

The importance of implementing quality control programs and TB proficiency testing

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Islamic Rep. OF IRAN TB LAB. NETWORK

Overview of the components of the laboratory service in the country

Reference Health laboratory (RHL)

National Reference Labs for every disease under surveillance

9 Regional Reference Labs

52 University Reference Labs

There are 52 universities all around the country
M.O.H has divided the country to 52 regions, the laboratories in each region work under supervision of their dedicated medical university

Office of laboratory affair in 52 universities

Supervises the laboratories in its dedicated region

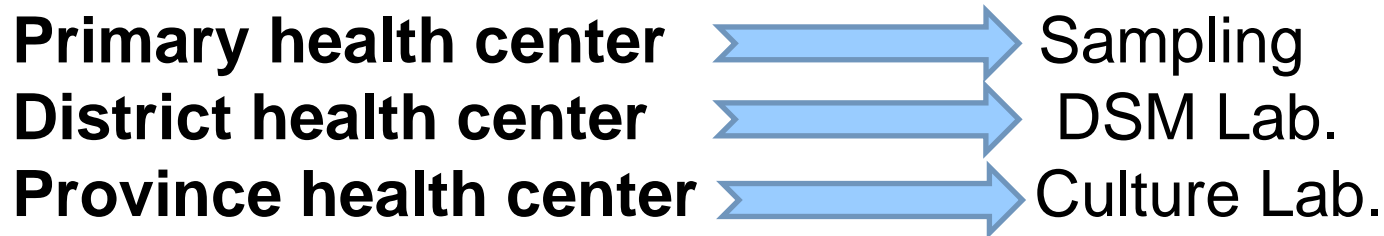
more than 5000 laboratories

Public health laboratories level
1,2,3

governmental laboratories

Private laboratories

Scheme of TB Lab Net Work In Iran



- Sampling
- DSM TB lab in each city (423 Lab)
- Culture TB Lab in province health center (51 Lab)
- Regional TB labs (Culture and Antibiogram) (9 Lab)
- National TB Reference Lab (NTRL) (1 Lab)
- Supernational Reference Lab - SRLN

ESSENTIAL QA CENTRAL LEVEL ACTIVITIES



Standardize policies & documentation



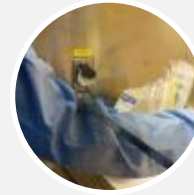
Maintain & service equipment



Conduct training



Coordinate onsite supervisory visits



Implement proficiency testing



Strengthen the supply chain



Monitor quality indicators

Accurate, reliable and timely results

ESSENTIAL QA TESTING SITE LEVEL ACTIVITIES



Environment
Safe and functional
Temperature control



Personnel
Trained and competent staff
Test user is documented
Current SOPs readily available



Equipment
Maintained and serviced



Supplies
Uninterrupted supplies
Appropriate transport and storage condition



Specimens
Good quality
Labelled with unique ID
Completed request form



Internal quality monitoring
Test working properly



External quality assessment
Lab's work checked by another lab



Accurate and timely reporting
Turnaround time
Results review

Accurate, reliable & timely results

Quality assurance/quality indicators

WHAT ARE QUALITY DIAGNOSTICS?

- Quality diagnostics are accurate, reliable and reported **timely** in order to be useful in a clinical or public health setting
- A QA programme ensures QA activities are implemented to ensure quality diagnostics
- Implementing quality activities for diagnostic testing guarantees that the right test results are provided for the right patient, at the right time

PROGRAMMATIC QA MANAGEMENT

- A QA programme is developed and implemented at **central level** by the Ministry of Health (MOH), National TB Programme (NTP) or National TB Reference Laboratory (NTRL)
- A QA programme provides general guidance and tools for standardized QA activities, as well as supervision of the QA activities and monitoring of the adherence to the procedures at the **testing site level**

Content outline

- There three main components of QA system and their importance
- Adhere to the QC and EQC procedures
- Quality indicators

Developing a quality assurance plan

- Practical
- Specific procedures are available for specific components of the plan
- Ensure the following are addressed:
 - General laboratory systems
 - Pre-analytical phase of testing
 - Analytical phase of testing
 - Post-analytical phase of testing

Quality assurance in mycobacteriology

System designed to improve:

- reliability
- efficiency
- use

of laboratory services in order to achieve the required technical quality in laboratory diagnosis

Quality assurance

Quality assurance (QA) is a *system* designed to continuously improve the reliability and efficiency of laboratory services. This system includes quality control, external quality assessment, and quality improvement.

Reference: APHL, CDC, IUATLD, KNCV, RIT, WHO, External Quality Assessment for AFB Smear Microscopy, October 2012

Quality control

- Quality control (QC)
 - A systematic internal monitoring of working practices, technical procedures, equipment and materials, including quality of stains.

Reference: APHL, CDC, IUATLD, KNCV, RIT, WHO, External Quality Assessment for AFB Smear Microscopy, October 2012

Quality control should be:

- Practical
- Workable
- Comprehensive

Quality control

- Process of effective and systematic monitoring of all laboratory activities
- Establish limits of acceptable standard of test performance
- Laboratory data should be accurate, reliable, reproducible, comparable

QC is the responsibility of all laboratory personnel

QC: General laboratory systems

- Laboratory arrangement
- Human resources (training health control)
- Laboratory equipment
- Collection and transport of specimens
- Handling of specimens
- Reagents and media
- Culture procedures
- Reporting of results

QC: Laboratory arrangement

- Ensure that doors in the laboratory are always closed
- Work areas, equipment and supplies arranged for logical and efficient work flow
- Work areas should be clean
- Benches swabbed after each use with an appropriate disinfectant

QA - laboratory administration

- Schedule of tests
- Every procedure is written
- Keep written procedures in the laboratory for easy reference
- Any changes must be dated and initialized by the laboratory supervisor
- Records retained for two years
- Management of procurements
 - Equipment/consumables acceptance
- Laboratory procedures used routinely should be SOPs, published in reputable microbiological books, manuals or journals

Human resources

- Documented credentials for staff
- Organizational flowchart/organogram
- Orientation
- Training
 - New staff: at initial hire, again at 6 months
 - Existing staff: once per year
 - All training should be documented
- Sufficient staff to support workload

Pre-analytical systems

- Instructions to submitters
 - Appropriate specimens
 - Collection, transport procedures
- Specimen monitoring requirements
 - Documentation of specimen quality
 - Specimen rejection policy
- Test requests
 - Essential documentation (patient name, specimen source, diagnostic vs. follow-up, collection date)
 - Compared to specimen for consistency

Analytical systems

- Standardized operating procedures (SOP)
 - Updated annually or more often as needed
 - Reviewed and initialed by staff annually
 - Retired procedures removed, labelled as “retired”, initialed and dated
- Equipment calibration
 - Thermometers
 - Pipettes
 - Timers

MAINTAIN & SERVICE EQUIPMENT

- The GeneXpert is a precision instrument that requires regular maintenance to ensure that it provides accurate and precise results
- Perform daily, weekly, monthly, and annual maintenance tasks according to manufacturer's instructions (refer to Cepheid training materials)
- Ensure all maintenance tasks are recorded on appropriate logs

MAINTAIN & SERVICE EQUIPMENT

- Troubleshoot testing or instrument failures:
 - Document corrective action(s) and ensure they have been effective
 - Ensure warranty or service contracts are in place and terms and conditions are adhered to
 - Maintain dated service records
 - Document all maintenance servicing

MAINTAIN & SERVICE EQUIPMENT

- GeneXpert verification:
 - **Verification** ensures that the GeneXpert is “fit for purpose” i.e. it can be used for testing clinical specimens
 - Verification is performed using a **verification panel** (Xpert Check)
 - Perform at least one verification test per module after:
 - Instrument installation
 - Post-calibration or swapping of instrument modules

Analytical systems

- Quality control procedures and corrective actions
 - Test procedures
 - Microscopy
 - Processing and culture methods
 - Identification/susceptibility testing
 - Media and reagents
 - Sterility checks/performance characteristics
 - Labelling/storage (name, concentration, temperature)
 - Dated (received/prepared, in use, expired)
 - Equipment (also includes preventive maintenance)
 - Centrifuge
 - Incubator, water-baths, etc.
 - Safety cabinets
 - Refrigerators/freezers
 - Culture instruments

Analytical systems

- **Validation of new methods/procedures**
 - All new methods are evaluated against the reference/gold standard for
 - Sensitivity
 - Specificity
 - Positive predictive value
 - Negative predictive value
 - Turn-around time

Corrective actions

- Identify (potential) problem
- Analyze the (potential) problem
- Identify the (potential) solution
- Select and plan solution
- Implement solution
- Evaluate solution
- Maintain and/or improve solution

Corrective actions: Example

- Identify (potential) problem: **suboptimal or poor quality media [LJ]**
- Analyse the (potential) problem: poor quality media may **impact the yield/recovery of MTBC**; **lack of media may impact turn-around time**
- Identify the (potential) solution: potential solutions include **purchasing** commercially prepared media or asking for **assistance from the NRL**
- Select and plan solution: gather catalogue and vendor information or contact NRL to establish relationship and determine the feasibility of this option
- Implement solution
- Evaluate solution: determine the cost-effectiveness of the solution and the amount of lead time required to receive the media
- Maintain and/or improve solution

Post-analytical systems

- Validation of test results
 - Review of positive and/or negative results by supervisor/lead microbiologist
- Routine monitoring of performance (performance indicators)
- Results audit
 - Monitoring of turn-around time for smear, culture, drug susceptibility results
 - Procedure for the delivery of timely positive results



EXTERNAL QUALITY ASSURANCE

External quality assurance

- External quality assurance (EQA)
 - A process that allows participant laboratories to assess their capabilities by comparing their results with those of other laboratories in the network (intermediate and central laboratory) through panel testing and blinded rechecking. EQA also includes on-site evaluation of the laboratory to review quality of performance and should include on-site re-reading of smears. EQA is an expansion of the proficiency testing as described by IUATLD.

Reference: APHL, CDC, IUATLD, KNCV, RIT, WHO, External Quality Assessment for AFB Smear Microscopy, October 2003

WHAT ARE EXTERNAL QUALITY ASSURANCE (EQA) AND PROFICIENCY TESTING (PT)?

EQA entails:

- Panel testing or Proficiency testing (PT)
- On-site supervision
- Slide re-checking
 - **Blinded re-checking (recommended for TB smear microscopy EQA)** is not appropriate for Xpert MTB/RIF (Ultra) testing since the entire specimen is usually required to perform the test and no specimen can be saved for later re-checking

PT entails:

- Sending a panel of biological materials with known results to testing sites for testing
- The PT panel results from the testing site are compared to a reference result (and with other laboratory results for the same panel of samples) to determine inter-testing site comparability

CLSA DEFINITIONS

- EQA

“Inter-laboratory comparisons and other performance evaluations that may extend throughout **all phases of the testing cycle**, including interpretation of results; determination of individual and collective laboratory performance characteristics of examination procedures by means of inter-laboratory comparison; NOTE: the primary objectives of EQA **are educational** and may be supported by additional elements.” [CLSI GP27-A2]

- PT

“A program in which **multiple specimens** are periodically sent to members of a group of laboratories for analysis and/or identification, in which each laboratory’s results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratory and others.” [CLSI GP27-A2]

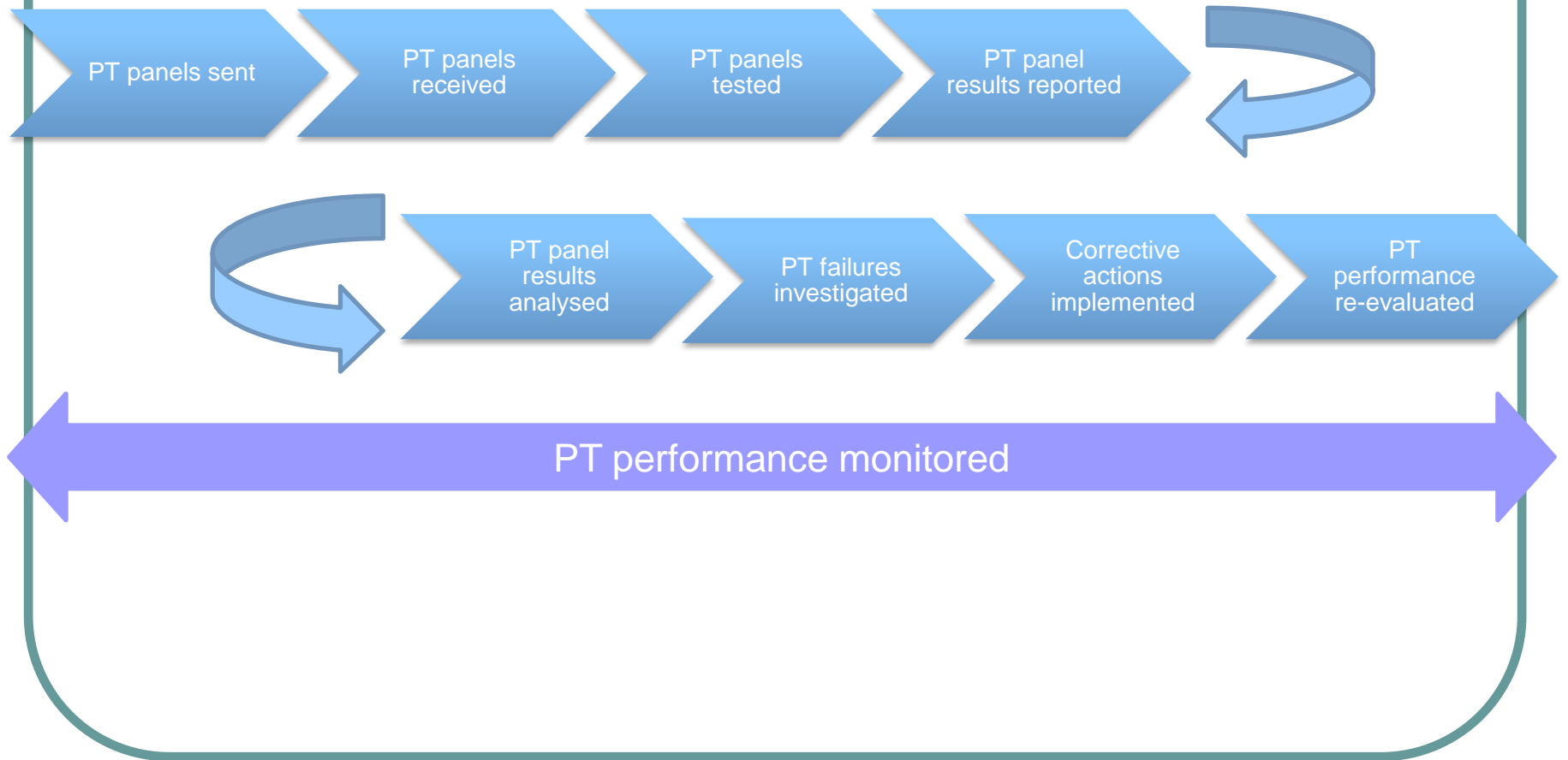
IMPORTANCE OF EQA

- It can be used to **improve performance** across the laboratory network
- It is an important tool for communicating with and **motivating staff**
- It's designed to identify and **resolve serious problems** with testing
- It can be used to assess the **competency** of test operators, and is a ISO requirement

INTRODUCTION TO PT

- PT programme checks pre-analytical, analytical, and post-analytical processes occurring at the testing site
- Panels of samples are sent to testing site several times per year
- PT samples are analyzed and the reported results are compared to reference values
- Results indicate quality of personnel performance and test site operations
- Results should be reviewed after each round and be monitored for trends over time
- PT does not measure routine laboratory performance but may identify laboratories with major deficiencies

PT CYCLE AT THE TESTING SITE



COMMON PT PROBLEMS

Problem	Cause
PT results were not submitted to PT provider	<ul style="list-style-type: none">• Testing site did not receive the PT panel• PT panels received damaged• PT panel not tested• Testing site sent PT report to wrong address• PT report not returned
PT result report not available or reviewed	<ul style="list-style-type: none">• PT result report misplaced
PT results did not match expected results	<ul style="list-style-type: none">• PT result report not completed correctly or transcription error• PT panel sample mix-up• PT panel sample over-diluted• PT panel sample contaminated

MONITORING PT

- The testing site should record **the outcome** of each proficiency testing **round and look for trends over the year**
- Any negative trends should be reviewed and corrective actions implemented
- Positive trends should be used to motivate the laboratory staff

PT RESULT COMPILATION AND REVIEW



This slide is not needed when training basic GeneXpert users

- Testing site proficiency testing data should be recorded by the PT programme (NTP/NTRL) and reviewed after each panel and annually for patterns
- All sites achieving less than 100% for the PT panel (even if scored a “Pass”) should investigate cause of errors and implement corrective actions
- All testing sites that fail a PT panel should receive a onsite supervisory visit
- Testing sites failing more than one panel should be retrained

ON-SITE SUPERVISION VISITS

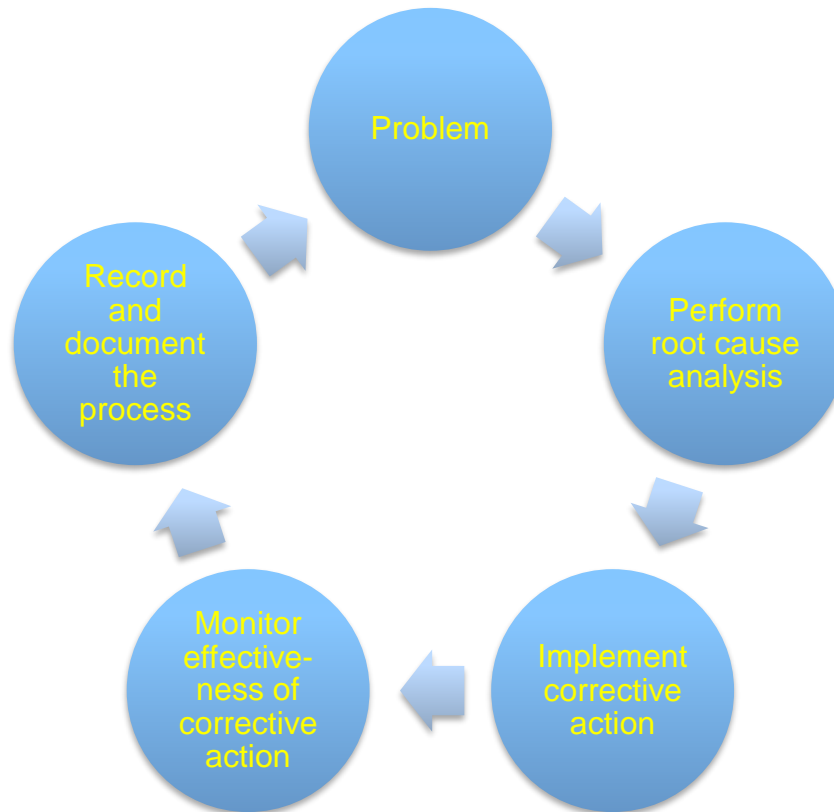
- On-site supervision visits should be conducted at **regular intervals** to assess laboratory/testing site practices
- On-site supervision visits are usually conducted by **NTP/NTRL and/or partners**
- The site will be contacted before the visit to ensure access and availability of staff
- On-site supervision visits are conducted using **standardized checklist** for consistency and completeness of information

DURING AND AFTER THE ON-SITE SUPERVISION VISIT

- During
 - Ensure assessor access to all testing areas and answer all their questions
 - Receive feedback from the assessor
- After
 - Review the assessors report
 - Implement recommendations
 - Address problems

ADDRESSING PROBLEMS

Problems (or non-conformities) identified during onsite supervision visits must be investigated



Performance indicators

- Proficiency testing performance
 - AFB smear microscopy
 - Culture
 - Drug susceptibility testing
 - Xpert MTB/RIF (Ultra)* quality indicators

Importance of monitoring EQA and PT performance

- EQA and PT programs should ideally address AFB microscopy, specimen processing, identification methods, susceptibility testing and molecular Diagnosis
- Lends credibility to laboratory results
- Identifies training needs within the staff

EQA and proficiency testing performance

- Expectation: Predetermined by the testing authority
- Unsatisfactory scores may be due to:
 - Recent changes in staff
 - Need for re-training staff
 - Problems with equipment, reagents, procedures
 - Problems with the proficiency panel

Quality improvement

- Quality improvement (QI)
 - A process by which the components of diagnostic services are analysed with the aim of looking for ways to permanently **remove obstacles to success**. Data collection, data analysis and creative problem-solving are the key components of this process. It involves continual monitoring and identification of defects, followed by remedial action including retraining when needed, in order to prevent recurrence of problems. QI often relies on effective on-site evaluation visits.

Reference: APHL, CDC, IUATLD, KNCV, RIT, WHO, External Quality Assessment for AFB Smear Microscopy, October 2012

Importance of performance indicators

- Establishes **“normal”** laboratory values/baseline for a given population or geographical region
- Identifies **potential problems** with pre-analytical, analytical and post-analytical phase of testing
- Lends **credibility** to laboratory results
- Ensures **optimization** of laboratory methods
- Identifies potential **training** needs

Approach to evaluating performance indicators

- Direct observation of microbiologists
- Review of the following
 - Laboratory Information System (LIMS)
 - AFB microscopy register
 - Culture worksheets
 - Final results
 - EQA or other PT results
 - Procedure manuals

Performance indicators

- Recovery rate of MTB
 - Percentage of MTB / total number of specimens
- Contamination rate (specimen, solid, liquid)
- Percentage of specimens reported as smear positive
 - distribution of smear grades (actual/scanty, 1+, 2+, 3+)
- Correlation between positive smears and positive cultures
- Percentage of negative smears resulting in positive cultures
- Turn-around time of AFB smear, culture and DST results
- Proficiency testing performance (AFB microscopy, culture, drug susceptibility testing and molecular Diagnosis)

Importance of monitoring MTB recovery rate

- Establishes a baseline for a given population or geographical area
- Assists in identifying potential false-positive or false-negative cultures (MTB)

Recovery rate of MTB

- Expectation: Population/geographical region/facility dependent/seasonal
- Increases may be due to:
 - Shift in patient population
 - Cross contamination/false positives
 - Contaminated reagents
 - Specimens contaminated during collection
- Decreases may be due to:
 - Shift in patient population
 - Problems with specimen quality
 - Problems with specimen processing or use of incompatible processing methods
 - Problems with equipment or media
 - Increase in contamination

Importance of monitoring contamination rates

- May reflect problems with pre-analytical phase of testing
- May reflect the technical proficiency of the laboratory
- May identify training needs (field and laboratory)
- Should ideally be stratified by media type

Contamination rate

- Expectation: 3-5% for solid media and specimens; 8-9% liquid medium
- Increases (>5% LJ; >10% liquid medium) may be due to:
 - Incomplete decontamination
 - Suboptimal reagents
 - Improper use of antibiotics (liquid)
 - Improper collection, storage or transport
 - Equipment (BSC, incubators, centrifuge)
 - Need for re-training staff
 - Changes in season
- Decreases (<3%) may be due to:
 - Harsh decontamination procedures
 - Stringent reagents

Importance of monitoring smear positivity rate, distribution of smear positivity grade, and smear and culture correlation

- Establishes a baseline for a given facility, population or geographical region
- Represents the type of specimens submitted (diagnostic vs follow-up)
- Identifies potential problems with microscopy
- Identifies potential problems with specimen processing or culture methods

Smear positivity rate

- Expectation: Population/geographical region/facility dependent
- Increases may be due to:
 - Shift in patient population
 - Cross contamination
 - Use of suboptimal slides
 - Use of contaminated or suboptimal reagents
 - Technical errors
- Decreases may be due to:
 - Shift in patient population
 - Suboptimal specimens submitted to the laboratory
 - Inadequate staining and evaluation of slides
 - Problems with equipment
 - Technical errors

Correlation between positive smear and positive culture

- Expectation: Majority
- Less than 95% may be due to:
 - Specimens submitted from patients on treatment (initial vs follow-up)
 - Reporting of false-positive smears
 - Excessive decontamination procedures
 - Stringent reagents
 - Problems with media
 - Problems with equipment
 - Excessive contamination

Proportion of smear negative/culture positives

- Expectation: Population/geographical region/facility dependent
- Increases may be due to:
 - Shift in patient population
 - Suboptimal staining reagents
 - Inadequate smear reading by staff
 - Reporting of false-positive cultures

Importance of monitoring turn-around time

- Critical to patient management
- Breaks the chain of transmission
- Ensures laboratory procedures are optimized
- Assists in identifying challenges with laboratory workflow algorithms, information systems and reporting systems

Turn-around time of results

- Expectation:
 - AFB smears: within 48 hours of specimen receipt of 80% of specimens
 - ID: laboratory/method dependent
 - DST: laboratory/method dependent
- Delays may be attributed to:
 - Batching specimens or isolates
 - Use of conventional ID and DST methods
 - Suboptimal use of technology
 - Use of National or other Reference Laboratory
 - Transport delays
 - Inadequate provision of supplies
 - Lack of communication between client and laboratory

Summary points

- A quality assurance programme consists of three components: quality control (QC), external quality assessment (EQA), and quality improvement (QI)
- Quality control should be practical and comprehensive
- Quality control is the responsibility of all laboratory personnel
- Monitoring performance helps to establish “normal” laboratory values, lends credibility to laboratory results, and helps to identify training needs among staff

QUALITY INDICATOR MONITORING



Adapt according to NTP guidelines in your country

- General indicators apply to all technologies and should be

Indicator	Target
Number of tests performed, by type of test	-
Service interruptions	No interruptions
Stock outs	No stock outs leading to service interruption
Equipment down time	No equipment downtime leading to service interruption
Turnaround time (TAT)	90% of results meet test-specific TAT
Test statistics (quality indicator) report	100% reports completed by defined due date
EQA results	>90% EQA panels are passed
QC results	>90% QC results meet expected criteria
Specimen rejection	<1% specimens rejected
Customer satisfaction	>80% surveyed customers are satisfied

GENEXPERT QUALITY INDICATOR MONITORING

- The recommended quality indicators for Xpert MTB/RIF (Ultra) are listed below
 - These indicators should be collected in addition to the general quality indicators listed above
 - Targets provided in the tables are intended as a guide, and laboratories should determine their own targets
 - Targets vary based on local situation, patient population tested, and other relevant factors
 - Deviations from the usual rates should be investigated

GENEXPERT QUALITY INDICATOR MONITORING

Indicator	Description	Target	Reference
Number and proportion of specimens with MTB detected, rifampicin resistance detected	Number of specimens with MTB detected rifampicin resistance detected / Total number of specimens tested	Dependent on population tested and country drug-resistance prevalence and patterns	Xpert MTB/RIF implementation manual. World Health Organization. http://www.who.int/tb/laboratory/xpert_launchupdate/en/
Number and proportion of specimens with MTB detected rifampicin indeterminate	Number of specimens with MTB detected rifampicin indeterminate / Total number of specimens tested	Dependent on population tested and country drug-resistance prevalence and patterns	GLI Practical Guide to TB Laboratory Strengthening. http://www.stoptb.org/wg/gli/assets/documents/GLI_practical_guide.pdf
Number and proportion of specimens with MTB not detected	Number of specimens with MTB not detected / Total number of specimens tested	Dependent on population tested and country drug resistance prevalence and patterns	

GENEXPERT QUALITY INDICATOR MONITORING

Indicator	Description	Target	Reference
Number and proportion of specimens with errors	Number of specimens with errors / Total number of specimens tested	<3%	<p>Xpert MTB/RIF implementation manual. World Health Organization. http://www.who.int/tb/laboratory/xpert_launchupdate/en/</p> <p>GLI Practical Guide to TB Laboratory Strengthening. http://www.stoptb.org/wg/gli/assets/documents/GLI_practical_guide.pdf</p>
Number and proportion of specimens with invalid results	Number of specimens with invalid results / Total number of specimens tested	<1%	
Number and proportion of specimens with no results	Number of specimens with no results / Total number of specimens tested	<1%	
Laboratory turnaround time	Time between receipt of specimen for Xpert MTB/RIF at the laboratory and result reporting	2–24hrs	

GENEXPERT ULTRA QUALITY INDICATOR MONITORING

Indicator	Description	Reference
Number and proportion of trace calls, disaggregated by patient group	Number of specimens with trace call results / Total number of specimens tested	GLI planning for country transition to Xpert MTB/RIF Ultra cartridges. http://www.stoptb.org/wg/gli/assets/documents/GLI_ultra.pdf
Number and proportion of patients whose first sample produces a trace result and who have a repeat test conducted, disaggregated by patient group	Number of first specimens with trace call results with a repeat test / Total number of repeat specimens tested	
Number and proportion of patients who have a repeat test conducted whose second sample gives a result for MTB detection and rifampicin resistance, disaggregated by patient group	Number of first specimens with trace call results with a repeat test that gives a MTB detection and rifampicin resistance / Total number of repeat specimens tested	

EXAMPLE: INCREASED ERROR RATE

- Target error rate < 3%
- Recorded error rate 10%
- Action:
 - Review error record log and compare to the GeneXpert results
 - Determine which module errors occur on
 - Determine which batch of reagents
 - Determine staff performing testing
 - Review for any patterns and determine root cause
 - Determine corrective action and how to determine success of action
 - Implement action
 - Monitor action
 - Document and record all steps

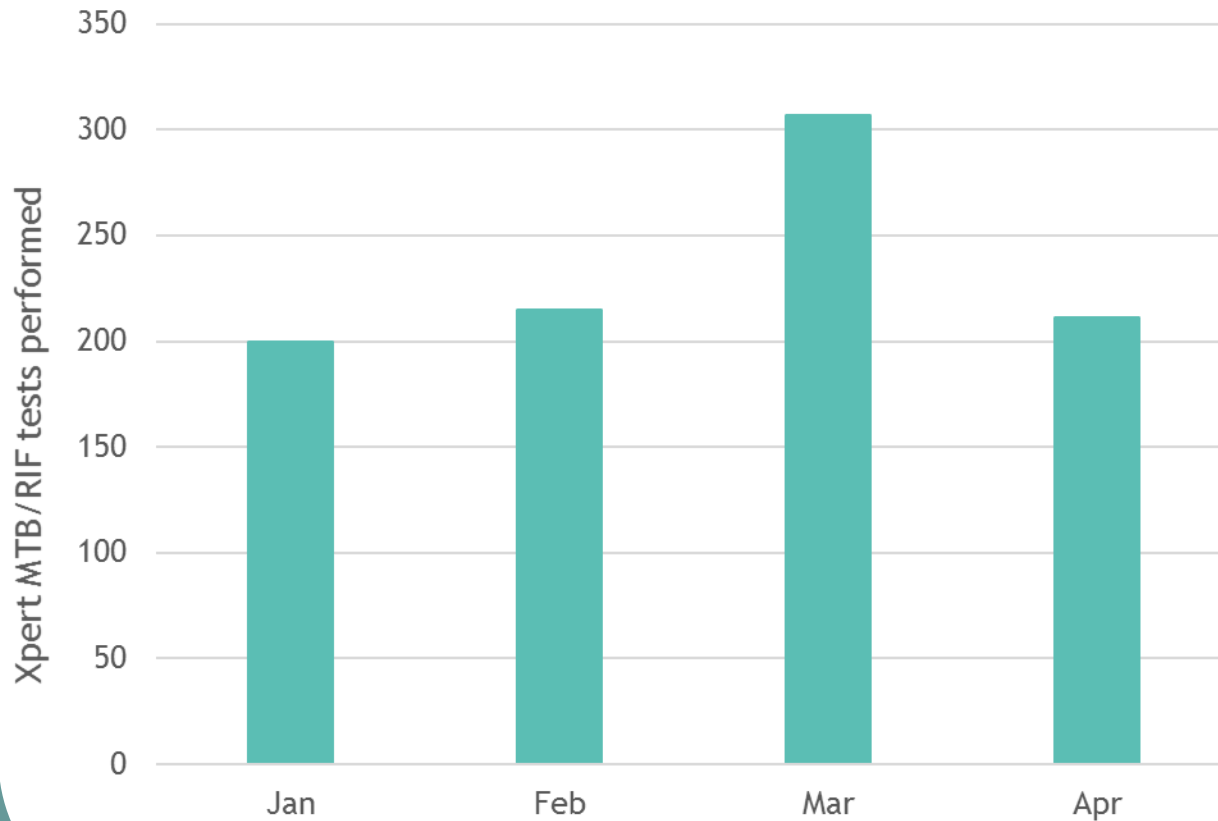
EXAMPLE: INCREASED INVALID RATE

- Target invalid rate < 1%
- Recorded error rate 4%
- **Action:**
 - Review invalid record log and compare to the GeneXpert results
 - Determine which batch of reagents, is this a new batch?
 - Determine staff performing testing
 - Review for any patterns and determine root cause
 - Determine corrective action and how to determine success of action
 - Implement action
 - Monitor action
 - Document and record all steps

ANALYSING QUALITY INDICATORS OVER TIME

- On a graph plot various quality indicators and look for trends or outliers e.g.
 - Change in testing volume
 - Increase in errors
 - Increasing shipment times
 - Sudden increases in errors/invalids or no results
 - One off increase in reporting errors
- Conduct further investigation to determine root cause
- Undertake corrective actions
- Monitor effectiveness of actions

EXAMPLE: CHANGE IN TESTING VOLUME

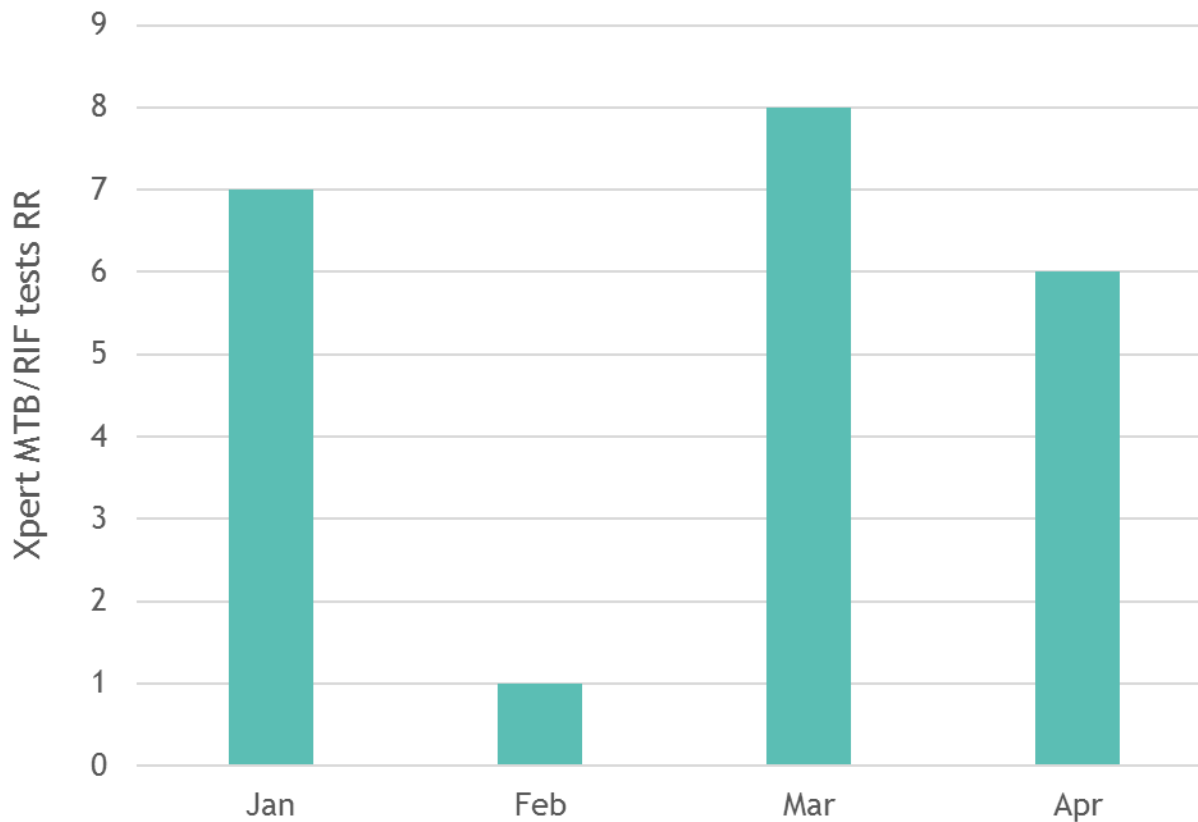


At the testing site, 200 and 215 Xpert MTB/RIF tests were performed in January and February respectively. In March the number increased to 307, and decreased to 211 in April

What could be the reason?

Increases in the number of Xpert MTB/RIF test performed could suggest that the the NTP conducted a special screening campaign

EXAMPLE: CHANGE IN NUMBER OF RIFAMPICIN RESISTANT RESULTS



At the testing site, seven rifampicin resistant Xpert MTB/RIF test were detected in January, one in February, and eight and six in March and April respectively

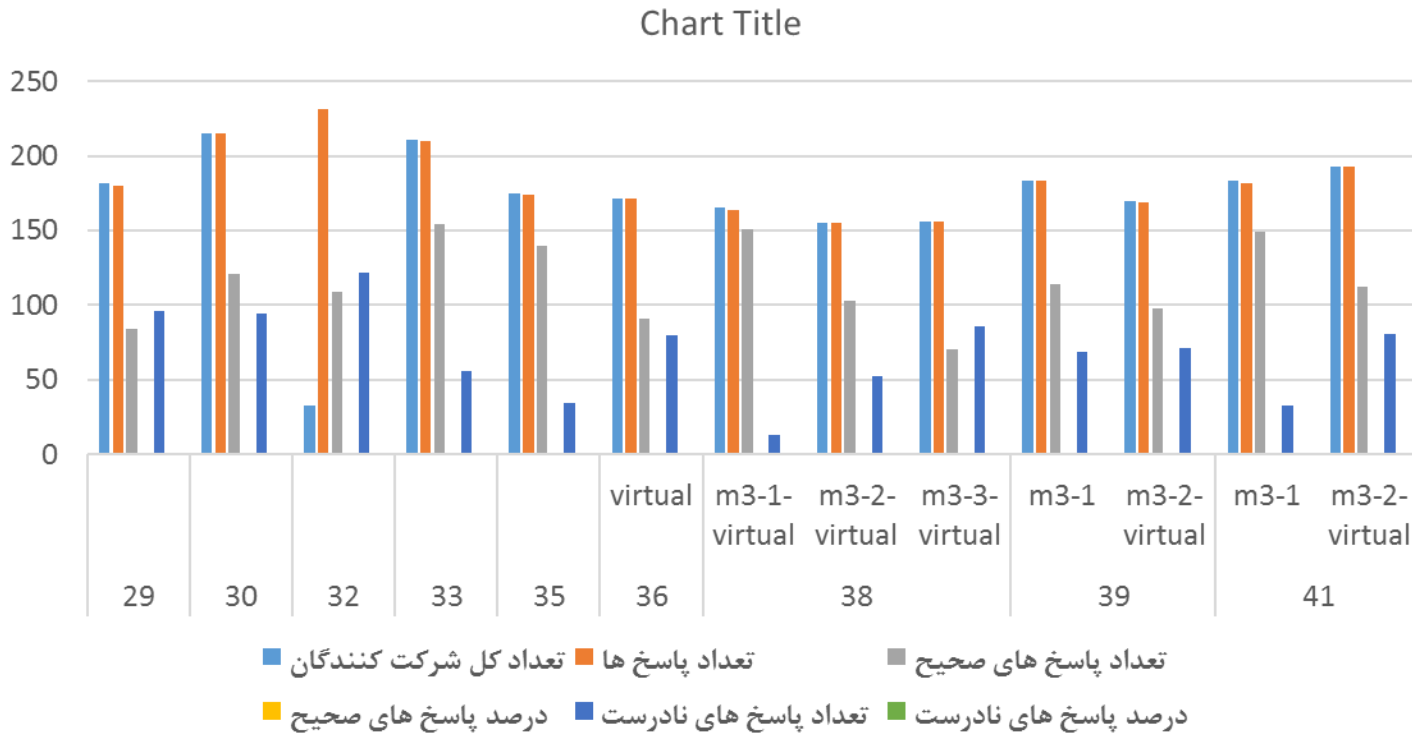
What could be the reason for the decrease in February?

Changes in the number of Xpert MTB/RIF RR results could suggest errors in sample collection, instrument malfunction or errors in processing. The number of RR cases is often small, variation in monthly reported cases is frequent but less evident when reviewed on quarterly basis

نتایج ۹ دوره برنامه ارزیابی کیفیت خارجی اجرا شده (EQAP) اسمیر BK از سال ۱۳۹۶ تا ۱۴۰۰ - انجمن دکترای علوم آزمایشگاهی تشخیص طبی ایران

BK Smear -EQAP							
دوره	تعداد	تعداد کل شرکت کنندگان	تعداد پاسخ ها	تعداد پاسخ های صحیح	درصد پاسخ های صحیح	تعداد پاسخ های نادرست	درصد پاسخ های نادرست
29		182	180	84	46.67%	96	53.33%
30		215	215	121	56.28%	94	43.72%
32		33	231	109	47.19%	122	52.81%
33		211	210	154	73.33%	56	26.67%
35		175	174	140	80.46%	34	19.54%
36	virtual	171	171	91	53.22%	80	46.78%
38	m3-1-virtual	165	164	151	92.07%	13	7.93%
	m3-2-virtual	155	155	103	66.45%	52	33.55%
	m3-3-virtual	156	156	70	44.87%	86	55.13%
39	m3-1	183	183	114	62.30%	69	37.70%
	m3-2-virtual	170	169	98	57.99%	71	42.01%
	m3-1	183	182	149	81.87%	33	18.13%
41	m3-2-virtual	193	193	112	58.03%	81	41.97%

نمودار مقایسه نتایج ۹ دوره ارزیابی کیفیت خارجی اسمیر TB



نتایج ۹ دوره برنامه ارزیابی کیفیت خارجی اجرا شده (EQAP) مولکولی TB از سال ۱۳۹۶ تا ۱۴۰۰ - انجمن دکترای علوم آزمایشگاهی تشخیص طبی ایران

درصد NO Answer	No Answer	درصد POOR	Poor	درصد GOOD	Good	درصد Excellent	Excellent	تعداد کل شرکت کنندگان	دوره
11.54%	3	3.85%	1	23.08%	6	61.54%	16	26	29
16.67%	8	0.00%	0	83.33%	40	0.00%	0	48	30
26.19%	11	0.00%	0	9.52%	4	64.29%	27	42	33
27.78%	10	8.33%	3	16.67%	6	47.22%	17	36	35
21.05%	8	2.63%	1	10.53%	4	65.79%	25	38	36
33.33%	12	11.11%	4	22.22%	8	33.33%	12	36	38
20.00%	7	8.57%	3	48.57%	17	22.86%	8	35	39
35.71%	15	14.29%	6	19.05%	8	30.95%	13	42	41

(بدون اشتباه)	عملکرد عالی	cellent
یک اشتباه	عملکرد مطلوب	Good
دو و بیشتر اشتباه	عملکرد ضعیف (مردود)	Poor



Folkhälsomyndigheten
PUBLIC HEALTH AGENCY OF SWEDEN



CERTIFICATE OF PROFICIENCY

2018

The Tehran University of Medical Science, Regional Reference of Tuberculosis Laboratory of Iran participated in the External Quality Assessment of the WHO TB Supranational Reference Laboratory Network (SRLN) for First and Second-Line Phenotypic Drug Susceptibility Testing using solid medium (LJ) and demonstrated very good proficiency for Isoniazid, Rifampicin, Ethambutol, Amikacin, Ofloxacin, Kanamycin and Capreomycin.

July 30, 2018 for the SRL in Stockholm


Ramona Groenheit, SRL Director


Melles Haile, Lab Supervisor



CERTIFICATE OF PROFICIENCY 2019

The Tehran Regional Reference Laboratory for Tuberculosis in Iran participated in the External Quality Assessment of the WHO TB Supranational Reference Laboratory Network (SRLN) for First- and Second-Line phenotypic Drug Susceptibility Testing and demonstrated excellent proficiency for Rifampicin, Pyrazinamide, Levofloxacin, Moxifloxacin, Amikacin and Kanamycin as well as very good proficiency for Isoniazid and Ethambutol.

June 13, 2019 for SRL Stockholm


Ramona Groenheit, SRL Director


Melles Haile, Lab supervisor



CERTIFICATE OF PROFICIENCY 2020

The Tehran Regional Reference Laboratory for Tuberculosis in Iran participated in the External Quality Assessment of the WHO TB Supranational Reference Laboratory Network (SRLN) for First Line phenotypic Drug Susceptibility Testing and demonstrated excellent proficiency for Isoniazid, Rifampicin, Pyrazinamide and Ethambutol.

July 20, 2020 for SRL Stockholm


Ramona Groenheit, SRL Director


Jim Werngren, NRL Contact person

Thanks

