Regulatory Panel Discussion

Oct 16, 2019

2018 CAP Deficiencies

CHECKLIST REQUIREMENT	CAP-WIDE*
GEN.55500 Competency Assessment	**1**
COM.01200 Activity Menu	**2**
COM.04250 Comparability of Instruments and Methods – Nonwaived Testing	**3**
COM.10000 Procedure Manual	**4**
COM.30600 Maintenance/Function Checks	**5**
COM.01700 PT and Alternative Assessment Result Evaluation	**6**
COM.30300 Reagent Labeling	**7**
COM.01400 PT Attestation Statement	**8**
COM.04200 Instrument/Equipment Record Review	**9**
COM.30400 Reagent Expiration Date	**10**

What's new: 2019 checklist edition

- What's new
  - 2019 checklist edition
    - Added new Digital Image Analysis to the Molecular (MOL) and Cytogenetics (CYG) checklists and improved the Digital Image Analysis sections in the Anatomic Pathology (ANP) checklist
    - Updated Predictive Marker checklist requirements for In Situ Hybridization (ISH) and Immunohistochemical (IHC) methods in the ANP, CYG, and MOL Checklists to generalize requirements for predictive marker testing when possible (previously focused only on HER2 and ER/PgR assays). Also modified PT requirements to require PT or alternative assessment for all predictive markers done by ISH or IHC.
    - Updated the microarray requirements in the MOL and CYG checklists
    - Clarified calibration, calibration verification, and analytical measurement range requirements across multiple checklists.

What's new: 2019 checklist edition

- What's new
  - 2019 checklist edition, continued
    - Moved/standardized checklist requirements for pipettes, analytic balances and weights to the All Common Checklist (COM) and deleted them from the discipline specific checklists, reducing redundancies.
    - Added new checklist requirement on investigating non- conformances and clarified when to conduct a root cause analysis in the Laboratory General (GEN) checklist
    - Introduced the concept of distributive testing for proficiency testing in the COM checklist.
    - Added a new section in the Point of Care (POC) checklist for Molecular-Based Microbiology Testing-Waived Tests
    - Revised multiple checklist requirements in the Histocompatibility (HSC) checklist to be compliant with the Foundation for the Accreditation of Cellular Therapy (FACT) standards

What's new: 2019 checklist edition

- What's new
  - 2019 checklist edition, continued
    - Revised the Biorepository (BAP) checklist for biorepository laboratories to be compliant with the Clinical Laboratory Improvement Amendment (CLIA) regulations.
    - Added a new checklist requirement in the Chemistry (CHM) checklist on opiate testing.
    - Added a new checklist requirement in the Transfusion Medicine (TRM) checklist to align with the FDA on the labeling of red blood cells with historical antigen typing.
    - Added a new checklist requirement regarding hazardous waste registration and regulations. Registration is required with the Environmental Protection Agency (EPA) and/or appropriate national, federal, state (or provincial), and local governmental agencies, as applicable.

COLA Update 2019

Lab Quality Confab
October 16, 2019

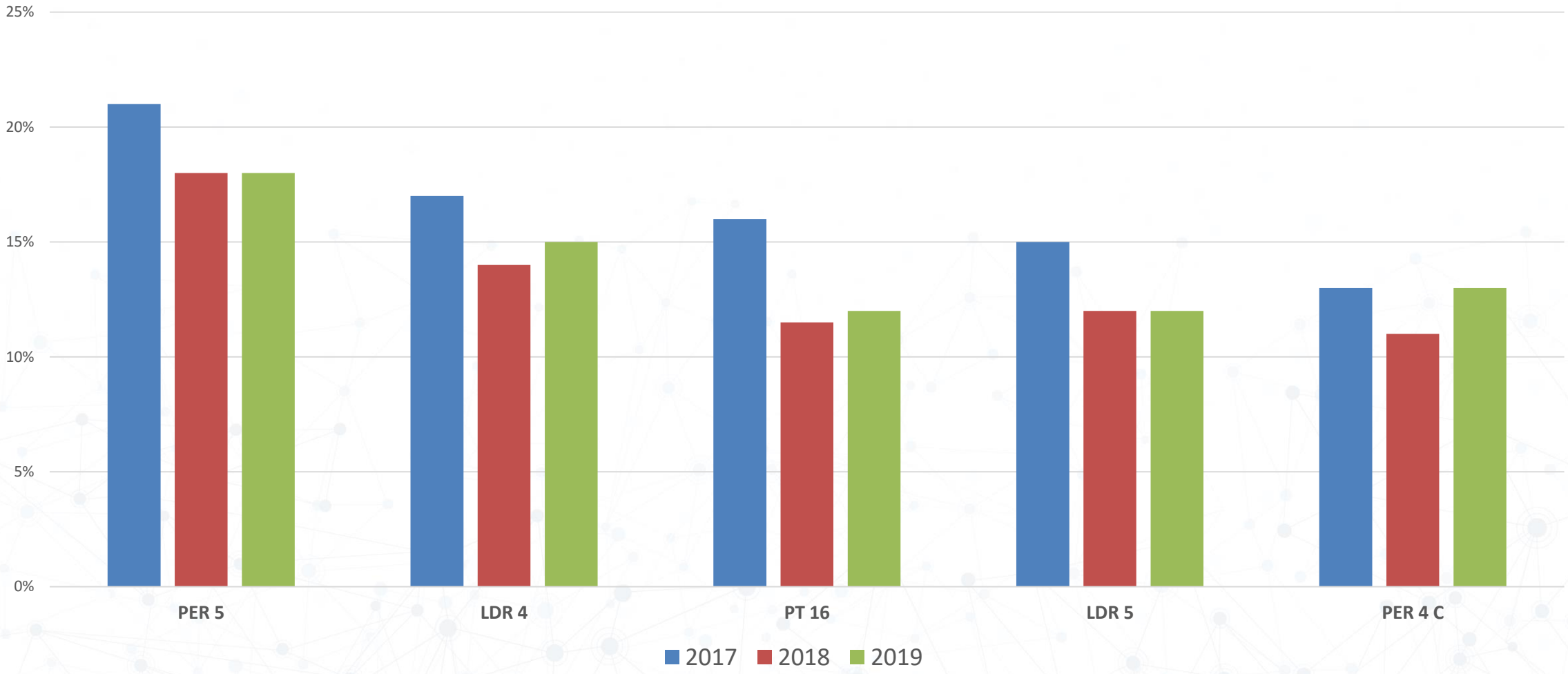
Top 10 citations 9/1/18 – 8/31/19

RANK	CITATION	#	%	REASON CITED
1	PER 5	621	18%	For not performing or documenting competency assessments as required
2	LDR 4	525	15%	For the Laboratory Director not fulfilling the Proficiency Testing responsibilities of the position
3	PER 4C	448	13%	For the Technical Consultant or Technical Supervisor not fulfilling the responsibilities of the position
4	LDR 5	426	12%	For the Laboratory Director not fulfilling the Quality Control / Quality Assessment responsibilities of the position
5	PT 16	422	12%	For not documenting review of PT scores by the Laboratory Director, supervisory personnel, and testing personnel

Top 10 citations 9/1/18 – 8/31/19

RANK	CITATION	#	%	REASON CITED
6	PER 4E	390	11%	For the testing personnel not fulfilling the responsibilities of the position
7	PT 15	333	10%	For not maintaining copies of the PT attestation statements, signed by the Lab Director and testing personnel
8	CA 2	294	8%	For not performing and documenting calibration verification as required
9	QC 16	281	8%	For not tracking and monitoring quantitative QC data, such as LJ charts, in order to assess accuracy, precision, shifts, etc.
10	WAV 2	280	8%	For not performing and documenting QC for waived testing as required by the manufacturer

COLA top 10 citations 2017-2019



Updates

- COLA's deemed status was reapproved and published in the Federal Register in February 2019

- 2020 COLA criteria updates on the horizon:
  - Proficiency Testing
  - Procedures
  - Transfusion Services

CLIAC updates

- Three workgroups made recommendations at the April 2019 meeting:
  - Personnel Regulations
  - Nontraditional testing workflow model
  - Next Generation Sequencing

- Public is invited to comment on emerging technologies at the upcoming CLIAC meeting in November:
  - https://www.cdc.gov/cliac/upcoming-meeting.html

Proposed PT changes

- Proposes the addition of 29 analytes to the “regulated” list
- Application of PT sanctions related to waived testing performed in non-waived laboratories
- Raises unexpected antibody passing PT score from 80% to 100%
- Requires PT for manual WBC differentials AND automated differentials
- Updates Microbiology PT
- Updates acceptable limits
- Additional requirements for PT providers

Personnel responsibilities

- CLIA defines responsibilities for all CLIA positions
- Not understanding and/or not fulfilling the responsibilities of the position(s) held is a significant root cause of laboratory noncompliances

Laboratory Quality Confab

Regulatory Panel Discussion

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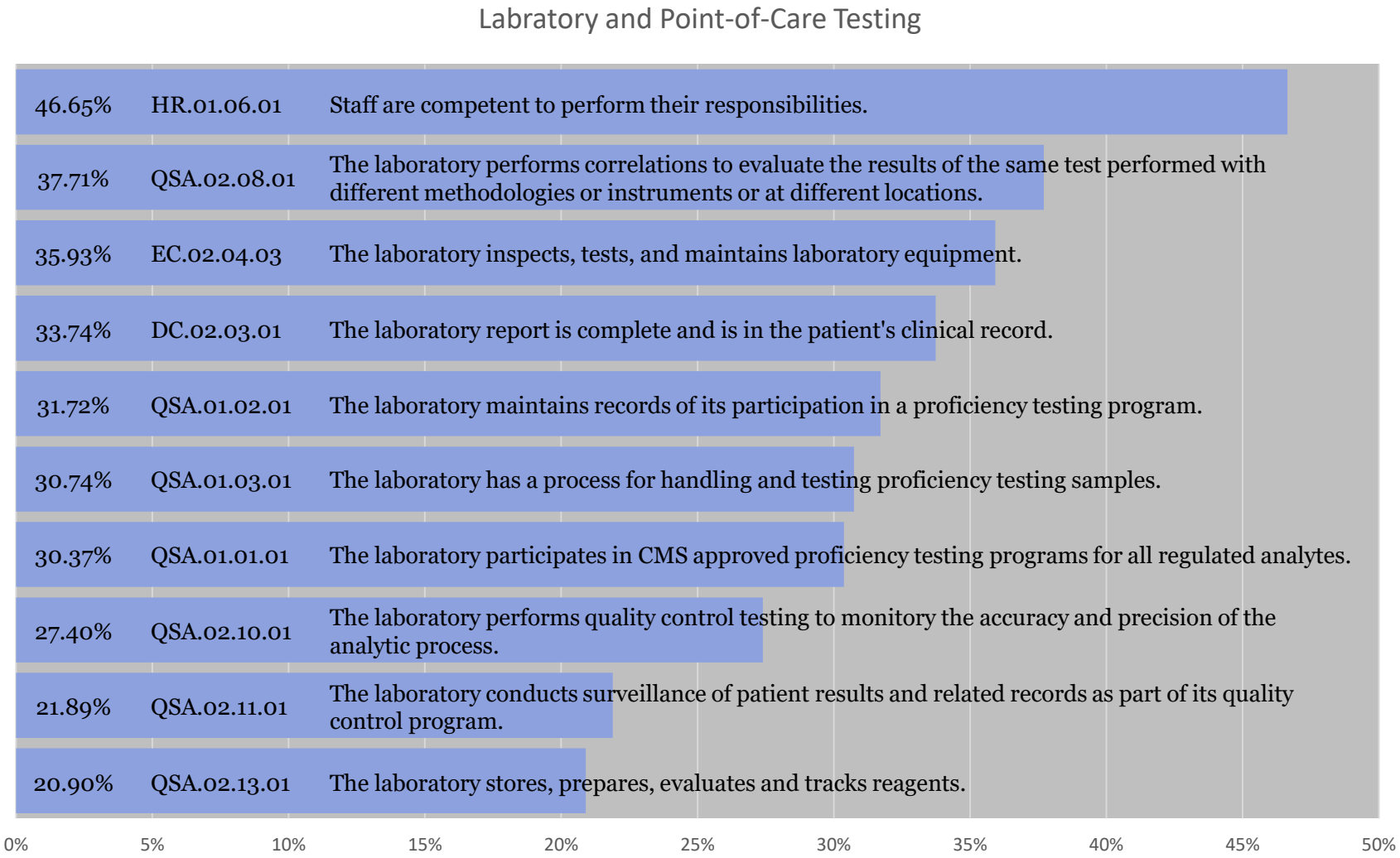
The Joint Commission

2018 Top Laboratory Standards Noncompliance



IQCP

The Joint Commission

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Where are we now

The Joint Commission

? Can your staff speak about it

? Are staff involved in updating risks

? Is it an active tool

The Joint Commission

2018-19 Top Ten CLIA Based Deficiency Comparison

Deficiency	CAP	COLA	TJC	Comments
Competency Assessment	1	1	1	
Activity Menu	2		2	
Proficiency Testing	6,8	5,7	6,7	Handling and record keeping
Method Comparisons	3		4	
Procedure Manual	4			
Calibration Verification		8	10	
Equipment Maintenance	5,9		5	Function checks and record keeping
Not Meeting Responsibilities of Position		2,3,4,6		LD, TC/TS, Testing Personnel
QC Monitoring		9,10	8	Waived and non-waived
Reagents Labeling and Expiration	7,10			
Complete Lab Report			3	

Why ISO?

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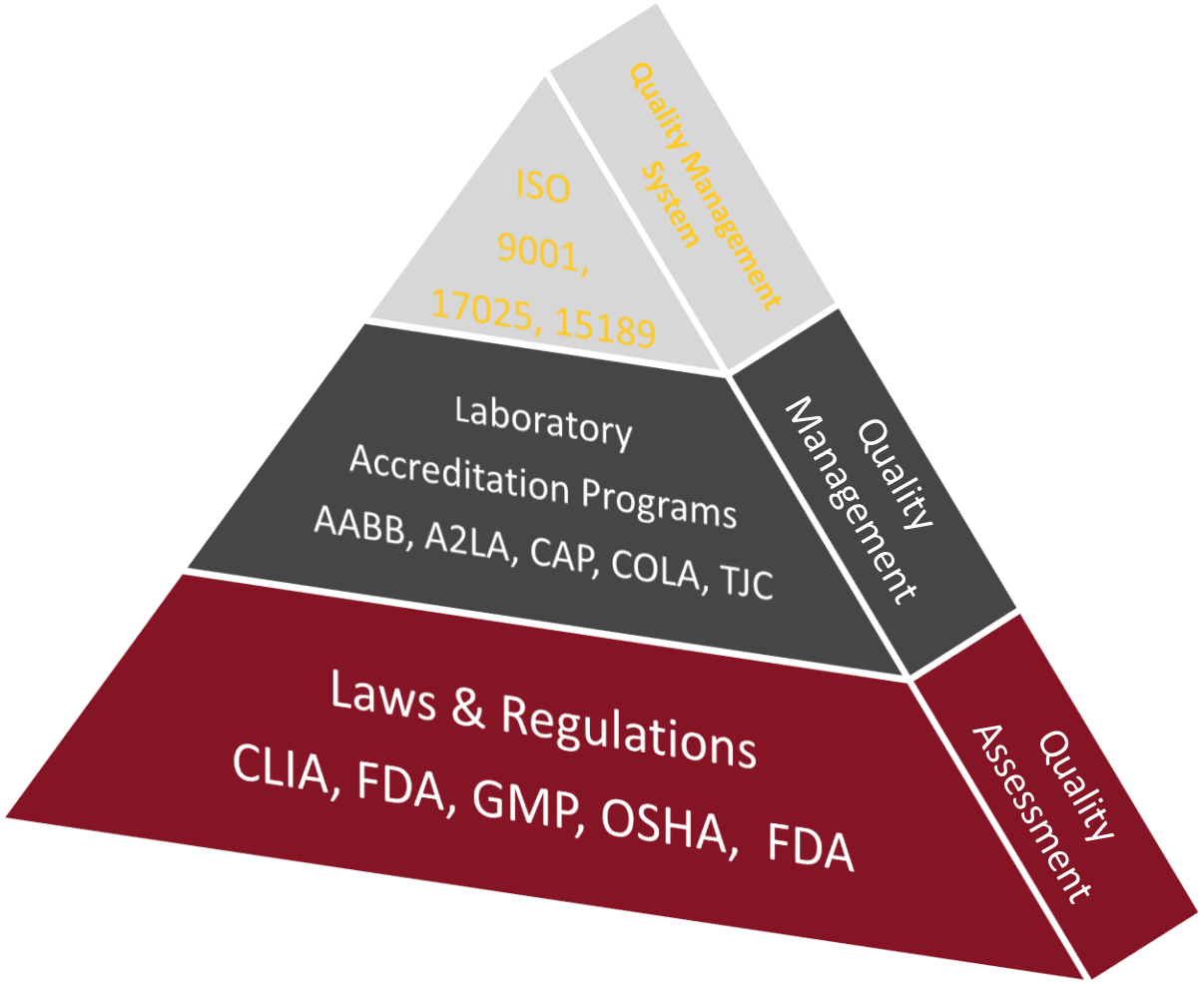
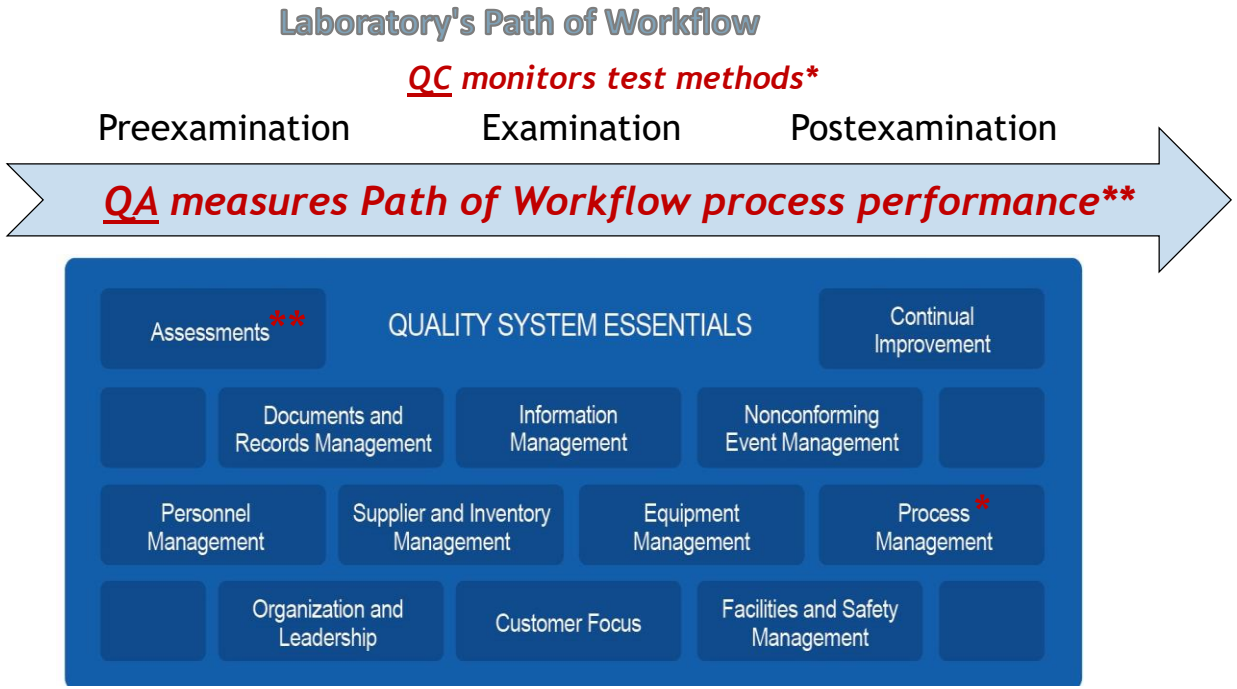
Quality Officer, ARUP Laboratories

Lab Quality Confab 2019

Taking Quality to the Next Level



The Roles of QC, QA, and QMS



QMS organizes *all the QSE and path of workflow processes*

Reference: CLSI QMS01: *Quality Management System Model for Laboratory Services*, 5th Ed., 2019

CLIA vs ISO – The Difference

Management requirements

4.1 Organization and management responsibility
4.2 Quality management system
4.3 Document control
4.4 Service agreements
4.5 Examination by referral laboratories
4.6 External services and supplies
4.7 Advisory services
4.8 Resolution of complaints
4.9 Identification and control of nonconformities
4.10 Corrective action
4.11 Preventive action
4.12 Continual improvement
4.13 Control of records
4.14 Evaluation and audits
4.15 Management review

ISO 15189:2012 Deficiency Trends

A2LA	IQMH	ISO 15189	Citation
8		4.1	Organization and management responsibility (ethical conduct, quality objectives, Lab Director responsibilities)
7		4.3 *	Document Control (documents reviewed/approved before use & periodically, master document list, change control)
6	2,3,4,10	4.14	Evaluation of audits (internal audits, quality indicators, risk management, external assessment of POCT)
	5	4.15	Management Review (discharging actions)
10	1	5.1	Personnel (training, competency – blood product admin)
9		5.2 *	Accommodation and environmental conditions (control, monitoring, and recording lab environmental conditions)
1,3	6	5.3 ***	Laboratory equipment, reagents, and consumables (maintenance, calibration, inventory records, traceability)
	7	5.4	Pre-examination processes (transport bag evaluation)
4	8,9	5.5	Examination processes (measurement uncertainty, validation, verification, documented procedure)
2,5		5.6	Ensuring quality of examination results (PT, defining QC)

Resource: A2LA data reported by Director of Government Relations on 9/27/2019
IQMH data reported by Director, Centre for Education on 10/8/2019

Quality Quote