Delayed Laboratory Tasks	DO CITE IF	DON'T CITE BECAUSE
Below is a list of areas that may have had delays due to the COVID-19 global pandemic. Please review each section. If you find an issue please review the "Do Cite If" and "Don't Cite Because" sections to the right as well. There are a few exceptions that are listed next to the specific requirements.	**For the following items identified for each category, you would cite a deficiency if:**	**For the following items you would not cite a deficiency if:**
	The check or process has not been performed at the laboratory defined frequency, as stated by the manufacturer, or as stated in the requirement and there is no documented reason for the exception/delay or plan of action.	The check or process has been performed at the laboratory defined frequency, as stated by the manufacturer, or as stated in the requirement.
	There is a documented reason for the exception/delay or plan of action but it was not followed.	There is a documented reason for the exception/delay or plan of action and it was followed.
	The reason for the exception/delay or plan of action is inadequate. For example, staffing shortage but there is no evidence of layoffs or furloughs and the check or process has not been performed by the laboratory.	The laboratory had ceased testing and followed their plan for intermittent testing.

Category	Requirement Summary	REQ #	DO CITE IF / DON'T CITE BECAUSE	Comments and Exceptions are detailed below
Equipment Checks				
Function Checks/ Routine Maintenance	Appropriate maintenance and function checks are performed and records retained for all instruments (eg, analyzers) and equipment (eg, centrifuges) following a defined schedule, at least as frequent as specified by the manufacturer.	FDT.24530, COM.30525, COM.30600, ANP.23570, ANP.57350, COM. 30860, COM.30680, HEM.32100	See top of page 1	
Alarm Checks	Alarm checks are performed for storage units according to the manufacturer requirements and/ or laboratory procedure whichever is more stringent and results recorded	TRM.42750, TRM.48180, GEN.77550		No exception for TRM if laboratory remained opened. Alarm checks must be performed to ensure viability of the items stored within the units.
Centrifuge Checks	Verification of operating speed and time as applicable for centrifuges is performed annually or at least as frequently as defined by the manufacturer.	GEN.41017,TRM.31900, HEM.37175, HEM.32050		
Defined Water Types (water quality testing)	The water quality is tested at least annually.	GEN.41500		
Accuracy and Reproducibility - Volumetric Glassware, Pipette, Balances	Volumetric glassware, pipettes, and balances are checked for accuracy and reproducibility initially and according to the manufacturer's recommended interval, or at least annually if not specified, and the results are recorded.	COM.30810, COM. 30820, COM.30860, COM.30880		
Safety				
Radiation Surveys (specifically wipe testing as per lab established frequency)	Routine radiation surveys and wipe tests to determine exposure rates and detect contamination must be performed and recorded at defined frequency.	GEN.77135	See top of page 1	
Safe Work Practices Review	There are records of periodic review (at least annually) of safe work practices to reduce hazards.	GEN.73400		
Fire Safety Training (specifically physical evaluation of escape routes, fire safety knowledge testing)	New personnel are trained on fire safety, with a fire safety review conducted at least annually.	GEN.75400		No exception for new employees
Eyewash testing (potentially related to closed lab sections)	There are records for the weekly activation of plumbed eyewash stations and weekly visual inspection of self contained eyewash stations.	GEN.77400		
Biological Safety Cabinet	The laboratory has a maintenance schedule of BSC function checks and records of testing and certification.	MIC.20520, MIC.33300, MIC.43300, MIC.43350, MOL.54570		No exception due to need to use for processing COVID specimens.

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Instrument Specific				
Analytical Measurement Range (AMR) Verification	Verification of the AMR is performed at least every six months and following defined criteria. Records are retained.	CHM.13600, CBG.12300, HEM.37375	See top of page 1	
Quantitative Cut-Off Values	The cut-off value is established initially, and verified with every change in lot or at least every six months.	CHM.13750, IMM.33905, MIC.65270 (Qual- LDT), MOL.34516(Qual)		
Comparability of Instruments and Methods - Nonwaived Testing	The laboratory compares the results produced by instruments/methods that test for a given analyte.	COM.04250		
Calibration/ Recalibration/Calibration Verification - Waived Tests	The laboratory follows manufacturer's instructions for calibration, calibration verification, and related functions for waived tests. Records are retained of calibration and recalibration if applicable.	CHM.12950, IMM.33337, POC.08050, URN.24342, POC.06330 Refractometer; URN.26100 refractometer		No exceptions required to perform testing.
Calibration/Recalibration/Calibration Verification-Non Waived Tests	Criteria are established and records are retained for the calibration, calibration verification and recalibration of non waived tests.	IMM.33670, MIC.65145, MOL.33860, POC.08300, URN.24355,CBG.14900, CBG.16000, HEM.35924, HEM.35986, ANP.29510, CHM.13400, CBG.12100, HEM.37365, CHM.16550 GC/HPLC, BAP.07800 BAP Storage Equipment, CHM.15900 Gamma Counter, CHM.22400 Wavelength, CHM.22600 Cal Curves, IMM.39520, MOL.44860 wavelength		No exceptions required to perform testing.
PT Participation and Review	The laboratory has evidence of participation in a proficiency testing (PT) program with evidence of enrollment for each analyte and review of results with signed attestation statements.	CYP.00125, CYP.00150, CYP.00190, FLO 18385, CYP 00170, COM.01100, COM.01500, COM.01300, COM.01400		Delaying the signing of the form until after the PT event is over. The form does not need to be signed prior to sending the results to PT provider. It can be completed after the event when the results are being reviewed. Remote review is acceptable. If ceased testing occurred, PT is not required.
Sampling Mode Comparison	Records of sampling mode comparisons performed annually.	HEM.30070		
LIS				
Autoverification Validation	Records that the autoverification process is validated initially and whenever there is a change that affects the logic.	GEN.43875	See top of page 1	No exceptions. It must be performed initially and whenever a change occurs that affects the logic.
Review of Calculated Patient Data Verification	Records of calculated data checks every two years and whenever there is a change that affects the calculation.	GEN.43450		No exceptions for changes that affect the calculation.
Patient Confidentiality (compliance audit)	The laboratory must perform an annual audit for compliance of patient confidentiality during transfer of data to external referral laboratories or other service providers.	GEN.41303		
Content/Format Report Review	The laboratory director reviews and approves the content and format of paper and electronic reports every two years.	GEN.41067		

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Quality Management				
Ongoing Quality Assessment Monitoring/Root Cause Analysis	The laboratory must have a written quality management (QM) program that covers all areas of the laboratory and its services. It must include monitoring of pre-analytic, analytic, and post- analytical phases of testing at laboratory defined frequencies. The program must identify and evaluate nonconforming events. It must include steps to perform a Root Cause Analysis for identified non conforming events and adequate documentation of the investigation. The QM program must be assessed annually for effectiveness.	ANP.30080, ANP.33120, GEN.13806,GEN.20100, GEN.20208, GEN.20310, GEN.20316, GEN.20326, COM.04000, CYG.31903, FDT.01666	See top of page 1	Remote review is acceptable.
Ongoing Quality Assessment Monitoring	There is ongoing quality monitoring of the quality control plan to ensure the Individualized Quality Control Plan (IQCP) is effective in mitigating the identified risks.	COM.50600		Remote review is acceptable.
Annual Result Comparison	Records of annual result comparison and evaluation of interobserver variability.	ANP.22970, MOL.39315		
Interim Self-Inspection	The laboratory has conducted a thorough interim self-inspection and has corrected all deficiencies.	GEN.23584		The CAP provided a 30-day extension to all laboratories that have a self-inspection due by June 1, 2020.
Training / Competency Assessments				
Competency assessment - Waived	The competency of personnel performing waived testing is assessed at the required frequency.	GEN. 55499, POC.06875	See top of page 1	There are no exceptions to the requirements for training and competency assessment during the COVID-19 health care emergency.
Competency assessment - Non Waived and PPM	The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.	GEN. 55500, POC.06910, POC.09600, TRM.45254, TRM.50150		There are no exceptions to the requirements for training and competency assessment during the COVID-19 health care emergency.
Competency assessment - not all six elements assessed	Competency assessment records must include all six elements for each individual on each test system during each assessment period, unless an element is not applicable to the test system.	GEN.55500, POC.06910		The use of virtual, remote review, or simulations of direct observations are not allowed (eg, Skype, Zoom, video).
Personnel Training	There are records that all laboratory and point of care testing (POCT) personnel have satisfactorily completed training on all tasks performed, as well as instruments/methods applicable to their designated job.	GEN.55450, POC.06850		There are no exceptions to the requirements for training and competency assessment during the COVID-19 health care emergency.
Morphologic Observation Evaluations	The laboratory evaluates consistency of morphologic observation among personnel at least annually.	HEM.34400, HEM.35566, HEM.35851, MIC.11350, URN.30800		
Director Duties or Designee				
Biennial Procedure Manual Review the Director or designee	Current technical policies and procedures are reviewed by the director or designee biennially.	COM.10100	See top of page 1	
Director Involvement -Visits	The involvement of the laboratory director is considered adequate and occur at the frequency defined in a written policy or agreement.	DRA.10435		Exception: Do not cite if visits delayed due to COVID pandemic.
Quality Control				
Monthly Quality Control (QC) Review - Waived Tests	The laboratory director or designee must review QC data of waived tests at least monthly or more frequently if specified in the laboratory QC policy.	CHM.13840, HEM.18038, IMM.33930, MIC.10060, POC.07037, URN.24320	See top of page 1	Remote review is acceptable.

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Quality Control				
Monthly QC Review/Monthly QC Statistics	For numeric QC data, statistics (eg, SD and CV) are calculated monthly to define analytic precision and monitor trends over time.	CHM.14500, CHM.14916, HEM.20050, HEM.20146, IMM.30100, IMM.34362, MIC.11020, MIC.65240, MOL.34475, MOL.34495, POC.07550, URN.25750	See top of page 1	Remote review is acceptable.
Supervisory Result Review	In the absence of an onsite supervisor, results of high complexity testing performed by high school graduates is reviewed by the director or designee within 24 hours.	COM.04100		No exceptions. It must be performed initially and whenever a change occurs that affects the logic.

Method Verification / Validations for all New Tests/ Instruments

Requirement Summary	REQ #	DO CITE IF	DON'T CITE BECAUSE
Must follow manufacturer instructions for use	COM.40250	Laboratory is using a test with a modification to manufacturer's instructions that has not been validated. For example, if the laboratory is using an EUA and is using a modification that is not EUA approved then cite COM.40250.	Laboratory followed manufacturer's instructions and FDA emergency use authorization (EUA) instructions. If the laboratory has modified the test but is using an EUA alternative specimen, move on as they are in compliance. For example, the laboratory cannot obtain VTM/UTM so they switched to using saline. Saline has been granted an EUA by the FDA for use as an alternative to VTM/UTM.
Verification of Food and Drug Administration (FDA) Cleared/Approved Test/Method	COM.40300	Cite COM.40300 if: 1) Limited verification study done on non EUA due to circumstances, but no plan approved for amended study 2) accuracy, precision and reportable range are not assessed 3) only one set of verification data used for multiple instruments 4) Non-EUA testing where QC only was used to verify accuracy	Verification performed following manufacturer instructions and includes three elements for verification of accuracy, precision and reportable ranges. If this is an EUA test and the laboratory did a shortened verification study which may include the use of QC to verify accuracy, precision and/or reportable, this is acceptable as part of the EUA. Move on as the laboratory is in compliance.
Validation of Laboratory Developed Test (LDT) or Laboratory Modified Test	COM.40350	Cite COM.40350 if: 1) Using a modified or LDT without a complete validation performed according to policy. 2) Less than 20 samples tested for validation without documented criteria as to why less than 20 samples accepted and approved by medical director. 3) Modification of an EUA without a required bridging study.	Laboratory performed the full validation for any modified tests or LDT including the required elements and it is approved for use by the laboratory director. For example, the laboratory modified an EUA test by changing to an alternative collection device like a nasal swab instead of nasopharyngeal however the nasal swab is an EUA approved alternative, the laboratory is in compliance, do not cite.
Verification and Validation Approval	COM.40475 (for 2019 and newer versions) COM.40000 (2018 or older versions)	Verification or validation studies performed by laboratory do not have documentation of review and acceptance by the medical director or designee who meets CAP director qualifications, then cite COM.40475/COM.40000. If summary is unavailable for laboratory testing implemented since 2009, cite COM.40475/COM.40000.	All verification and/or validations studies have been approved by the medical director or designee who meets CAP director qualifications prior to reporting patient results.
Analytic Interferences	COM.40500	If one of the below are not found then cite COM.40500: 1) Procedure or documentation that was reviewed addressing analytical interferences of each test and steps to follow if they are present is not available. 2) Laboratory did not perform interfering substance studies.	If the laboratory director has reviewed and approved manufacturer interference studies for EUA or FDA cleared/approved testing, move on as the laboratory is in compliance.

Method Verification / Validations for all New Tests/ Instruments

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Intermittent Testing	COM.40805	Cite COM.40805 if one of the following is found: 1) Test was discontinued due to reduced menu or laboratory/department closing and no PT or alternative assessment was performed 30 days prior to the start of patient testing. 2) Method verification was not performed, as applicable, within 30 days of the start of patient testing. 3) Testing was verified then FDA clearance revoked then reinstated but no reverification of testing performed (ie, testing was not validated during the FDA revocation and was reinstated without verifying testing after FDA clearance or EUA granted).	A plan for intermittent testing is followed. The plan addresses method verification process and require PT or alternative testing be performed before patient testing is resumed. Laboratory did something to show that reinstating testing was acceptable and approved to return to use.
LDT and Modified Test List	COM.40830	Cite COM.40830 if one of the following is found: 1) Laboratory has implemented an LDT that is not under EUA approval and is not on the list. 2) Laboratory modified manufacturers instructions that is not under EUA and did not add to the list.	List is up to date with all testing including an new or modified tests.

Temporary Testing Sites

Site Description	Items to Review	Items to Cite if Missing Documentation	Do Not Cite
Testing was performed/site discontinued prior to inspection	Review training records for qualified testers	If training records are not available – cite GEN.55450	If all of these items are acceptable, move on as the laboratory is in compliance.
	Review sampling of QC for time that testing was performed	If QC was not documented as performed as required – cite POC.07300	
		If QC was not effectively reviewed –cite POC.07550	
Short-term testing Testing is Still Being Done and Inspection is in 2020	Training records for testing personnel	If training records are not available – cite GEN.55450	If all of these items are acceptable, move on as the laboratory is in compliance.
	Sampling of QC	If QC was not documented as performed as required – cite POC.07300	
		If QC was not effectively reviewed – cite POC.07550	
	Mechanism to capture errors – QM	If no identification or evaluation of errors - GEN.20208	
	Method verification for any instrumentation that was moved to temp sites	If instrument relocated and not verified - cite COM.30550	
	Result reporting and traceability	If report missing any required elements - cite GEN.41096; if report not retained so that it is retrievable - cite GEN. 41300	
	Temperature records for testing area	If temperature of equipment or testing environment is not recorded or does not meet manufacturer's requirements - cite COM.30750	
Long term testing Inspection in 2021, Testing is still performed at temporary site	Training records for testing personnel	If training records are not available – cite GEN.55450	If all of these items are acceptable, move on as the laboratory is in compliance.
	Sampling of QC	If QC was not documented as performed as required – cite POC.07300	
		If QC was not effectively reviewed – cite POC.07550	
	Mechanism to capture errors – QM	If no identification or evaluation of errors - GEN.20208	
	Method verification for any instrumentation that was moved to temp sites	If instrument relocated and not verified - cite COM.30550	
	Result reporting and traceability	If report missing any required elements - cite GEN.41096; if report not retained so that it is retrievable - cite GEN. 41300	
	Temperature records for testing area	If temperature of equipment or testing environment is not recorded or does not meet manufacturer's requirements - cite COM.30750	
	Competency assessment at appropriate times for new or existing testers	See "competency assessment" tab	
	Correlations if more than one instrument or method tested and > 6 months of testing	If correlations not performed - cite COM.04250	
	QM plan includes temporary testing sites	If QM plan does not address temporary sites - cite GEN.20100	
	Safety requirements: Waste Disposal Chemical Hygiene	If laboratory has not defined Safety practices - cite appropriate requirement - Universal Precautions starting with GEN.74000; Chemical Hygiene starting with GEN.76000; Waste Disposal - GEN.77800	
Temporary sites added due to COVID - pathologists and cytogeneticist reading cases at home, for example.	Plan for intermittent testing	If plan for intermittent testing is in place but has not been followed - cite COM.40805	If all of these items are acceptable, move on as the laboratory is in compliance.
		If plan for intermittent testing is not in place - cite COM.40805	
Testing was temporarily suspended and is being restarted	Plan for intermittent testing	If plan for intermittent testing is in place but has not been followed - cite COM.40805	If all of these items are acceptable, move on as the laboratory is in compliance.
		If plan for intermittent testing is not in place - cite COM.40805	