Meeting Dynamic Challenges for Quality and Patient Safety

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Developing strategies to meet today's and tomorrow's challenges to enhance POC & laboratory testing's contribution to patient care

Goal: Laboratory & POC Testing



Positive contribution to healthcare team for quality patient care



Quality Results: Part of Solution



Common quote -60 – 80% of clinical decisions are based on laboratory/POCT results

Tactics:

As a healthcare "team" member --- where to start?



Stay in the "KNOW"











Don't forget your state requirements too





All provide useful information and help!

Quality – Complying with Requirements



The established testing regulations, requirements, and standards do represent Good Laboratory Practices (GLP)

• BUT...Always do the "right" thing and this may mean more (e.g., think waived testing as one example)

SARS CoV-2 Corona Virus Worldwide Impact



https://www.google.com/sea rch?client=firefox-b-1d&q=covid+statistics



Nov 20, 2020: 58 M global cases; 1.4 M deaths

Emergency Use Authorization (EUA) Testing* – Confused?



*In emergencies, when no products are available, EUA legally permits FDA to authorize unapproved medical products to diagnose, treat, prevent serious or life-threatening diseases/conditions caused by chemical, biological, radiological, and/or nuclear agents

EUA Tests – March – October 2020 So Many Tests: ~300

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													Oct 14	DNA Genotek Inc.	Sept 24	Cept				
													Oct 14 Oct 12	LuminsOx UK Ltd. Abbott Laboratories	Sept 24	Clear				
													Oct 9	Beckman Couter	Sept 23	Assure				
Date	Manufa	Manufacturer(s) Tes			Test F	Receiving EUA							Oct 9	Access Bio	Sept 21	KinForest En				
M 40		.,,											Oct 8	Genalyte	Sept 18	Bio-Rad Lai				
May 18				Lyra	Direct	SARS-CoV-2 Assa	у						Oct 6	UCLA	Sept 18	Infinity E				
May 15	May 15 Hologic		Ap	otima S	ARS-CoV-2 assay							Oct 5	Seasun Biomaterials I	Sept 18	GK Pharms Contract Ma Opera					
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May 15	Assurance			rersity									Oct 1 Sept 30	Tempus Labs, Inc.	Sept 14	Kaiser Perry				
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May 15	Fulgent The	-	-	Biosciences	April 24	MicroGenDx						Sept 30	NanoEntek America	Sept 9	Beijing Want Pharmacy Ent Ltd					
May 15	One Health	May 6		Systems, Inc.		1200	SARS-Co				_		Sept 30	DiaSorin	Sept 8	Verily Life				
	A E 10	May 5	University of	of Tennessee ence Center	April 24	AIT Laboratories	April 15	Ortho Clinical Diagnos		os Immunodiagnostic Products RS-CoV-2 Total Reagent Pack			Sept 30	Aeon Global Health	Sept 8	BillionToC				
May 13	Applied D	-	Heatil SO	ence Center	April 24	Ultimate Dx	April 15	Ortino Clinical Diagnost	IICS SA				Sept 29	Centogene	Sept 4	Suger				
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May 12	Thermo Fis	May 4	Euroimmun		April 24 Ortho Clinical Diagnosti			total or to be	April 3	Becton Dickinson + BioGX	assay for use on BD Max system		Sept 28	Quotient Limited	Sept 1	Detectaci				
		May 3	Ro	xhe	April 23	SD Biosensor	April 14	Integrity Labs	April 2	Ipsum Diagnostics	COV-19 IDx, an RT-PCR-1 CoV-2 test	ased SARS-			Sept 1 Aug 31	OPTOLANE 1				
May 11	Columbia				April 23	Altona Diagnostics	April 13	Orig3n	April 2	Cellex	qSARS-CoV-2 lgG/lgM R	apid Test (s)			Aug 31	TBG Biote				
May 11	1dr	May 1	Bio-Rad L	aboratories	April 23	Diatherix Eurofins	April 13	Origini		Yale New Haven Hospital				Aug 31	University					
Iviay 11	luit	April 30			NY State Department of		April 23	Abbott Laboratories	April 13	Specialty Diagnostic Laboratories	April 1	Clinical Virology Laboratory	SARS-CoV-2 RT-PO NeuMoDx SARS-CoV-2				Aug 31 Aug 31	T2 Bosyst Mra		
May 11	May 11 Abbott N		Health's Wad	Isworth Center			April 13	Atila Biosystems	March 30	NeuMoDxt	use on NeuMoDx 288 N NeuMoDx 9				зуменн					
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			1.10		April 20	Trax Management Services	April 9	DiaCarta	March 27	7 Luminex	NxTag Cc March 16 /				0-19 RT-PCR test, reissued as to					
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May 7								KorvaLabs	April 8	Viracor Eurofins Clinic	march 2	T ORGINEATION				Wadsworth				
May 7	Opti Medi	April 27	Nationwide Children's				<u> </u>	Diagnostics	March 24	4 BioMérieux	BioFire COVI BioFire March 2 New Yo		Department of SARS-Col		/-2 Real-time	e Reverse				
			Hos	spital April 1		Hackensack University	April 7	Gnomegen	March 24		Accula :			Transcriptas	e (RT)-PCR Panel	Diagnostic				
			200	2000	7411110	Medical Center		Diagnostic Molecula	March 23	3 Primerdesign	COVID-19 Gr February			2019 Real Time		liagnostic Te				
		April 26 Di		Sorin April 16		Maccura Biotechnology	April 6	Laboratory at Northwes Medicine	March 21	1 Cepheid	Xpert Xpress SARS-CoV-2 point-of-car		DC	1	Panal					
					April 16	Mount Sinai Laboratory		Infectious Disease		- Ospilaru	test									
					April 15	Boston Children's Hospital	April 6	Diagnostics Laboratory Children's Hospital o Philadelphia	March 20	DiaSorin Molecular	Simplexa COVID-19 Direct firm's Liason MDX real- instrument									
					April 15	Chembio Diagnostics	April 6	Massachusetts Gener	March 10	GonMark Disannetire	ePlex SARS-CoV-2 Test	run on firm's								

١	Date	Manufacturer(s)	1000	Test Receiving EUA													
- 1	Oct 30	Quansys Biosciences	Q-Plex	SARS-CoV-2 Human IgG (Plex) immunoassay(s)													
	Oct 29	DNA Genotek Inc.	OR	Acollect RNA OR-100 and collect RNA ORE-100 saliva													
	Oct 26	Agena Bioscience	Mass	collection devices sArray SARS-CoV-2 Panel	-												
- 1	Oct 26	Celtrion	Sampin	ute COVID-19 Antipen WAG	10	er new Loronavrus nucleic											
١	Oct 20	binx health, inc.	Sept 25	PerkinElmer, Inc.		Acid Detection Kit											
	Oct 15	DNCInical Enterprise,	Sept 25	Genetrack Biolebs	825057	Genetrack SARS-CoV-2 Molecular test											
- 1			Sept 24	Jiangeu Well Biotech	Oray	Orawell igtt/IgG Rapid Test(s)											
	Oct 14	DNA Genotek Inc.	Sept 24	Cepheld	Aug 31	Mammoth Biosciences, Inc.	SARS-CoV-	2 DETECTR Reagent Kit									
- 1	Ort 14		5400000	000000000000000000000000000000000000000	Aug 31	BayCare Laboratories		RS-CoV-2 RT PCR Assay									
-	****	LuminaDx UK Ltd.	Sept 24	Clear Labs	Aug 28	Patients Choice Laboratories	PCL SARS-0	PCL SARS-CoV-2 Real-Time RT-PCR Assay									
	Oct 12	Abbott Laboratories	Sept 23	Assure Tech	Aug 25	Abbott Laboratories		igentions COURT 19 An	Wise	Laboratories COVID-19 PCR	-						
	Oct 9	Beckman Couter		100000000000000000000000000000000000000	Aug 25	Cuur Diagnostics	Aug 3	Wiren Laboratories LL	-	Test							
- 1	Oct 8	Access Bio	Sept 21	KimForest Enterprise C	_	-	Aug 3	Ethos Laboratories	Emo	Laboratories SARS-CoV-2 pervices	LOVE AND	ey - nome cosection six					
	Oct 8	Genelyte	Sept 18	Bio-Rad Laboratories	Aug 25	Biocan Diagnostics			July 10	Beijing Wantai Biological Pharmacy	SARS-CI	V-2 Ab Rapid Test(s)					
- 1	Oct 6	UCLA	Sept 18	infinity BiologiX GK Pharmaceuticals	Aug 25	Fluidigm	July 31	Siemens Healthineer	July 10	Boston Medical Center (BMC)	BMC-C	Relf COVID-19 Test					
	Oct 5	Seasun Biomaterials I	Sept 18	Contract Manufacturin Operations	Aug 25	QDx Pathology Services	July 31	Xamen Zeesan Biotei	H		Automated	d version of its ViroKey					
	Oct 2	Thermo Fisher Scient	Sept 17	Abbett Diagnostics	Aug 21	DxTerity Diagnostics, Inc.	July 31	University of California Diego Health	July 9	Vela Diagnostics	2088 52	""Biblion outprosesses			пятиловавау(х)		
	0ct 2	Quidel	Sept 16	Visby Medical, Inc.	Aug 21	Texas Department of State Health Services	July 30	Clinical Reference	July 9	Diazyme Laboratories	June 23	HealthGuest Easterice	reath	CoV-2	rics TagPath SARS- Assay		
	Oct 2	BioFire Diagnostics	Sept 15	Helogic	Aug 21	Guardant Health		Laboratory (CRL)	July 9	BioSewoom		Univ. of Alabama			CoV-2 Test		
			Sept 15	Color Genomics	Aug 18	LuminaDx	July 29	Quest Diagnostics		Univ. of California, San	June 23	Birmingham Fungal Reference Lab		PHL SARS	Cov-2 rest		
-	Oct 1	Beckman Couter	Sept 14	Roche	Aug 17	BioCheck	July 28	Access Sie and Acce	July 8	Francisco + Mammoth Biosciences	June 23	Gencurk			RS-CeV-2 Test		
	Oct 1 Sept 30	Tempus Labs, Inc. Alimetrix, Inc.	_	Kaiser Permanente Mic	<u> </u>	Zhulfai Sinochips	July 27	Truvian Sciences		Clinical Research Sequencing Platform	June 19	Laihe Biotech	Lyf mCn5	er Novel Co	ronavirus (2019- ribody Combo Test		
	Sept 30	Nirmidas Biotech	Sept 9	Atlantic States	Aug 17	Bioscience Co., Ltd.	July 27	EX Lifty and Company	July 8	(CRSP), LLC at Broad Institute of NIT and Harvard			_		OI .		
			Sept 9	Beijing Wantai Biologic Pharmacy Enterprise O	Aug 15	Diazyme Laboratories	July 27	Sandis National Laboratories	July 7	Enzo Life Sciences, Inc.	June 18	Jiangsu Bioperfectus Technologies	COVE	-19 Corona	virus Real Time PCR		
-	Sept 30	NanoEntek America	2000	LM.	Aug 15	Yale School of Public Health	July 24	Xiamen Biotime			June 15	38 Blackbie Biotech India		TRUPCR SA	RS-CeV-2 KI		
	Sept 30	DiaSorin	Sept 8	Verily Life Sciences	Aug 13	Pro-Lab Diagnostics		Biotechnology Jiangau CoWin Biotech	July 7/Sept 30	Access Bio, Inc.	June 17	ADS Biotec			Shody Detection Kit		
	Sept 30	Aeon Global Health	Sept 8 Sept 4	BillionToOne, Inc.	Aug 13 Aug 11	LuminaDx UK Ltd.	July 24	Ltd.	July 7	Gene By Gene	June 17	Ohio State University			D-19 RT-PCR test		
	Sept 29	Centogene		Sugertech	Aug 11	Biomeme, Inc.	July 23	Hebs	_		June 17	Bighit Healthcare Overloathology Solutions			gG Antibody Test Kit ASSAY by RT-PCR		
	Sept 29	Akron Children's Hoso	Sept 2	Roche	-		July 21	DisCarta	July 6	Assure Tech	-				D IgG ELISA-based		
Н	Sept 29	National Jewish Heal	Sept 2	Bloeksen R&D Technolog	Aug 10	Alpha Genomix Laboratories	July 18	Quest Diagnostics	July 6	Becton Dickinson	June 16	Empry University	_	ter	it(s)		
			Sept 1	Detectachem Inc.	Aug 10	Solaris Diagnostics George Washington	July 17	Megna Health	July 6	Laboratorio Clinico Toledo	June 15	Applied BioCode, Inc. Kainer Permanente Mid.			S-CeV-2 Assay		
Н	Sept 28	Quotient Limited	Sept 1	OFTOLANE Technologic	Aug 7	University Public Health Laboratory	July 17	Access Genetics	July 2	cnc	June 13	Atlantic States		KPMAS CO	IVID-19 Test		
١	\rightarrow		Aug 31	Color	Aug 6	Helix OpCo LLC (dba Helix)	July 16	Luminex	July 1	Inflios International		RTA Laboratories Biological Products Pharms +					
Н			Aug 31	TBG Biotechnology	Aug 5	Capstone Healthcare	July 16	Boston Heart Diagnost	July 1	Centogene	June 12	Machinery Industry	54	May 29	Healgen Scientific L	LLC	COVID-19 lgG/lgM Rapid Test Cassette (Whole Blood/Serum/Rasma)(s)
Ц		ı			Aug 5	Vela Diagnostics	July 15	Quest Diagnostics	<u> </u>	-	June 10	Diagnovital TBG Batechnology Corp.	Exf	May 29	Siemens Healthinee	ers	Atelica M SARS-CoV-2 Total (COV2T)(t)
			Aug 31	University of Arizona	Aug 3	Poplar Heathcare	July 15	Quest Diagnostics	June 30	The Kroger Co.	June 10	Tide Laboratories, LLC	0	May 29	Siemens Healthinee		ADVIA Centaur SARS-CoV-2 Total
_			Aug 31	T2 Bosystens, Inc.		Cleveland Clinic Robert J.	-		June 30	TNS Co., Ltd (Bio TNS)	June 10	Cue Health Inc.		May 28	Quest Disconsistion		(COV2T)(t) Self-collection Kit for COVID-19
			Aug 31	MiraDx	Aug 3	Tomsich Pathology and Laboratory Medicine Institute	July 15	Quest Diagnostics	June 30	Psomagen, Inc.	June 9	Rumma	COV	May 25	PrivaPath Diagnostics		LetsGetChecked Coronavirus
-		1	эуынш		L .		July 13	KogeneBiotech Co., L	June 29 June 29	Acupath Laboratories Beckman Couter	June 9		HOP	577.70	Avera institute for Hu	_	(COVID-19) Test SARS-CoV-2 assay detecting two
		Lyra SARS-Col		CR assay fi	Aug 3	Wren Laboratories LLC	July 13	Trax Management Servi	June 29	LifeHope Labs	June 9	ChromaCode		May 26	Genetics		regions of virus' nucleocapsid gene
Qui	idel	qualitative deter	ction of nu	cleic acid fro	Aug 3	Ethos Laboratories	July 13	Compass Laborator; Services	-	-	June 8	Siemens Healthineers	Dine	May 26	Express Gene Molec Diagnostics Laborat	tory	2019-nCoV RT-PCR Diagnostic Panel
		Si	ARS-CoV-2	2		1		Ballon Wantsi Bininois	June 25	Inform Diagnostics, Inc.	June 8	Siemens Hosthineers	Din	May 26	Exact Sciences		SARS-CoV-2 (N gene detection)
Uni	ogic	Panther Fusion	SARS-Co	IV-2 assay fi					June 25	PreciGenome	June 5	Euroimmun	EUR	May 22	SpectronRx		Hymon SARS-CoV-2 Test KE P23 Labs TeoPath SARS-CeV-2
IIVI	.gc	use on firm's	Panther Fu	ision system					June 25	PlexBio	June 5	Genetros Health	-	May 21	P23 Labs, LLC	5	Assay
obi	°om	COVID-19 RT-P	CR test, re	eissued as ti					June 25	Diagnostic Solutions Laboratory, LLC	June 4	Hangzhou Biotest Biotech Co. Ltd.	Rgt	May 21	Seasun Biomaterials.		AQ-TOP COVID-19 Rapid Detection Kit DisPlexQ Novel Coronavirus (2019-
.dDI	Corp	using at-home s	self-collect	on on April :					June 24	Univ. of Texas MD Anderso Cancer Center, Molecular		Univ of Nebraska Hedical		May 21	SolGent Co., Ltd.		nCoV) Detection Kit
		TagPath CO	VID-19 Co	mbo Kit for					10.42	Diagnostics Laboratory	June 4	Center		May 21	BioCore Co., Ltd.		BioCore 2019 nCoV Real Time PCR Kit SARS-CoV-2 LAMP Diagnostic Assay
Fish	er Scientific	qualitative del	tection of S	ARS-CoV-2							June 4	Phosphorus Diagnostics LLC	Phos	- Jan 45 -			I Pro Comp Colif Colif
		n	ucleic acid								June 4	Vibrant America Clinical	-		19 Ab Assay(s)		
Ro	the	Cobas S	SARS-CoV	-2 Test							June 9	Labs Roche	-		immunosassy		
		Wadsworth C	Center, Nev	v York State							June 1	CS/Laboratories			RT-PCR Test		
		Department of F	Public Hea	th's New Yo							June 1	Aspirus			RT-PCR Assay		
Yo.	rk State	SARS-CoV-	2 Real-tim	e Reverse							hose f	County Disposation 117	Grand	v Nisonnatio	14 CC0/ID-10 Assess		

FDA <u>Approved</u> Coronavirus Tests.

https://www.g2intelligence.com/coronavirus-eua-chart/. Nov. 4, 2020.

Requirements for EUA Testing?

Always, check CLIA and/or your accrediting agency for guidance



CMS: QC/IQCP

- 15.Can a lab develop an Individualized Quality Control Plan (IQCP) for COVID-19 test systems?
- ...manufacturer's quality control (QC) instructions for all EUA must be followed, to include QC
- ...because QC for EUAs must be followed, and no deviations to the QC requirements in the EUA are permitted, IQCP is not applicable to EUAs.

Note: lab director may determine, based on risk assessment that additional QC needs to be implemented above what is required in the EUA Instructions for Use

When EUA is over:

"Regulatory Testing Life" returns to "normal"

ALL CLIA, COLA, TJC, and CAP regulatory requirements based on test complexity apply

Regulations bring Inspections

Be prepared

Pay attention to <u>frequent deficiencies</u>

Don't fall into the deficiency trap



Regulations bring Inspections

Make sure all testing policies and procedures "line up" with requirements

Make sure all staff are doing what P/P state

CLIA: Top 10 (Oct. 2018) Conditions

(problems with potential to or adversely affect patient test results/care)

Regulation	Deficiency	% All Lab Cited	% POLs Cited
493.1403	Director meets qualifications (493.1405) and provides management/direction (493.1407)	2.5%	2.5%
493.1441	Director meets qualifications (493.1443) and provides overall management/direction (493.1445)	1.6%	0.8%
493.801	Enrolled in HHS approved PT for each specialty and subspecialty tested and tests samples like patients	1.1%	0.9%
493.1250	Nonwaived testing meets requirements (493.12511283); monitor, evaluate quality and correct problems (493.1289)	1.4%	1.2%
493.803	Nonwaived testing enrolled in HHS approved PT; lab successfully passes PT	0.7%	0.7%
493.1409	Lab has qualified technical consultant (493.1411) who provides oversight (493.1413)	1.1%	1.0%
493.1421	Lab has sufficient qualified individuals (493.1423) to perform functions (493.1425)	1.1%	1.0%
493.1415	For hematology testing, meets requirements (493.12301256, 1269, 12811299)	0.4%	0.3%
493.1487	High complexity labs have sufficient qualified individuals (493.1489) to perform functions (493.1495)	0.6%	0.4%
493.1447	High complexity labs have a qualified technical supervisor (493.1449) to perform functions (493.1451)	0.4%	0.2%

19

CAP Top Deficiencies (2019 data)

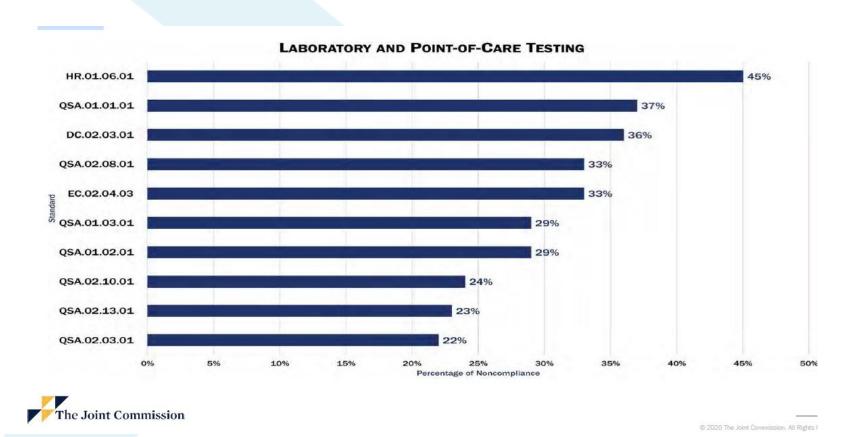
CHECKLIST REQUIREMENT	CAP-WIDE*
COM.10000 Procedure Manual	1
GEN.55500 Competency Assessment -Nonwaived Testing	2
COM.01200 Activity Menu	3
COM.04250 Comparability of Instruments and Methods – Nonwaived Testing	4
COM.30600 Maintenance/Function Checks	5
COM.01700 PT and Alternative Performance Assessment Result Evaluation	6
COM.30300 Reagent Labeling	7
COM.04200 Instrument/Equipment Record Review	8
COM.01400 PT Attestation Statement	9
COM.30750 Temperature Checks	10

^{*} Based on 2019 CAP inspection data

COLA Top Deficiencies (2019)

RANK	CITATION	#	%	REASON CITED
1	PER 5	658	18%	For not performing or documenting competency assessments as required
2	LDR 4	561	16%	For the Laboratory Director not fulfilling the Proficiency Testing responsibilities of the position
3	PER 4C	472	13%	For the Technical Consultant or Technical Supervisor not fulfilling the responsibilities of the position
4	LDR 5	427	12%	For the Laboratory Director not fulfilling the Quality Control / Quality Assessment responsibilities of the position
5	PT 16	414	12%	For not documenting review of PT scores by the Laboratory Director, supervisory personnel, and testing personnel

TJC (2019 and so far in 2020) Top Deficiencies

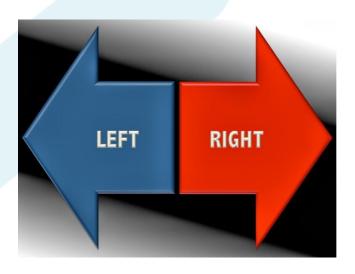


Deficiencies: Common Denominators



Why most deficiencies?

Not having *right* qualified personnel doing the *right* things!



Qualifications/Qualified...Means?

Education
Training
Competency (Assessment)
AND
Fulfillment of responsibilities

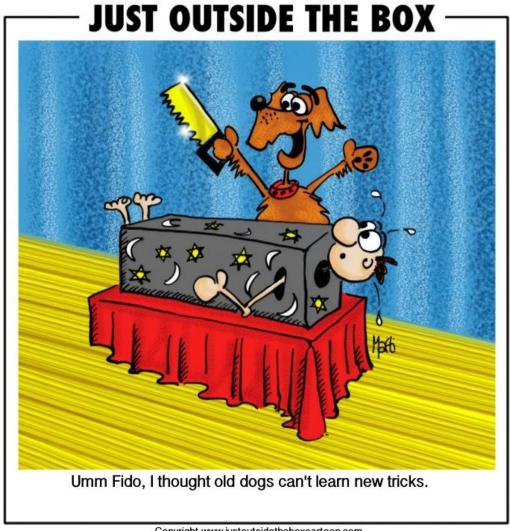
Best Practices for establishing a quality laboratory

- Established and well-defined quality management plan
- Laboratory director involvement
- Thorough training and competency assessment program
- Clear policies/procedures for all staff

Deficiency Avoidance



New Tricks? REALLY!



Important Mantras for Avoidance

Check, check, check

Train, train, train

Assess, assess, assess

Remind, remind, remind

Check Personnel Credentials to fulfill Requirements:

- Moderate complexity testing (CLIA Subpart M, §§493.1403 .1425)
 - Director
 - Technical Consultant
 - Clinical Consultant
 - Testing Personnel
- High complexity testing (CLIA Subpart M, §§493.1441 .1495)
 - Director
 - Technical Supervisor
 - Clinical Consultant
 - General Supervisor
 - Testing Personnel

Director Requirements - Mod. Complex

1. M.D., D.O. with current medical license to practice in State of laboratory's location and certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications. Doctors of Optometry can serve for testing in their specialty area. Optometrists may perform waived or moderately complex tests when tears are the specimen. 2. M.D., D.O., or D.P.M (after September 1, 1993). with current medical license to practice in State of laboratory's location and laboratory training/experience consisting of (check one): 1 year directing or supervising nonwaived tests. □ a. 20 CME credit hours in laboratory practice commensurate with director responsibilities. □ b. Equivalent laboratory training (20 CMEs) obtained during medical residency. □ C. 3. Doctorate in chemical, physical, biological or clinical laboratory science and certification by HHS-approved Board. 4. Doctorate in chemical, physical, biological or clinical laboratory science and 1 year directing or supervising nonwaived testing. 5. Master's in clinical laboratory science, medical technology or chemical, physical or biology science and 1 year laboratory training/experience in nonwaived testing and 1 year supervisory experience in a laboratory in nonwaived testing. 6. Bachelor's in clinical laboratory science, medical technology or chemical, physical or biological science and 2 years laboratory training/experience in nonwaived testing and 2 years supervisory experience in a laboratory in nonwaived testing. 7. ON OR BEFORE 2/28/92 qualified or could have qualified as a director under the laboratory regulations published March 14, 1990 (see § 493.1406). 8. ON OR BEFORE 2/28/92 qualified as a director by the State in which the laboratory is located.

Train, Train, Train* Assess, Assess, Assess*

- Training provides essential knowledge, skills and behaviors for analysts to meet policies and procedures. Must be done before testing and with changes. Records must be maintained.
- Competency of analysts is the correct application of knowledge, skills and behaviors.
- Competency assessment *confirms* that application of knowledge, skills and behaviors is correct. CA must be performed at prescribed intervals and records maintained.

^{*}Waived Testing – training/CA varies with accrediting agency

Competency Assessment Includes: Technical Consultant's Responsibility (Mod. Complex)

- (1) Direct observations of routine patient test performance, including patient preparation (if applicable), specimen handling, processing and testing;
- (2) Monitoring recording and reporting of test results;
- (3) Review of intermediate test results or worksheets, QC records, PT results, and preventive maintenance records;
- (4) Direct observation of performance of instrument maintenance and function checks;
- (5) Assessment of test performance through testing -- previously analyzed, internally blind, or external PT samples; and
- (6) Assessment of problem-solving skills.

TIPs from COLA for CA

Free webinar addressing meaningful CA:

https://outlook.office.com/mail/inbox/id/AAMkAGYxYzQyYjE5LWFiZTktNGM2OC04OTY2 LTVhYzgyZGNjNWViMABGAAAAAACtvT04z%2FyySoX9RoxKu%2FOrBwBYhY5fsGZ6R piqDTiwseFNAAAAAAAAANABYhY5fsGZ6RpiqDTiwseFNAAYtdFEKAAA%3D

- Competency assessment does not have to be done all at once.
- Keep a running file on each person and add to it as they resolve problems, perform PT, etc.
- Include copies of documentation in the file, for example a write-up of a non-conforming event where the testing personnel resolved the situation. Include copies of routine maintenance logs, documentation of critical value communication, etc.

Make Your Lab Assessment Ready in 2020. Dark Daily. 2/25/20 Webinar.

CAP's Common CA Deficiencies

- Incomplete documentation of all 6 elements
 - Each test system/method must have all 6 elements assessed for all nonwaived testing
- Ineligible competency assessor
 - For all moderately complex testing, must meet technical consultant qualifications
 - Must have a bachelor's degree in a chemical, physical, biologic or laboratory science
 - Must have at least two years of experience in the same complexity of testing
 - Must be delegated in writing

Jean Ball, MBA, MT(HHS), MLT(ASCP), "Preparing for Your CAP POC Inspection"

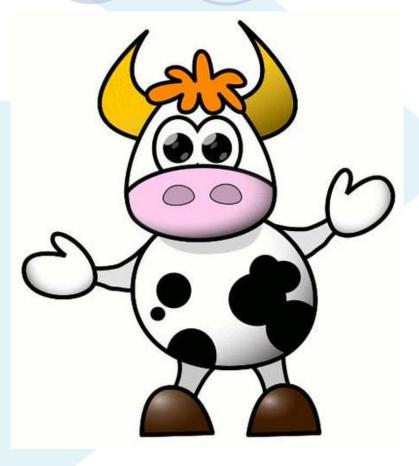
Wonderful!!

Whitehat Communications:

Thursday, October 8, 2020 Point of Care Group Webinars 2020

https://www.whitehatcom.com/POC_Group_Webinars_ 2020.htm

Remind Staff: Yes, Responsible for Responsibilities



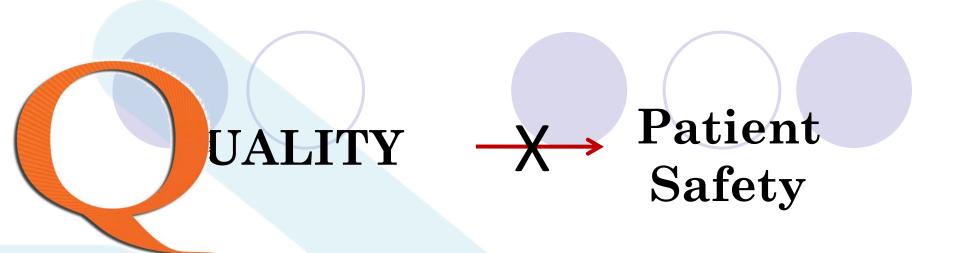
Not fulfilling/providing required responsibilities remains a major deficiency!

Who Me?

Our Goal



Positive contribution to healthcare team for quality patient care



Failure to recognize lack of quality and Improve quality in the entire testing process can jeopardize patients' safety

Need effective quality management

Quality Assessment/Assurance: Monitor & Improve

- Continually and seriously be involved to ensure (ongoing) effectiveness
 - Think monitoring
 - Think problem investigation
 - Think corrective actions
 - Think quality improvement



Quality Assessment/Assurance: Monitor & Improve

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Quality Improvement: How?









DOING THE SAME THING AND EXPECTING A DIFFERENT RESULT IS THE DEFINITION OF INSANITY.



prometheuscomic.wordpress.com/

@ 2011 Mark Weinstein

Consequences: § 493.1812: Action when deficiencies pose immediate jeopardy

CMS requires immediate action to remove jeopardy due to condition level deficiencies

• ≥1 or more sanctions may be imposed

If jeopardy is <u>not</u> eliminated, CMS suspends/limits CLIA certificate (can be revoked later, if necessary)

When activity is a significant hazard to public health

 CMS can seek temporary injunction/restraining order regardless of CLIA certificate and State-exemption status.

CAP: Investigating non-conforming Events

CAP's revised (2020) GEN.20208 QM Patient Care/Client Services

The QM program includes a process to identify and evaluate non-conforming events -- errors and incidents that may interfere with patient care/client services

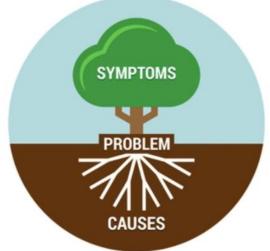
CAP's new (2020) GEN.20310 Investigation of Non-conforming Events

QM program requires a RCA when a non-conforming event occurs that results in death, permanent harm or severe temporary harm (e.g., sentinel event). For nonconformances that ... are not sentinel events (e.g., near misses), QM program includes a process to define the scope and extent of the investigation required.

Root Cause Analysis Approach

 Root cause analysis: A systematic process for identifying the causal factor(s) that underlie errors or potential errors in care.

- In more general terms:
 - Looking deeply into problems to find out why they are happening.
 - Uncovering causes that are not obvious.



RCA's in-depth look often requires a cultural change

Culture Change for Quality and Patient Safety



Quality/Safety: Requires "Right" Culture

"Quality and Patient Safety NOT associated with mismanagement, hostilities, "in-fighting," incompetence, disorganization"

TJC enhanced focus: Culture of Safety and Zero Harm

Leadership (LD) standards...[for] a just and learning culture to reach zero harm

(LD.03.01.01, LD.03.09.01, LD.03.02.01, Pl.01.01.01)

Leaders have essential role...with consistent activities...

 Leadership participation is crucial to ...facilitate transparent, non-punitive approach to reporting and learning from adverse events, close calls, and unsafe conditions

Surveyors look for engaged leadership and their participation in developing/sustaining a culture of safety.

COLA's Quality and Safety View: Testing is more than Compliance; its Culture

...Within total healthcare system...[there is] awareness of importance of accurate lab information to improve patient outcomes ...we know that accuracy emerges through relevant, practical, quality and safety-centered processes combined with a continuous "quality-on-themind" focus during daily actions of caring for patients...

Leadership* is required for lab safety (and patient safety)

- Building a culture of safety
- Encouraging openness and transparency
- Ensuring safety competency
- The incident management plan
- Process for incident investigation

^{*}Irwin Rothenberg. Technical writer/quality advisor: COLA Resources, Inc.

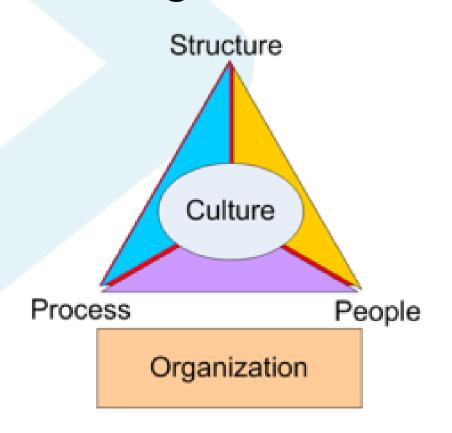
"Right" Culture Requires Shift in Thinking

Not Effective Thinking	Effective Thinking
Who did it?	What happened? Why?
Punitive	Fair and just
Bad people	Bad systems
Penalize the reporter	Thank the reporter
Confidential	Transparent learning
Investigation	Root cause analysis
Independent silos; no/little communication	Inclusive and interdisciplinary team; lots of communication

"Right" Culture Requires Shift in Thinking

Not Effective Thinking	Effective Thinking
Thinking errors are rare	Realizing errors are everywhere
Great care	Great care in a high-risk environment
Lack of direction; staff make it up as they go along	Principles of fair and just culture, guidelines algorithms, flow charts
Risk of disclosure/confidentiality	Moral duty, risk of non-disclosure
Great staff; poor systems	Great staff; great systems
Deliver care to patients	Partner with team, patients and families

"Effective" Thinking for The Right Culture



Summary of Today, we addressed

Tactics based on survey/inspection findings to be aware and avoid deficiencies Quality assessment and quality improvement techniques for quality results and patient safety

Importance of the "right" laboratory culture for quality and patient safety

What about Tomorrow?

Who knows?

- Keep current, keep "ear to ground", be in the know
- Be flexible
- Be ready for the next "surprise"

But how?

Planning Guidance

Lab Preparedness During the COVID-19 Pandemic



Strategies for curtailing test menus, implementing social distancing, and supporting staff morale in response to a surge in testing and staffing shortages

Author: Jonathan Hoyne, PhD, DABCC, FAACC // Date: MAY.1.2020 // Source: Clinical Laboratory News

Topics: Lab Management, Change Management, Emergency Preparedness/Response, Lab Safety, Personnel Management, Test Utilization

The past few months have been a whirlwind of news about, and activities in response to, the emergence and spread of the novel coronavirus, SARS-CoV-2. As this pandemic unfolds, laboratory personnel are key to the efforts to halt the virus's spread and treat patients.

The consequences of the pandemic on laboratories are likely to go beyond those of more familiar emergencies, like floods or hurricanes. In addition to a possibly overwhelming surge in patients with COVID-19 illness, we might experience planned reductions in other patient populations, a changed patient mix to mostly or nearly all COVID-19 patients, supply shortages, and staff shortages as team members need to self-quarantine or stay home to care for family members.

SARS-CoV-2 Quality Solutions

Version 2 now available with expanded genome coverage including the 5 gene

My last Word on Quality and Safety --Continue to:





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