QUALITY ASSURANCE

TRAINING PROGRAMME

for

Primary Healthcare Laboratory Services

Gabriele Mallapaty
Public Health Laboratory Services &
Health Services Management Expert
Acknowledgement

This manual is the result of contributions and ideas that the author has gathered over the years from laboratory workers at peripheral laboratories in Sudan, Zaire (Congo), China, Jordan and Nepal. It is the dedicated commitment of those that work under extremely difficult circumstances at peripheral laboratories in developing countries that inspired and encouraged the author to write down this manual.

The author acknowledges the helpful comments and contributions received from all those that supported the preparation of this manual in Nepal with sincere appreciation. The manual could not have been completed in such a short period of time without the support and directorship of Dr. G. B. Shrestha at the NPHL. The field-testing of the course outline and part of the manual during a quality assurance training programme in Surket, which was jointly conducted by the NPHL and INF, also contributed to the speedy completion.

Special thanks are due to:

Dr. G.B. Shrestha, Director, National Public Health Laboratory, DHS, Ministry of Health, HMG of Nepal, Teku, Kathmandu.

Dr. Chandrika Devi Shrestha, Pathologist, Microbiologist, NPHL.

Mr. M.P. Poudel, Medical Technologist, Virology, NPHL

Ms. Marianne Brocqueville, Medical Technologist, Head of the INF (International Nepal Fellowship) Quality Assurance Programme, Kathmandu, Nepal.

Ms. Vanessa Thomson, Medical Technologist, INF, Surket, Nepal.

Mr. S.P. Khanal, Medical Technologist, Planning, NPHL

Mr. B.R. Rai Medical Technologist, Training, NPHL

Mr. A. Sapkota, Medical Technologist, Biochemistry, NPHL

All staff at the NPHL that contributed with valuable suggestions and comments.

Gabriele Mallapaty, July 2000
Direction for use of the Manual

The manual has been designed as teaching aid for trainers conducting the quality assurance training programme. It includes material on all topics of the programme. Each page can either be used as transparency to support lectures or as a reference to prepare more detailed teaching material for class work and practical sessions.

Handouts for trainees are not included. However, some of the pages may be adapted and used as students’ handouts. Standard operating procedures for all practical tests should be given to the trainees. Standard operating procedures should be written in the form of bench level SOPs as shown in the example SOP.

An evaluation form to evaluate the training programme at the end of the twelve days programme has been included. The evaluation form is designed to evaluate the organisation of the training programme, learning outcome and learning transfer to the work place.

The author grants permission to the National Public Health Laboratory, Department of Health Services, Teku, Kathmandu to use the training programme and the material for all quality assurance training programmes conducted by the NPHL and conducted jointly by NPHL and INF (International Nepal Fellowship). Any further use of the material requires prior permission from the author. The sole copyright of the material rests with the author.

Kathmandu, 21st July 2000

Gabriele Mallapaty
QUALITY ASSURANCE, 12 DAYS TRAINING PROGRAMME

Course Objectives:

Quality Assurance Programmes ensure laboratory staff, clinicians and patients that laboratory test results are reliable, reproducible and relevant. A National Quality Assurance programme that includes Internal Quality Control, External Quality Assessment and Quality Management is an effective tool to improve trust in laboratory test results.

Therefore, all laboratory personnel must be familiar with terms and procedures of the National Quality Assurance Programme. This 12 days training programmes has been specifically designed for laboratory personnel working in public health laboratories in Nepal. The course content has been selected based on laboratory tests performed at district level laboratories. It could easily be adapted to needs in other developing countries.

This training programme will provide trainees with general knowledge on the National Quality Assurance Programme and specific skills on Internal Quality Control procedures for a wide range of tests.

Course Outline:

The training programme is divided into theoretical sessions in the morning and practical sessions in the afternoon. The programme begins with introductory sessions on the National Quality Assurance Programmes, the three stages of Quality Assurance (Pre-analytical Stage, Analytical Stage and Post-Analytical Stage) and an introduction to Standard Operating Procedures.

Following sessions are divided by subject areas: Haematology, Biochemistry, Microbiology, Parasitology and Urine Analysis. Each subject is introduced with a theoretical session on sample collection, sample storage & transportation, and waste disposal & precautions. Internal Quality Control procedures for selected tests are highlighted. Practical sessions in the afternoon focus on selected tests. Practical work is done through group work. Practical sessions are concluded by discussions and grading of the best performing group of the day. The course outline may be adjusted to correspond with the level of training of participants (i.e., laboratory assistants might receive more elaborate training on haematology and parasitolgy and receive only limited instruction in microbiology).

Participants:

The course is suitable for both laboratory assistants and laboratory technicians, with at least three years of practical work experience.

⇒ As far as possible, laboratory assistants and technicians should be grouped in different training courses to maintain an equal level of background knowledge.
⇒ Laboratory personnel who have worked only in vertical disease-specific programmes should not be included, unless they have received two months refresher training.
Practical Sessions:

During the practical sessions trainees will do all tests that have been taught in the morning. Trainees are divided into groups of two. Trainees will receive SOPs for each test and perform the test with only little supervision by the trainer. At the end of the session test results are compared and problems are discussed. The best group of the day is awarded with a symbolic certificate.

Working in Groups

- Working in groups creates a team environment.

- Comparing results with other groups encourages competitions and the desire to perform better.

- Competitive behaviour raises service quality.

Trouble shooting and discussion:

- This encourages the learner to think about problems.

- It helps to develop analytical thinking skills

- Points out ways to solve problems.

- A good forum to exchange experiences.

Grading of best performing group of the day:

- Creates a sense of competition and striving for perfection.
<table>
<thead>
<tr>
<th>Day</th>
<th>Time</th>
<th>Morning Session</th>
<th>Time</th>
<th>Afternoon Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td></td>
<td><strong>Introduction to Quality Assurance Programme</strong></td>
<td>12:30 - 01:30</td>
<td><strong>The Three Stages of Quality Assurance</strong></td>
</tr>
<tr>
<td></td>
<td>10:00 - 11:00</td>
<td>Quality Assurance Programme in Nepal, External Quality Assessment, Internal Quality Control, Quality Management</td>
<td>15 min break</td>
<td>Pre-analytical Stage, Analytical Stage, Post Analytical Stage</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>01:45 - 02:45</td>
<td><strong>Introduction to Standard Operating Procedures</strong></td>
</tr>
<tr>
<td></td>
<td>15 min break</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11:15 - 12:15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd</td>
<td>10:00 - 11:00</td>
<td><strong>Quality Assurance in Haematology</strong></td>
<td>12:30 - 03:30</td>
<td><strong>Practical Sessions</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sample Collection, Sample Storage and Transportation, Universal Precautions, Waste disposal and cleaning</td>
<td></td>
<td>Haemoglobin, Salhi Method, Total WBC Count, Differential WBC Count, ESR</td>
</tr>
<tr>
<td></td>
<td>15 min break</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11:15 - 12:15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Internal Quality Control Procedures for selected tests:</strong></td>
<td></td>
<td><strong>Working in groups</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Haemoglobin, Salhi Method, Total WBC Count, Differential WBC Count, ESR</td>
<td></td>
<td>Result comparison, Trouble shooting and Discussion, Grading of best performing group of the day</td>
</tr>
<tr>
<td>3rd</td>
<td>10:00 - 11:00</td>
<td><strong>Quality Assurance in Haematology</strong></td>
<td>12:30 - 03:30</td>
<td><strong>Practical Sessions</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Haemoglobin, Colorimetric method, Preparation of a calibration graph</td>
<td></td>
<td>Preparation of calibration graph, Haemoglobin measurement</td>
</tr>
<tr>
<td></td>
<td>15 min break</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11:15 - 12:15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Internal Quality Control Procedures for selected tests:</strong></td>
<td></td>
<td><strong>Working in groups</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Haemoglobin, Colorimetric method</td>
<td></td>
<td>Result comparison, Trouble shooting and Discussion, Grading of best performing group of the day</td>
</tr>
<tr>
<td>Day</td>
<td>Time</td>
<td>Morning Session</td>
<td>Time</td>
<td>Afternoon Session</td>
</tr>
<tr>
<td>------</td>
<td>---------------</td>
<td>------------------------------------------------------</td>
<td>----------</td>
<td>------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>4th</td>
<td>10:00 - 11:00</td>
<td>Quality Assurance in Biochemistry</td>
<td>12:30 - 03:30</td>
<td>Equipment Maintenance: Cleaning, Handling and Simple Preventive Maintenance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sample Collection</td>
<td></td>
<td>• The Microscope</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sample Storage and Transportation</td>
<td></td>
<td>• The Centrifuge</td>
</tr>
<tr>
<td></td>
<td>15 min break</td>
<td></td>
<td></td>
<td>• The Colorimeter</td>
</tr>
<tr>
<td></td>
<td>11:15 - 12:15</td>
<td>Internal Quality Control Procedures for selected tests:</td>
<td></td>
<td>• The Auto-pipette</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Blood Sugar</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Urea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5th</td>
<td>10:00 - 11:00</td>
<td>Quality Assurance in Biochemistry</td>
<td>12:30 - 03:30</td>
<td>Practical Sessions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Precision</td>
<td></td>
<td>• Blood Sugar</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Accuracy</td>
<td></td>
<td>• Urea</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Mean</td>
<td></td>
<td>• Prepare Calibration Graph</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Standard Deviation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Calibration Graph</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>15 min break</td>
<td></td>
<td></td>
<td>Working in groups</td>
</tr>
<tr>
<td></td>
<td>11:15 –12:15</td>
<td></td>
<td></td>
<td>• Result comparison</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Trouble shooting and Discussion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Grading of best performing group of the day</td>
</tr>
<tr>
<td>6th</td>
<td>10:00 - 11:00</td>
<td>Quality Assurance in Microbiology</td>
<td>12:30 - 03:30</td>
<td>Practical Sessions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sample Collection: Sputum, Skin smear and skin scrapping for fungus.</td>
<td></td>
<td>• Gram Stain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sample Storage and Transportation</td>
<td></td>
<td>• Ziehl Neelsen Stain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Waste Disposal</td>
<td></td>
<td>• Fungus and Scabies scrapping</td>
</tr>
<tr>
<td></td>
<td>15 min break</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11:15 - 12:15</td>
<td>Internal Quality Control Procedures for selected tests:</td>
<td></td>
<td>Working in groups</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Gram Stain</td>
<td></td>
<td>• Result comparison</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ziehl Neelsen Stain</td>
<td></td>
<td>• Trouble shooting and Discussion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Fungus and Scabies scrapping</td>
<td></td>
<td>• Grading of best performing group of the day</td>
</tr>
<tr>
<td>Day</td>
<td>Time</td>
<td>Morning Session</td>
<td>Time</td>
<td>Afternoon Session</td>
</tr>
<tr>
<td>-----</td>
<td>------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>7th</td>
<td>10:00 - 11:00</td>
<td>- Quality Assurance in Microbiology &lt;br&gt; • Sample Collection: Urine and Blood &lt;br&gt; • Sample Storage and Transportation &lt;br&gt; • Disinfecting and Sterilisation &lt;br&gt; - Internal Quality Control for selected tests: &lt;br&gt; • Urine culture &lt;br&gt; • Blood culture</td>
<td>12:30 - 03:30</td>
<td>- Practical Sessions &lt;br&gt; • Urine culture &lt;br&gt; • Blood culture &lt;br&gt; - Working in groups &lt;br&gt; • Result comparison &lt;br&gt; • Trouble shooting and Discussion &lt;br&gt; • Grading of best performing group of the day</td>
</tr>
<tr>
<td>8th</td>
<td>10:00 - 11:00</td>
<td>- Quality Assurance in Parasitology &lt;br&gt; • Sample Collection: Stool &lt;br&gt; • Sample Storage and Transportation &lt;br&gt; • Waste Disposal and Precautions &lt;br&gt; - Internal Quality Control Procedures for: &lt;br&gt; • Stool examination for Helminths &lt;br&gt; • Stool examination for Protozoa</td>
<td>12:30 - 03:30</td>
<td>- Practical Sessions &lt;br&gt; • Direct wet smear preparation &lt;br&gt; • Saturated Saline Concentration &lt;br&gt; - Working in groups &lt;br&gt; • Result comparison &lt;br&gt; • Trouble shooting and Discussion &lt;br&gt; • Grading of best performing group of the day</td>
</tr>
<tr>
<td>9th</td>
<td>10:00 - 11:00</td>
<td>- Quality Assurance in Parasitology &lt;br&gt; • Introduce Formol-ether Concentration method and modified Ziehl Neelsen for Cyclospora</td>
<td>12:30 - 03:30</td>
<td>- Practical Sessions &lt;br&gt; • Formol-ether Concentration &lt;br&gt; • Modified Ziehl Neelsen for Cyclospora &lt;br&gt; - Working in groups &lt;br&gt; • Result comparison &lt;br&gt; • Trouble shooting and Discussion &lt;br&gt; • Grading of best performing group of the day</td>
</tr>
<tr>
<td>Day</td>
<td>Time</td>
<td>Morning Session</td>
<td>Time</td>
<td>Afternoon Session</td>
</tr>
<tr>
<td>-------</td>
<td>----------</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 10<sup>th</sup> | 10:00 - 11:00 | ❖ **Quality Assurance in Parasitology**  
   - Sample Collection: Blood  
   - Sample Storage and Transportation | 12:30 - 03:30 | ❖ **Practical Sessions**  
   - Blood film examination for Parasites  
   ❖ **Working in groups**  
   - Result comparison  
   - Trouble shooting and Discussion  
   - Grading of best performing group of the day |
|       | 15 min break | ❖ **Internal Quality Control Procedures for selected tests:**  
   - Malaria  
   - Filaria  
   - Leishmania |          |                                                                                   |
|       | 11:15 - 12:15 | ❖ **Internal Quality Control Procedures for selected tests:**  
   - Malaria  
   - Filaria  
   - Leishmania |          |                                                                                   |
| 11<sup>th</sup> | 10:00 - 11:00 | ❖ **Urine analysis**  
   - Sample Collection  
   - Sample Storage and Transportation  
   - Code of Conduct | 12:30 - 03:30 | ❖ **Practical Sessions**  
   - Sugar  
   - Protein  
   - Bile pigment  
   - Urinary deposit  
   ❖ **Working in groups**  
   - Result comparison  
   - Trouble shooting and Discussion  
   - Grading of best performing group of the day |
|       | 15 min break | ❖ **Internal Quality Control Procedures for selected tests:**  
   - Sugar  
   - Protein  
   - Bile pigment  
   - Urinary deposit |          |                                                                                   |
|       | 11:15 - 12:15 | ❖ **Internal Quality Control Procedures for selected tests:**  
   - Sugar  
   - Protein  
   - Bile pigment  
   - Urinary deposit |          |                                                                                   |
| 12<sup>th</sup> | 10:00 - 11:00 | ❖ **Final test with Multiple Choice Questions** | 12:30 - 03:30 | ❖ **Discussion**  
   ❖ **Evaluation of Training** |
|       | 15 min break |                                                                                   |          |                                                                                   |
|       | 11:15 - 12:15 |                                                                                   |          |                                                                                   |
The Quality Assurance Programme in Nepal

Laboratory quality assurance programmes ensure that test results are relevant, reliable and reproducible.

The Quality Assurance Programme in Nepal includes Internal Quality Control (IQC) procedures, an External Quality Assessment (EQA) programme and Quality Management (QM).

Internal Quality Control Procedures are done every day at the laboratory. IQC procedures are applied to all work processes and to every test done in the laboratory. IQC procedures ensure that test results are done with utmost care and to the best ability of the staff doing the test. IQC procedures identify problems immediately.

Examples of IQC procedures are: recording daily the temperature of the incubator or refrigerator, repeating tests, following SOPs and proper work organisation.

All staff working at the laboratory are responsible to follow established IQC procedures. Many mistakes can be avoided and the quality of test results can be raised if IQC procedures are followed strictly.
The Quality Assurance Programme in Nepal

External Quality Assessments are organised by the National Public Health Laboratory in Kathmandu. So far only district and higher level laboratories have been included in the EQA scheme.

In the past EQA samples were dispatched to 22 hospitals in the Central Regions, 12 in the Mid-Western and the 17 in the Western Region. Control-samples included the following tests: Haemoglobin, Total WBC Count, Differential WBC Count, Urea, Glucose, Gram and Ziehl Neelsen Stain.

Quality control samples are sent from the NPHL to your laboratory in regular intervals. A form accompanies each control sample. (See sample form!)

Like patient samples the control samples are examined and the test results recorded in your register and on the EQA form. The form is sent back to the National Public Health Laboratory as soon as possible.

Staff from the quality control programme at the NPHL will evaluate the results and in return inform you about the outcome.
The Quality Assurance Programme in Nepal

If your test results are out of the control range, staff from the NPHL will contact you to discuss the problem and find solutions. Most likely all patient samples for the out of control test are also not correct so it is very important that you correct the mistakes quickly.

Quality Management includes all the support functions that are required to produce quality test results. It includes the support and supervision that you receive from NPHL staff. QM includes training of laboratory staff, the use of standard operating procedures (SOP), standard supply management, standard equipment management and supervision of peripheral laboratories.
Quality Assurance Programme in Nepal

Quality Management

National Public Health Laboratory

External Quality Assessment Programme

Training

Control samples to District Hospital

Results to NPHL

Feedback and advice from NPHL

Supervision

Equipment

Supplies

SOPs

District Hospital

IQC Procedures

DAILY

©Mallapaty – June 2000
<table>
<thead>
<tr>
<th>Test</th>
<th>Expected mean result</th>
<th>Acceptable range within 2SD</th>
<th>Your laboratory’s result</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobin QA 4.1</td>
<td>g/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total WBC Count QA 4.1</td>
<td>/cm3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Differential WBC Count QA 4.2</td>
<td>Poly % Lympho % Mono % Eosino % Baso % MP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Sugar, QA 4.3</td>
<td>mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Urea, QA 4.3</td>
<td>mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gram Stain, QA 4.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum for AFB,QA 4.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum for AFB,QA 4.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
National Public Health Laboratory
Quality Control Programme
Teku, Kathmandu
Quality Control Answer sheet for the Hospital Laboratory in:
…………………………………………………………………….
Quality Control No: QC 4

Date of Arrival in your hospital:
Please sent this answer sheet back to NPHL until: 2057/02/25

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Date of Testing</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobin QC 4.1</td>
<td>g/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total WBC Count QC 4.1</td>
<td>/cmm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Differential WBC Count QC 4.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Poly</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lympho</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mono</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Eosino</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Baso</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Sugar QC 4.3</td>
<td>mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Urea QC 4.3</td>
<td>mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gram stain QC 4.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum for AFB QC 4.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum for AFB QC 4.6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature:
QUALITY ASSURANCE PROGRAMME

- Internal Quality Control (IQC) Procedures
- External Quality Assessment (EQA)
- Quality Management

The ultimate goal of any quality system is to obtain test results that are reliable, relevant and reproducible.
Internal Quality Control (IQC) Procedures

- Done during daily routine work
- Provides an immediate control
- Errors are corrected immediately

External Quality Assessment (EQA)

- Evaluates past performance
- Testing of unknown samples
- Compare performance with others
- Provides a forum for improvements and correction of errors

Quality Management

- Training of laboratory staff
- The use of SOPs
- Standard supply management
- Standard equipment management
- Supervision and organisation
QUALITY ASSURANCE PROGRAMME

Why do we need Internal Quality Control?

- Ensure that test results are reliable
- Ensure that test results are reproducible
- Control quality of daily routine work

Why do we need External Quality Assessment?

- To detect hidden problems
- To receive help and support from the NPHL
- To compare our performance with others and improve quality

Why do we need Quality Management?

- Enables us to produce quality results
- Ensure that test result are affordable
- Ensure that test results are relevant
- Ensure that test results are interpreted correctly

©Mallapaty –June 2000
THE THREE STAGES OF QUALITY ASSURANCE

- Pre-analytical Stage
- Analytical Stage
- Post-analytical stage

©Mallapaty – June 2000
• **Pre-analytical Stage**
  - Management and organisation of the laboratory
  - Usefulness of the requested test
  - Patient preparation
  - Specimen collection
  - Specimen storage
  - Specimen transportation

• **Analytical Stage**
  - Routine work organisation
  - Test method used
  - Reagents used
  - State of the equipment
  - Standard Operating Procedures followed
  - Internal Quality Control procedures

• **Post-analytical stage**
  - Organisation of recording and reporting
  - Reporting and interpretation of results
  - Speed of reporting
Standard Operating Procedures (SOPs)

- SOPs are an important part of the quality assurance programme.

- SOPs are written instruction protocols that include all aspects of laboratory work practices.

- SOPs help prevent mistakes rather than detecting them.
SOPs have the following features:

- SOPs are written in accordance with a standard format
- SOPs are written in simple language, readily understood by employees
- SOPs contain sufficient procedural details to enable trained staff to perform the task without supervision
- SOPs are written by qualified and experienced laboratory officers
- SOPs must be followed exactly by all staff
- SOPs must be given a title, identification number and date
- SOPs are reviewed and updated on a regular basis
## Example SOP

### ERYTHROCYTE SEDIMENTATION RATE (ESR)

#### WESTERGREN METHOD

<table>
<thead>
<tr>
<th>Authorised signature:</th>
<th>Issuing Date:</th>
<th>Next Revision Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>April 12, 2000</td>
<td>April 12, 2001</td>
</tr>
</tbody>
</table>

### Staff able to perform test: Laboratory Assistant and higher

### Principle of the Test Method

The ESR expresses in mm per hour the rate at which red blood cells settle when anti-coagulated blood is allowed to stand in a narrow tube (Westergren). It is shown by the height of the column of clear plasma at the end of one hour.

### Clinical Significance of the Test:

ESR is used as a screening method for all diseases that are associated with a modification of the plasma proteins like globulin, albumin and fibrinogen. ESR is not a very reliable screening method as it can be raised when there is no disease and can be normal when disease is present. It also does not indicate the type of disease.

### Specimen:

- 2 ml fresh Venous Blood or
- 2 ml fresh EDTA Blood (If kept at 4°C not older than 24 h)

### Equipment Requirements:

- Westergren rack
- Westergren tubes, internal diametre 2.5mm
- Dilution bottles to hold 2 ml (4 volumes of blood/1 volume of anticoagulant diluent solution)
- Timer (1 hour)

### Reagents & Stain Requirements:

3.8% Trisodium Citrate Solution

**Preparation of 3.8% Tri-sodium Citrate Solution**

- Tri-sodium Citrate, anhydrous ........................................ 3.8 g
- Distilled water......................................................... up to 100 ml

**Important:** Keep the solution in the refrigerator. If the solution is cloudy or contains particle discard and prepare a fresh solution!
**Example SOP**

<table>
<thead>
<tr>
<th>ERYTHROCYTE SEDIMENTATION RATE (ESR) WESTERGREN METHOD</th>
<th>A – 001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorised signature:</td>
<td></td>
</tr>
<tr>
<td>Issuing Date:</td>
<td>April 12, 2000</td>
</tr>
<tr>
<td>Next Revision Date:</td>
<td>April 12, 2001</td>
</tr>
<tr>
<td>Staff able to perform test:</td>
<td>Laboratory Assistant and higher</td>
</tr>
<tr>
<td>Test Procedure Instructions:</td>
<td></td>
</tr>
<tr>
<td>• Measure exactly 0.4 ml of the 3.8% Tri-sodium citrate solution, with the help of a pipette or a syringe into a clean and dry small bottle.</td>
<td></td>
</tr>
<tr>
<td>• Draw 2ml of venous blood and immediately place 1.6 ml into the Trisodium citrate solution. <strong>Note:</strong> You can also use EDTA blood. If kept at 4°C, it can be used after up to 24 hours. In this case mix the EDTA blood well, and place 1.6 ml into the Tri-sodium citrate solution.</td>
<td></td>
</tr>
<tr>
<td>• Mix the blood and Trisodium citrate solution well.</td>
<td></td>
</tr>
<tr>
<td>• Fill a clean and dry Westergren ESR Tube with the mixture up to the 0 mark.</td>
<td></td>
</tr>
<tr>
<td>• Do not mouth pipette. Use a pipetting device.</td>
<td></td>
</tr>
<tr>
<td>• Wipe the outside of the Westergren tube with a tissue.</td>
<td></td>
</tr>
<tr>
<td>• Make sure no air bubbles enter the tube.</td>
<td></td>
</tr>
<tr>
<td>• Recheck that the tube is filled up to the 0 mark, exactly.</td>
<td></td>
</tr>
<tr>
<td>• Close the top of the tube firmly while you place the tube into the tube holder, otherwise the mixture could escape the tube.</td>
<td></td>
</tr>
<tr>
<td>• Immediately set your timer for 1 hour or write down the time on a sheet of paper.</td>
<td></td>
</tr>
<tr>
<td>• Exactly after 1 hour read how far the red cell layer has fallen. Give the result in mm per hour.</td>
<td></td>
</tr>
</tbody>
</table>
# Example SOP

**ERYTHROCYTE SEDIMENTATION RATE (ESR) WESTERGREN METHOD**

<table>
<thead>
<tr>
<th>Authorised signature:</th>
<th>Issuing Date: April 12, 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next Revision Date:</td>
<td>April 12, 2001</td>
</tr>
</tbody>
</table>

**Staff able to perform test:** Laboratory Assistant and higher

**Reporting and Interpretation of Results:**

**Normal Value:**
- Male: 1 - 10 mm /hour
- Female: 3 - 14 mm /hour

**Increased Values of ESR:**
- Are found with all diseases associated with a modification of the plasma proteins like globulin, albumin and fibrinogen. ESR shows especially high values in:
  - Tuberculosis
  - Leishmaniases
  - Malignant condition
  - Hepatic Amoebiasis
  - Acute and Chronic Inflammation

**Special Note:**
- While reading the result you should also pay attention to the following:
  - The colour of the plasma:
    - Dark yellow, indicates Hepatitis
    - Clear as water, indicates lack of iron
    - White and turbid, indicates Nephrosis, Diabetes, Lipaemia.

- The layer of white blood cells just above the red cells:
  - If increased, indicates Leukaemia.

**Internal Quality Control Procedures and Sources of Error:**

- Correct dilution of blood and Tri-sodium Citrate Solution
- Store Tri-sodium Citrate Solution in the refrigerator
- Tri-sodium Citrate Solution should not be turbid
- Avoid air-bubbles in the Westergren tube
- Place the Westergren tube in a vertical position
- Temperatures above 23 °C increase the speed of the ESR, therefore keep the ESR rack at the coolest place of the lab and out of direct sun light.

**Reference:**
- Maurice King, 1973 A Medical Laboratory for Developing Countries, London, Oxford University Press
Sample Collection 1:

Haematological tests are carried out with fresh capillary blood or anti-coagulated venous blood.

**Capillary blood**

- Capillary blood is obtained by directly pricking the finger, the ear-lobe or the heel of the foot in infants.
- Capillary blood is used immediately and therefore does not need anticoagulants to be added.
- Capillary blood can be used for Haemoglobin estimation with the Sahli-Method, Total WBC-Count, Differential WBC-Count, Platelet count, Reticulocyte count and Blood film for Malaria or Filaria.
- Proper collection of Capillary blood for haematology: See separate sheet!
QUALITY ASSURANCE IN HAEMATOLOGY

Sample Collection 2:

Venous blood

⇒ Venous blood is obtained by veni-puncture.
⇒ Anti-coagulant must be added to the blood to prevent the blood from clotting.
⇒ Commonly used anti-coagulants for haematology are EDTA, Heparin or Trisodium-citrate.

Anti-coagulated blood with EDTA

⇒ The correct dilution of EDTA and blood is very important. See separate sheet!
⇒ Differential WBC films and blood films for malaria parasites should be made within one hour of collecting the blood into EDTA.

Anti-coagulated blood with Trisodium-citrate

⇒ Trisodium citrate is mainly used to dilute blood for ESR.
⇒ ESR can be done with EDTA blood but blood must still be diluted with Tri-sodium citrate.

©Mallapaty – June 2000
QUALITY ASSURANCE IN HAEMATOLOGY

Sample Collection 3:

Preparation of EDTA anti-coagulant bottles

Step one: Prepare 10% EDTA solution

EDTA (Ethylene Diamine Tetra-Acetate) powder….. 10 g
Distilled water…………………………………………… 100 ml

Weigh the powder and dissolve in 100 ml of distilled water. Place the solution into a labelled reagent bottle.

Step two: Prepare the sample collection (Bijou) bottles

• Place dry clean sample bottle (Bijou) on the bench
• Pipette exactly 0.05ml of 10% EDTA solution into each bottle.
• Keep the sample bottles open in a dust-free place over night to completely dry.
• When dry cap the sample bottles and label “EDTA”
• Bottles can be stored at room temperature up to one year.

Step three: Collect patient blood into the bottles

• Add between 2.5 to 5 ml of blood

  NEVER add a pinch of EDTA powder directly to the sample bottles! - High concentration of EDTA leads to shrinking of RBC and destroys the structure of WBC and platelets.

  NEVER add the blood before the EDTA solution is completely dried! - It will dilute the blood and destroy RBC.
QUALITY ASSURANCE IN HAEMATOLOGY

Sample Collection 4:

Capillary blood collection:

Step one: Arrange all items required:

- Sterile lancets
- Dry cotton wool
- Cotton wool soaked in 70% alcohol
- Clean glass slides or 20 µl pipettes
- Reagents as needed

Step two: Collect the blood

1. Clean the skin thoroughly with an alcohol swab.
2. Let dry.
3. Prick the finger deep enough so that blood flows freely.
4. Wipe the first drop of blood with a dry cotton swab.
5. Use the next drop for your sample.

NEVER use absolute alcohol for disinfecting the skin! Use only 70% alcohol!

NEVER use blood that has been squeezed out by force! Rub the hand and prick another finger again!
QUALITY ASSURANCE IN HAEMATOLOGY

Sample Storage and Transportation:

Blood films:

⇒ When EDTA blood is used blood films should be prepared within one hour after collection.
⇒ Store unstained blood films in a dry place and protected from direct sunlight, dust and flies.
⇒ Stain blood films as soon as possible.
⇒ Keep malaria and filaria positive slides in a box for future inspection by the supervisor.
⇒ Keep doubtful slides in a separate box for inspection by the supervisor.
⇒ For transportation wrap each slide into a piece of paper and keep it in a box to avoid breakage.

EDTA anti-coagulated venous blood

⇒ If examination is not possible immediately store the blood in the refrigerator at 4 – 8 °C.
⇒ For most haematological test EDTA anti-coagulated blood can be used for up to 1 week.
⇒ Only blood films must be prepared within one hour.
⇒ If transportation is needed transfer the blood into a screw capped bottle or tube. Transport the blood at appropriate temperature.
QUALITY ASSURANCE IN HAEMATOLOGY

Universal Precautions:

✧ Consider all blood specimens as potentially infectious!

✧ Consider all equipment that has been in contact with blood specimens as potentially infectious!

✧ Keep the laboratory clean!

✧ After work, wipe benches with disinfectant!

✧ Do not mouth pipette!

✧ Wear protective coats at all times!

✧ Do not eat, drink or smoke in the laboratory!

✧ Cover open wounds with band-aid!

©Mallapaty – June 2000
Waste Disposal and Cleaning:

Blood:

- Where running water is available, pour blood into a sink that is connected to a soak pit.
- Where running water is not available pour blood into a bucket that contains 10% Phenol solution (e.g. Lysol) dispose off with solid waste (bury)

Glass slides:

- Soak glass slides in 5% Phenol solution (e.g. Lysol) at least over night.
- Clean and rinse next day.

Needles and Lancets:

- Keep needles in an empty metal container. Burn and bury.
- If needles are reused soak in 5% Phenol solution (e.g. Lysol) at least over night.
- Boil or autoclave.
QUALITY ASSURANCE IN HAEMATOLOGY

IQC Procedures:

Haemoglobin Sahli Method
- After pricking the finger, remove the first drop of blood.
- Avoid blood clots while collecting the blood.
- Do not allow air-bubbles to enter the pipette.
- Wipe the tip of the pipette before entering the hydrochloric acid solution.
- Add the hydrochloric acid drop by drop and compare the colour after each drop.
- If the haemoglobin concentration is very low inform the doctor or health-care worker immediately.

ESR Westergren
- Correct dilution of blood and Tri-sodium Citrate Solution
- Store Tri-sodium Citrate Solution in the refrigerator
- Tri-sodium Citrate Solution should not be turbid
- Avoid air-bubbles in the Westergren tube
- Place the Westergren tube in a vertical position
- Temperatures above 23 °C increase the speed of the ESR. Therefore keep the ESR rack at the coolest place of the lab and out of direct sun light.
QUALITY ASSURANCE IN HAEMATOLOGY

IQC Procedures:

Total White Blood Cell Count
• Mix the blood and Turk’s solution well before filling the counting chamber.
• Place the cover-slip firmly onto the chamber. You should see rain-bow colours at both sides of the inner rim of the chamber.
• Only use cover-slips of the counting chamber, do not use ordinary glass-slips.
• Do not let air-bubbles enter while filling the counting chamber
• Count the WBC in all four corners of the chamber
• Properly calculate the results

Differential White Blood Cell Count
• Only examine slides that have an appropriate thickness. See example!
• Examine the slide at the right place of the slide
• Count exactly 100 cells before reporting the result
• Evaluate the RBC morphology
• Report the morphology of platelets
QUALITY ASSURANCE IN HAEMATOLOGY

The calibration graph for haemoglobin

- Calibration graphs are used to calibrate (fine tune) the test method.
- The calibration graph verifies if the light- absorbence of the substance being measured increases in a linear way with its concentration.
- When using a colorimeter you must prepare a calibration graph to check for linearity, because you are measuring with a filter of a range (480-504 nm) and not a filter of a specific wavelength.
- Only calibration graphs that are linear can be used for reading haemoglobin concentrations.
- If the graph is repeatedly not linear check your instruments (bulb, filter, etc.).
- You can prepare a table of values from the calibration graph, where the reading of absorbance on the colorimeter relates directly to the concentration of the haemoglobin in the sample. This makes reading easier.

  e.g.  Absorbance  Hb concentration
        0.20       =  5.8 g/dl
        0.21       =  6.1 g/dl
        0.22       =  6.4 g/dl
        ↓          ↓
        0.40       =  11.6 g/dl
QUALITY ASSURANCE IN HAEMATOLOGY

The calibration graph for haemoglobin

A linear graph
Beer-Lambert law applies

A non-linear graph
Beer-Lambert law does not apply

The Beer-Lambert law

\[
CT = \frac{AT}{AS} \times CS
\]

CT = Concentration of test sample
AT = Absorbance of test sample
AS = Absorbance of standard
CS = Concentration of standard
QUALITY ASSURANCE IN HAEMATOLOGY

IQC Procedures:

Haemoglobin Colorimetric method

• Prepare a new calibration graph whenever changing the colorimeter, cuvettes type or the test method.
• After switching on the colorimeter, always allow the colorimeter to warm up before measuring the test sample.
• Always make sure to use the right filter of 540nm wavelength (yellow/green filter)
• Repeat test on a single specimen to control for reproducibility (precision)
• Repeated testing of the same specimen can not control for accuracy, as you are measuring on the same instrument and use the same pipettes and reagents.
• Accuracy needs to be tested with control samples of known value.
• Control samples are either commercially available control samples or samples of known (true value) value measured by a very reliable laboratory.

©Mallapaty – June 2000
QUALITY ASSURANCE IN HAEMATOLOGY

IQC Procedures:

Haemoglobin Colorimetric method

• Always check a new stock of Drabkin’s solution with the old stock of the solution on a known sample before using it for patient samples.

• Drabkin’s solution should be clear and pale yellow in colour. If it is turbid or loses its colour discard it.

• Drabkin’s solution is very poisonous, handle with care. Do not mouth pipette!

• Make sure to leave the blood mixed with Drabkin’s solution for 10 minutes so that the haemoglobin can convert to haemiglobincyanide.

• Careful with cuvettes with frosted sides, the clear side must face the light path.

• Avoid air bubbles in the cuvette.

©Mallapaty – June 2000
QUALITY ASSURANCE IN BIOCHEMISTRY

Sample Collection:

Venous blood sample collection for biochemistry:

Serum is used for most biochemistry tests carried out at a district hospital.

⇒ Do not leave the tourniquet on the arm for more than 2 minutes, as this will affect the concentration of cells and substances in the blood.
⇒ Do not collect the blood from an arm in which an intravenous infusion is being given.
⇒ Remove the needle from the syringe before pouring the blood into the collection tube. Transferring the blood through the needle may cause haemolysis, breaking of the red cells.
⇒ The collection tube must be clean and dry.
⇒ Allow the blood to clot at room temperature away from direct sunlight.
⇒ Centrifuge the blood and separate the serum as soon as possible, latest within 1 hour after collection.
⇒ Never store whole blood in the refrigerator, as the cold will cause haemolysis, breaking of the red cells.
⇒ After centrifugation remove the serum carefully without sucking up red cells.
QUALITY ASSURANCE IN BIOCHEMISTRY

Sample Collection:

Blood sugar

Blood for blood sugar estimation is normally requested as a fasting specimen. You should be familiar with the following terms:

Fasting specimen
⇒ This means no food has been taken since the night before and the blood sample is collected in the morning before breakfast.

Post-prandial specimen (PP)
⇒ This means the specimen has been taken about two hours after the last meal.

Random
⇒ This means the specimen has been collected any time of the day, disregarding food intake.

The normal range of blood sugar differs in serum & plasma, plasma levels are about 15% higher.

Below find normal values for adults:

<table>
<thead>
<tr>
<th></th>
<th>Fasting</th>
<th>Random</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Less than 120 mg%</td>
<td>Less than 180 mg%</td>
</tr>
<tr>
<td>Plasma</td>
<td>Less than 140 mg %</td>
<td>Less than 200 mg %</td>
</tr>
</tbody>
</table>
QUALITY ASSURANCE IN BIOCHEMISTRY

Sample Storage and Transportation:

⇒ After separation of the serum from the blood clot, carry out the biochemistry test as soon as possible.
⇒ Not all analytes are stable, which means their concentration will reduce over time.
⇒ Generally, stability is prolonged if the serum is kept in the refrigerator.
⇒ Some analytes such as bilirubin are also affected by light.

Below is a list indicating the stability of analytes in serum:

<table>
<thead>
<tr>
<th>Test</th>
<th>Stability at Room temperature</th>
<th>Affected by Haemolysis</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>Few hours only</td>
<td>Yes</td>
<td>Red blood cells cause glycolysis</td>
</tr>
<tr>
<td>Urea</td>
<td>1 day</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td>Few hours only</td>
<td>Yes</td>
<td>Examine as soon as possible</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>1-2 hours only Away from light</td>
<td>Yes</td>
<td>Light reduces the concentration of bilirubin</td>
</tr>
<tr>
<td>Albumine</td>
<td>Few hours only</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Amylase</td>
<td>1-2 days</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
QUALITY ASSURANCE IN BIOCHEMISTRY

IQC Procedures:

General

- Do not examine the specimen, when blood is haemolysed.
- Do not examine the specimen, when the time of the sample collection is not clear.
- Label the specimen with patient name and lab number to avoid confusion.
- Take great care when pipetting samples and reagents.
- Care for your colorimeter, cover it with a protective cover when not in use.
- Handle filters with great care. Do not touch the filter with fingers, always hold from the side.
- Prepare standard curves, whenever you use new reagents or equipment.
- If possible use commercially available control sera to control accuracy.
- Do repeated tests or redo test from the day before, to check your precision.
- Be careful when repeating and redoing tests some analytes are not stable.
- The serum for blood sugar has to be separated from the blood clot within one hour after the blood collection and the test should be done within two hours after collection as the concentration of glucose decreases over time due to glycolysis.
QUALITY ASSURANCE EQUIPMENT

The Microscope:

• The microscope is the most important instrument in a peripheral laboratory.
• It allows us to diagnose numerous infectious diseases and count and identify cells in many specimens.
• Protect your microscope against: dust, humidity, scratches and jolts.
• Always cover the microscope with a dust cover.
• Always wipe off immersion oil from the 100x objective.
• Use xylene only to wipe off oil from the 100x objective, never use it on other objectives.
• Never place the microscope into direct sunlight.
• Wipe objectives only with a soft cloth, avoid scratches.
• Always keep a spare bulb and a spare fuse in your laboratory.
QUALITY ASSURANCE EQUIPMENT

The Centrifuge

• Always place the centrifuge on a sturdy level bench.
• Only use tick-walled centrifuge tubes for centrifugation.
• Make sure that the content on each side of the tube holder is equal to void breakage.
• Always close the lid during centrifugation to avoid dangerous aerosol.
• Never attempt to stop the moving centrifuge by hand. (Injury and aerosol).
• When using a swing-out rotor centrifuge, make sure the size of the tubes is correct, otherwise tubes can break when the bucket swings out to its horizontal position.
• Regularly clean the centrifuge with disinfectant.
• Always keep a spare carbon brush in your laboratory.
QUALITY ASSURANCE EQUIPMENT

The Colorimeter

• The colorimeter is a sensitive instrument and must be protected from dust, shock and heat.
• Use only correct types of cuvettes for your colorimeter as recommended by the manufacturer.
• Make sure the cuvettes are free from dirt and finger prints
• Always check if you are using the filter of the correct wavelength for the test method.
• Calibrate the colorimeter for each test method
• Always keep a spare bulb in your laboratory.
• When zeroing of the colorimeter becomes difficult the bulb needs to be changed.
• Do not touch the glass of the bulb with your fingers.
QUALITY ASSURANCE EQUIPMENT

The Auto-pipette

- Auto-pipettes will only function accurately if they are well maintained and kept clean.

- Auto-pipettes are expensive, handle them with care.

- Use only tips recommended by the manufacturer for the auto-pipette.

- Auto-pipettes should be dismantled and cleaned from time to time. Follow manufactures instructions.

- Plastic pipette tips can be reused but must be disinfected and well cleaned before reuse.
ACCURACY

For example:
Expected result of Blood Glucose is 120 mg%

- EXCELLENT ACCURACY
  Actual result of the Blood Glucose is 118 mg % or 123 mg %

- POOR ACCURACY
  Actual result of the Blood Glucose is 150 mg % or 92 mg %

©Mallapaty – June 2000
QUALITY ASSURANCE IN BIOCHEMISTRY

ACCURACY

Errors In Accuracy = Error Of Bias
Consistent and systematic

- Incorrect calibration
- Tests being read at an incorrect wavelength or filter
- Consistent wrong pipetting
- Incorrect factor calculation
- Use of poor quality reagents, standards.
- Set the wrong temperature

Accuracy is best checked with:

- Commercial available control sera or
- Through EQA programme sera

Two control sera should be used:

- Normal range
- Pathological Value
QUALITY ASSURANCE IN BIOCHEMISTRY

When to check for Accuracy?

- Always when changing reagents
- Always when changing instruments
- Always when changing methodology
- As a routine once a week or as appropriate

How to economise on commercially available control sera?

- Dissolve the control serum as directed
- Fill into small containers about double the quantify required for the test
- Label each container and Deep-freeze immediately
- When required remove from freezer.
- Use as required after the sera has reached room temperature
QUALITY ASSURANCE IN BIOCHEMISTRY

PRECISION

Precision Error = Error of scatter
Irregular and random

- Incorrect pipetting
- Inadequate mixing of sample with reagents
- Wrong or inconstant incubation
- Glassware not clean
- Malfunctioning equipment (dirt, air-bubbles)
- Wrong storage of samples
- Wrong handling of samples

How to avoid errors of precision?

Many errors can be avoid by applying:

- Internal Quality Control procedures &
- Quality Management
QUALITY ASSURANCE IN BIOCHEMISTRY

PRECISION

SHOWS HOW WELL A VALUE IS REPRODUCED IF DONE REPEATEDLY.

EXCELLENT PRECISION

140 mg % 

120 mg % 

100 mg % * * * *

EXCELLENT PRECISION

140 mg % 

120 mg % * * * *

100 mg % 

©Mallapty – June 2000
QUALITY ASSURANCE IN BIOCHEMISTRY

Expected result of Blood Glucose 120 mg %

Example One
• Repeated Results of the Blood Glucose show the following values:
  101, 103, 99, 101, 102 mg %

EXCELLENT PRECISION
POOR ACCURACY

Example Two
• Repeated Results of the Blood Glucose show the following values:
  122, 119, 121, 120, 123 mg %

EXCELLENT PRECISION
EXCELLENT ACCURACY
QUALITY ASSURANCE IN BIOCHEMISTRY

Mean:

Describes the midpoint of a population or in other words gives the calculated average of a set of values.

<table>
<thead>
<tr>
<th>No.</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>107 mg%</td>
</tr>
<tr>
<td>2</td>
<td>120 mg%</td>
</tr>
<tr>
<td>3</td>
<td>102 mg%</td>
</tr>
<tr>
<td>4</td>
<td>114 mg%</td>
</tr>
<tr>
<td>5</td>
<td>110 mg%</td>
</tr>
<tr>
<td>6</td>
<td>108 mg%</td>
</tr>
<tr>
<td>7</td>
<td>118 mg%</td>
</tr>
<tr>
<td>8</td>
<td>109 mg%</td>
</tr>
<tr>
<td>9</td>
<td>112 mg%</td>
</tr>
<tr>
<td>10</td>
<td>113 mg%</td>
</tr>
</tbody>
</table>

Total 1113 mg%

\[ \frac{1113 \text{ mg}\%}{10} = 111.3 \text{ mg}\% \text{ (Mean)} \]
QUALITY ASSURANCE IN BIOCHEMISTRY

Standard Deviation:

⇒ In statistical terms the distribution or scatter of values around the mean can be expressed as standard deviation.

⇒ A range of 2 standard deviations (± 2 SD) is generally considered as the limit for a control value to be acceptable.

⇒ The calculation of standard deviation is necessary when using a daily control chart. It requires commercially produced or stabilised quality control sera.
QUALITY ASSURANCE IN MICROBIOLOGY

Sample Collection:

Sputum for TB

As a rule, three sputum samples are collected:

1. When the patient comes to the health centre.
2. The following morning at home
3. At the clinic during the second visit at the health centre.

⇒ It is best to collect the first sputum in the morning
⇒ The patient may drink a glass of hot water before collecting the sputum.
⇒ The patient should stand if possible. He should take a very deep breath, filling his lungs.
⇒ He should empty his lungs in one breath, coughing as hard and deep as he can.
⇒ He should spit what he brings up into the collection container. Make sure the container is clean!
⇒ Write the name and patient number onto the container to avoid confusion.
QUALITY ASSURANCE IN MICROBIOLOGY

Sample Collection:

Skin scraping for leprosy

⇒ Label the new glass slide with a diamond pencil.
⇒ Make sure to take the smears from the indicated sites: the right ear lobe, the left ear lobe, any anaesthetic patches or around the right elbow and the left knee.
⇒ Mark clearly from which site each smear is.
⇒ Take a fold of skin between your index finger and thumb and squeeze tightly to prevent blood flow.
⇒ Collect only tissue fluid.
⇒ If there is lots of blood do not collect the sample. Make a new cut once again squeezing the skin tightly.

Skin scraping for fungus

⇒ With a scalpel scrap the edges of the lesion to obtain skin scales.
⇒ Collect onto a piece of paper or into a petri-dish.
⇒ Fold the piece of paper and label with patient name and lab number.

Pus
⇒ Collect the pus with a sterile cotton swab
⇒ Spread onto a sterile glass slide.
⇒ After it is completely dry, heat-fix or alcohol-fix the smear and Gram stain.
QUALITY ASSURANCE IN MICROBIOLOGY

Sample Storage and Transportation

Sputum for TB

⇒ After the sputum is received at the laboratory, sputum smears are prepared and heat-fixed.
⇒ Usually slides are prepare and heat-fixed before sending them to a reference laboratory.
⇒ Sputum is only sent when culture is required.

Instructions for sputum smear preparation:

⇒ Use only new slides.
⇒ Label the slide with a diamond pencil.
⇒ Prepare the smear, look especially for the mucus particles in the sputum.
⇒ Leave slides to air-dry, protect the slides from flies, insects and dust while drying.
⇒ Heat-fix the smear only after the slide is completely dry to avoid aerosol. Health hazard!
⇒ Stain the smear with Ziehl Neelsen stain.
⇒ For transportation wrap each individual smear into a piece of paper or use the slide box.
⇒ Store slides in a box away from flies, dust and direct sunlight.
QUALITY ASSURANCE IN MICROBIOLOGY

Waste Disposal:

- Sputum containers, slides and wooden applicators must be collected in a waste container that is covered with a lid.

- Dig a deep pit of 1 metre, through the waste into the pit and cover the pit with soil when it is about half filled.

- You may also burn all the waste material.

- Do not leave the waste uncovered in the open.

- Do not through the waste into a river.

- Do not reuse slides of Tb and leprosy smears.
QUALITY ASSURANCE IN MICROBIOLOGY

IQC Procedures:

Gram stain:

- Follow proper sample collection procedures.
- Don’t overheat the slide when heat-fixing the smear.
- Filter the crystal violet before use.
- Discard Lugol’s iodine when colour has faded.
- Di-colourise carefully, just few seconds and wash off with water immediately.
- Stain known samples of Gram-negative and Gram-positive bacteria once a week and whenever new stains have been prepared.
QUALITY ASSURANCE IN MICROBIOLOGY

IQC Procedures:

Ziehl Neelsen Stain:

- Follow proper sample collection procedures.
- Label slides with diamond pen, grease pencil will wash off.
- Do not recycle slides for Ziehl Neelsen stain.
- Use only new slides for Ziehl Neelsen stain.
- Don’t overheat the slide when heat-fixing the smear.
- Filter the carbol fuchsin stain onto the slide.
- Stain known sample of AFB positive sputum once a week or whenever using new carbol fuchsin stain.
- Store all positive slides in a box for re-checking by an expert.
- Store all negative slides for two weeks for possible re-checking.
QUALITY ASSURANCE IN MICROBIOLOGY

Sample collection:

Urine

⇒ For urine culture mid-stream urine collected into a sterile container is required to avoid secondary contamination of the urine sample.
⇒ Collection of mid-stream urine. See separate sheet!
⇒ It is very important to examine the urine immediately after collection; delay will increase the number of bacteria in the urine and give wrong results.

Note: It is advisable to screen all urine samples sent for culture with a screening method for urinary tract infection (UTI).
Note: The screening method avoids unnecessary culture of uninfected samples, and saves cost and time.

Screening for urinary tract infection (UTI)

⇒ Inform the physician or health worker about the screening method.
⇒ Follow the Gram staining technique of uncentrifuged urine.
⇒ Do not culture urine samples that give a negative screening method unless specifically requested by the physician.
QUALITY ASSURANCE IN MICROBIOLOGY

Sample collection:

Blood

Blood for culture must be collected under complete sterile conditions to avoid secondary contamination.

⇒ Always collect blood for culture before antibiotic treatment has been started.
⇒ If possible collect the blood at the time when the patient’s temperature is raising.
⇒ Prepare the blood culture bottle for collection. Remove the culture bottle from the fridge and bring to room temperature.
⇒ Do not use culture bottle if the culture broth appears turbid.
⇒ Disinfect the skin at the point of collection thoroughly with 70% alcohol. Let the alcohol evaporate do not touch again with your fingers.
⇒ Collect the blood and under complete sterile condition transfer about 5 ml of blood into the culture bottle. Mix gently.
⇒ Incubate the culture bottle immediately.
QUALITY ASSURANCE IN MICROBIOLOGY

Sample collection:

Tell the patient to collect mid-stream urine as follows:

- Wash your hands with soap and water.
- Take a sterile, wide-mouth collection container.
- Go to the lavatory.

**Female**

- Spread the legs apart, with your left hand spread the labia apart. Keep holding the labia apart during the entire collection process.

**Male**

- Pull back the foreskin and hold back during the entire collection period.
- Pass a small amount of urine first. Do not collect.
- Thereafter move the collection container under the stream of urine to collect it into the container.
- Do not collect the last few drops of urine.
- Close the lid of the container and bring the urine sample immediately to the laboratory for examination.
QUALITY ASSURANCE IN MICROBIOLOGY

Sterilisation:

Sterilisation is the killing of all living micro-organisms including bacterial spores.

Methods of sterilisation:

1) **Steam under pressure** (Autoclave, Steam Steriliser or Pressure Cooker).
   - Sterilisation is achieved through pressure and temperature.
   - Recommended 121°C for 15 minutes and pressure of 15 psi.
   - Used for sterilisation of culture media and instruments.

2) **Incineration**
   - Incineration is burning of material.
   - It is the most effective method of destroying infected disposable material.
   - Waste that is kept for incineration should be kept covered and well protected. Prevent access by people, animals and insects.

3) **Flaming**
   - Fire kills all living organisms.
   - Use to disinfect reusable metal or glass objects, like wire-loops, glass slides and bottle necks of culture bottles.
QUALITY ASSURANCE IN MICROBIOLOGY

Disinfection:

Disinfection is the killing or removal of pathogenic (causing disease) micro-organisms.

Methods of Disinfection:
1) Chemicals
   The chemicals most commonly used for disinfection are Phenols, Aldehydes, Alcohols and Halogens.

2) Boiling in water
   Boiling in water for 20 – 30 minutes. At altitudes above 2000 feet 30 minutes is recommended.

Where to use chemical disinfectants:
- Work benches
- Floors
- Instruments and Equipment
- Spills of potential infectious and infectious material
- Skin
- Hands
- In collection basins of glass slide, cover slips, pipettes and other re-usable.
- Body fluids

Note: Do not use weak phenols such as Dettol and Savlon for disinfection in the laboratory.

©Mallapaty – June 2000
QUALITY ASSURANCE IN MICROBIOLOGY

Disinfection:

Most commonly used chemicals for disinfection (Effective against HIV viruses)

<table>
<thead>
<tr>
<th></th>
<th>Dilution</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenols</td>
<td>• 5% solution of Lysol to disinfect glassware and other reusable items.</td>
<td>Glassware</td>
</tr>
<tr>
<td></td>
<td>• 10% solution of Lysol to disinfect body fluids.</td>
<td>Floor, Benches, Body fluids.</td>
</tr>
<tr>
<td>Aldehydes</td>
<td>• 10% Formalin Not commonly use for disinfection of instruments, highly</td>
<td>Preservation of stool parasites.</td>
</tr>
<tr>
<td></td>
<td>irritating to skin, eyes and lungs.</td>
<td></td>
</tr>
<tr>
<td>Alcohols</td>
<td>• 70% alcohol</td>
<td>Skin disinfecting, Smear fixation</td>
</tr>
<tr>
<td></td>
<td>• Methylated spirit (no need to dilute)</td>
<td></td>
</tr>
<tr>
<td>Halogens</td>
<td>• 0.5% Hypochlorite solution (Bleach)</td>
<td>Hand disinfecting, Glassware,</td>
</tr>
<tr>
<td></td>
<td>• 0.5% Iodine solution</td>
<td>Skin disinfecting</td>
</tr>
</tbody>
</table>
QUALITY ASSURANCE IN PARASITOLOGY
STOOL PARASITES

Stool Sample Collection:

⇒ Provide the patient with a suitable wide-mouthed, container with a lid.
⇒ Ask the patient to collect a walnut size piece or about 10ml of a watery specimen. It is not necessary to fill the whole container.
⇒ Ask the patient to keep the outside of the container clean, health hazard!
⇒ Do not accept stool samples collected in matchboxes, newspapers or other containers that leak, health hazard!
⇒ Ask the patient not to mix urine with the stool, destroys trophozoites if present.
⇒ A fresh specimen is required, tell the patient to bring the sample within 1 hour of collection.
⇒ Label the container clearly with the patient name and laboratory number.

Sample collection for Giardia:
⇒ If the first sample is negative request at least two more samples on alternate days.
⇒ It is better to advice the patients to bring the sample during diarrhoeal episodes!

Sample collection for Enterobius vermicularis(Pinworm):
⇒ Collect an anal swab, as ova are concentrated in the anal skin area.

Sample collection for Amoeba
⇒ Fresh sample is required and examination must be done immediately.
## QUALITY ASSURANCE IN PARASITOLOGY

### STOOL PARASITES

#### Stool examination flow-chart

<table>
<thead>
<tr>
<th>Macroscopic examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examine the colour and consistency</td>
</tr>
<tr>
<td>Look for adult worms and segments of tapeworms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Formed or soft stools</th>
<th>Liquid, watery or bloodstained stools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examine within 24 hours!</td>
<td></td>
</tr>
<tr>
<td>Keep in cool place!</td>
<td></td>
</tr>
<tr>
<td>Examine within 1 hour after collection!</td>
<td></td>
</tr>
</tbody>
</table>

### Microscopic examination

### Direct Smear Preparation

- **Normal Saline/Iodine**
- **Modified Ziehl Neelsen**

| Search for helminths eggs or larvae and protozoa cysts! | Search for helminths eggs or larvae, protozoa and Amoebic trophozoites! |

### Report

- Write the name of the intestinal parasite found and the grade of infection (few, some, many).
- Report the presents of red blood cells and faecal leukocytes.
QUALITY ASSURANCE IN PARASITOLOGY
STOOL PARASITES

Sample Storage and Transportation:

⇒ Stool samples should be examined the same day.

⇒ Liquid, watery or bloodstained stool should be examined within one hour after collection.

⇒ If you find eggs or cysts that you do not know you can preserve the stool sample in 10% Formalin till an expert comes or till the sample can be carried to the reference laboratory. **See separate sheet!**

⇒ Stool specimens for stool culture can not be preserved in 10% Formalin, they must be sent preserved in a special culture media. (Stuart or Amies)

⇒ Samples stained by modified Ziehl Neelsen stain can be stored in a box for future examination by a visiting expert.
Sample Storage and Transportation:

How to preserve stool samples in 10% Formalin

Step one: Prepare 10% Formalin solution

Formalin (neutral formaldehyde, at least 37%) 10 ml
Distilled water ........................................ 90 ml

Step two: Label sample bottles

Label a screw-capped brown glass bottle as 10% Formalin and write the patient name and lab number.

Step three: Add patient sample

- Put about 2 ml of 10% formalin into the bottle.
- Add an Amla size piece of stool and close the screw cap tightly.
- Keep refrigerated or in a cool place.
QUALITY ASSURANCE IN PARASITOLOGY

STOOL PARASITES

Waste Disposal and Precautions:

✧ Consider all stool samples as highly infectious.

✧ Avoid contact with bare fingers, wear gloves if possible or handle with care.

✧ Do not reuse stool containers, burn stool sample containers and wooden applicators.

✧ Soak glass slides in 5% Phenol solution (e.g. Lysol) at least over night.

✧ Cover slips break easily and may cause injuries, therefore soak in a separate container in 5% Phenol solution (e.g. Lysol) at least over night.

Chemical waste disposal

✧ Pour old and used chemicals into the sink and flush with water if the sink is connected to a soak pit.

✧ Otherwise, pour chemicals directly into the soak pit. Ensure that the soak pit is not near a natural water source.

✧ Formalin is irritating to the skin and the vapour should not be inhaled.
IQC Procedures:

Intestinal Parasites:

- Follow proper collection procedures to ensure accurate diagnosis, e.g. Amobic trophozoites begin to degenerate within 1-2 hours after collection.

- Cystes, flagelates and eggs also undergo changes especially if the stool is left at high temperatures.

- Properly label the specimen with patient name and lab number to avoid confusion.

- Only accept fresh specimens and refuse specimens contaminated with dirt or urine.

- If you can not examine specimens immediately, leave them in a cool place and not exposed to sun.

- Always examine watery and blood-stained specimens first.
QUALITY ASSURANCE IN PARASITOLOGY
STOOL PARASITES

IQC Procedures:

Intestinal Parasites:
- Store Lugol’s iodine in brown bottles. Prepare Lugol’s iodine fresh every two weeks.
- When preparing the smears, select portions of the stool that are coated with blood or mucus.
- Keep prepared slides in a wet chamber to prevent them from drying up.
- Do not touch the stool or the smear with your bare fingers. Stool may contain infectious material, health hazard!
- Refer to pictures and charts if you are in doubt about structures that resemble eggs or cysts.
- If in doubt preserve the stool in 10% formalin for examination by a visiting export or for referral of the specimen.
- Always examine the slide systematically.
QUALITY ASSURANCE IN PARASITOLOGY
BLOOD PARASITES

Sample Collection:

Malaria parasites & Microfilariae
Usually capillary blood (See separate sheet!) is used and the following preparations are examined:

Thick blood film
⇒ Screening for Microfilariae
⇒ Screening for Malaria parasites

Thin blood film
⇒ Identification of Microfilariae
⇒ Identification of Malaria parasites

Direct wet preparation
⇒ Screening for Microfilariae

Note: You can prepare a thick and a thin film on one slide together.

Thick film Mark with pencil Thin film

©Mallapaty – June 2000
QUALITY ASSURANCE IN PARASITOLOGY
BLOOD PARASITES

Sample Collection:

**Leishmania**
It is difficult to find Leishmania amastigotes in capillary blood.
It is best to examine the layer of white cells (buffy coat) after centrifugation of EDTA anti-coagulated blood.

**Buffy coat**
⇒ EDTA blood is used for buffy coat examination.

**Aldehyde test – screening for an increase in IgG**
⇒ Venous blood is used for the Aldehyde test.

**Collection time**
The number of certain parasites in the blood depends on the time of collection.

**Malaria**
⇒ Highest number of parasites is found during fever attacks and before the start of treatment

**Microfilariae**
⇒ *W. bancrofti* and *Brugia malayi* – take specimen at night between 10 p.m. – 2 a.m.
QUALITY ASSURANCE IN PARASITOLOGY
BLOOD PARASITES

IQC Procedures:

Smear for Malaria Parasites

- Follow proper collection procedures.
- Glass slides must be clean and free from grease.
- Thick films and thin films must be prepared properly.
- While drying protect blood films from dust, flies and insects.
- Do not dry exposed to direct sun light
- When fixing the thin film, be careful not to let methanol touch the tick film.

Smear for Microfilaria

- Filaria are seldom found in the early and in the late stage of the disease.
- The proper time of collection is important (10 p.m. to 2 a.m.)
- Unsheated non-pathogenic filaria can be found any time of the day. (Refer to picture atlas!)
- Patients with filaria in the blood show also eosinophilia in the blood.
QUALITY ASSURANCE IN URINE

Sample Collection:

Biochemical tests:

⇒ For chemical tests as sugar, protein or bile pigment the method of collection is not very important any random urine sample can be used. It is always best to request for a mid-stream urine sample.
⇒ The concentration of analytes will be highest in the first morning urine.
⇒ Tell the patient to collect about 20 ml of urine into a clean, dry container.
⇒ Label the container immediately with the patient’s name and the laboratory number.
⇒ Examine as soon as possible

Urinary deposit:

⇒ For urinary deposit you must instruct the patient to collect a clean urine sample or a so-called mid-stream urine sample (MSU) See separate sheet!

Urine culture:
⇒ For urine culture you need a mid-stream urine sample collected into a sterile container.
QUALITY ASSURANCE IN URINE

Sample Storage and Transportation

Biochemical tests:
⇒ After receipt at the laboratory keep the urine samples in a cool place away from direct sunlight.
⇒ Urine sugar must be tested as soon as possible because of glycolysis, caused by bacteria. Bacteria multiple rapidly in urine if kept at room temperature.
⇒ Bile pigment is affected by light, examine urine as soon as possible.

Urinary deposit:
⇒ Urine for urinary deposit must be examined within one hour after collection.
⇒ Prolonged storage at room temperature causes bacteria to multiply which leads to chemical changes in the urine. This causes cells to degenerate and crystals to increase, making it difficult to examine to deposit under the microscope.

Urine culture:
⇒ Urine for urine culture **must** be examined within 30 minutes after collection.
QUALITY ASSURANCE IN URINE

IQC Procedures:

- Always examine the colour of the urine as well and report unusual colours. For example, urine can show a red colour when containing blood, or brownish green colour in patients with hepatitis, or pale almost white colour in patients with diabetes, or milky white colour when urine contains lymph gland fluid (chyluria – search for microfilaria).

- The urinary deposit must be examined within one hours after collection otherwise bacteria can multiply, cells become unclear & crystals increase.

- Examine urine for culture within 30 minutes after collection.

- When preparing new reagents, test the reagent with a known positive urine sample or prepare your own positive control.

- Always refer to a picture atlas if you find structures that you do not know very well.
Code of Conduct

➤ Keep your laboratory clean and in order! For example: clean the workbench every day after work with disinfectant, label your chemicals, and cover your microscope with a protective cover.

➤ Keep your glassware and instruments clean and handle them with care!

➤ You are dealing with infectious material, carelessness can harm you and your patients! Examine each specimen with the same accuracy and care, as you would examine your own!

➤ Never give false reports! If you are not sure about a result, repeat it or tell the doctor that you are not sure and that you would like to receive a fresh sample!
1. **Overall**, how **useful** was the training for you?

<table>
<thead>
<tr>
<th>of no use</th>
<th>of little use</th>
<th>of some use</th>
<th>useful</th>
<th>very useful</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

2. **Overall**, was the **content of the theoretical sessions** of use/fitting to your needs at works?

<table>
<thead>
<tr>
<th>of no use</th>
<th>of little use</th>
<th>of some use</th>
<th>useful</th>
<th>very useful</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

3. **Overall**, was the **content of the practical sessions** of use/fitting to your needs at works?

<table>
<thead>
<tr>
<th>of no use</th>
<th>of little use</th>
<th>of some use</th>
<th>useful</th>
<th>very useful</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

4. As a result of this training course:

   a) I am able to understand the meaning and usefulness of a Quality Assurance Programme and I understand the difference between Internal Quality Procedures, the External Quality Assessment Scheme and Quality Management.

<table>
<thead>
<tr>
<th>strongly disagree</th>
<th>disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

   b) I understand how the Pre-analytical (before the test) stage, the analytical (during the test) stage and the post-analytical (after the test) stage affects the quality of a laboratory test result.

<table>
<thead>
<tr>
<th>strongly disagree</th>
<th>disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
4.

c) I am able to perform all tests that I have been taught during the training course independently and know about Internal Quality Procedures of those tests.

<table>
<thead>
<tr>
<th>strongly agree</th>
<th>disagree</th>
<th>strongly disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


d) I have learnt about the importance of the External Quality Assessment Scheme and I understand that the EQA sample sent by the QA unit of the NPHL help to improve the quality of laboratory test result in my laboratory.

<table>
<thead>
<tr>
<th>strongly agree</th>
<th>disagree</th>
<th>strongly disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

e) I can identify minor defects of equipment (e.g., Microscope, Centrifuge, Colorimeter and Auto-pipette) and know how to care for and handle those equipment during daily work routine.

<table>
<thead>
<tr>
<th>strongly agree</th>
<th>disagree</th>
<th>strongly disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5a. List the 3 most important things you have learned during this training that you will be able to apply in your work.

One:

Two:

Three:

5b. What constraints (problems or difficulties) might prevent you from applying at work what you have learned in this training course?
6. Overall, the **teaching methods** used in this training course were appropriate.

<table>
<thead>
<tr>
<th>strongly disagree</th>
<th>disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

What suggestions do you have for improving the teaching method in future?

7. Overall, the **training team members** were well prepared and their sessions well designed.

<table>
<thead>
<tr>
<th>strongly disagree</th>
<th>disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

What suggestions do you have for the training team members?

8. Overall, the **materials** (such as using overhead transparencies, handouts, SOPs, etc.) used during the training course were appropriate.

<table>
<thead>
<tr>
<th>strongly disagree</th>
<th>disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

What suggestions do you have for improving the training materials?
9. **The organisation** (location, set-up, refreshments, etc.) was well arranged.

<table>
<thead>
<tr>
<th>strongly disagree</th>
<th>disagree</th>
<th>not so sure</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   What suggestions do you have for improving the organization for future courses?

10. **Time-wise** the training course was:

<table>
<thead>
<tr>
<th>just right</th>
<th>too short*</th>
<th>too long*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   *Please explain:

12. What other **suggestions** or **comments** would you like to make?

   OPTIONAL: Name: _______________
References:


King M. (1973) A Medical Laboratory for Developing Countries, London, Oxford University Press


©Mallapaty –June 2000