

VERIFICATION AND VALIDATION TOOLKIT

Cost Analysis and Budget

To ensure correct diagnosis and treatment, clinical laboratory testing must be accurate and reliable. A key component of the quality assurance process is the verification or validation of new instruments and tests to confirm their ability to perform prior to implementation.

The Verification and Validation Toolkit walks users through this process and provides additional resources, templates and examples for use in the laboratory.

Find the complete toolkit at aphl.org/VV-Toolkit

The toolkit has eight sections:

1. Verification and Validation 101
2. Verification and Validation Process Checklist
3. Obtaining Appropriate Test Samples
4. Qualitative Assays
5. Quantitative Assays
6. Related Processes
7. Safety Considerations and Risk Assessments
8. Cost Analysis and Budget

Testing must occur within an approved budget to ensure fiscal responsibility and sustainability. A cost analysis, or summary of expenses, is a useful tool to determine and compare the cost per test prior to verification or validation of a new or changing method.

There are a number of ways to perform a cost analysis and this section provides only basic cost accounting guidance. Costs can be categorized as direct, indirect, fixed and variable (see **Glossary (page 3)** for definitions). When implementing new testing or modifying current testing, start-up costs must also be considered.

The basic cost per test can be determined using the cost of instrumentation, direct materials and direct labor. For annual budgeting planning, it may be helpful to estimate the yearly spend on a new test system or method and additional information may be needed, such as laboratory information management costs, maintenance costs, site-preparation costs, and depreciation costs (purchased equipment). Within this document, only site preparation costs and yearly maintenance costs will be considered.

Labor Costs

The cost to perform a test per unit of time is called labor cost. The time to perform a test includes all phases of testing —pre-analytical, analytical and post-analytical—and should include all employees involved in the direct production of the actual test result. Other than the hands-on testing time, consider any sample or instrument preparation and maintenance as well as result review and reporting. Estimate labor costs with the the equations in **Figure 1**.

Figure 1. Estimation of labor costs

Labor Costs

$$= \frac{\text{Salary with Fringe/Year}}{\text{Number of Tests/Year}}$$

or

$$= \frac{\text{Salary with Fringe}}{1 \text{ Year}} \times \frac{1 \text{ Year}}{2080 \text{ Hours}} \times \frac{1 \text{ Hour}}{60 \text{ Minutes}} \times \frac{\# \text{ Minutes}}{1 \text{ Test}}$$

Materials Costs

Any reagents and consumables including proficiency testing materials used in the performance of the test are considered direct materials. Laboratorians should consider at least the following: price per kit or total expense for all reagents; number of tests per kit or total reagent volume; controls and calibrators per analysis; consumables; and it may be necessary to try and predict retests. See **Figure 2** for an estimation equation.

Figure 2. Estimation of materials costs

Material Costs

$$= \frac{(\text{Cost of Reagents} + \text{Cost of Consumables})}{\text{Number of Tests}}$$

Site Preparation Costs

The purchase of new or updated instrumentation may require site preparation. Expenses related to site preparation include work area renovation or any utilities required for proper operation, including electrical, plumbing, ventilation and air-conditioning. This is often a one-time expense that should be considered part of the start-up costs.

Maintenance Costs

Instrumentation requires routine maintenance to ensure optimal operation for its expected lifetime. This maintenance can be both expected and unexpected. While unexpected maintenance is hard to predict, the user may speak to laboratories using the same equipment or the vendor to create a realistic estimate for unexpected events. Estimated costs related to equipment maintenance can be incorporated into the per test costs or yearly expenses. Consideration for maintenance costs should include not only the instrumentation and materials, but also supporting systems and their associated maintenance costs as well (e.g., LIS service agreements, temperature monitoring systems).

The laboratory can more effectively plan and estimate routine preventive maintenance activities over a period of time and this information should be included in the annual budget. Consider any consumables needed for daily, weekly, monthly, or other routine maintenance. Maintenance contracts may be purchased from the vendor and can also be included as an annual cost.

Glossary

- **Direct Costs**

Specific costs traceable to the test produced. These can be fixed or variable. Examples include supplies, reagents, consumables, labor, instrument costs, standards and controls.

- **Indirect Costs**

Any cost that is not assigned to the direct production of a test but contributes to the adequate provision of the work environment. Examples include supervisory salaries, quality assurance, education, travel, administrative costs, building maintenance, security and training.

- **Fixed Costs**

A cost that remains constant regardless of workload and within a specific range of activity. Examples include Labor, rent, equipment depreciation, equipment/instrumentation.

- **Variable Costs**

A cost that varies with changes in test volume. Examples include reagents and consumables. Labor costs can sometimes be variable when significant increases or decreases in test volume occur, but typically labor will be a fixed cost.



Association of Public Health Laboratories

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