

Modified Inspection Practices Tip Sheet: Inspection Planning				
Inspection Planning Actions	Details	Additional Considerations		
Please contact the CAP if assistance is needed 800-323-4040				
Inspection Planning	Discuss Restrictions on a state/local/facility level	Laboratory is performing patient testing (inspection site)	If not, inspection should be postponed	
		Confirm staffing availability (inspection team/inspection site)	eg, furloughs, remote working	
		On-site screenings (inspection site only)	eg, temperature checks	
		Questionnaires (Inspection site only)	Share questionnaire with team and ensure everyone meets entry requirements	
		No visitor/vendor policy (Inspection site only)	If there are any restrictions, inspection should be postponed	
		Required quarantines (Inspection team/Inspection site)	If there are any restrictions, inspection should be postponed	
		Business travel restrictions (Inspection team)	If there are any restrictions, inspection should be postponed	
	Discuss ability to practice social distancing while on-site	Adequate sized conference room availability for pre-summation/summation	If not available, discuss video/phone conferencing options	
		Inspectors will not access patient care units while on-site	Discuss using alternative location that allows for social distancing or video/phone conferencing	
		Adequate space for interviews	If not available, discuss video/phone conferencing options	
	Discuss Personal Protective Equipment (PPE) Requirements	All inspectors should follow Centers for Disease Control and Prevention (CDC) guidance	https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html	
		Inspection site to provide all required PPE	If inspection site cannot provide minimum PPE, team should bring their own.	
	Discuss On-Site Inspection Scheduling	Inspection date should be determined by the inspection team		
		Inspection team announces date of inspection to laboratory director and inform Inspection Assignment Specialist as soon as available	If inspection site has a concern with scheduled date and another option is not available contact Inspection Assignment Specialist	
		Discuss duration of on-site inspection	Consider multiple days with fewer inspectors each day covering multiple checklists	Possible reduced time on-site (ie, determined if prior document review completed)
			Possible reduction of number of inspectors if on-site multiple days	Possible reduced team size (ie, determined if prior document review completed)
		Discuss team count	Possible reduction of the number of inspectors with experienced inspectors covering multiple checklists	No trainees/observers at this time
				Notify Inspection Assignment Specialist of number of inspectors for on-site inspection
	Discuss Availability for Remote Document Review	Inspection site is able to provide access to documents electronically	Setting up conference/video call to review documents interactively	
			Provide requested documents via email	
			Provide guest login to web-based systems	
		Identify potential documents for remote review (remember to adhere to HIPAA regulations)	If not available, inspection team will review documents when on-site	
Current Quality Management Plan and minutes from meetings				
Review of effectiveness of Quality Management Plan from prior two years				
Safety Policies and Procedures				
LIS Policies and Procedures				
Investigations for unacceptable proficiency testing results (if any)				
Validations summary statements (not data) for any new tests/instruments implemented since last inspection				
Specimen collection manuals/SOP				
Instrument calibration, maintenance, AMR verification, calibration verification, and comparison studies				
New reagent/kit/media lot verification records				
Temperature records				
Others as identified by team/laboratory				

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Inspection Planning	Discuss Availability for Remote Document Review (cont.)	Confirm who will participate in remote document review (inspection team/inspection site)	Person providing documents or access to documents Key staff for relevant documents from inspection site Inspectors performing document review Multiple sessions required?	
		Confirm when document review will occur (Inspection team/Inspection site)	Timeframe and duration of access to a document control system All review must occur within the two weeks prior to on-site inspection	
		Food & Beverage Options	Availability at inspection site or will inspectors need to bring their own	
		Do not participate in inspection if ill (inspection team/inspection site)	Notify pertinent parties	
	Finalizing On-site Inspection Details	Discuss final inspection plan including any remote document review already completed		Team leader or designee to distribute inspection materials (electronically if possible) Distribute Inspection Summation Report (ISR) pages for each inspector (limit sharing) Discuss keeping focus of inspection on key areas such as personnel, quality management, new method validation/verifications, quality control, instrument maintenance, safety, etc.
				There will be no observations in patient care areas for point of care testing (including ABG and other near-patient testing).
				There will be no transfusion observation and evaluation of blood product storage outside of the laboratory.
				There will be no observation of inpatient or outpatient phlebotomy collections .
				Limit exposure of patients, staff, and inspectors by conducting interviews to describe processes via electronic means
		Arrange Travel if needed	CAP Travel Desk 847-832-7800 Email: captraveldesk@cap.org For more information refer to travel section	
		Continuous communication up until day of on-site inspection	Change in status of restrictions Illness Additional impacts to the inspection	