the PVS Pathway Laboratory Mission are in EUROS (€).
- Cells **H3**, **H4**, and **H5** are extracted from '1. Current & Proposed Budget' sheet of the Calculation Tool.
- Reagents are not included in the calculation of cell **H7** because they are linked to the number of tests conducted and are handled separately in column **(o)**.
- Column **(f)**, 'Proposed standard relative value in points', indicates the relative value of the main veterinary analyses in terms of a number of points per test. Knowing the price of one of them is sufficient to calculate the value of one point and therefore the value of all other tests and is used to calculate cost in the case of incomplete information.
- Columns **(o)**, **(l)**, and **(m)** are extracted from '2. Tariff Estimation' sheet of the Calculation Tool.
- Columns **(j-k)** enable the country team to better understand which tests might create the most revenue if full cost recovery is applied (% of economic activity) and which tests represent the biggest workload (% of volume of activity) and therefore the highest revenue potential and need for streamlining and efficiency.

How to use the Estimated Cost of Analysis sheet of the Calculation Tool

- The only data that the Expert Team needs to enter in this sheet is column **(v)**. All other data is extracted automatically from the '1. Current & Proposed Budget' and '2. Tariff Estimation' sheets of the Calculation Tool.
- Row **(n)** 'Total Number of Tests' from the Demand Tool will provide the data for column **(v)** 'Number of Tests' of this sheet of the Calculation Tool.
- Cell **(u)** calculates the value of a point (excluding reagents) of a test using relative values. This value is calculated by dividing the annual budget (capital investments, staff, and other costs except reagents and external services) by the total number of points in column **(w)**.
- Column **(w)** calculates the number of points based on the relative values in column **(f)** and the number of tests in column **(v)**.
- Column **(x)** calculates the estimated cost of each test in euros **based on the volume of activity of the national laboratory network** –or the number of tests that were calculated in the Demand Tool– and the annual budget (capital investments, staff, and other costs except reagents and external services).
- Column **(y)** is the possible income generated in the case of full cost recovery, or the fee charged in its entirety to the client, without subsidies funded by the government.
 - Column **(j)** provides the percentage of economic activity of each test compared to the total economic activity of the national laboratory network.
 - Column **(k)** provides the percentage of the volume of activity of each test compared to the total volume of activity of the laboratory.

Estimated Staff and Finances: The fourth sheet estimates automatically the required human resources based on the number of tests, and the financial balance between real costs and proposed tariffs. It allows simulating different programmes and budgetary and financial options. This sheet is completely protected, as there is no data to enter.

It should be noted that the approach taken by the PVS Pathway Laboratory Mission is global in nature, meaning that the entire network's volume of activity determines the total required resources as well as the profit created or subsidies needed. As only one Calculation Tool is filled out for the national laboratory network during this mission due to time constraints, the PVS Pathway Laboratory Mission does not give advice on *individual* laboratories, geographical placement, and staffing optimisation. A comprehensive approach involving the in-depth assessment of the issues handled during this Mission, laboratory by laboratory, may require additional expertise and time and is outside of the scope of this Mission.

Practical tips

- All prices and costs indicated in all four Tools of the PVS Pathway Laboratory Mission are in EUROS (€).
- Column **(f)** is the proposed standard relative value in points indicates the relative value of the main veterinary analyses in terms of a number of points per test. Knowing the price of one of them is sufficient to calculate the value of one point and therefore the value of all other tests and is used to calculate cost in the case of incomplete information.
- Columns **(w)**, **(v)**, **(x)**, **(m)** and **(s)** are extracted from '2. Tariff Estimation' and '3. Estimated Cost of Analysis' of the Calculation Tool.
- Column **(z)** estimates the number of laboratory technicians required based on its volume of activity (one technician for 30,000 relative value points).
- Column **(aa)** estimates the number of laboratory managers required to supervise appropriately the national laboratory network based on its volume of activity (one manager for five (5) technicians).
- Column **(bb)** estimates the number of support staff needed for the national laboratory network based on its volume of activity (one support staff for five technicians and for three managers).
- Column **(cc)** calculates the benefit (+) created or subsidies (-) needed for each test.
- Column **(dd)** calculates the total benefit (+) created or subsidies (-) needed.

Table 5: Estimated Staff and Finances (sheet n°4) of the Calculation Tool

4. Estimated Staff & Finances											
Laboratory Tests	Proposed Standard Relative Value in points (f)	Number of Points (Standard Relative Value) (w)	Number of Tests (v)	Estimated Number of Laboratory Technicians (z) = w / 30000	Estimated Number of Laboratory Managers (aa) = z / 5	Estimated Number of Support Staff (bb) = (z / 5) + (aa / 3)	Estimated Test Cost in € (x)	Total Estimated Reference International Price in € (m)	Chosen National Tariff for Tests in € (s)	Benefit (+) or Subsidies (-) per Test (cc) = s - x	Total Benefit (+) or Subsidies (-) (dd) = cc * v
Agent Identification											
Parasitology	2,5	750	300	0,03	0,01	0,01	14,37	16,40	11	- 3,37	- 1 011
Bacteriology	15	18 000	1 200	0,60	0,12	0,16	85,22	26,40	20,5	- 64,72	- 77 666
Virology	25	75 000	3 000	2,50	0,50	0,67	141,10	51,40	41,5	- 99,60	- 298 810
PCR or RTPCR	15	285 000	19 000	9,50	1,90	2,53	87,22	36,40	35	- 52,22	- 992 217
Serology											
VN	10	5 000	500	0,17	0,03	0,04	74,88	51,00	6,5	- 68,38	- 34 191
IPMA	5	0	0	0,00	0,00	0,00	26,94	7,00	6,5	- 20,44	-
ELISA	5	65 000	13 000	2,17	0,43	0,58	26,94	7,00	5,5	- 21,44	- 278 728
CF	2,5	750	300	0,03	0,01	0,01	14,97	7,00	4	- 10,97	- 3 291
AGID	2	2 000	1 000	0,07	0,01	0,02	11,78	5,00	9	- 2,78	- 2 776
IFA	5	6 000	1 200	0,20	0,04	0,05	28,94	11,00	1,7	- 27,24	- 32 689
BBAT	0,3	600	2 000	0,02	0,00	0,01	2,92	2,00	2,5	- 0,42	- 833
Agg	1	0	0	0,00	0,00	0,00	6,59	3,00	2,5	- 4,09	-
PRN/CAT	1	0	0	0,00	0,00	0,00	6,59	3,00	5,5	- 1,09	-
HI	1,5	150	100	0,01	0,00	0,00	11,18	7,00	20	8,82	882
MAT	15	0	0	0,00	0,00	0,00	81,82	21,00	5	- 76,82	-
FPA	5	0	0	0,00	0,00	0,00	25,94	6,00	6,5	- 19,44	-
NPLA	5	0	0	0,00	0,00	0,00	26,54	7,00	10,50	- 16,04	-
gamma interferon test	10	3 000	300	0,10	0,02	0,03	50,88	11,00	10,5	- 40,38	- 12 114
Other Tests											
Anatomical Pathology	10	0	0	0,00	0,00	0,00	51,38	38,50	24,5	- 26,88	-
HPLC	35	0	0	0,00	0,00	0,00	173,08	43,50	39	- 134,08	-
CPG	35	0	0	0,00	0,00	0,00	179,08	58,50	52,5	- 126,58	-
Spectrophotometry	30	0	0	0,00	0,00	0,00	147,14	33,50	31,5	- 115,64	-
Food Microbiology Standard 5 Parameters	40	0	0	0,00	0,00	0,00	203,03	43,50	31,5	- 171,53	-
Totals		461 250	41 900	15,38	3,08	4,10					- 1 733 445

3. Costing of the veterinary laboratory network and functions

General principle for optimisation of budget

This budget will go into more detail and be more precise than the PVS Gap Analysis Costing Tool for laboratories that was issued in the PVS Gap Analysis Report.

There is no single, standardised way of estimating costs because the parameters are numerous and varied. Nevertheless it is possible to follow a logical sequence.

After using the data and results of the Demand and Supply Tools to determine the need for laboratory analyses, they can be distributed into functions or analytical lines. The different Tools provide all the elements for costing laboratory analyses, physical, human and operational costs using reference prices and variables such as the cost of reagents, staff, equipment and infrastructure. An examination of the real cost of laboratory analyses is estimated using relative values of tests (using 'points'), in the Calculation Tool.

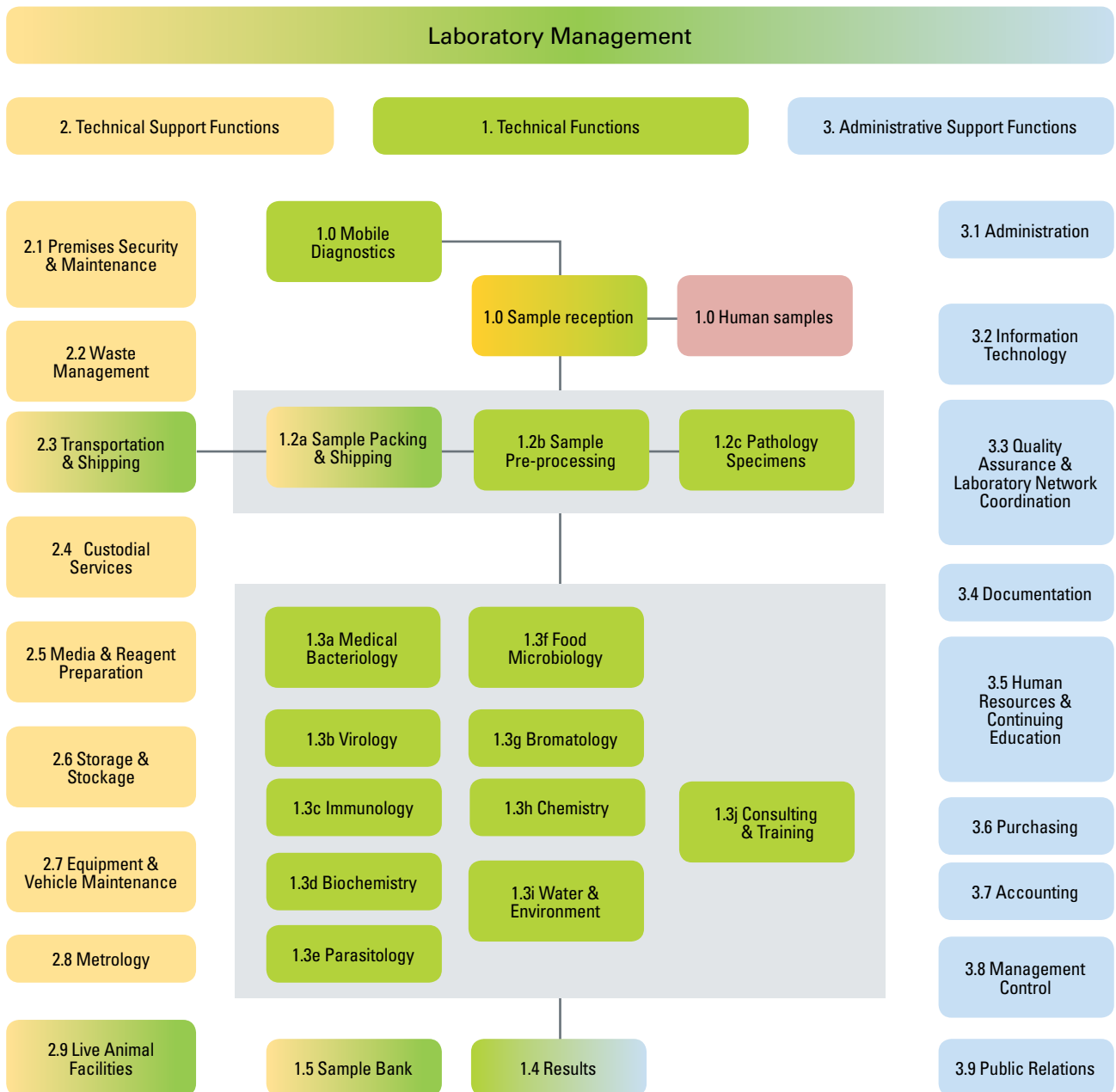
Functions

Different functions can be identified in a diagnostic laboratory, some of which are highly specialised and others cross-cutting. So, while a parasitology laboratory might be autonomous or free-standing, it may still require administrative and technical support functions.

The specialisation of a function and the need to supplement it with dedicated support functions will depend mainly on its size. In principle, an autonomous, appropriately-sized laboratory is usually more efficient than a large structure that slows down decision-making and initiative. Therefore, a small parasitology laboratory can be envisaged as part of the 'anatomical pathology' function because it can be housed in the same room. This removes the need for a specialised Department Head or a dedicated secretary.

However, if the parasitology laboratory performs thousands of analyses, it will require special premises, it will house several technicians that need to be supervised by a Department Head and, if the administrative burden is heavy, it would be logical to attach them directly to the Department Head. **The criterion of volume of activity is therefore important in assessing whether or not to individualise or even duplicate a function, or instead to attach it to a larger unit.** The main functions are summarised in Diagram 5.

Diagram 5: The laboratory function technical distribution



Many organisational charts are constructed in this way, but often they are not the most economical because they lead to replicated activities in the various functions when they could be shared or specialised. For example, the virology function primarily uses serology, and now polymerase chain reaction (PCR) techniques and many virology laboratories do not perform activities requiring special premises. The virology function could easily be distributed among the various functions concerned. This would remove the need for a virologist. While this is of little consequence to a diagnostic laboratory, it is unacceptable in a research laboratory where such competency is required. This is one reason why PVS Pathway Laboratory Missions distinguish diagnostic aspects from research aspects, which follow a different rationale.

Analytical lines

Various functions share common methods. For example, an enzyme-linked immunosorbent assay (ELISA) test can equally well be used to look for antibodies or antigens in various matrices (e.g., food, blood, etc.). This means that it could be more efficient to have an ELISA technical unit that deals with all laboratory needs, rather than an underused analytical line in each function or discipline (e.g., serology, virology, food microbiology, etc.). It could also be imagined that the function or discipline team perform the interpretation of results from a distance or at the central level.

The limitation of this approach is the quantity of analyses. When the ELISA line needs to be duplicated, this choice can be reconsidered from a manual to an automatic line. The same applies where biosecurity measures necessitate separate premises for separate techniques.

Costing of laboratory equipment

Subject to the above and without prejudice to the organisational choices specific to each PVS Pathway Laboratory Mission, costing of laboratory equipment can be done according to the category of equipment, to the function, or to the analytical line. Below are lists of categories of equipment, or functions of analytical lines. These lists are purely indicative and not exhaustive.

The Laboratory Analytical Line Tool proposes a check-list of analytical lines, including pre-determined sets of equipment and proposed international prices. This Tool may be used to determine the cost of laboratory equipment in the absence of other sources of information by using the proposed prices in column F or by using another price that experts have validated or referenced elsewhere (e.g. invoices or other documentation). For the purposes of this mission, only one Analytical Line Tool should be filled in for the national laboratory network.

How to use the Analytical Line Tool

- The country team and the Expert Team should first decide which functions, equipment, and/or analytical lines are needed given the options and Scenarios discussed during the country meetings, as well as the number of each needed in the national laboratory network.
- Next, the country team and the Expert Team should validate the prices of equipment, or propose different prices based on invoices. This value should be entered into column **H**.
 - If the real price is not known, the reference price (unit price in column **F** and total price in column **G**) should be entered into column **H**, depending on the number required of each unit.
- Please enter the standard renewal period, or the number of years after which the equipment will need to be replaced, in column **I**.

Table 6: Excerpt of the Analytical Line Laboratory Tool

Analytical Line Tool : Laboratory Equipment Budget (BSL2)									
Analytical Purpose	Standard Analytical Line Equipment	Main Specifications	Number	Unit Price in €	Total Cost	Simulation	Standard Renewal Period	List of Consumables Needed	Comments
General Equipment									
	Cold chamber (4°C)	15m ³	1	7 000	7 000			Micropipette tips	
	Cold chamber (-20°C)	10m ³	1	8 000	8 000			Gloves, masks, micropipette tips	
	Nitrogen tank (20 L)	For safe and efficient storage and handling of liquid nitrogen. Lightweight aluminum dewars assure low-static evaporation rates	1	1 000	1 000				If nitrogen distributor exists
	Refrigerator	Temperature: 4°C, Auto defrost, forced air, Capacity: 16.7 cu. ft. (472.9L)	2	2 000	4 000				True specific laboratory refrigerator
	Freezer	Operating Temperature: -10°C to -20°C Auto defrost, forced air, adjustable temperature control. Capacity: 20.3 cu. ft. (575L).	2	2 000	4 000				True specific laboratory freezer
	General purpose centrifuge	Benchtop centrifuges accommodate a variety of rotors. Capacity: 1.6L (4 x 500mL), Maximum speed/RCF: 14,000rpm/20,800 xg. Spin up to 48 x 15mL conical tubes or up to 30 microtubes per run	1	4 500	4 500				
	Refrigerated centrifuge	Benchtop centrifuges accommodate a variety of rotors, Capacity: 1.6L (4 x 500mL), Maximum speed/RCF: 14,000rpm/20,800 xg. Spin up to 48 x 15mL conical tubes or up to 30 microtubes per run	1	8 000	8 000				
	Autoclave (waste)	Steam sterilization, 80 liters, complete line of baskets, inserts and cans available separately	1	6 000	6 000				
	Balance (0,01)		1	1 000	1 000				
	Balance (0,001)		1	2 000	2 000				
	Pure and Ultrapure Water Purification System		1	4 000	4 000				

By category of equipment

- Agitator
 - Magnetic
 - Heater
 - Vortex
- Autoclave (all types)
- Balance
- Biosafety Cabinet and chemical hood
- Centrifuge (all types)
- Equipment
 - CpG with any detection system
 - Electrophoresis
 - Enzyme-linked immunosorbent assay (ELISA) or other immunoassay
 - Washer
 - Incubator
 - Reader
 - Histology
 - High Performance
- Liquid Chromatography (HPLC) with any detection system
- Polymerase Chain Reaction (PCR)
- Photometry/Spectrophotometry
- Thin Layer Chromatography
- Freezer -20°C
- Freezer -80°C
- Incubator
 - Normal
 - Gas
- Liquid nitrogen container
- Lyophilizer
- Micropipette
 - mono
 - multi
- Microscopy
 - Dark Field
 - Fluorescent
 - Inverted
 - Loupe
 - Microscope
- Oven
- pH meter
- Refrigerator
- Standards
 - Mass
 - Temperature
- Vacuum pump
- Washing machine for glassware
- Waste disposal (crusher/shredder)
- Water bath
- Water purification

By function

- Anatomical pathology
- Bacteriology
- Clinical pathology
- Drug quality
- Feed content
- Feed safety
- Food microbiology
- Molecular
- Parasitology
- Residues
- Serology/Immunology
- Toxicology
- Virology culture

By analytical line

- Animal health (AH) microbiology
 - Anaerobic microorganisms
 - Food and water microbiology
 - Mycology
- Gas Chromatography (GC)
- General equipment
- General microbiology
 - Media
 - Sterilisation
- Histology
- High Performance Liquid Chromatography (HPLC)
- Molecular biology
 - Polymerase Chain Reaction (PCR)
 - Real-time Polymerase Chain Reaction (RtPCR)
- Parasitology
 - Baerman
 - Culture larvae
 - Direct, flotation, sedimentation
 - Haemo parasite
 - Identification
 - Trichinella
- Serology
 - Agglutination (Agg), Complement fixation (CF), Agar Gel Immunodiffusion (AGID), Immunohemagglutination (IHA), etc.
 - Base
 - Enzyme-linked immunosorbent assay (ELISA)
 - Standard ELISA
 - Automated ELISA
 - Microscopic Agglutination Test (MAT) for Leptospirosis
 - Immunofluorescent technique
- Spectrophotometry
- Virology

Costing of human resources

The fourth sheet of the Calculation Tool estimates the number of staff on the basis of one laboratory technician for every 30,000 points³¹, one professional (veterinarian or university) for every five technicians, and one support staff for every five technicians and for every three professionals. Please see III.2 'Use of the Calculation Tool: Estimated Staff and Finances' for detailed instructions on how to use this sheet.

Use of the Current and Proposed Budget sheet of the Calculation Tool

In the Calculation Tool, the 'Current & Provisional Budget' sheet gives a model for calculating the budget. It should be included in the Final Report (see Report Template). This sheet includes automatic calculations for some elements (e.g., renewal rate, administrative fees, continuing education, maintenance, metrology and calibration).

Practical tips for use

- All prices and costs indicated in all four Tools of the PVS Pathway Laboratory Mission are in EUROS (€).
- This sheet is the tool that will help the Expert Team to discuss the possible Scenarios for the organisation, management, staffing, and financing of the national laboratory network.
- There are two tables in this sheet: the 'Current Budget (extracted from the Supply Tool)' and the 'Proposed Budget based on PVS Laboratory Mission'.
- The country team should have collected all elements needed to complete the 'Current Budget' table prior to the mission and entered the data into the '6. Budget Information' sheet of the Supply Tool.
- The 'Proposed Budget' table will be the result of the discussions held with the country team based on the different Scenarios developed by the Expert Team.
- Some data from the Demand Tool (in cells **AB152** or **AB154**) will need to be used here depending on the proposed Scenarios retained by the country team after discussions during the 'Strategy, management and financing brainstorming' session (see II.3 'Day 5' of this Manual).

How to use the Current and Proposed Budget sheet of the Calculation Tool

- Please fill in all applicable pale blue boxes in the 'Unit Cost' and 'Number' columns.
- It is helpful to project the proposed budget table during the discussions so that they country team can see the impact of modifications in one area on the total budget.

³¹ Relative value of a test.

Table 7: Example of budget format in Sheet n°1 of Calculation Tool

Proposed Budget	Unit Cost	Number	Renewal Rate	Annual Budget	%
Capital Investment				133 250	13,17%
Buildings and Premises	870 000		0,05	43 500	4,30%
Vehicles	30 000	1	0,2	6 000	0,59%
IT and Office Equipment	2 000	10	0,33	6 600	0,65%
Telecommunications Equipment	300	5	0,2	300	0,03%
Refrigerators	1 000	5	0,1	500	0,05%
Deep freezers -20°C & -80°C	13 500	1	0,1	1 350	0,13%
Laboratory Equipment			0,1	-	0,00%
Other Equipment	375 000		0,2	75 000	7,41%
Salaries and Remuneration				184 300	18,21%
Veterinarians and Other Professionals	12 000	4		48 000	4,74%
Laboratory Technicians	7 200	16		115 200	11,38%
Support Staff	3 000	5		15 000	1,48%
Per diem and travel allowance in the country	30	50		1 500	0,15%
Per diem and travel allowance abroad	230	20		4 600	0,45%
Operating Costs				694 550	68,62%
Continuing Education	salaries	5%		8 910	0,88%
Administrative Expenditures	salaries	20%		35 640	3,52%
Reagents and Consumables	50 000	11		550 000	54,34%
Maintenance, Calibration and Metrology	laboratory equipment	20%		75 000	7,41%
External Services				25 000	2,47%
Other				-	0,00%
Total				1 012 100	100,00%

Renewal rate of physical resources

Laboratory equipment is automatically costed with 20 % renewal rate per year. Other physical resources are automatically costed on the basis of their real cost in the country and with renewal rate of 20 % for vehicles, 33 % for IT and telecommunication equipment, and 10% for cold chain and miscellaneous equipment. If renewal rates do not appear relevant in the country's context³², removing the protection of the sheet will enable the user to change them.

As it concerns buildings and permanent infrastructure:

- Exceptional budget is not automatically calculated, as it is mainly necessary for financing the construction of new buildings.
- Building maintenance is calculated at 5% of construction costs, which are automatically calculated in sheet 1 of the Calculation Tool.
- The surface area³³ (number of m²) to maintain is calculated as:

existing m² + m² needing renovation + m² to be built

- However, the surface area must be differentiated by BSL construction costs:
 - BSL1 = typical construction costs, to be provided by country team
 - BSL2 = typical construction costs × 2
 - BSL3 = 5 000 USD/m², regardless of the country.

Operational budget

Most elements are costed on a proportional basis:

- Administrative fees (e.g., water, electricity, telephone, office supplies, etc.) at 30% of total salaries
- Continuing education at 5% of total salaries
- Preventive and corrective maintenance, calibration and metrology at 20% of the value of laboratory equipment. It could be changed if not appropriate in the context.

Reagents (including sampling kits and sample transport) are calculated on the basis of local market prices (which may be referenced or calculated in the second sheet of the Calculation Tool) or reference prices (which may be referenced or calculated in the Demand Tool).

³² Especially in terms of building and construction, as these are one-time investments they can be excluded from consideration in terms of renewal rates.

³³ All measurements should be provided in metric measures, i.e., m² and not ft².

PVS Pathway Laboratory Mission Explanatory Note and Supply Tool Guidelines for the Country Team

(Usually sent by e-mail and may be modified by the Team Leader)

Supply Tool Guidelines for the Country Team, Supply Tool

Helvetica 18 B I U E A

To: DELEGATE
 Cc: Regional Activities Department (OIE Headquarters) ; PVS Laboratory Expert Team; Country-designated Focal Point
 Subject: PVS Pathway Laboratory Mission
 Attachment: Supply Tool Guidelines for the Country Team, Supply Tool
 Firma: ANG-firm

FROM: Team Leader

Date

TO: Delegate of [country] to the OIE

Dear Delegate,

Further to the OIE letter dated ... agreeing to a PVS Pathway Laboratory Mission, please find enclosed a short description of the working arrangements, a planned schedule for the mission and the data collection tool, called the Supply Tool, of which one file should be filled by each veterinary laboratory, and to the extent possible, as well as by the other laboratories (e.g., private, human health, etc.) that compose the larger national laboratory network.

The confirmation of the PVS Pathway Laboratory Mission depends on this preliminary exchange of information concerning each of the laboratories composing the national laboratory network and as such, **it is essential that all data be received within a period of three months** in the absence of which we will not be able to confirm the dates and Expert Team for this mission.

I would be grateful if you would kindly inform me with whom this preparatory work should be finalised.

I look forward to your confirmation of receipt of this message and any questions you may have concerning the Supply Tool.

Team Leader

Copy: Regional Activities Department (OIE Headquarters);
 PVS Laboratory Expert Team;
 Country-designated Focal Point

ATTACHMENT:
 - Supply Tool Guidelines for the Country Team
 - Supply Tool

Supply Tool Guidelines for the Country Team

A PVS Pathway Laboratory Mission facilitates the definition of a country's Veterinary Services' objectives in terms of compliance of veterinary laboratories with OIE quality standards, suitably adapted to national constraints and priorities. It is based on the findings of the PVS Evaluation and on the PVS Gap Analysis that the OIE carried out in your country to determine the current levels of advancement for the different Critical Competencies of the OIE PVS Tool.

PVS Evaluation and PVS Gap Analysis missions allow for the evaluation of Veterinary Services' official need for laboratory analysis as well as their availability and cost but do not allow an in-depth analysis of the pertinence and suitability to the needs of the national laboratory network. In particular, the important cost of a national laboratory network is not considered in terms of Veterinary Services' official need for laboratory analysis.

The objective of the PVS Pathway Laboratory mission is therefore not only to determine the resources needed by the national laboratory network but also to evaluate the pertinence of its structure and its viability in the national context in order to present elements needed for strategic decision making to the Veterinary Services. This approach allows an analysis of the network of laboratories under the authority of the Veterinary Services, as well as those laboratories (e.g., private, human health, etc.) that are a part of the larger national laboratory network.

Before the mission

The preliminary data collection phase is essential. Depending on data collected and explanations given during email exchanges, the mission may be confirmed or postponed for further data collection. This approach enables a more productive mission and better outcomes and outputs for the country. Attached to this email is the Excel file Supply Tool to be filled in by the Laboratory Directors.

Key definitions

Analytical line: all equipment necessary excluding consumables and reagents to conduct any given test.

Client: all persons or institutions that request laboratory analysis results. In the first instance, it may be the Veterinary Services themselves for the purpose of official programmes, or in the second instance, other public or private institutions, private veterinarians, farmers, donor projects, etc.

Cost: the amount of money necessary for the laboratory to purchase or maintain any consumable (e.g., reagents, sampling kits, etc.), service (e.g., local transport, international transport, etc.), utilities (e.g., electricity, water, etc.), salaries, equipment and other physical resources (e.g., buildings).

Demand: includes two facets depending on the context: more broadly, 1) the Veterinary Services' expectations for laboratory analysis related to national programmes, including type of analysis, geographic location, and volume, and at a smaller level, and 2) every request that is submitted to the laboratory by a client. It may include several samples and several tests.

Laboratory: a physical entity carrying out all or part of the laboratory function.

Laboratory function: defined in relation to the service rendered, is distinguished from the term 'laboratory'.

Price/Tariff: the fee charged by a laboratory to conduct a test of a sample.

Reference Price: the price of a laboratory service on the free market often charged by a private laboratory in the country or by an international reference laboratory which has taken into account the real cost of analysis due to its interest in profitability.

Sample: any biological product, organ or dead animal sent to the laboratory, irrespective of the tests to be conducted.

Strategy: logical and consistent actions in order to implement objectives.

Supply: includes those laboratory tests and services that are currently offered by the national laboratory network or accessed through an international laboratory network. This term also refers to what laboratory tests and services the national laboratory network in question is able to offer the market, or efficiently access on the international market.

Test/Analysis: laboratory-specific method to be conducted on any sample.

Every public laboratory of your country, regardless of the Competent Authority under which it falls, as well as every private laboratory providing diagnostic or quality control services within the Veterinary Domain, should fill in a copy of this file.

Practical tips for use

- The Supply Tool includes several sheets: general organisation, human resources, equipment inventory, equipment management, transport, premises, quality assurance, activities, and budget information.
- Laboratory Managers should fill in these sheets with the information and data that they have or can collate. Ideally and to the extent possible, all data should be from the same and most recent year available.
- All fields that you should fill in are in pale blue. All fields in yellow are automatic calculations; please do not modify these fields. Different types of cells exist. Some cells include a menu where elements should be ticked, whereas others are open fields where you can fill in words or figures.
- The last sheet, '7. List', is protected by a password, as it should not be modified. It allows internal calculations and distributions and ensures the proper functioning of the spreadsheet.
- This tool establishes automatic ratios for human, physical, and financial resources. Please familiarise yourself with the tool before attempting to fill it in in order to facilitate data entry and discussion during the mission.

Instructions on how to fill in the different sheets of the Supply Tool

1. General Information

- This information is necessary for contact and background purposes for all laboratories composing the national laboratory network.
- Fill in all sections with current information
- Tick the status of documents to be prepared and supplied
 - Please prepare to supply these documents to the Team Leader prior to the mission

2. Human Resources

- This information will allow an assessment of personnel age distribution and continuing education needs.
- Indicate the total number of veterinarians in cell **F2**.
- Fill column **A** with the Name or any other ID number of all staff members.
- Fill in column **C** with the birth year.
- Choose the correct response in the pull-down menus in column **B, E, F, G, H & I**.
- Indicate the correct number in column **J** (days). Ratios will be generated automatically in rows **3 & 4** and column **D, N, Q & R**.

3. Equipment

a. Inventory

- This information will allow an assessment of the need and relevance of current laboratory equipment.
- This sheet has been filled in with common laboratory equipment. If there is additional equipment in your laboratory, please include it in the list. This relates only to laboratory equipment included on the inventory. Do not include expendable equipment, glassware, or vehicles.
- Column **B** should reference the detailed floor plan of the laboratory, indicating where the equipment is located.
- Please prepare or obtain the floor plans in advance of the mission.
- Indicate relevant information for each piece of equipment in columns **A** through **G, J, K & O**.
- For column **K**, if the exact value is not known, please fill in the approximate acquisition value.
- Choose the correct response in the pull-down menu of columns **H, I, L, M**, and **N** for each piece of equipment. Ratios will be automatically generated in columns **R & S**.

b. Management

- Provide correct responses in the pull-down menus and relevant information or comments in the pale blue fields.

c. Transport

- If the laboratory has vehicles, please provide relevant information on this sheet in the pale blue fields.

d. Premises

- Please provide relevant information in each of the bold boxes (surface area, refrigeration, telecommunication availability, water, electricity, waste management, office equipment) in the pale blue fields.
- Please indicate the unit of measure (m² or ft²) in cell **E3**.
- Surface areas should be detailed by biosafety level in columns **G, H**, and **I** and are automatically summed in column **F**.
- Unit cost of premises may be provided by administration, invoices, etc.

4. Quality Assurance

- Please provide relevant information or choose the correct response in the pull-down menus in the pale blue fields.

5. Activities

a. Demand

- Please fill in the reference year in cell **C6**.
- Insert the number of clients, requests, samples, and tests requested by origin and by purpose.
- If you do not have information broken-down by purpose, please insert generalized data in the columns **O, P & Q** for 'undetermined purpose'
- In column **U**, input the amount actually paid by the client. If the analyses are not paid for, enter 0.
- In column **V**, input the cost of the services provided (including reagents, consumables, local transport, and sampling kits), regardless of the official fee charged by the laboratory.
- The difference (column **W**) will be positive if the laboratory achieves a profit and negative if it has to cover a part of the cost of providing the service through an indirect subsidy.
- Totals are automatically generated in columns **R, S, T, & W** and row **21**.

b. Samples

- Please fill in the reference year in cell **B3**.
- Insert relevant numbers of samples by species and type in the pale blue fields.
- Column (by species) and row (by type) totals are automatically generated in row **22** and column **M**.
- Fill in the food products totals in the second table at the bottom of the sheet.

c. Tests

- In columns **A & B**, list all the parameters analysed by the laboratory. Use a new line for each method: e.g. brucellosis-RBT, brucellosis-ELISA, brucellosis-CF, etc.
- In column **D**, input the unit price of the test as shown on the official price list, regardless of whether or not it is the price actually paid by the client.
- In column **E**, input the unit cost of test including consumables, reagents, sampling kits, and local transport, regardless of the official price, if known.
- Totals are automatically calculated in column **F**.
- The total number of tests appears in cell **C30**.

d. Prospective activities

- Input the number of farms and population figures by species and by administrative area in the pale blue fields.
- The totals by species are automatically calculated in row **15**.
- The names of the competing or collaborating laboratories are automatically filled in from the General Information sheet. Fill in the tests that both your laboratory and theirs offer.
- Fill in any information about prospective markets of which you are aware. This information is important for further prospective market analyses.

6. Budget Information

- This information is fundamental for the mission. If you do not have it in your possession, it should be acquired from the relevant administrations (e.g., finance, human resources, etc.) as soon as possible before the mission.
- Budget information for the current year up to three years prior should be available prior to the mission.
- External funding from donors or projects should also be included in this sheet.
- Revenue information should be included in this sheet.
- Remuneration of staff should include fringe benefits (i.e., social benefits and bonuses) on average for each category.

7. Lists

- This sheet should not be modified in any way and is password-protected.
- It allows internal calculations and distributions and ensures the proper functioning of the entire spreadsheet.

Organisation of the mission

During this mission, the participation of upper-level management of Veterinary Services and of Laboratories Services is *crucial* and will necessitate a high degree of cooperation, especially when the laboratory function is under a Competent Authority than the Veterinary Services. The country PVS Pathway Laboratory Report will include an indicative operational budget for five years and an exceptional budget (i.e., necessary investments) when relevant. This budget will go into more detail and be more precise than the PVS Gap Analysis Costing Tool for laboratories that was issued in the PVS Gap Analysis Report.

The mission will unfold in the following order (also see the annexed chart):

- An opening meeting will be held to establish the mission objectives and review the recommendations of the OIE PVS Evaluation and PVS Gap Analysis Reports. During this meeting, the Expert Team will describe the process and approach of the PVS Pathway Laboratory Mission and ensure common understanding of important concepts.
- A plenary session will be organised with you and the relevant senior personnel of Veterinary Services and Laboratory Services as well as the senior personnel of other laboratories that participate in the national laboratory network, to analyse and confirm the demand for laboratory analysis in your country. Representatives from industry, importation, cattle farmers' organisations, veterinarians' organisations, human health and the environmental sectors should also be invited where possible in order to better understand the prospective demand for laboratory analysis and services. All those present should come to the meeting with concrete data already collected and collated from Day 1.
- The general demand from Veterinary Services is already outlined in the PVS Gap Analysis Report, but will need to be further detailed. Other current or potential demand from other clients (e.g., private veterinarians, farmers, other institutions, donors, research, etc.), which are usually not taken into account in the PVS Gap Analysis, may be discussed and analysed.
- Another plenary session will be organised with you, laboratory directors or managers, and managers of other laboratories working in the veterinary domain and having responded to the Supply Tool (e.g., private, research, human, etc.), to analyse and confirm the laboratory analyses offered in your country. **This work will be largely influenced by the quality of the preliminary data collection.** Depending on the preliminary data collection, we will plan a brief visit to your central laboratory or to different laboratories as necessary. This may take between one half and 2 days. The purpose of such visits is NOT to assess the technical aptitude of the laboratory, but to ensure a common understanding of the real situation.
- Another plenary session with all relevant staff will be organised to brainstorm about possible organisation, management and financing solutions. You may also consider this session as a part of continuing education for laboratory managers.
- Following working sessions with the experts and the collection of additional information, a final meeting will be held at which the experts will present their preliminary findings and highlight the main areas requiring strengthening. This will include proposals for human, physical and financial resources, with a budget for five years. During this last session, the relevant staff will rank and validate proposals. **Participation by you and the appropriate stakeholders in this meeting is very important.**
- A closing meeting will be organised, especially if you wish to involve political authorities. It may also be organised as a courtesy visit to their office.

After the mission

Within one month after the end of the mission the Team will submit a Draft Report, which will be sent to you by the OIE after review. You are encouraged to discuss this Report with the relevant senior personnel to ensure that it is accurate and appropriate. Following receipt of your comments, the OIE will send you the Final Report.

I. Laboratory Analysis Demand Tool

1. Laboratory Test Data

II. Laboratory Analysis Supply Tool

1. General Information
2. Human Resources
3. Equipment
 - a. Inventory
 - b. Management
 - c. Transport
 - d. Premises
4. Quality Assurance
5. Activities
 - a. Demand
 - b. Samples
 - c. Tests
 - d. Prospects
6. Budget Information
7. Lists

III. Calculation Tool

1. Current & Proposed Budget
2. Tariff Estimation
3. Estimated Cost of Analysis
4. Estimated Staff & Finances

IV. Analytical Line Tool

1. Laboratory Equipment Budget

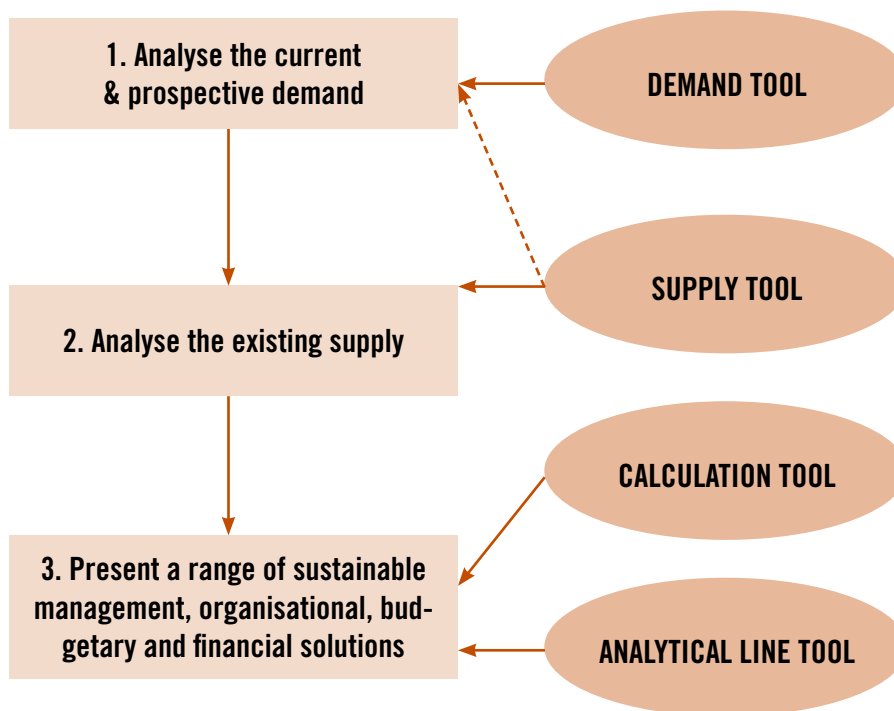


Notes



PVS Laboratory Tool

The PVS Pathway Laboratory Mission Approach and Tools



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Protecting animals, preserving our future