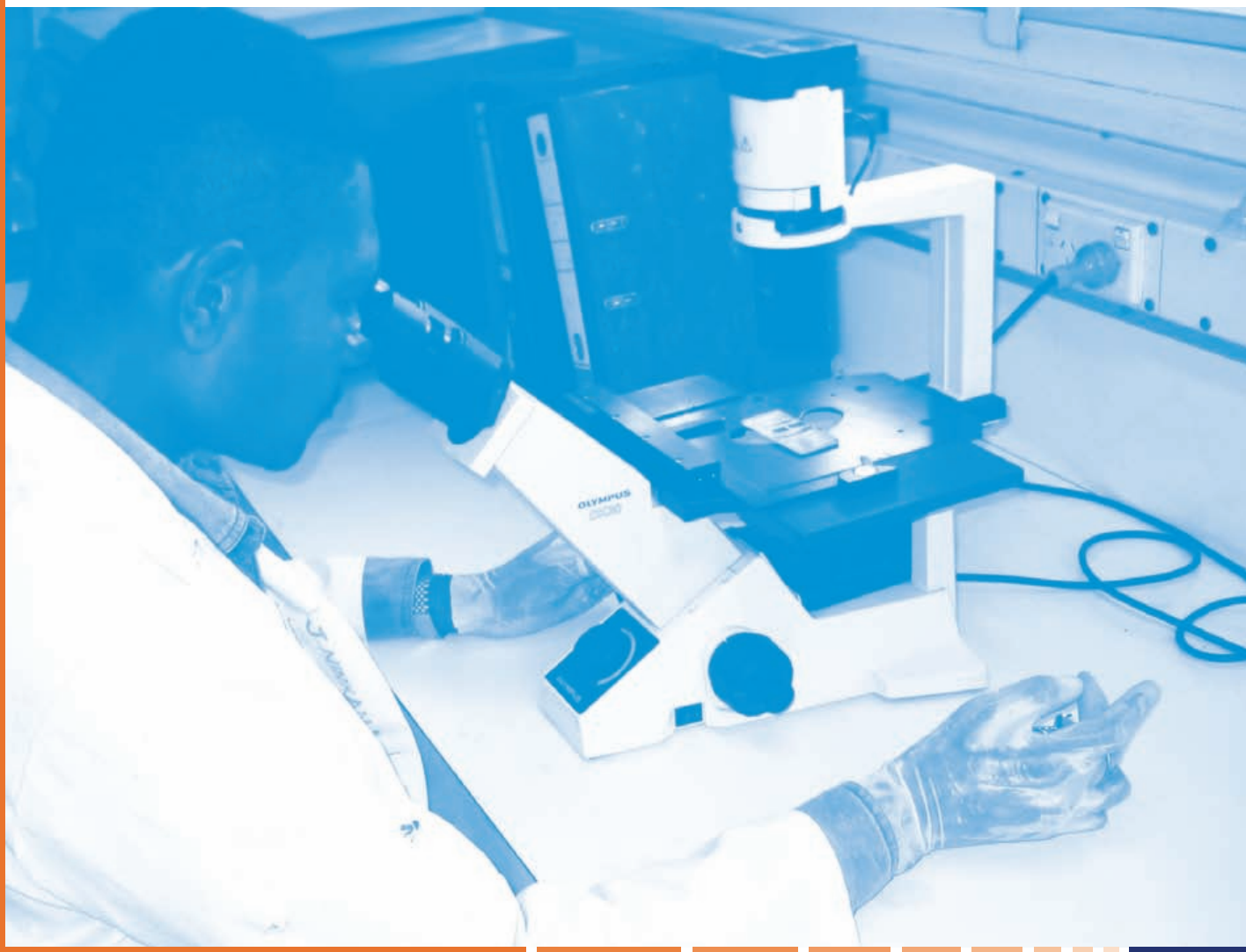
Laboratory Quality Management System

Handbook



World Health Organization

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7-2: Control materials

Defining control materials

Controls are substances that contain an established amount of the substance being tested—the analyte. Controls are tested at the same time and in the same way as patient samples. The purpose of the control is to validate the reliability of the test system and evaluate the operator's performance and environmental conditions that might impact results.

Differentiating controls and calibrators

It is important not to confuse calibrators and control materials. Calibrators are solutions with a specified defined concentration that are used to set or calibrate an instrument, kit, or system before testing is begun. Calibrators are often provided by the manufacturer of an instrument. They should not be used as controls since they are used to set the instrument. Calibrators are sometimes called standards, but the term calibrator is preferred. They usually do not have the same consistency as patients' samples.

Characteristics of control materials

It is critical to select the appropriate control materials. Some important characteristics to consider when making the selection are:

- Controls must be appropriate for the targeted diagnostic test—the substance being measured in the test must be present in the control in a measurable form.
- The amount of the analyte present in the controls should be close to the medical decision points of the test; this means that controls should check both low values and high values.
- Controls should have the same matrix as patient samples; this usually means that the controls are serum based, but they may also be based on plasma, urine or other materials.

Because it is more efficient to have controls that last for some months, it is best to obtain control materials in large quantities.

Types and sources of control material

Control materials are available in a variety of forms. They may be frozen, freeze-dried or chemically preserved. The freeze-dried or lyophilized materials must be reconstituted, requiring great care in pipetting in order to ensure the correct concentration of the analyte.

Control materials may be purchased, obtained from a central or reference laboratory, or made in-house by pooling sera from different patients.

Purchased controls may be either assayed or unassayed. Assayed controls have a predetermined target value, established by the manufacturer. When using assayed controls, the laboratory must verify the value using its own methods. Assayed controls are more expensive to purchase than unassayed controls.

When using either unassayed or "in-house" controls, the laboratory must establish the target value of the analyte.