IQCP-Massachusetts Experience

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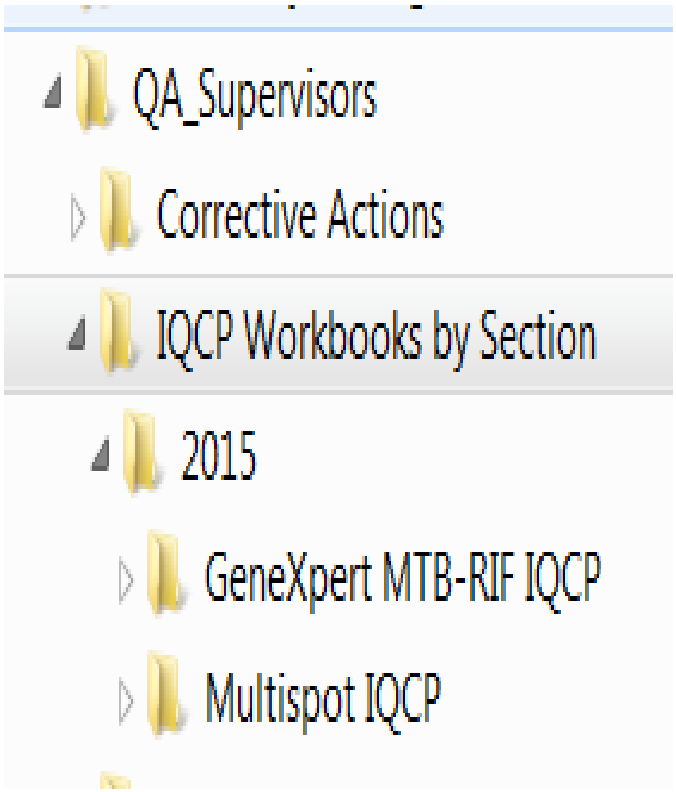
Getting Started

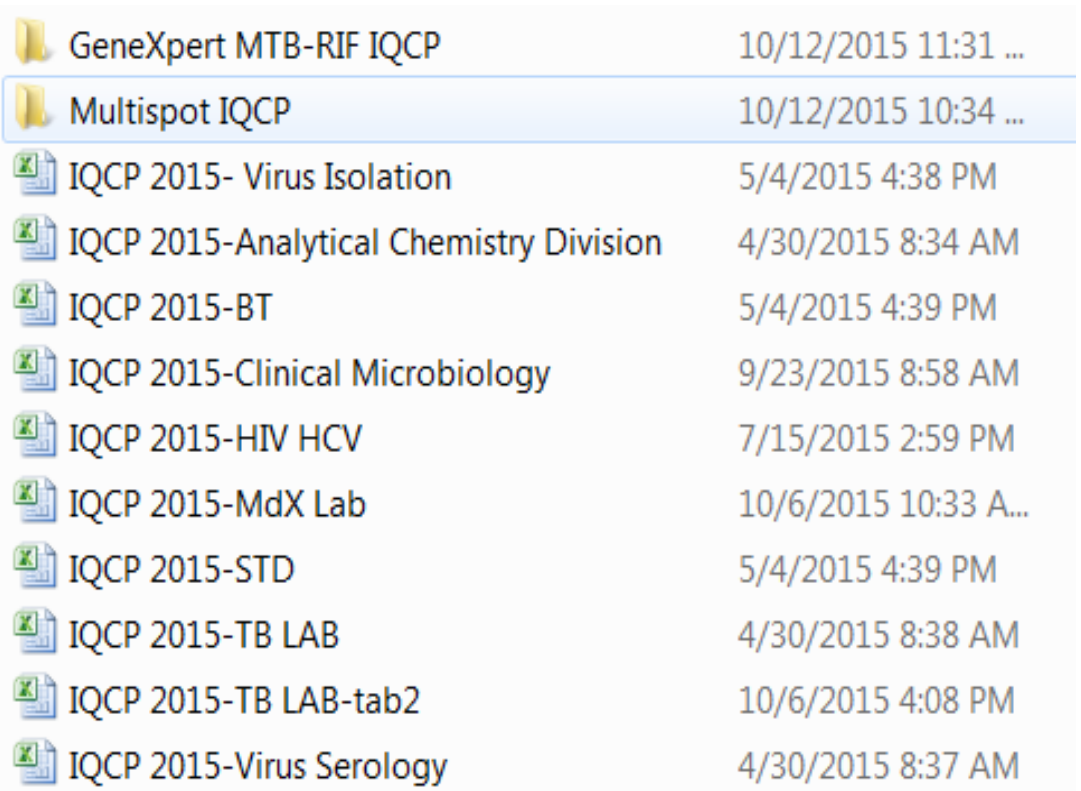
- Discussed with our CLIA inspector during our January 2015 inspection
- Reviewed all the notifications, brochures, materials available at that time
- Started the process prior to when all the guidance documents and examples were issued

Staff Acceptance–Prep Work

- Two education sessions

Electronic Process





Tab 1 Completion Instructions

Completion of the IQCP Workbook–Tab 1

1. Access the workbook template at P:\Quality Assurance\IQCP Workbooks by Section
2. Open the workbook and go to the tab named "Test List"
3. Complete the header section with:
    a) your section
    b) the year
    c) your name (person completing the chart)
4. Rename the workbook using this format and save it to your documents:
    a) IQCP 2015–<*your section designation*>
5. List all the tests and their corresponding methods used in your section

Tab 1 Completion Instructions

6. For each test/method fill in the fields under each heading.

a) Frequency of Patient Testing-Daily? Weekly? As ordered (this for infrequently performed tests-add approximately how often)

b) Current Frequency of QC & # of levels: 2 levels every day of patient testing? 2 levels with every run even if >1 run per day? Weekly? Only upon receipt of new shipment/lot #?

c) Manufacturer's QC Recommendation? List what the package insert states for QC.

i) If it is a lab developed test list "LDT"

ii) if there are no recommendations in the package insert list "N/A" (if it says "conduct QC in accordance with federal, state or local regulatory req")

How Did We Pick Tests for IQCP?

IQCP RISK ASSESSMENT WORKBOOK

Section: **Year:** **TAB 1 Complete?**

Person Completing Chart:

Test Name	Method	Frequency of Patient Testing	Current Frequency of QC & # of QC Levels Run	Manufacturer's QC Recommendation if Available	Is Manufacturer Recommendation More or Less Rigorous than CLIA requirements (2 levels per day of testing)	Are We Meeting or Exceeding CLIA Recommendations for Running QC?	Recommendation for need for IQCP (No or Yes); give rationale including cost of QC per test or easier to revert to CLIA requirements	CLIA Director: Perform IQCP? Yes or No

TB Section Test List

Test Name	Method	Frequency of Patient Testing	Current Frequency of QC & # of QC Levels Run	Manufacturer's QC Recommendation if Available	Is Manufacturer Recommendation More or Less Rigorous than CLIA requirements (2 levels per day of testing)	Are We Meeting or Exceeding CLIA Recommendations for Running QC?	Recommendation for need for IQCP (No or Yes); if Yes give rationale including cost of QC per test	CLIA Director: Perform IQCP? Yes or No
CULT ID	ACCUPROBE	2-3 X WEEK	EACH USE(2)	RUN +,- CONTROL	EQUAL	meeting	NO(discontinuing)	No
CULT ID	MALDI	2-3 X WEEK	EACH USE(2)	N/A	N/A	meeting	NO (cheap and easy to do)	No
NAAT	GENEXPERT	DAILY	SHIPMENT/LOT/MONTHLY	in accordance with local, state, and federal requirements as applicable.	N/A	NO	YES DAILY QC COST-2 LEVELS $120	Yes

How long did it take?

- Deadline for each section to complete the test list worksheet: May 1, 2015
- 9 lab sections
  - 3 done by the deadline
  - 4 done by May 4th
  - 2 done by June 29th
- Depending on the # of tests for their section it took no more than one hour to complete the list and all the questions.
- Review by Lab Director: total of ~1 hour
- **Total**: 10.5 hours for initial determination of which tests we would do (includes my time for preliminary review)

Risk Assessment Worksheet Section 1

Assessment of potential risk for preanalytic, analytic and post analytic areas for:

- Specimen
- Environment
- Test System
- Reagents
- Personnel

Risk Assessment Worksheet Section 1

Specimen		Environment		System		Reagents		Personnel	
Risk	Level of Risk (0,1,2 3)	Risk	Level of Risk (0,1,2 3)	Risk	Level of Risk (0,1,2 3)	Risk	Level of Risk (0,1,2,3)	Risk	Level of Risk (0,1,2 3)

Level of Risk Ratings

0=no measurable impact on test result

1=slight risk; easily mitigated

2=moderate risk; can be mitigated but may require additional resources

3=significant risk; not easily mitigated

Preanalytic

Required Component: Specimen

Risk: using only approved respiratory specimens

Level of Risk: 1 (slight risk-easily mitigated)

Mitigation: we only perform testing on FDA-approved specimens

Preanalytic

Required Component: Specimen

Risk: can only use specimens processed with NaIC-NaOH or NaOH methods; what about sediment submitted from other labs?

Level of Risk: 1

Mitigation 1: we only use the NaIC-NaOH method
Mitigation 2: interaction with submitting labs reveal they use the same method
Mitigation 3: education sent to submitting labs prior to implementation of testing.

Preanalytic

Required Component: Specimen

Risk: unlabeled/mislabeled specimens

Level of Risk: 1

Mitigation 1: we verify labeling upon receipt and do not test specimens with issues relating to identification without follow-up (request resubmission, etc)

Preanalytic

Required Component: Environment

Risk: maintain 2-8 degrees C in transport

Risk Level: 1

Mitigation: we can reject specimens shipped at improper temperature or if required to test, add a qualifier to report

Preanalytic

Required Component: Test System

Risk: poor instrument calibration

Risk Level: 1

Mitigation 1: internal probe checks run with every test

Mitigation 2: perform instrument maintenance and annual calibration.

Preanalytic

Required Component: Reagents

Risk: reagents/kits stored at improper temperature

Risk Level: 1

Mitigation: reagents/kits are stored at temperature controlled and monitored units

Preanalytic

Required Component: Reagents

Risk: use of a non-QC'd reagent or kit

Risk Level: 1

Mitigation: all kits are clearly marked with colored labels as to whether or not they have been QC'd and if they passed QC

Analytic

Required Component: Specimen

No additional risks identified

Required Component: Environment

No risks identified (no required temp/humidity range for operation of instrument)

Analytic

Required Component: Test System

Risk: must load cartridge within 30 minutes of inoculation

Risk Level: 0

Mitigation: internal controls

Analytic

Required Component: Reagents

Risk: use of expired reagents/kits

Risk Level: 0

Mitigation 1: reagent lot #s/expiration dates recorded prior to use

Mitigation 2: instrument will not accept an expired cartridge (scanned when loading)

Analytic

Required Component: Personnel

Risk: improper conduction of test

Risk Level: 1

Mitigation 1: all staff have documented training and competency upon hire, six months later and then annually thereafter. No one performs test independently until signed-off as competent.

Mitigation 2: Proficiency Testing

Postanalytic

Required Component: Specimen

No additional risks identified

Required Component: Environment

No additional risks identified

Required Component: Test System

No additional risks identified

Required Component: Reagents

No additional risks identified

Postanalytic

Required Component: Personnel

Risk: incorrect result reported

Risk Level: 1

Mitigation 1: all results undergo second person review prior to being issued

Mitigation 2: results that are called require a “read back”

Risk Assessment Worksheet Section 2

Risk to Patient			
False Negative Impact	Degree of Impact (0, 1, 3, 4)	False Positive Impact	Degree of Impact (0, 1, 3, 4)

Degree of Impact Ratings:

0=no measurable impact

1=slight impact; easily mitigated

2=moderate impact

3-significant impact

4=severe impact

Risk to Patient

False Negative Impact

Risk: patient does not receive therapy

Risk: patient is not put in isolation

Risk Level: 2 or 3

False Positive Impact

Risk: patient is started on unnecessary therapy

Risk: patient is put in isolation

Risk Level: 2 or 3

Mitigation: most providers make treatment and isolation decisions on clinical presentation and risk factors not solely on the NAAT result

Risk Assessment Worksheet Section 3

Historical QC Data

PAST QC DATA		# QC Run per Level and # of Failures Per Level		
Years Reviewed	**Total # of QC runs**	**MTB/Rif S**	**MTB/Rif R**	**NTM**
2.5	16	1* out of 16	1* out of 16	0 out of 16
QC Frequency	New lot/shipment recently added monthly	6.25%*	6.25%*	0.0%

How Long Did it Take? Risk Assessment Worksheet

Time to complete: 1.5 hours

Time to review/discuss by QA and Lab Director: 1 hour

Quality Control Plan

IQCP Assessment Summary:

Preliminary data suggests the external negative and positive controls are reliably reproducible across a moderate period of testing. In order to gather more data and yet conserve resources, the TB Lab will conduct two levels of QC per target on all new lot#s and shipments of MTB/RIF cartridges as well as two levels monthly.

Quality Control Plan

Detection of errors for each phase of the testing occurs as follows:

1. **Before Testing**:
   a. evaluation of specimen acceptance/rejection criteria for identifying specimens not suitable for testing.
   b. checking of the lot#/expiration date and reviewing the last QC results for that lot # prior to using the kit.

2. **During Testing**: each cartridge has Sample Processing Control (SPC) and a Probe Check Control (PCC) to indicate whether or not the sample was processed correctly and to monitor bead rehydration, reaction-tube filling, probe integrity and dye stability. The instrument will not issue a result if the instrument QC and the SPC and PCC do not pass criteria for acceptability.

3. **After Testing**: all instrument printouts and worksheets are reviewed by a second person prior to releasing results

Quality Control Plan

Control Types/Levels:

The use of these controls will include running the following levels as described in the frequency section to monitor assay performance:

1. *Mycobacterium tuberculosis*, Rifampin resistant-(State Lab DST Control "QC3")
2. Non-tuberculosis Mycobacterium (NTM)-(*M.avium* complex ATCC 25291)
3. *Mycobacterium tuberculosis*, Rifampin susceptible- (Mtb ATCC 2794)

Quality Control Plan

Criteria for acceptability:

1. The Mtb/Rif resistant strain must give results of “MTB detected;Rif Resistance Detect”
2. The NTM strain must give results of “MTB Not Detected”
3. The Mtb/Rif sensitive strain must give results of “MTB Detected; Rif Resistance Not Detected”
4. All of the instrument and cartridge controls must pass

Quality Control Plan

<u>The frequency for running the above QC is:</u>

1. For a newly trained operator, prior to testing specimens. (should include a NTM, a Mtb that rifampin susceptible and Mtb that is rifampin resistant)
2. With each new lot# **or** shipment (must include the NTM and one of the Mtb strains)
3. Monthly for lot# in use (must include the NTM and one of the Mtb strains)

Quality Control Plan

QC Frequency (cont'd)

4. If the storage temperature of the kit falls outside of 2°-28°C. Test prior to use using all three control strains.

5. When review of QA indicates a deviation from expected results. Test using all three control strains.

The manufacturer's instruction/package insert recommends performing QC in accordance with local, state, and federal accrediting organizations' requirements as applicable.

Quality Control Plan

Records:

1. All QC data will be recorded and is to indicate the circumstance under which quality control was performed.
2. Statistics on patient testing should be compiled on a weekly basis and reviewed by the technical supervisor to identify trends that may indicate a problem with the kit.

QC Log

Date	Tech	Reason	Lot #	Exp Date	Date Recd	MTB Rif R	NTM	Mtb Rif S	SPC/ PPC Cont	Rev Date	Rev By

Reason for QC run options (record the # in the reason column

1. New Lot #
2. New Shipment
3. New Analyst
4. Storage temp excursion
5. Potential issue identified during monitoring

Quality Control Plan

Monitoring:

Routine monitoring of quality control data and overall patient result statistics will occur at the monthly QA meetings held by the Lab Division Director. When any of this data indicates there may be a problem with the kits, troubleshooting will occur and QC will be run with each testing event until the issue is resolved. Refer to the Quality Assessment Plan for details.

Approval/Signature of Laboratory Director

Review/Approval of the Quality Control Plan for Cepheid GeneXpert MTB/RIF

LABORATORY/CLIA DIRECTOR SECTION:

☐ Based on this data I **approve** the implementation of this Quality Control Plan.
Comment:_____
_____
_____

☐ I do **NOT** approve the implementation of this Quality Control Plan.
Comment:_____
_____
_____

_____ _____
Laboratory/CLIA Director Date

Approval/Signature of Laboratory Director

Upon approval by the CLIA Director, the Quality Control plan will be inserted into the Quality Control Section of the SOP. The SOP will be approved by the CLIA Director and staff will be trained on the new QC procedure prior to implementation.

Final Implementation Date:_____

_____	_____
QA Division Director	Date
_____	_____
Laboratory Division Director	Date
_____	_____
Technical Supervisor	Date

How Long Did it Take? Quality Control Plan

- Writing the first Quality Control Plan took about 1.5 hours to make sure I covered all the required elements.

- Subsequent QC Plans used the first one as a template-only about 30-45 minutes

Quality Assessment

Monitoring: Quality Control results are evaluated each time they are run. The Quality Control Plan will be evaluated by routine monitoring of the activities/records listed in Table 1

Quality Assessment

Component	Records to Review/Monitor	Frequency
Specimen quality	Problem logs for unacceptable specimens	Monthly
Test System	GeneXpert QC Log	Monthly for trends
Test System	Patient Result Statistics	Monthly (for changes)
Test System	Proficiency Testing	Upon receipt of evaluations
Test System	Equipment logs (PM, repairs, routine maintenance)	Monthly
Test System	Manufacturer notifications/FDA Alerts	As issued
Test System	Manufacturer's Package Inserts	Annually (SOP QA.004)
Test System	Calibration curves	Monthly
Reagents	QC data	Monthly for trends
Reagents	Reagent/Kit storage environment temp charts	Weekly/Monthly
Reagents	Calibration Curves	Monthly
Environment	Problem logs (facility issues)	Monthly
Testing Personnel	New employee training/competency	6 months of employment and then annually
Testing Personnel	Annual Competency Assessment (may include PTs)	Annually

Quality Assessment

- When any of this data indicates there may be a problem with the kits, troubleshooting will occur and QC will be run with each testing event until the issue is resolved.

- Corrective Action Requests (CAR) are initiated when a nonconformity is identified in pre-analytic, analytic or post-analytic areas of testing. Corrective actions will include a root cause analysis. When the analysis indicates that the Quality Control Plan is not sufficient to detect problems in any of the area, it will updated accordingly. Corrective Actions are monitored for six months post implementation of the corrective action to ensure that it was effective. SOPs or practices are revised when necessary and staff training on changes is recorded.

Quality Assessment

- Lab Division Directors hold monthly QA meetings where the above records are reviewed on a scheduled basis. These reviews are recorded on a Monthly QA Meeting Coversheet as well as on the records when appropriate. The coversheets are reviewed and approved by the Quality Assurance Division Director and the Laboratory Director. QA Meeting Coversheets are kept in the lab section.

- Evaluation of the QCP will occur on an annual basis or when monitoring of the components listed above indicates an issue potentially associated with the QCP. Changes to the QCP will occur as necessary.

Quality Assessment

- Approval/Sign-off
  - Same as for the QCP

How Long Did it Take? Quality Assessment

- Writing the first Quality Assessment took about 1 hour to make sure that I covered the required elements.
- Each Quality Assessment after that took less time because I could use the first one as the template.
- Routing for signatures and getting the final copy back took the longest.

Lessons Learned

- The Guidance Document appears to be far more detailed and time consuming–did we do everything right?
- Be more systematic about gathering all resources prior to initiating IQCP for a test– Create a checklist
- Save all resources used in a single place
- Develop an SOP for annual review and new tests

Total Time & Cost

Approximately 5 hours per test that underwent IQCP

Cost related only to labor

Staff Acceptance

Other Tests

- Multispot
- BioFire for Respiratory Pathogens
- Luminex GPP for Enteric-test just now being implemented