

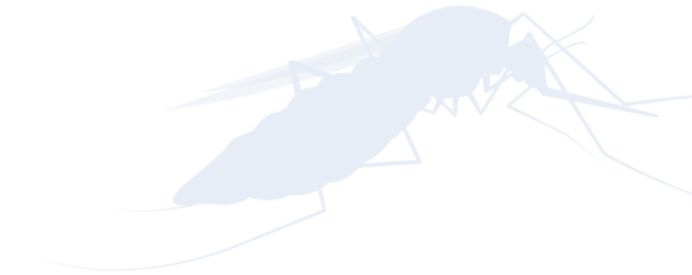
Total Quality Management for Malaria Microscopy

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“Quality is never an accident. It is always the result of intelligent effort” John Ruskin

Definitions



Quality assurance

Both internal and external processes to provide confidence that quality requirements are being met.

Quality control

Internal set of coordinated activities focused on fulfilling defined quality requirements.

Total Quality Management

Broad set of management and control processes designed to focus on the entire organization and all of its employees on providing products or services that do meet customer requirements.

Total Quality control in Microscopy

Broad set of management and control processes (internal and external) designed to focus on the entire microscopy process, from slide collection to the reporting of results, and all the people involved (management, clinicians, and microscopists) to satisfy the customer (clinicians and patients).

Factors Affecting the Accuracy and Reliability of Microscopy Results (6Ms)



Manpower

Well-trained and competent microscopists will know how to appropriately stain and read the slide



Machines (Equipment)

Good quality weighing balances, pH meters and microscopes will ensure quality staining and examination



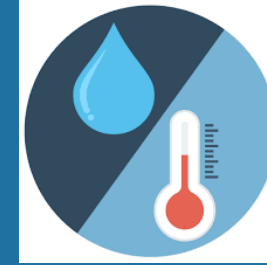
Materials (reagents & supplies)

Good quality reagents and supplies will produce quality blood slides and staining



Methods

Blood film preparation, stain preparation, staining and slide examination should follow recommended procedures to produce quality results



Milieu (Environment)

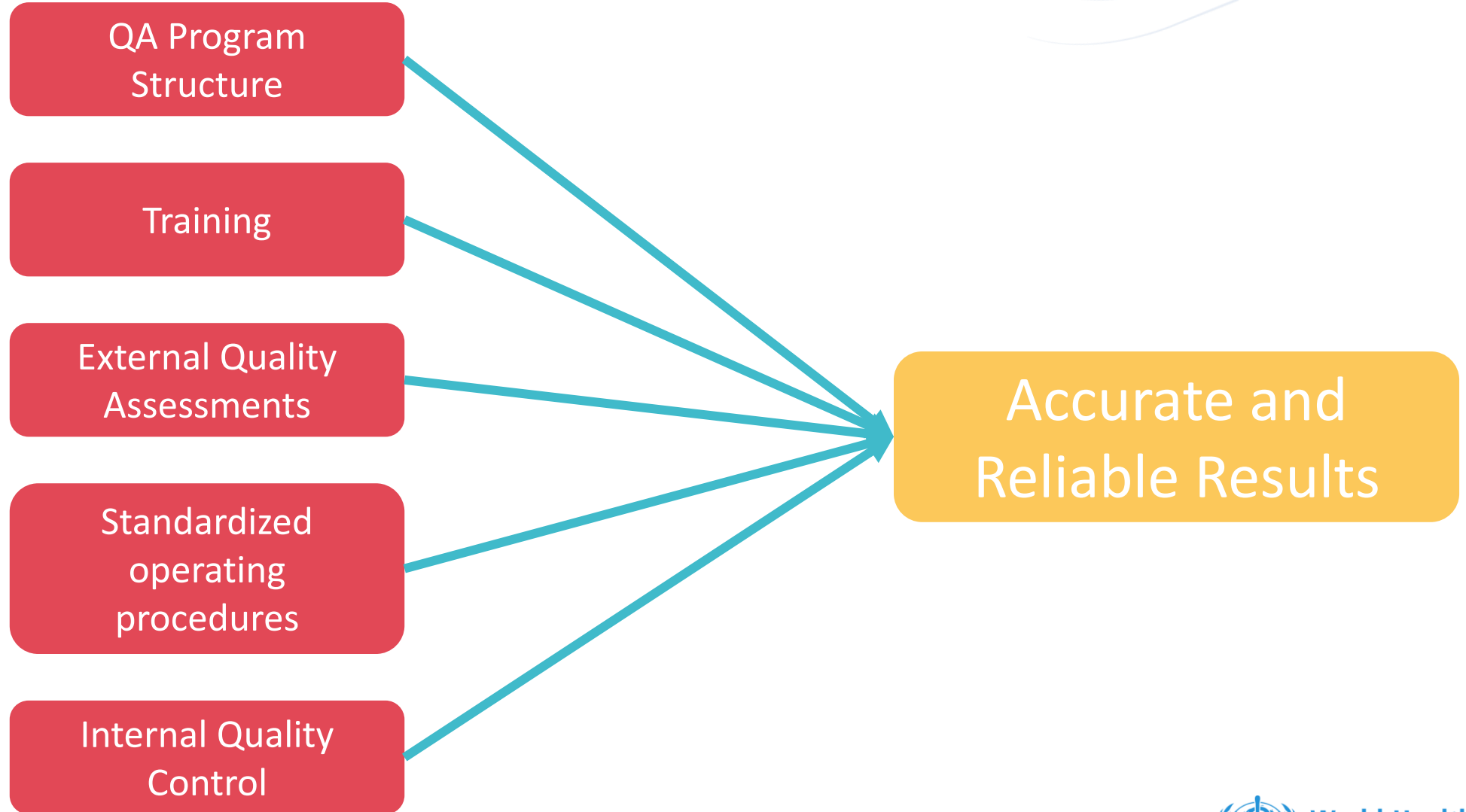
Reagents and Equipment should be stored under the right environmental conditions



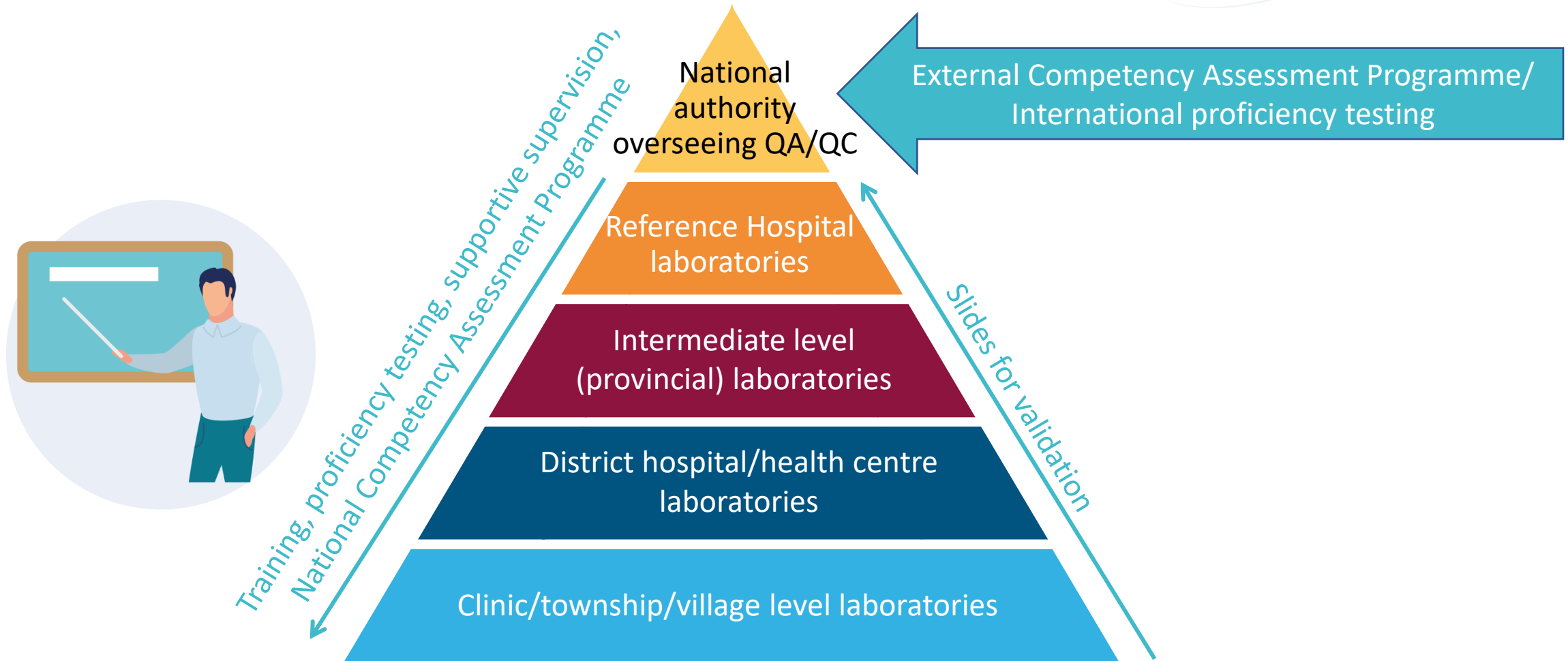
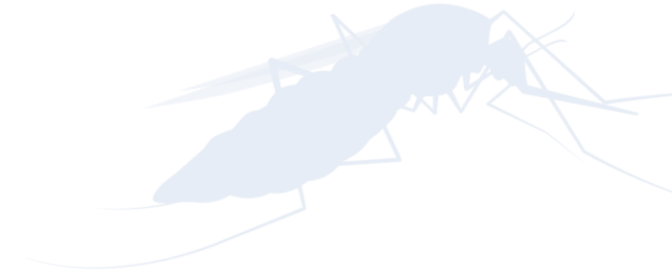
Measurement

Accurate examination of controls and patient blood films should be performed

Improving the Quality of Microscopy Results



Quality Assurance Program Structure



Role and Responsibilities of the National Authority in Charge of Quality Assurance



The national authority in charge of quality assurance is responsible for

- 1 Developing and updating guidelines for malaria diagnosis
- 2 Overseeing training and supervision
- 3 Developing and disseminating written standard operating procedures
- 4 Providing technical assistance to laboratories to implement the procedures
- 5 Establishing and maintaining a quality control system based on cross-checking blood slides and regular supportive supervisory visits
- 6 Coordinating the servicing and maintenance of equipment in the laboratory network
- 7 Organizing external quality assessments

Training

- A functional skill-based training program is required to provide microscopists with the required technical knowledge, skills, and competencies necessary to perform malaria microscopy.
- Training should be combined with a system for certifying the competence of microscopists (national competency assessment).
- Ideally, microscopists need to undergo competency assessment at least once every 3 years.
- A good training program should have competent trainers, usually WHO-certified level 1 or 2 microscopists, supported by a well-stocked malaria slide bank.

Standard Operating Procedures (SOPs)

- Microscopists require malaria technical SOPs to address pre-analytic, analytic and post-analytic processes.
- Adherence to recommended standard operating procedures ensures malaria microscopy procedures are performed consistently in all laboratories.
- Where appropriate, the QA program should develop job aids that summarise the key steps of critical procedures and display these in testing areas.

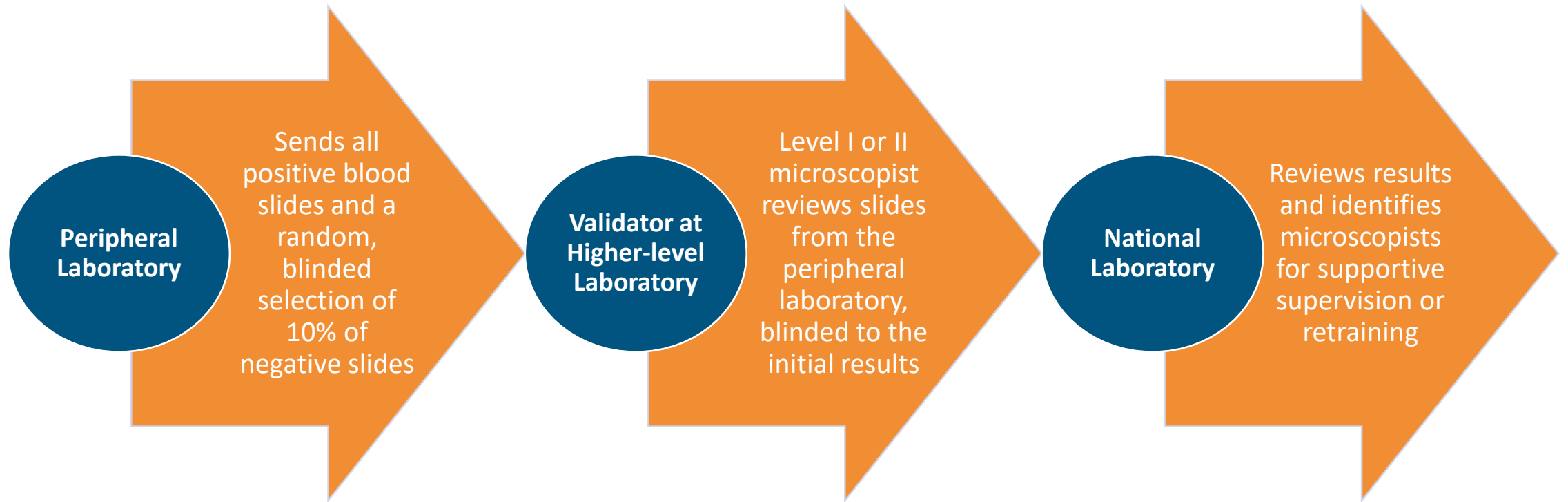
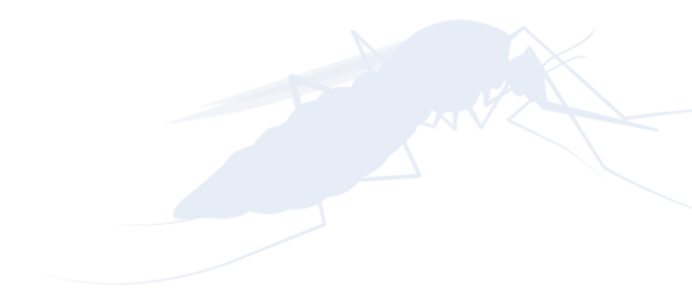
Internal Quality Control (IQC)

- The objective of IQC is to detect and rectify errors/mistakes in the processes of handling samples, stain preparation, staining of blood films, examination of slides, and reporting.
- Quality control data should be analyzed and where it is found to be outside pre-defined criteria, planned corrective and/or preventative action should be taken to correct the problem and to prevent incorrect results from being reported.

External Quality Assurance (EQA)

- The aim of an EQA program is to objectively evaluate the performance of all testing facilities and personnel for the purpose of quality improvement.
- There are three main EQA methods applicable to malaria microscopy:
 - Cross checking of malaria slide results
 - Proficiency Testing
 - External Competency Assessments

Cross-checking Malaria Slide Results



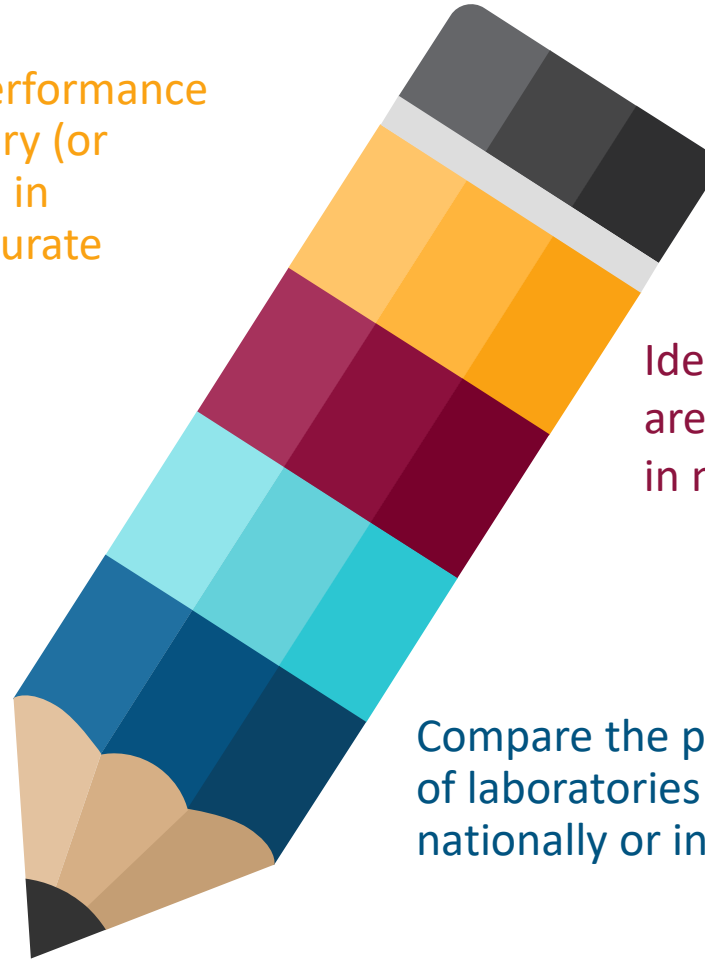
Proficiency Testing



Assess the performance of a laboratory (or microscopist) in providing accurate results



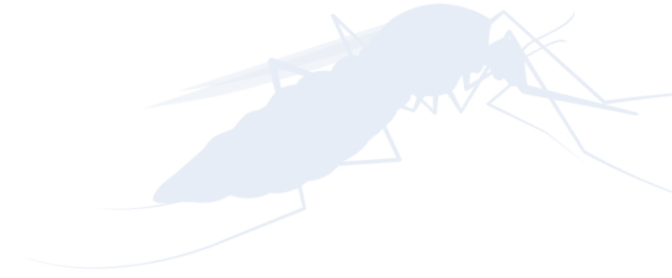
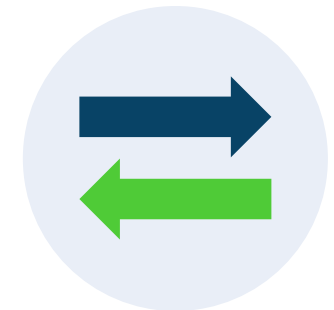
Monitor a laboratory's (or microscopist's) continuing performance over time



Identify problems or areas for improvement in malaria diagnosis



Compare the performance of laboratories regionally, nationally or internationally



External Competency Assessments



Elements of a Quality Management System for Rapid Diagnostic Tests.

Quality RDT Product

- Procurement of RDT products that are prequalified and that are appropriate for the epidemiological setting and for the parasite species/strains encountered.
- Conduct pre- and post-shipment Lot Testing on procured RDT batches.
- Store and transport malaria RDTs at the manufacturer's recommended environmental conditions (Temperature and Humidity).

QA Programme

- Develop and distribute RDT SOPs and job aids to testing facilities.
- Ensure training of testing personnel.
- Conduct regular supportive supervision and mentoring visits.

Post Market Surveillance System

- Collect and analyse feedback and complaints from testing personnel.
- Conduct regular HRP2/3 gene deletion surveys.

**“Cost is more important than quality, but quality is the best way to reduce costs”
Genichi Taguchi.**

Thank You