INNOVATIVE APPROACHES TO EQA

for Mycobacteriology

Presented at the IMPAACT and ACTG Annual Conferences June 2018

This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services.

Contract Number: HHSN227201300004C

Project Title: Patient Safety Monitoring in International Laboratories

ACKNOWLEDGEMENTS

- The presenters would like to thank.
  - Daniella Livnat and Joe Fitzgibbon, NIH Division of AIDS
  - Dr. Alexandra Valsamakis, SMILE Principal Investigator
  - The Lab Science Groups of the IMPAACT and ACTG Networks
    - Dr. Grace Aldrovandi
  - The entire SMILE team

PRESENTATION OUTLINE AND SPEAKERS

- Moderator: Anne Leach
- QuantiFERON: Orlinda Maforo
- HAIN LPA MTBDR: Afton Dorasamy
- GeneXpert MTB/RIF: Peggy Coulter
- MTB 2nd Line DST: Peggy Coulter

Evolution of TB Testing Methodologies

The development of new technologies as well as the emergence of MDR TB has rendered the standard EQA panels for TB testing ineffective.

Evolution of EQA for TB

- In 2007 there were only 7 laboratories that received the CAP E panel.

- 13 received the E1 (smear and screen only).

In 2018:

31

Labs participating in AFB Smear/TB Culture and Identification EQA

IMPAACT TB Protocols

- QuantiFERON:
  - P1078 (this study is completed and in data analysis)
  - P1108 (will do this if TST not available)
  - I2005 (not protocol-required)
  - I2001
  - PHOENiX
- HAIN LPA:
  - P1108 and I2005
  - PHOENiX
- GeneXpert MTB/RIF: P1108, I2001, I2005, PHOENiX
- 2nd line DST: P1108 and I2005, PHOENiX.

ACTG TB Protocols

- QuantiFERON:
  - A5302
  - A5300B/I2003B
- HAIN LPA:
  - A5343
  - A5349
  - A5356
- GeneXpert MTB/RIF: A5349, A5300B/I2003B, A5365
- 2nd line DST: A5356, A5362

29

Labs participating in GeneXpert MTB/RIF EQA

21

Labs participating in QuantiFERON EQA

14

Labs participating in HAIN LPA EQA

6

Labs participating in MTB 2nd Line DST EQA Pilot

Protocol Analyte List (PAL)

Assay	Instrument Name	Instrument Manufacturer
Mycobacteriology		
AFB Smear	Manual	N/A
Liquid Culture	BACTEC MGIT 960	Becton Dickinson
Solid Culture	L-J	N/A
Culture speciation	HAIN	HAIN LIFE SCIENCE
Drug Susceptibility Testing (DST)	BACTEC MGIT 960	BECTON DICKINSON
Hain Genotype MTBDR Plus Line Probe Assay	HAIN	HAIN LIFE SCIENCE
GeneXpert MTB/RIF assay	GeneXpert	Cepheid
Interferon gamma release assay (IGRA)	Microplate washer, Microplate reader	TECAN Austria GmbH.

Separate procedures

QuantiFERON TB

EQA coverage for TB

Assay	External QA provider	Frequency of EQA
Mycobacteriology		
AFB Smear	INSTAND/CAP	2 / year
Liquid Culture	INSTAND/CAP	2 / year
Solid Culture	INSTAND/CAP	2 / year
Culture speciation	INSTAND/CAP	2 / year
Drug Susceptibility Testing (DST)	INSTAND/CAP/IQLS*	2 / year
Hain Genotype MTBDR Plus Line Probe Assay	SmartSpot Quality* MTS Online EQA*	3 / year
GeneXpert MTB/RIF assay	SmartSpot Quality	3 / year
Interferon gamma release assay (IGRA)	UKNEQAS/CAP	6 or 2 / year

*Current pilot studies

TB ‘analytes’ on SMILE EQA summary

		2017			2018
Survey		1	2	3	1
Mycobacteriology	AFB Smear	100%	100%		
	M. tuberculosis ID	100%	100%		
	MTB/RIF, DNA	100%	100%	62%	100%
	MTB/RIF, DNA (Inst 2)	100%	100%		100%
	MTB/RIF, DNA (Inst 3)	100%	75%		100%
	Susceptibilities, MTB	92%	92%		
	MOTT Identification				

GeneXpert MTBDR assay	GeneXpert

Liquid Culture	MGIT
Solid Culture	L-J
Culture speciation	HAIN

	MGIT
Solid Culture	L-J
Culture speciation	HAIN

SMILE EQA Summary….

Where did my QuantiFERON results go??

		2016		2017					2018	
Survey		3	1	2	3	4	5	6 (Trial)	1	2
Mycobacteriology 2	M. tuberculosis, IGRA		0%	100%				100%	100%	100%
	M. tuberculosis, IGRA (Mtd 2)							100%	100%	

Interferon gamma release assay (IGRA)	Microplate washer, Microplate reader

AKA: QuantiFERON TB

QuantiFERON

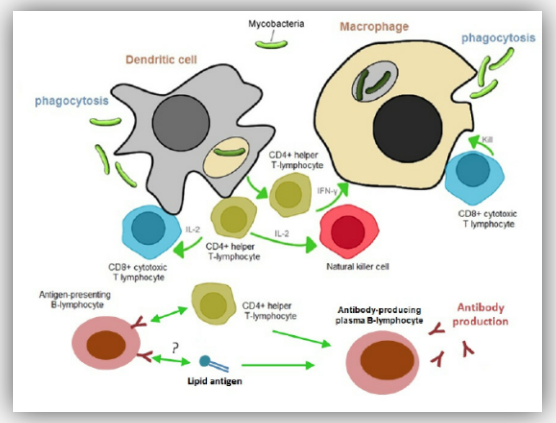
Providing EQA for QuantiFERON –TB Gold (QFT Gold) and QuantiFERON®-TB Gold Plus (QFT-Plus) assays

Outline

- Background to QuantiFERON TB Assays
- Conventional EQA Approach
- Pilot Study and Observations
- Customized EQA Approach

What is QuantiFERON (QFT)?

- **Simulated-** QFT measures the cell-mediated immune responses to peptide antigens that simulate two specific, mycobacterial proteins, namely, early secretory antigenic target-6 (ESAT-6) and culture filtrate protein-10 (CFP-10).



- **ESAT-6 & CFP-10**
  - Secreted by all M. tuberculosis (MTB) and pathogenic M. bovis strains
  - Absent from BCG strains
  - Absent from most NTM except M. kansasii, M. szulgai, and M. marinum

- **Indirect** -Measures immune response to MTB. Exposure to the Tubercle bacillus elicits a cell mediated response which ultimately releases a cytokine called IFN-γ. **IGRA -** An interferon-gamma (IFN-γ) release assay
  - IFN-γ is released when fresh heparinized whole blood from sensitized persons, incubated with mixtures of synthetic peptides simulating ESAT-6 & CFP-10 proteins present in M. tuberculosis.
  - ELISA to detect the IFN-γ

Two Types of QFT Tests

Mitogen – Positive Control
Low response may indicate inability to generate IFN-γ

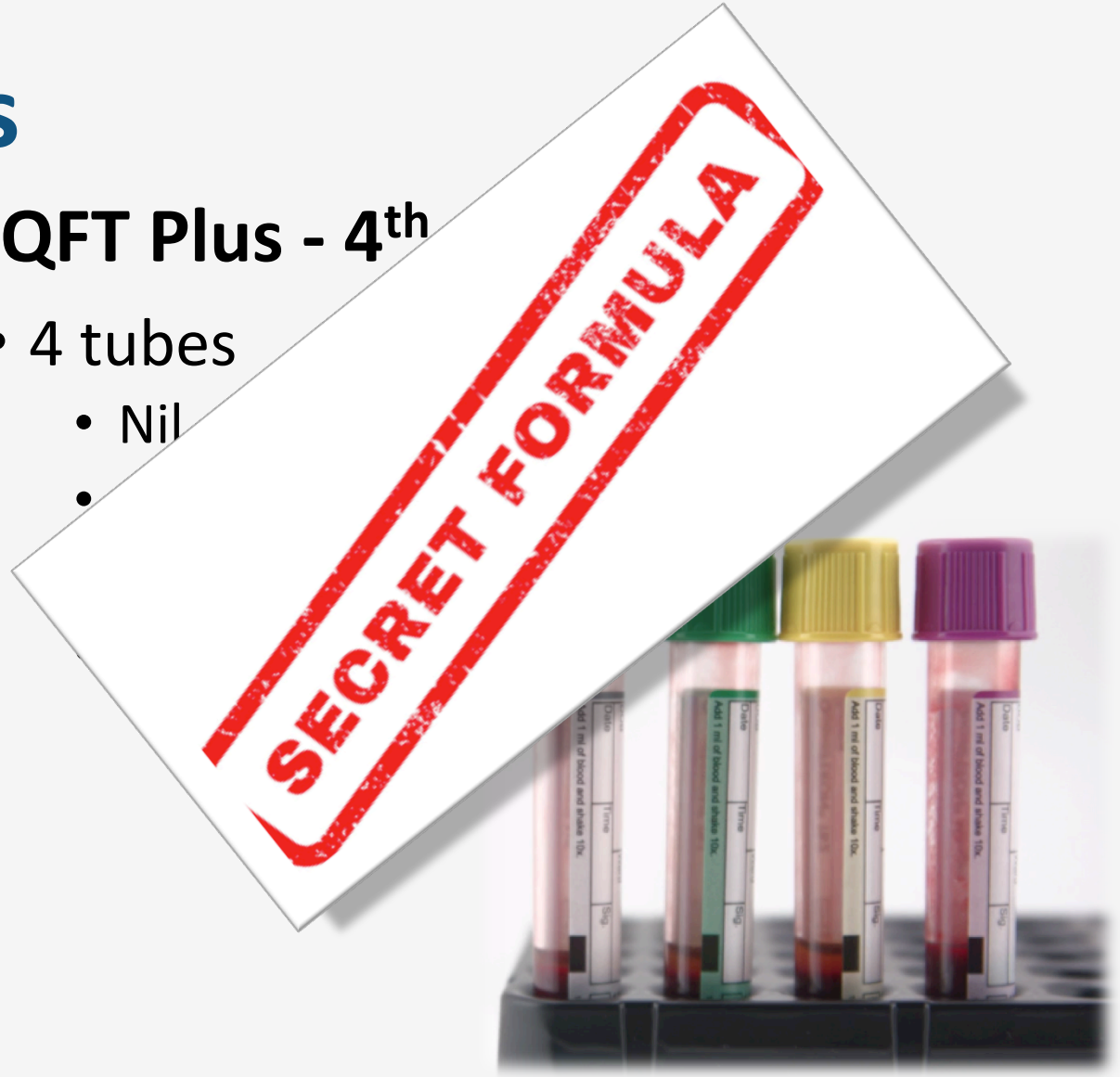
Nil – Negative Control
Adjusts for background IFN-γ

TB1 – Primarily detects CD4 T cell response

TB2 – Optimized for detection of CD4 and CD8 T cell responses

QFT Plus - 4th

- 4 tubes
  - Nil
  -



College of American Pathologists (CAP)

- M. Tuberculosis-Simulated Infection Detection QF Survey **(QF)**

Early 2017 Announcement:
"Beginning with this mailing, QuantiFERON Gold Plus user can participate in this Survey"

COLLEGE of AMERICAN PATHOLOGISTS
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • cap.org

CAP Number: [redacted] Kit# 1
Institution: [redacted] Laboratory
Attention: [redacted]
City / State: [redacted]

Kit ID: 29668979
Kit Mailed: 10/17/2016
Original Evaluation: 11/15/2016

EVALUATION
ORIGINAL

QF-B 2016 QuantiFERON TB

Test Method	Specimen	Your Result	Intended Response	Your Grade
M. tuberculosis, qual. QIAGEN QFT GOLD I-T	QF-04	POSITIVE	POSITIVE	Good
	QF-05	POSITIVE	POSITIVE	Good

COLLEGE of AMERICAN PATHOLOGISTS
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • cap.org

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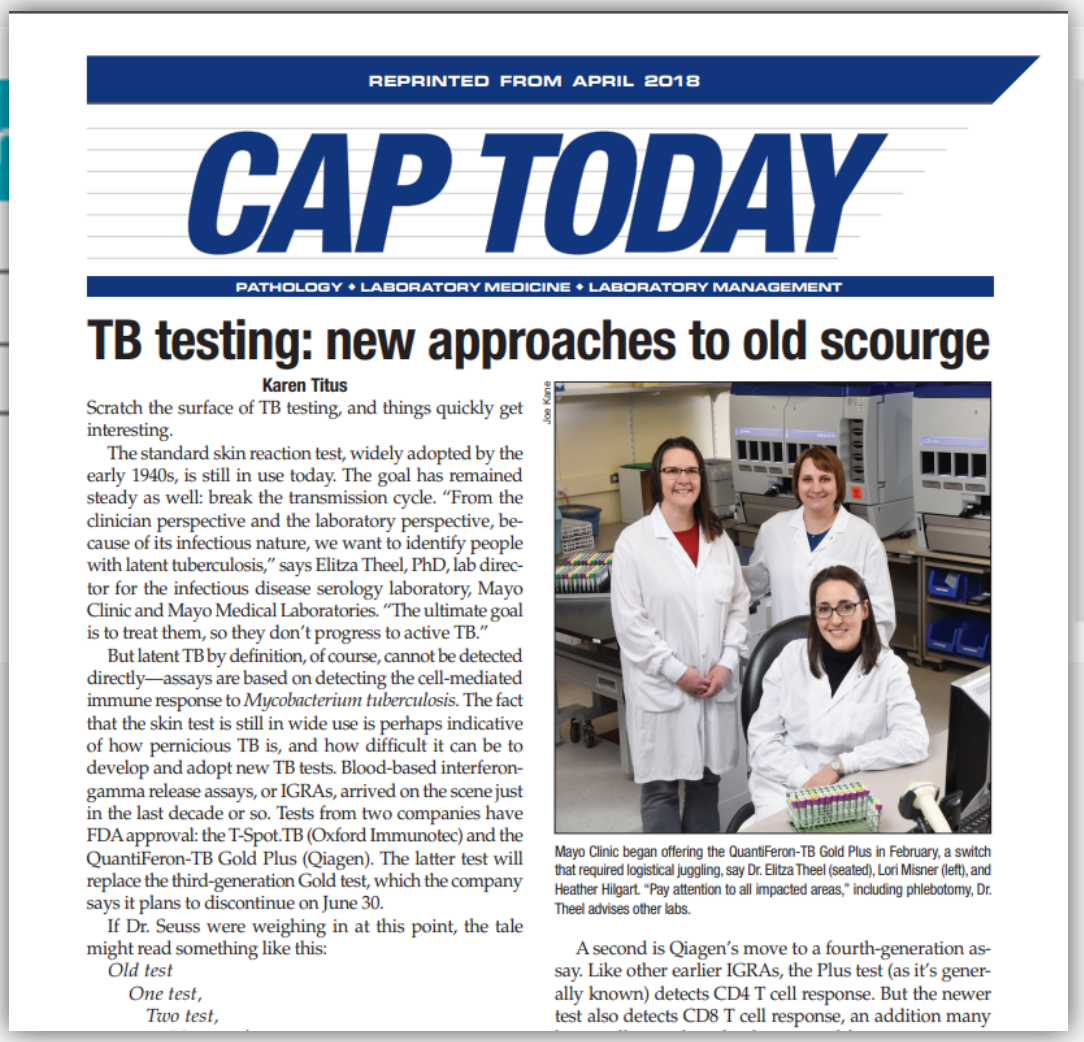
	QF-05	POSITIVE	POSITIVE	Good

SMILE Experiences with CAP QF Survey

M. tuberculosis-Stim
Analyte
M. tuberculosis



REPRINTED FROM APRIL 2018

CAP TODAY

PATHOLOGY • LABORATORY MEDICINE • LABORATORY MANAGEMENT

TB testing: new approaches to old scourge

Karen Titus

Scratch the surface of TB testing, and things quickly get interesting.

The standard skin reaction test, widely adopted by the early 1940s, is still in use today. The goal has remained steady as well: break the transmission cycle. "From the clinician perspective and the laboratory perspective, because of its infectious nature, we want to identify people with latent tuberculosis," says Elitza Theel, PhD, lab director for the infectious disease serology laboratory, Mayo Clinic and Mayo Medical Laboratories. "The ultimate goal is to treat them, so they don't progress to active TB."

But latent TB by definition, of course, cannot be detected directly—assays are based on detecting the cell-mediated immune response to *Mycobacterium tuberculosis*. The fact that the skin test is still in wide use is perhaps indicative of how pernicious TB is, and how difficult it can be to develop and adopt new TB tests. Blood-based interferon-gamma release assays, or IGRAs, arrived on the scene just in the last decade or so. Tests from two companies have FDA approval: the T-Spot.TB (Oxford Immunotec) and the QuantiFeron-TB Gold Plus (Qiagen). The latter test will replace the third-generation Gold test, which the company says it plans to discontinue on June 30.

If Dr. Seuss were weighing in at this point, the tale might read something like this:

Old test
One test,
Two test,

Joe Kane

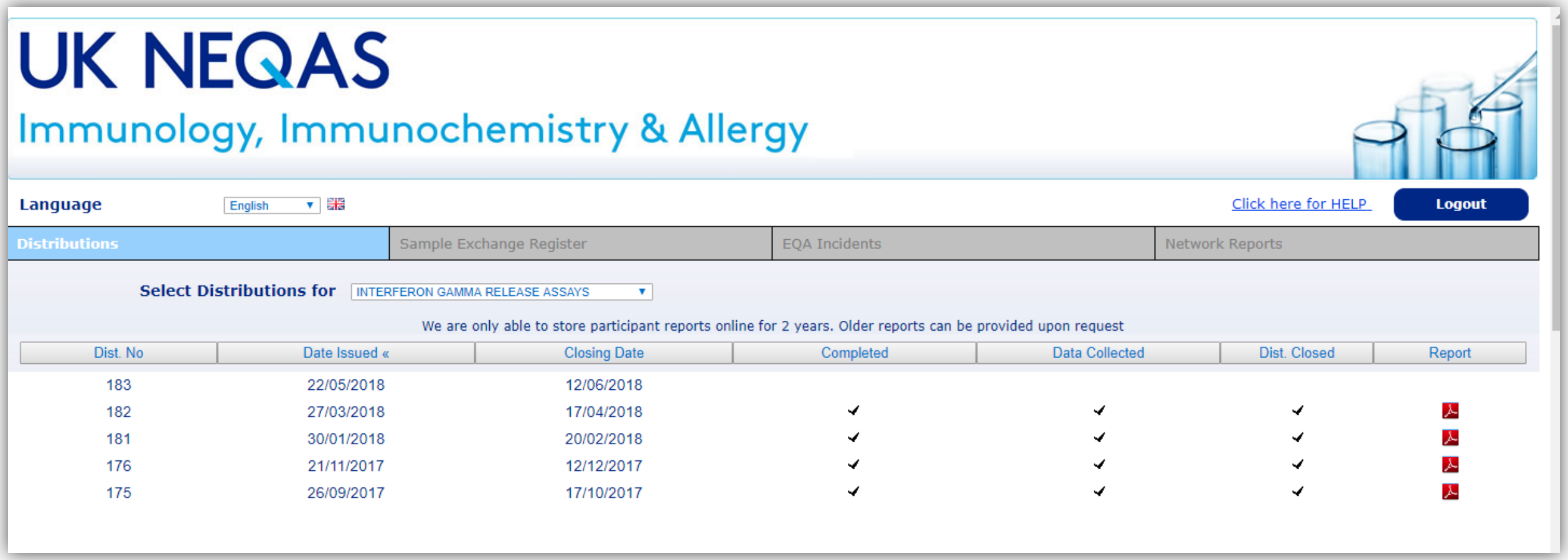
Mayo Clinic began offering the QuantiFeron-TB Gold Plus in February, a switch that required logistical juggling, say Dr. Elitza Theel (seated), Lori Misner (left), and Heather Hilgart. "Pay attention to all impacted areas," including phlebotomy, Dr. Theel advises other labs.

A second is Qiagen's move to a fourth-generation assay. Like other earlier IGRAs, the Plus test (as it's generally known) detects CD4 T cell response. But the newer test also detects CD8 T cell response, an addition many

Program Information

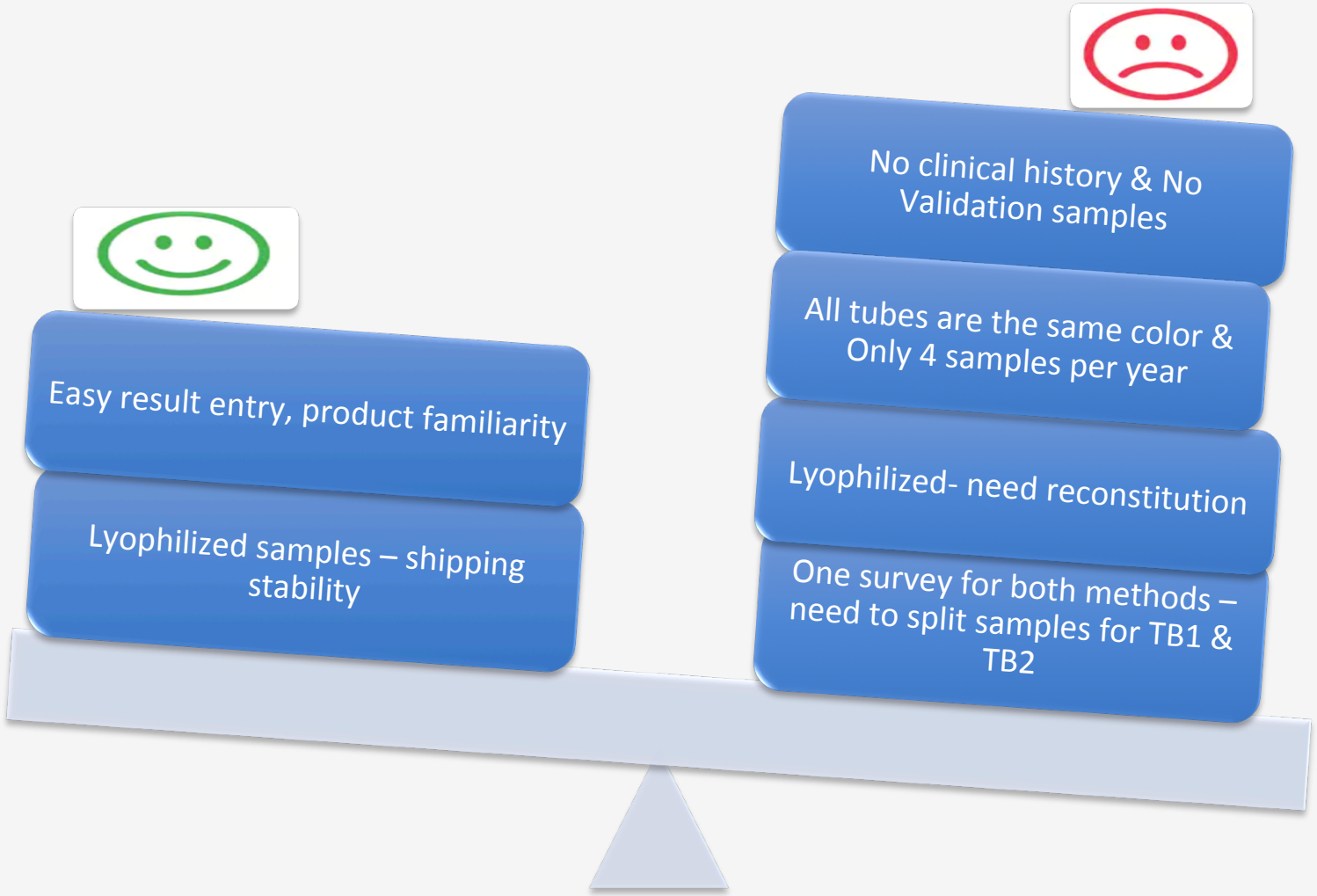
- Two 1.0-mL lyophilized specimens and one lyophilized mitogen control
- For use with the QuantiFERON®-TB Gold and Gold Plus methods only
- Two shipments per year

UKNEQAS (UKN) Interferon Gamma Release Assays Mycobacterium tuberculosis (IGRA TB) Scheme Pilot Study



Dist. No	Date Issued «	Closing Date	Completed	Data Collected	Dist. Closed	Report
183	22/05/2018	12/06/2018				
182	27/03/2018	17/04/2018	✓	✓	✓	
181	30/01/2018	20/02/2018	✓	✓	✓	
176	21/11/2017	12/12/2017	✓	✓	✓	
175	26/09/2017	17/10/2017	✓	✓	✓	

Pilot Study: CAP QF Survey Observations

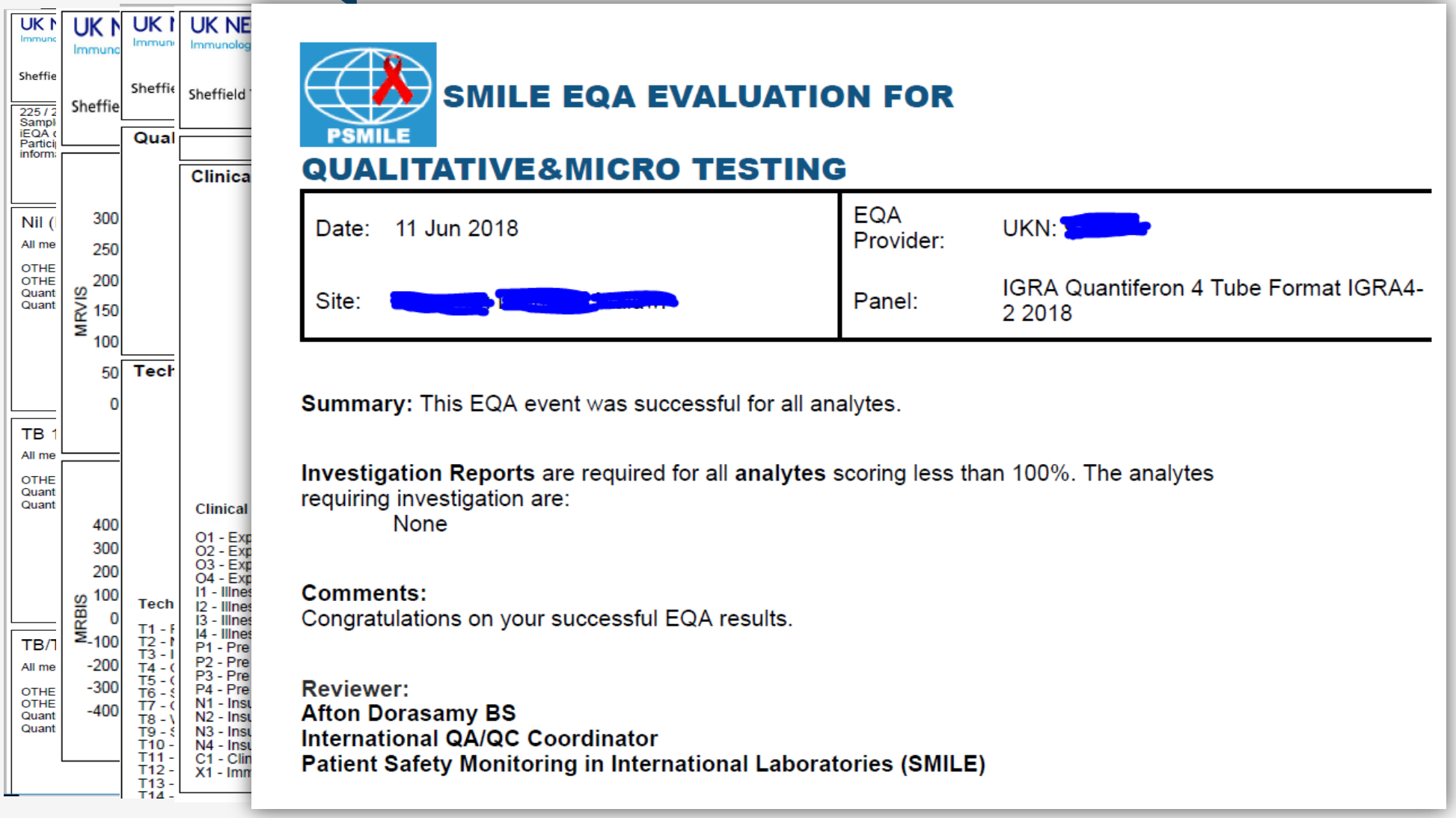


Pilot Study: UKN IGRA TB Survey Observations

- Clinical history & quantitative result data
- Validation samples
- Serum based & 12 samples/ year
- Separates 3/ 4 tube, color coding on tubes & result entry to match assay

- Unfamiliar website and survey evaluations
- 6 shipments & serum samples less stable

UKN QuantiFERON 4 Tube Format IGRA Survey



SMILE EQA EVALUATION FOR

QUALITATIVE&MICRO TESTING

Date: 11 Jun 2018	EQA Provider: UKN: [redacted]
Site: [redacted]	Panel: IGRA Quantiferon 4 Tube Format IGRA4-2 2018

Summary: This EQA event was successful for all analytes.

Investigation Reports are required for all **analytes** scoring less than 100%. The analytes requiring investigation are:

None

Comments:
Congratulations on your successful EQA results.

Reviewer:
Afton Dorasamy BS
International QA/QC Coordinator
Patient Safety Monitoring in International Laboratories (SMILE)

pSMILE
SAFETY·QUALITY·RESULTS

THANK YOU

EQA for HAIN LPA Strip Interpretation

Providing EQA for the HAIN Line Probe assay

Outline

- HAIN LPA testing
- The need for an innovative approach
- The HAIN LPA strip interpretation panel

  (MTS Dry Panel)

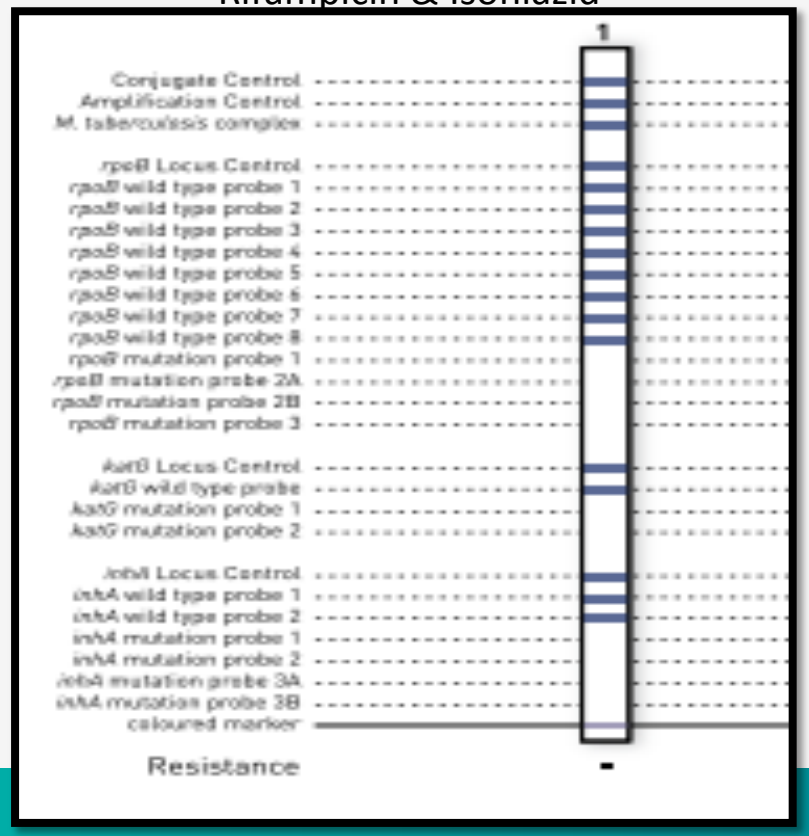
HAIN line probe assay (LPA)

At a glance

Molecular genetic assay for the detection of *M. tuberculosis* complex and its resistance to specific antimycobacterial drugs from clinical specimens and cultures.

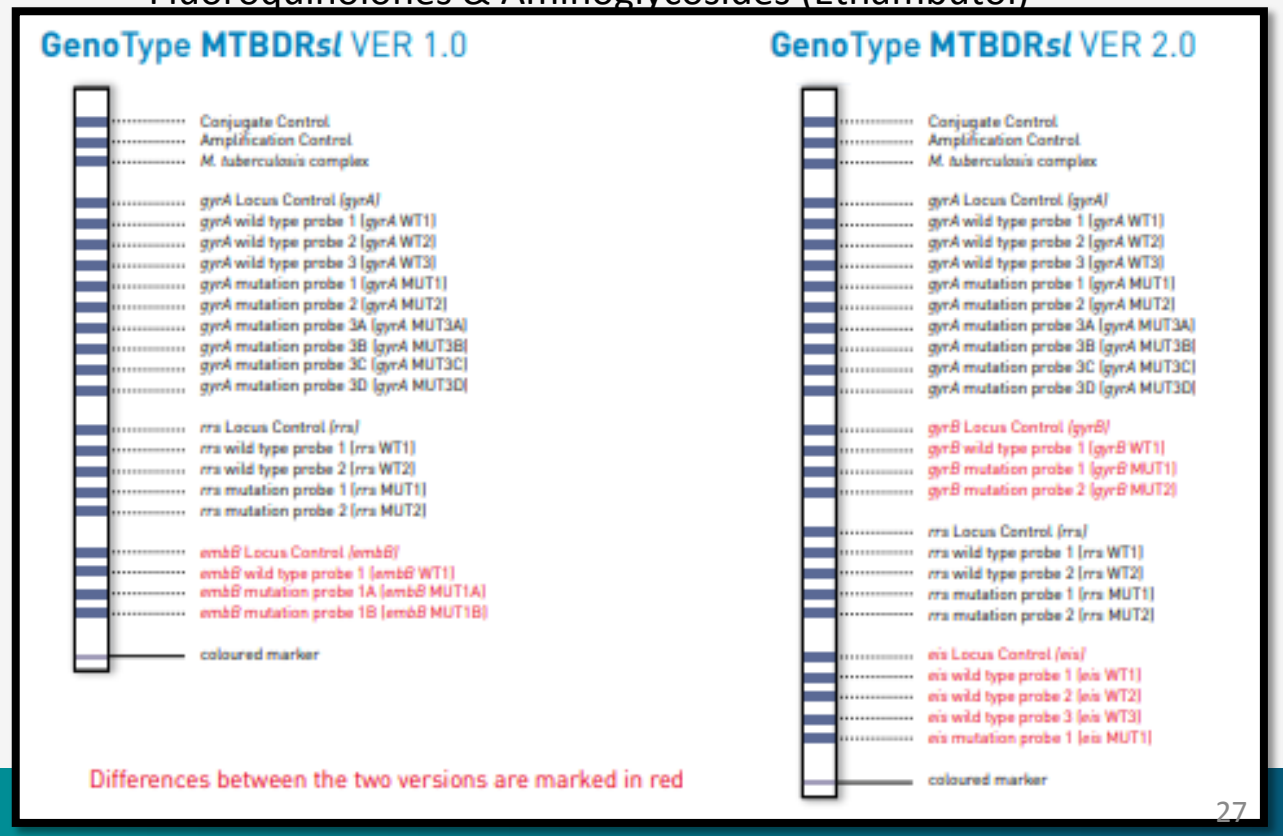
MTBDRplus

Rifampicin & Isoniazid



MTBDRsl

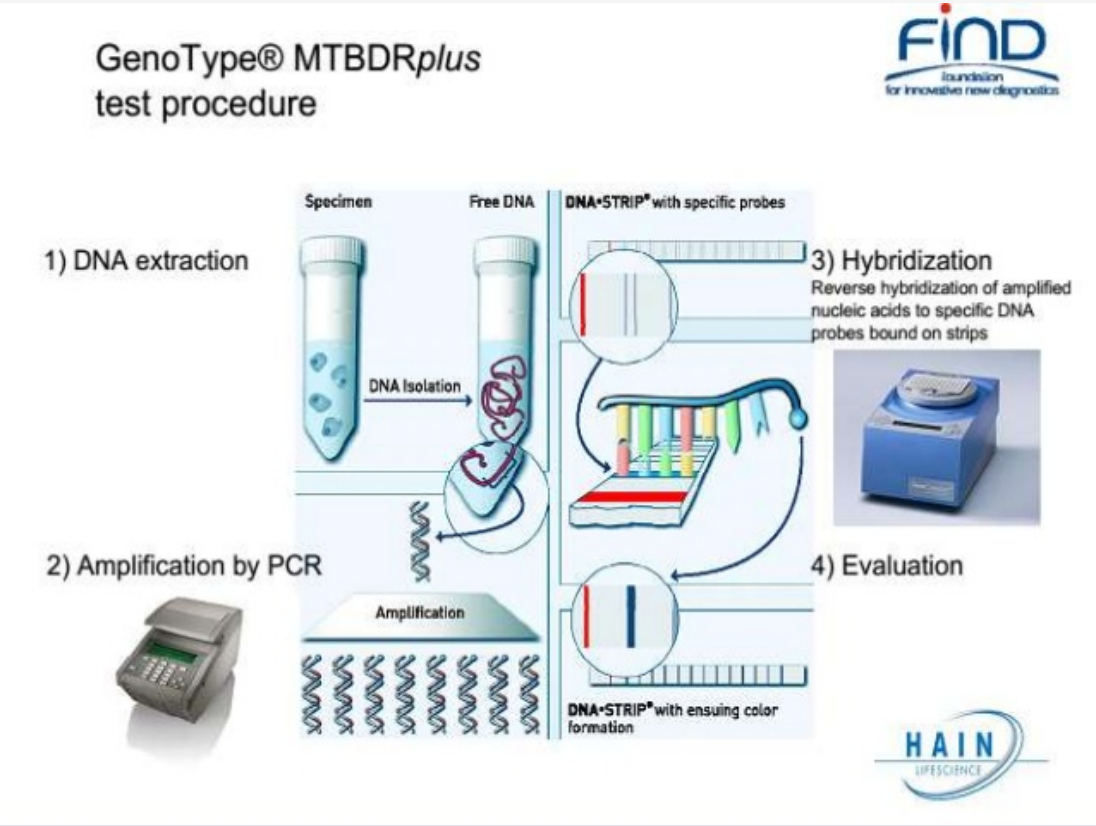
Fluoroquinolones & Aminoglycosides (Ethambutol)



Test Procedure

How does it work?

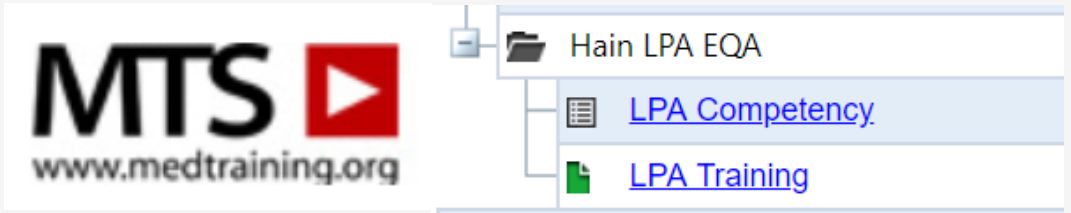
- DNA Extraction
- PCR Amplification
- Reverse Hybridization
- Evaluation of results



HAIN Strip interpretation EQA panel

What is the Med Training Solutions (MTS) platform?

An online resource for training, building competency and improving the quality of laboratory services.



Training module

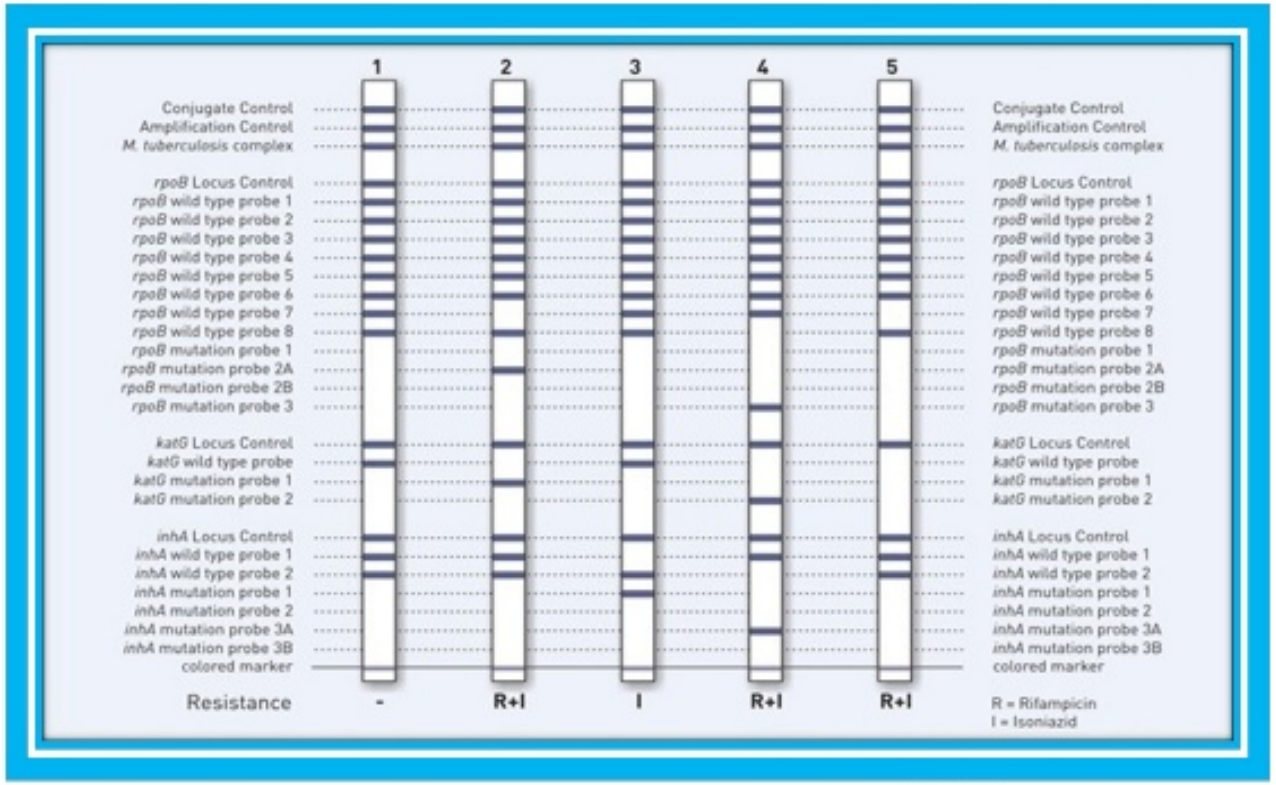
This module will provide strip interpretation training for the assay. This will be discussed by the TBQA group.

EQA/Competency module

Three surveys per year, comprised of 5-10 questions and strip images.

Rainbows & Unicorns!

GenoType® MTBDR*plus* assay

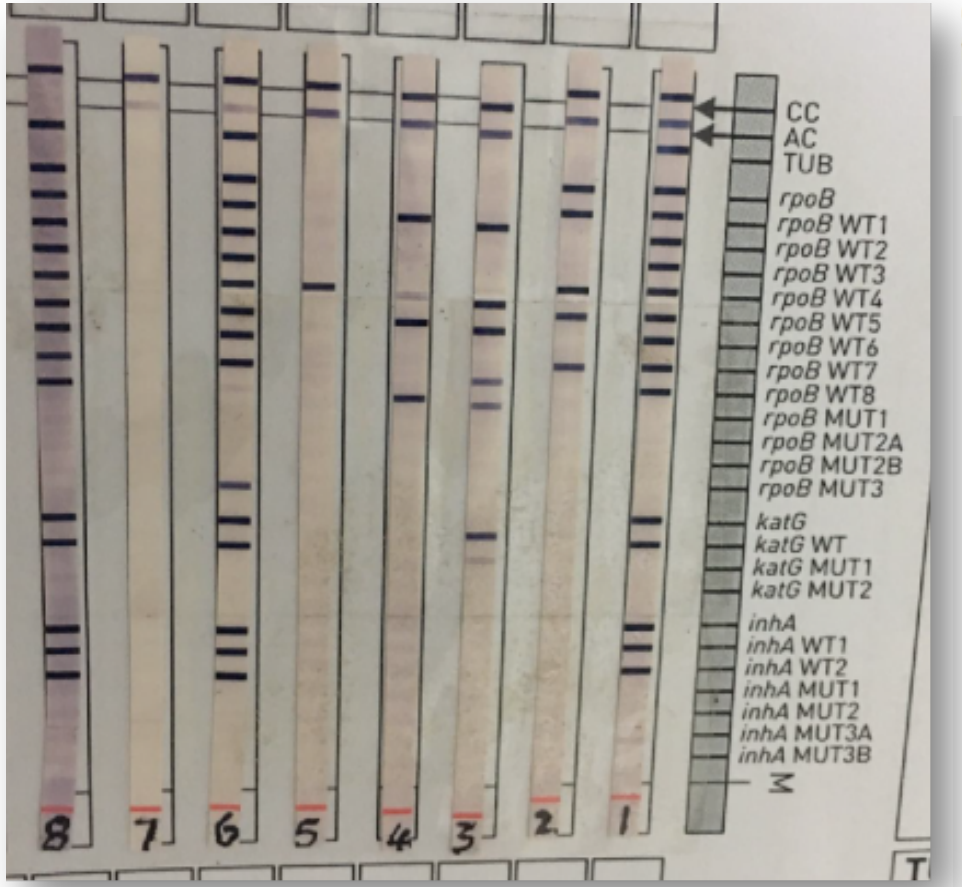


HAIN LPA
Strip Interpretation EQA

3 Interpret the result for strip 4

- ○ MTB Complex detected, RIF resistant, INH susceptible
- ◉ MTB Complex not detected
- ○ MTB Complex Detected, RIF susceptible, INH susceptible

Submit Answer



EXPLANATION

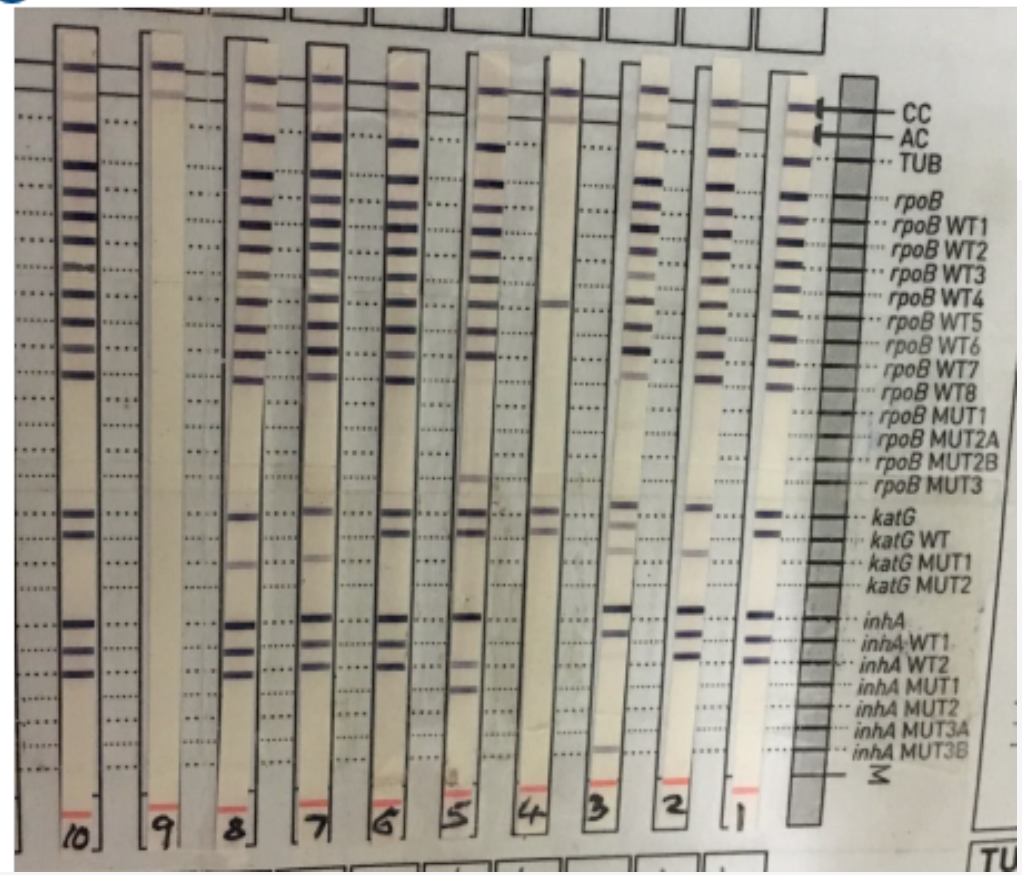
The TUB band is absent with no evaluable resistance pattern therefore MTB Complex Not Detected

HAIN LPA
Strip Interpretation EQA

4 Interpret the result for strip 5

- MTB Complex Detected, RIF resistant, INH resistant
- MTB Complex Detected, RIF susceptible, INH resistant
- **c) MTB Complex Detected, RIF resistant, INH susceptible**

Submit Answer



EXPLANATION

This strip shows MTB Complex Detected - rpoB WT8 absent with MUT3 band observed and inhA WT1 absent with MUT1 band observed

Protocols that require this test

ACTG

- PHOENiX (ACTG/IMPAACT study)
- A5343:
- A5349:IMPAACT

IMPAACT

- P1108
- I2005
- I2003B/PHOENiX (ACTG/IMPAACT study)

pSMILE
SAFETY·QUALITY·RESULTS

THANK YOU

GeneXpert EQA

SmartSpot Quality

Now under
SMILE oversight

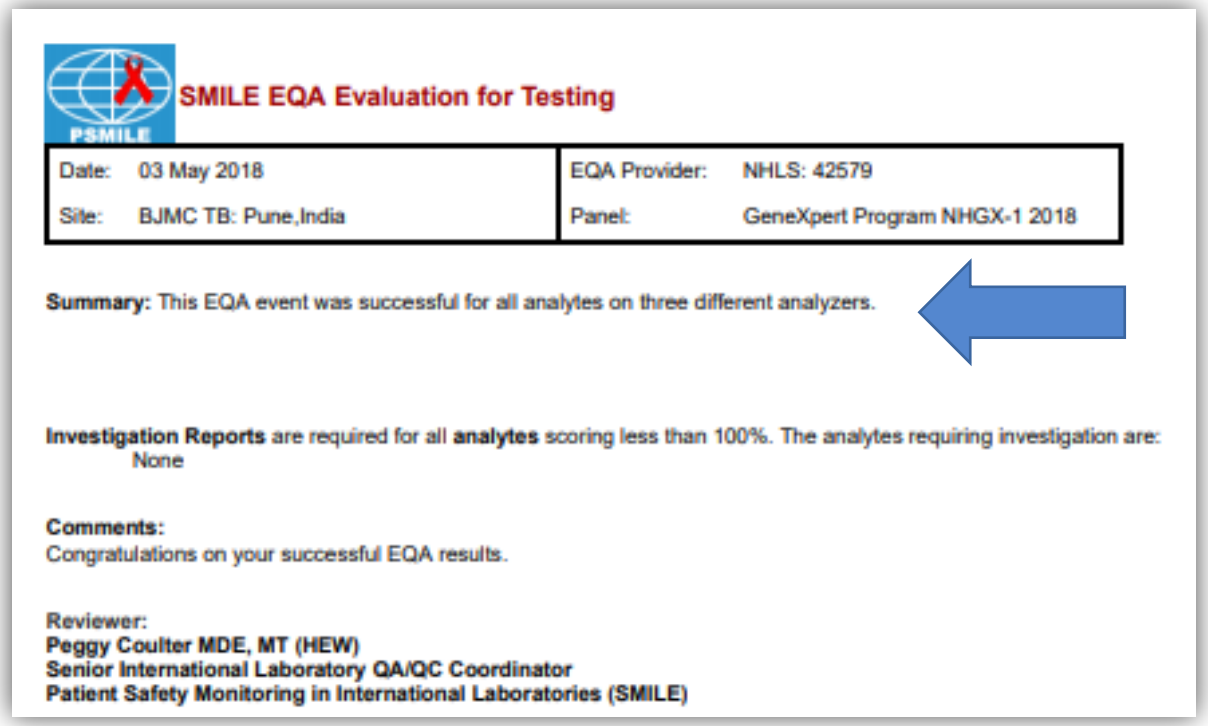
EQA Schedule

	2018				CMC TB Lab		
	Ship Date	EQA Provider	Survey Sequence	Module Code	Test Group Name	SMILE Reviewed (Date)	
1	18-Jan-18	INS	1	**Mycobact**	Mycobacteriology		
2	27-Apr-18	NHLS	1	**NHGX**	GeneXpert Program	17-May-18	
3	31-Aug-18	NHLS	2	**NHGX**	GeneXpert Program		
4	26-Sep-18	INS	2	**Mycobact**	Mycobacteriology		
5	30-Nov-18	NHLS	3	**NHGX**	GeneXpert Program		

EQA Summary

Mycobacteriology			
Analyte	**INS2016 2nd**	**2016 3rd**	**NHLS2017 1st**
AFB Smear	100%	—	—
M. tuberculosis ID	100%	—	—
MTB/RIF, DNA	—	100%	100%
MTB/RIF, DNA (Inst 2)	—	—	100%
MTB/RIF, DNA (Inst 3)	—	100%	100%
Susceptibilities, MTB	90%	—	—
MOTT Identification	—	—	—

EQA Reviews



SMILE EQA Evaluation for Testing

Date:	03 May 2018	EQA Provider:	NHLS: 42579
Site:	BJMC TB: Pune,India	Panel:	GeneXpert Program NHGX-1 2018

Summary: This EQA event was successful for all analytes on three different analyzers.

Investigation Reports are required for all **analytes** scoring less than 100%. The analytes requiring investigation are:
None

Comments:
Congratulations on your successful EQA results.

Reviewer:
Peggy Coulter MDE, MT (HEW)
Senior International Laboratory QA/QC Coordinator
Patient Safety Monitoring in International Laboratories (SMILE)

IR Process

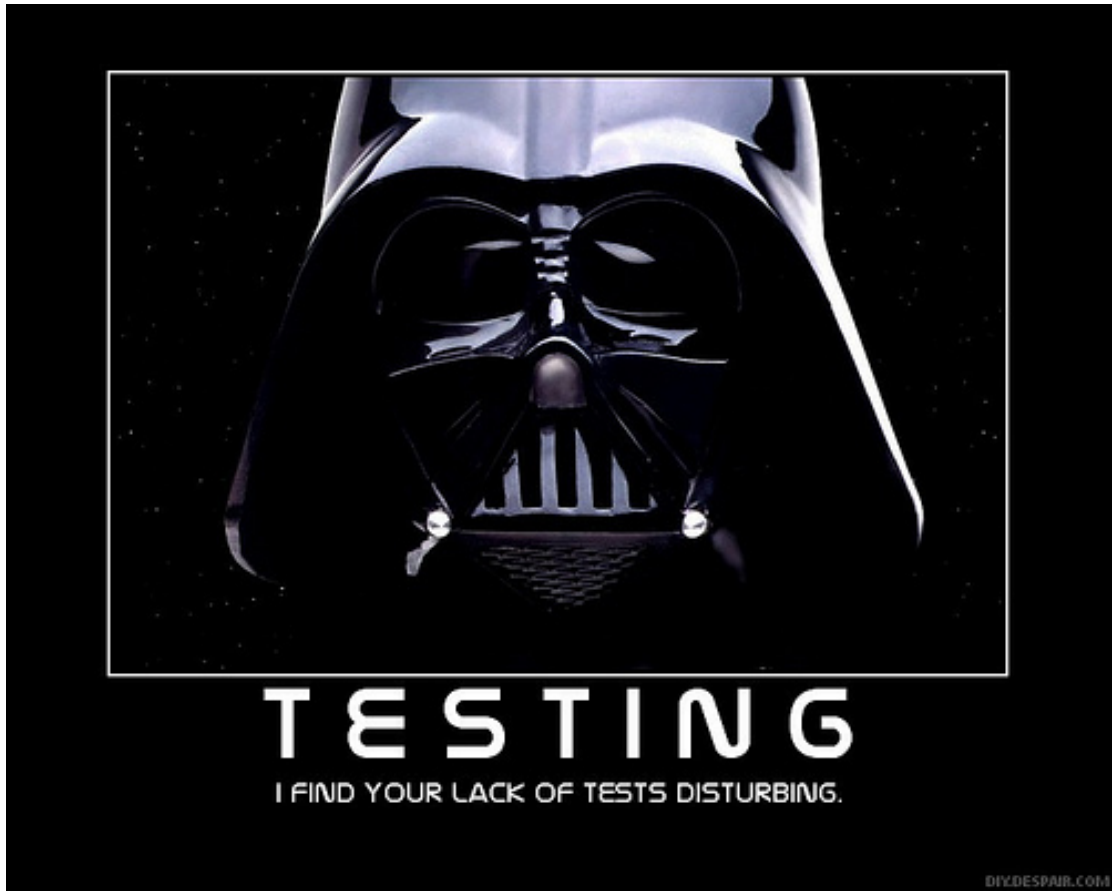
Note: Please complete this IR
ado

FOR EQA PROVIDER USE ONLY				
Review:	☐	*Acceptable and complete Investigation.*	☐	*Investigation is incomplete. See comments.*
Comments:				
Name/Title:				
Signature:		**Date:**		

FOR SMILE USE ONLY (WHERE APPLICABLE)				
Review:	☐	*Acceptable and complete Investigation.*	☐	*Investigation is incomplete. See comments.*
Comments:				
Name/Title:				
Signature:		**Date:**		

FOR NETWORK USE ONLY (WHERE APPLICABLE)				
Review:	☐	*Acceptable and complete Investigation.*	☐	*Investigation is incomplete. See comments.*
Comments:				
Name/Title:				
Signature:		**Date:**		

New Pilot!
EQA for 2nd line DST




IQLS
INTEGRATED QUALITY LABORATORY SERVICES
www.iqls.net
Call +33 472 714 498
or
Contact us here
Google Custom Searc
QA/EQA
• Organization of EQA programme (TB, dengue, chikungunya, malaria)
• Development of policies & procedures
• Development of online application for EQA program management
• Country mentoring
Read More
Home
About
Activities
Diseases
Software
Projects
Brochures
Photos
News & Events
IQLS Training Hub

IQLS Pilot Laboratories

Laboratory Location
Makati City, Philippines
Johannesburg, South Africa
Pune, India
Johannesburg, South Africa
Rio de Janeiro, Brazil
Kampala, Uganda

IQLS Program

Two events per year.
Included in each shipment:

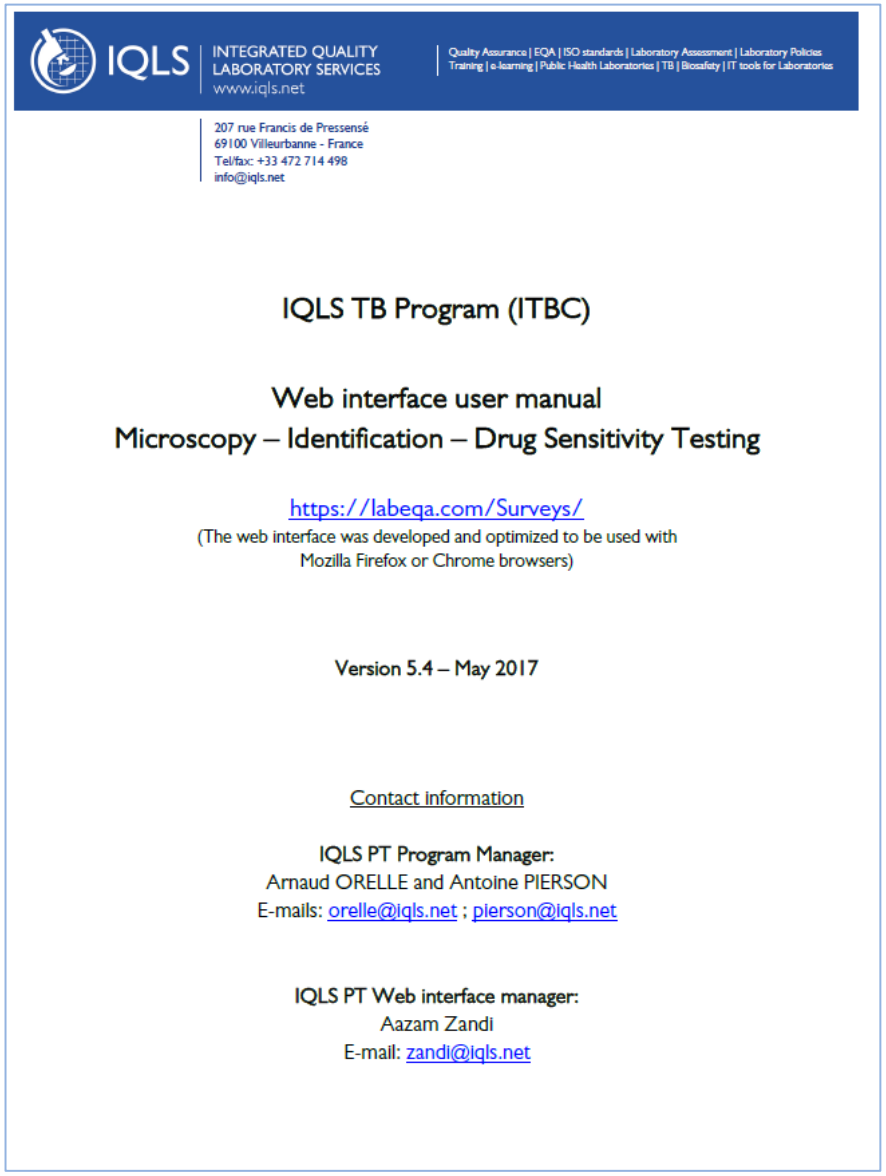
- 10 microscopic slides in each of 2 shipments for detection of AFB
- 10 simulated sputum specimens in 2 shipments for culture of mycobacteria

IQLS program

- Isolates from the cultures would be differentiated between TB and NTM (MOTT)
- Drug Susceptibility testing for both **first and second** line drugs performed in the laboratory would be tested against any organisms identified as *M. tuberculosis*.
  - Ofloxacin
  - Levofloxavin
  - Amikacin
  - Capreomycin
  - Kanamycin

Labs are asked to perform testing only on the drugs they currently test. Not adding additional for EQA purposes only.

Online Entry



IQLS | INTEGRATED QUALITY LABORATORY SERVICES
www.iqls.net

Quality Assurance | EQA | ISO standards | Laboratory Assessment | Laboratory Policies
Training | e-learning | Public Health Laboratories | TB | Biosafety | IT tools for Laboratories

207 rue Francis de Pressensé
69100 Villeurbanne - France
Tel/fax: +33 472 714 498
info@iqls.net

IQLS TB Program (ITBC)

Web interface user manual
Microscopy – Identification – Drug Sensitivity Testing

https://labeqa.com/Surveys/
(The web interface was developed and optimized to be used with
Mozilla Firefox or Chrome browsers)

Version 5.4 – May 2017

Contact information

IQLS PT Program Manager:
Arnaud ORELLE and Antoine PIERSON
E-mails: orelle@iqls.net ; pierson@iqls.net

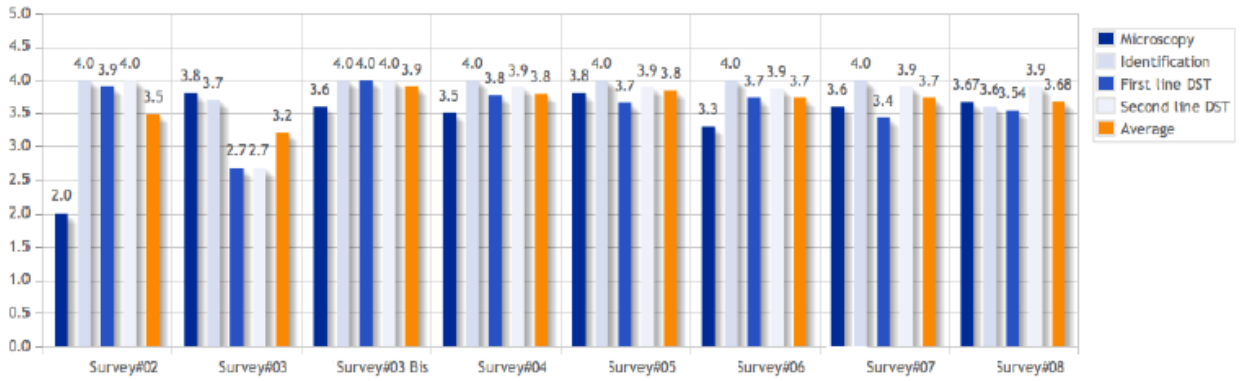
IQLS PT Web interface manager:
Aazam Zandi
E-mail: zandi@iqls.net

Survey History

IQLS® INTEGRATED QUALITY LABORATORY SERVICES www.iqls.net

Laboratory X
Survey#08 (01/09/2015)

Evaluation from Previous Surveys



Area	Survey#02 (03/29/2012)	Survey#03 (10/05/2012)	Survey#03 Bis (02/11/2013)	Survey#04 (02/12/2013)	Survey#05 (09/20/2013)	Survey#06 (11/07/2014)	Survey#07 (12/12/2014)	Survey#08 (13/07/2015)
Microscopy	2.00	3.80	3.60	3.50	3.80	3.30	3.60	3.67
Identification	4.00	3.70	4.00	4.00	4.00	4.00	4.00	3.60
First Line DST	3.90	2.67	4.00	3.77	3.66	3.73	3.43	3.54
Second Line DST	4.00	2.67	4.00	3.89	3.89	3.87	3.90	3.90
Average	**3.48**	**3.21**	**3.90**	**3.79**	**3.84**	**3.73**	**3.73**	**3.68**

IQLS® INTEGRATED QUALITY LABORATORY SERVICES www.iqls.net

Laboratory X
Survey#08 (01/09/2015)

Microscopy

Specimen	Grading Area
Slide01	Microscopy
Slide02	Microscopy
Slide03	Microscopy
Slide04	Microscopy
Slide05	Microscopy
Slide06	Microscopy
Slide07	Microscopy
Slide08	Microscopy
Slide09	Microscopy
Slide10	Microscopy
	Average

- 4: Perfect response
- 3: 1 minor mistake (small quantification e
- 1: 1 major mistake (large quantification e
- 0: More than 1 major mistake (false posit
- NE: not evaluated
- NA by Admin: Inactivated by Admin

6 rue Villon 69003 Lyon, France Tel/fax: 33 472 714 4

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Identification

Specimen	Grading Ar
SputumA	Identificatior
SputumB	Identificatior
SputumC	Identificatior
SputumD	Identificatior
SputumE	Identificatior
SputumF	Identificatior
SputumG	Identificatior
SputumH	Identificatior
SputumJ	Identificatior
SputumK	Identificatior
	Av

- 4: Perfect response
- 0: More than 1 major mistake(false posit
- NE: not evaluated

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Laboratory X
Survey#08 (01/09/2015)

Your laboratory DS

Drug	SputumA
Streptomycin	Sensitive
Isoniazid	Sensitive
Rifampicin	Sensitive
Ethambutol	Sensitive
Pyrazinamid	Sensitive
Ofloxacin	Sensitive
Levofloxacin	Sensitive
Amikacin	Sensitive
Capreomycin	Sensitive
Kanamycin	Sensitive

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Laboratory X
Survey#08 (01/09/2015)

Identification Results / Technology

Specimen	Expected Result	Solid Culture	Liquid Culture	Line Probe Line
SputumA	Mycobacterium tuberculosis complex	TB/ TB complex positive	TB/ TB complex positive	Not Done
SputumB	Mycobacterium tuberculosis complex	TB/ TB complex positive	TB/ TB complex positive	Not Done
SputumC	Mycobacterium tuberculosis complex	TB/ TB complex positive	TB/ TB complex positive	Not Done
SputumD	Non tuberculosis mycobacteria	Non tuberculosis mycobacteria	Non tuberculosis mycobacteria	Not Done
SputumE	Mycobacterium tuberculosis complex	TB/ TB complex positive	TB/ TB complex positive	Not Done
SputumF	Mycobacterium tuberculosis complex	TB/ TB complex positive	TB/ TB complex positive	Not Done
SputumG	Negative	Non tuberculosis mycobacteria	Non tuberculosis mycobacteria	Not Done
SputumH	Non tuberculosis mycobacteria	Non tuberculosis mycobacteria	Non tuberculosis mycobacteria	Not Done
SputumJ	Mycobacterium tuberculosis complex	TB/ TB complex positive	TB/ TB complex positive	Not Done
SputumK	Mycobacterium tuberculosis complex	TB/ TB complex positive	TB/ TB complex positive	Not Done

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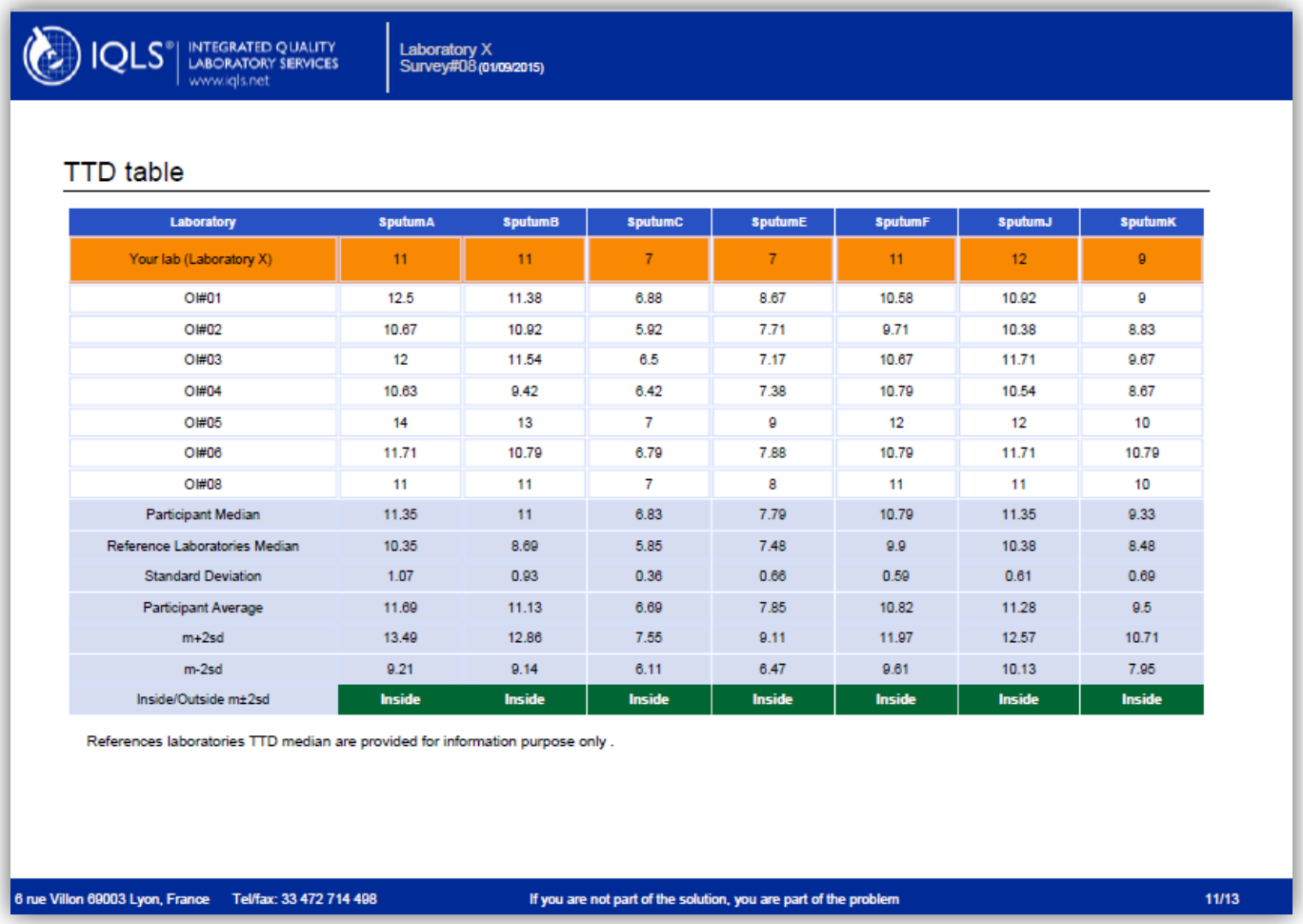
Culture Time to Detection



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Laboratory X
Survey#08 (01/09/2015)

TTD table

Laboratory	SputumA	SputumB	SputumC	SputumE	SputumF	SputumJ	SputumK
Your lab (Laboratory X)	11	11	7	7	11	12	9
OI#01	12.5	11.38	6.88	8.67	10.58	10.92	9
OI#02	10.67	10.92	5.92	7.71	9.71	10.38	8.83
OI#03	12	11.54	6.5	7.17	10.67	11.71	9.67
OI#04	10.63	9.42	6.42	7.38	10.79	10.54	8.67
OI#05	14	13	7	9	12	12	10
OI#06	11.71	10.79	6.79	7.88	10.79	11.71	10.79
OI#08	11	11	7	8	11	11	10
Participant Median	11.35	11	6.83	7.79	10.79	11.35	9.33
Reference Laboratories Median	10.35	8.69	5.85	7.48	9.9	10.38	8.48
Standard Deviation	1.07	0.93	0.36	0.66	0.59	0.61	0.69
Participant Average	11.69	11.13	6.69	7.85	10.82	11.28	9.5
m+2sd	13.49	12.86	7.55	9.11	11.97	12.57	10.71
m-2sd	9.21	9.14	6.11	6.47	9.61	10.13	7.95
Inside/Outside m±2sd	Inside	Inside	Inside	Inside	Inside	Inside	Inside

References laboratories TTD median are provided for information purpose only .

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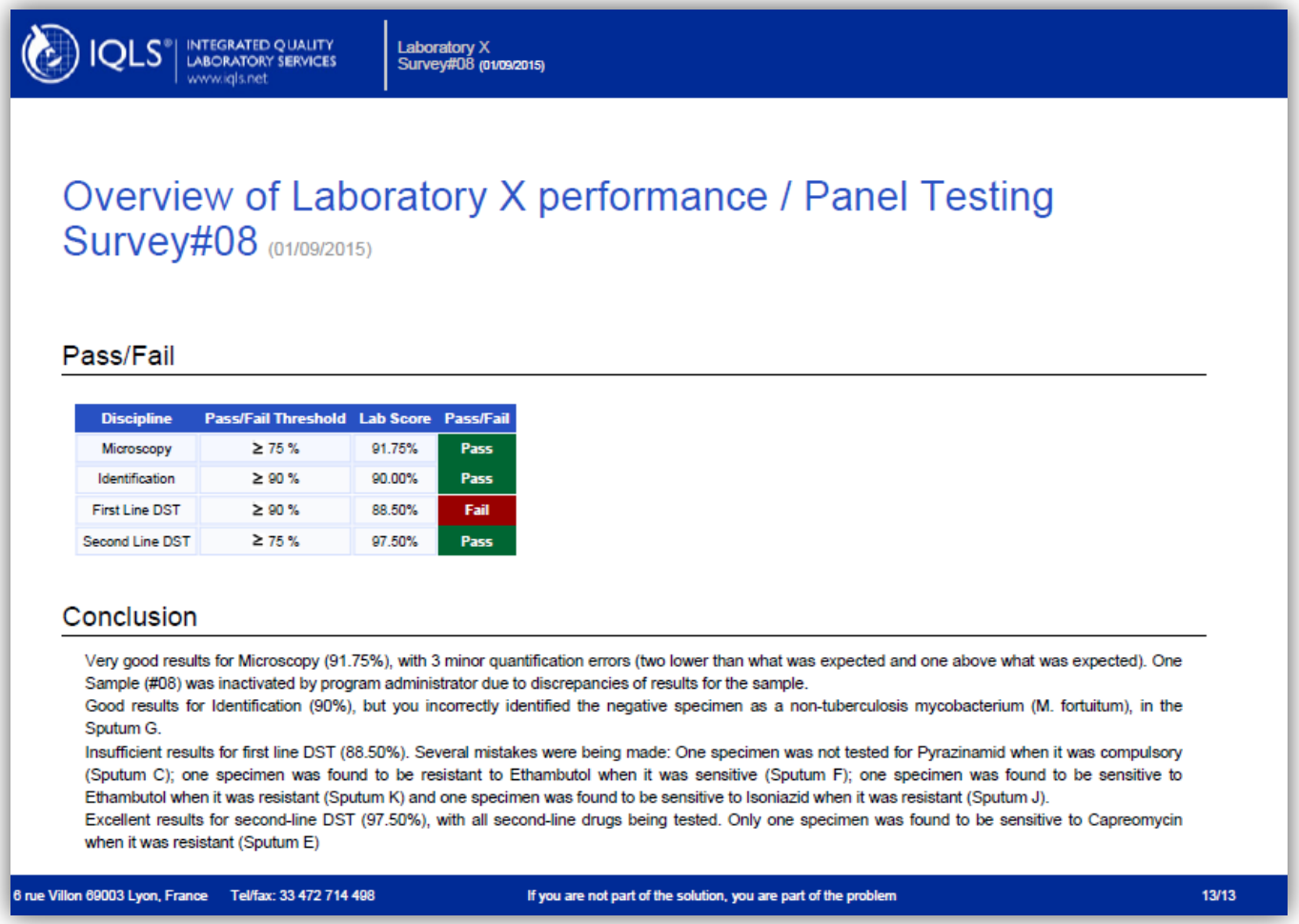
Performance Review



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Laboratory X
Survey#08 (01/09/2015)

Overview of Laboratory X performance / Panel Testing Survey#08 (01/09/2015)

Pass/Fail

Discipline	Pass/Fail Threshold	Lab Score	Pass/Fail
Microscopy	≥ 75 %	91.75%	Pass
Identification	≥ 90 %	90.00%	Pass
First Line DST	≥ 90 %	88.50%	Fail
Second Line DST	≥ 75 %	97.50%	Pass

Conclusion

Very good results for Microscopy (91.75%), with 3 minor quantification errors (two lower than what was expected and one above what was expected). One Sample (#08) was inactivated by program administrator due to discrepancies of results for the sample.
Good results for Identification (90%), but you incorrectly identified the negative specimen as a non-tuberculosis mycobacterium (M. fortuitum), in the Sputum G.
Insufficient results for first line DST (88.50%). Several mistakes were being made: One specimen was not tested for Pyrazinamid when it was compulsory (Sputum C); one specimen was found to be resistant to Ethambutol when it was sensitive (Sputum F); one specimen was found to be sensitive to Ethambutol when it was resistant (Sputum K) and one specimen was found to be sensitive to Isoniazid when it was resistant (Sputum J).
Excellent results for second-line DST (97.50%), with all second-line drugs being tested. Only one specimen was found to be sensitive to Capreomycin when it was resistant (Sputum E)

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SMILE Summary

		IQLS#	7190816-04			
		NHLS#	42579			
		INS#	48002			
			2017			2018
Survey		**1**	**2**	**3**	**IQLS 1st(Trial)**	**1**
Mycobacteriology	AFB Smear	100%	100%		100%	
	M. tuberculosis ID	100%	100%		100%	
	MTB/RIF, DNA	100%	100%	62%		100%
	MTB/RIF, DNA (Inst 2)	100%	100%			100%
	MTB/RIF, DNA (Inst 3)	100%	75%			100%
	Susceptibilities, MTB	92%	92%		100%	
	Susceptibilities, 2nd Line				100%	

Pilot Results

Compilation of results

- Obtain feedback from participating laboratories
- Provide feedback to the IQLS provider for quality improvement
- Present results to ACTG and IMPAACT Networks
- DAIDS POCs

Additional Resources and Information

If you have additional questions….

- pSMILE Drop-in Room
  - Wednesday, 20 June—2 pm until 5 pm
- pSMILE Website – www.psmile.org
- Contact your pSMILE Coordinator

Questions

pSMILE
SAFETY·QUALITY·RESULTS

THANK YOU