



January 19th, 2022

Inspecting Virtually: The Next Best Thing to Being There!

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Loyola Medicine – Regional Laboratory Services

- Background and Inspection Goals
- Inspection Timeline and Process
- Inspection
 - *Inspection preparation*
 - *Inspection*
 - *Summation*
- Benefits and Challenges
- CAP resources and tools to streamline inspections
- Lessons Learned and recommendations for future success

Learning Objectives



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Upon completion of this webinar, participants will be able to:

- Identify available resources to plan for a virtual CAP inspection
- Maximize the accessibility of document control systems to facilitate a transparent and efficient inspection process
- Discuss strategies of inspectors to organize tasks to enable a thorough and focused audit of laboratory operations
- Recount several challenges and advantages of inspecting virtually
- Foster collaborative relationships between inspection teams and virtually inspected laboratories

Background



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- Late last year, the laboratory at Loyola Medicine, a 550 bed, academic medical center inspected a similarly sized academic medical center.
- The site inspected had multiple physical locations and an extensive activity menu.
- Due to rising COVID-19 cases and institutional restrictions for traveling and visitors, both sites and CAP agreed to a completely virtual inspection.



Background

Total Number of inspectors – 14 with 2 not pictured as they were completely virtual inspectors. 5 of our inspectors were first time inspectors.



Inspection Goals

- Conduct a fair and thorough inspection following the "Read, Observe, Ask, Discover" inspection methodology
- Encourage an environment of continuous improvement
- Engage with our peers to learn and share ideas for quality and workflow improvement

READ



OBSERVE



ASK



DISCOVER



CAP Resources and Tools



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Application/Reapplication Process

Accreditation Manuals/ Retention Guidelines

Laboratory Webinars

Focus on Compliance

Laboratory Inspection Preparation Course

Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox

PT Compliance Notice (PTCN)

Checklist Resources

Accreditation Checklists

Checklist Requirement Q&A

Templates

Quality Management

IQCP Toolbox

External Resources

CAP Laboratory Director Education, Information & Resources

Inspector Training & Tools

Self & Post Inspection Toolbox

Contact Us

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Inspector Training & Tools

! So, you want to be an inspector? We can help train and guide you.

On-line Inspector Training

Compliance Decision Flow Chart (PDF)

2020 Inspection Resources

Important: Special instructions for inspectors during the COVID-19 pandemic

Performing Virtual Inspections: Being the CAP's "Eyes and Ears" From Home

Supplemental inspector training for virtual inspections

Virtual Inspection Process Overview (PDF)

2020 Modified Inspections Overview(PDF)

Overview of changes to our modified inspection process (audience: inspectors and laboratory staff)

Inspection Scenarios (PDF)

Identifies common scenarios and questions inspectors are likely to encounter due to the impacts of COVID-19 on laboratories, with recommendations on how to handle each (audience: inspectors and laboratory staff)

COVID-19 Checklist Requirements Tip Sheet (PDF)

Identifies the checklist requirements applicable for inspecting laboratories that are performing COVID-19 testing and what to look for to ensure the lab is in compliance.

Document Review Tip Sheet (PDF)

Outlines the proposed process change to allow for performing a document review prior to the on-site inspection (audience: inspectors)

Document Review Tracking Sheet (Word)

Optional tool to keep track of documents review, any concerns, questions or additional information that needs to be evaluated at the on-site inspection (audience: inspectors)

Inspection Planning Tip Sheet (PDF)

Outlines some of the changes and/or new considerations for planning inspection teams if the modified inspection process is used (audience: inspectors)

Travel Planning Tip Sheet (PDF)

Suggestions to consider when traveling or planning travel for an inspection (audience: inspectors)

Inspector Tip Sheets - Summation Conference (PDF)

Inspector Reimbursement Form (PDF)

Fast Focus on Compliance

Inspection Tip Sheets

Anatomic Pathology (PDF)

All Common (PDF)

Chemistry (PDF)

Cytopathology (PDF)

Forensic Drug Testing (PDF)

Flow Cytometry (PDF)

Hematology (PDF)

Immunology (PDF)

IQCP (PDF)

Laboratory General (PDF)

Microbiology (PDF)

Point of Care Testing (PDF)

Reproductive Laboratory (PDF)

Team Leader Day of Inspection (PDF)

Transfusion Medicine (PDF)

Urinalysis (PDF)



CAP Resources and Tools

- Utilize Virtual Inspection Process Overview Document
 - *Details the requirements of virtual inspections*
 - *Digital Requirements*
 - *Highlights that the inspection team will still perform a thorough review of the laboratory while not actually going on site.*
 - *Details the overview of the inspection planning and requirements from both teams on the day of inspection.*
- Utilize the Inspection Planning and Tracking Tool
 - *Can aid the inspecting team in structuring the document review process.*
 - *Can serve as a “To Do List” and ensure that all documents that were requested are reviewed.*
- Utilize the section specific Inspection Tip Sheets – Great tool for 1st time inspectors!
 - *Tailored to each specific section and can ensure that inspectors are focusing on the elements for that particular section.*



Inspection Preparation

- Selecting inspectors
 - *Skill level – mix of experience and new inspectors*
 - *Meet with prospective inspectors to give an overview of expectations, goals, and workflow*
- CAP inspector training
 - *Inspection Team Member Training*
 - *Performing Virtual Inspections: Being the CAP's 'Eyes and Ears' from Home*
 - *Review of Section-Specific Tip Sheets*
 - *Utilize the resources available from CAP Accreditation Resources*



Inspection Preparation

- Digital experience:
 - *Technical challenges – having enough microphones, webcams, computers available*
 - *Inspection site had access to iPads for giving tours. This provided great visual capabilities but was shaky and had connection issues as well.*
 - *This allowed for the inspector to be able to engage and ask questions about their workspace and workflow directly with their team*
 - *Lesson learned: Add digital platform training for users less familiar with these platforms*
 - *Recommend testing audio/visual components ahead of time*
- Record management:
 - *Having scanned records made the inspection process substantially easier for both teams. This takes more time during preparation but makes inspection workflow much smoother.*



Inspection Preparation

- Preparing content packages for each inspector:
 - *Provide CAP inspector resources including tip sheets*
 - *Include all relevant items provided by CAP: activity menu, equipment lists, past inspection information, and proficiency testing, etc.*
 - *For the virtual inspection: also needed to include Inspection Planning and Tracking Tool excel sheet which guides request lists by CAP Number and Checklist.*
 - *We modified the Document Request sheet from CAP tailored to each department.*
 - *Used past deficiencies and other provided information to guide areas of focus for document sampling.*
 - *Added specimen tracers to cover key testing components from pre-analytical to post analytical testing.*

Heme Tracer 1: CBC	Select a sample from May 15th 2020 with a critical value. Show instrument maintenance for this month, QC, temperature records, Final report with critical call documentation, competency records for performing tech.
Heme Tracer 1: Coag	Select a sample from January 16th 2021. Show instrument maintenance for this month, QC, temperature records, Final report with critical call documentation, competency records for performing tech.

Inspection Preparation

- After providing inspection packets to inspectors – hold an inspection prep meeting with each inspector regardless of their level of inspection experience
 - *Virtual/modified inspections are new for all*
 - *New inspectors can really benefit from talking through their section specific tip sheets*
 - *Focus on areas that are common citations in their section-specific checklist and the All Common checklist.*

Inspector Training & Tools



- *Confirm their comfort level with the technology platforms that will be used*
- *Discuss the overall timelines for their part of the inspection and if they will need to share a leader from the institution with another member of our inspection team.*

Inspection Preparation



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Documents Requested	Comments
	PLEASE NOTE - Document Request must be for sampling purposes only.
Training and competency	
Records of degree/transcript and work history	* Will request specific users
Written protocol of activities and nature of supervision for each non-pathologists performing gross examinations	Please provide policy
Assessment by a pathologist of non-pathologists assisting with gross examination	Provide an example for a recently hired employee
Training documents for:	Embedding, microtomy, tissue processing, IHC (with examples for the same specific users requested above)
Competency documents for:	IHC, telepathology
Quality	
Notification of methodology changes	If any methodology changes occurred
Records of daily review of histologic slide quality	Nov 2020, May 2021
IF QC records	Nov 2020, May 2021
IHC QC records	Nov 2020, May 2021
Examples of failed QC with troubleshooting	If any available
Statistical records and annual summary	2020
Records of retrospective review and evidence of corrected reports, if applicable	If any available
HER2, ER, PgR proficiency testing records	PM-B 2020, PM-A 2021

Inspection Preparation



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Documents Requested	Comments
PLEASE NOTE - Document Request must be for sampling purposes only.	
Equipment	
Microscope maintenance	Annual for 2020
Check NIST thermometer standard	Most recent certificates
Temperatures logs for completion, appropriate ranges, corrective action and monthly review	Autopsy, histology: Nov 2020, May 2021
Instrument/equipment maintenance logs and repair records	Nov 2020, May 2021
Cryostat decontamination records	Nov 2020, May 2021
Microwave reproducibility and ventilation checks	Most recent records
Sampling of EM calibration records	Most recent calibration
Pipette Verification	2020, 2021 records
Bench maintenance: Microtomy	Nov 2020, May 2021
Chemical fume hood maintenance	2020, 2021 records
Chemical monitoring records for Xylene, Formaldehyde	2020, 2021 records
Waterbath temperatures	Nov 2020, May 2021
Oven temperature checks	Nov 2020, May 2021

Inspection Preparation

- Scheduling
 - *Setting schedules guided by CAP recommendations for time spent inspecting is key.*

Estimated Time for Remote Document Review		
Documents	Limited Service Laboratory	"Full" Service Laboratory
General/Administrative	2-3 hours	3-4 hours
Proficiency Testing	1 hour	1.5 hours
Core Lab	3 hours	4-5 hours
POC	1 hour	2 hours
TRM	1 hour (limited)	3-4 hours (full with ID)
MIC	1 hour (limited)	3-4 hours (full with ID/Sens, possibly)
Blood Gas	1 hour	1.5 hours
Personnel files and competency	1 hour	2 hours
ANP/CYP	0.5 (FS only)	2 hours

- ***Lessons learned:***
 - *Specify time in schedule for document review vs. video meetings and schedule team members away from lab so that inspectors don't feel like they have to "multi-task" their regular job responsibilities with inspector responsibilities.*



Inspection Preparation

- Scheduling with inspection site
 - *Plan time for virtual safety walkthrough – technology may be a challenge.*
 - *Discuss expectations for what will be provided for document review vs. in meetings.*
 - *What is available in policy manager and accreditation manager?*
 - *What will be scanned vs. shared via camera?*
 - *Pathology slide review – can telepathology be utilized?*
 - *Scheduling introductory meeting and summation*



Timeline

2 months in
advance



- Determine inspection date and type of inspection with inspection site
- Begin recruiting team members

1 month in
advance



- Schedule meeting with site leaders to discuss expectations, logistics, and accessibility
- Schedule Introduction, Summation, interviews for each lab area, and leadership interviews with Team Leader
- Discuss virtual walkthroughs and what technology barriers to expect
- Have team members complete Inspector Team Member training and Performing Virtual Inspections: Being the CAP's 'Eyes and Ears' from Home

2 weeks in
advance



- Have team members perform document review and submit record requests using the Inspection Planning and Tracking Tool.

2 days of
inspection



- Conduct interviews to ask questions, observe practices, and complete the “discovery” phase of inspecting. Leave time for follow up interviews if needed, in case not all requested information is able to be provided.
- Provide list of citations and recommendations to site leaders in “real-time” to allow for corrections.
- Wrap up and hold Summation

- Virtual Inspection Challenges
 - *Distractions: It's easy to be distracted by routine work when inspecting from your lab.*
 - **Lessons learned:** Try to schedule quiet inspection space away from the lab, set out of offices messages, and treat the inspection time as if you are completely off-site.
 - *Missing “perks” of away inspections*
 - **Lessons learned:** Schedule a group meal (either virtually or socially distanced) so that the team is still able to bond and discuss the inspection.
 - *Virtual bottlenecks: Different inspectors want to meet with the same leader at the same time*
 - **Lessons learned:** Creating a schedule for all to follow helps alleviate any confusion.

- Virtual Inspection Benefits
 - *Time saved on traveling between sites and meetings.*
 - *Allows for additional team members to sit in and learn the process of an inspection.*
 - *Able to accommodate inspector schedule better – able to inspect on their own prior to the rest of the team if scheduling conflict doesn't allow inspectors to participate during main inspection days.*
 - *More experienced inspectors have the opportunity learn a new way of inspecting.*
 - *Allows for all involved to be socially distanced.*



Team Leader's Role

1. Help inspectors remain on task and focused on their assignments
2. Assure coverage of work-related tasks to not distract/detract from inspection
3. Assure adequate training and preparation
4. Confirm accessibility to document control system or receipt of shared documents



Team Leader Interviews

Viewed as a major advantage to schedule virtual interviews with Directors, Institution Executive(s), and Chief Medical Officer

Scheduling Interviews with Directors, CMO, CEO/VP

Suggest using leading, open-ended and engaging Interview Questions

1. How did the laboratory respond to the early demands of the pandemic in providing key diagnostic services?
2. Describe a quality initiative led by the laboratory that has resulted in improvements in patient care.

Compliment! Offer praise/accolades for lab staff

Communicate concerns regarding unresolved or serious deficiencies

End with a forward-looking statement – offer reassurance – i.e. guidance is available to help resolve/address issues



Inspection Summation Conference

- Hold a pre-summation meeting to discuss findings – this is a great opportunity to have a group lunch/dinner
 - *Discuss what worked well, what could be improved*
 - *What ideas inspectors will take back to their own labs*
 - *Discuss trends and items to highlight during the summation*
 - *Check A-V connection and controls prior to live summation*
- Potential benefit of a virtual inspection: More frontline engagement – summation is more accessible to the lab being inspected as it can be joined from anywhere
- Zoom etiquette is key:
 - *Microphones muted for non-speaking participants*
 - *Setting an agenda to prevent people from speaking over each other*
 - *Preparing for technical challenges*

Team Leader's Role (continued)

1. Wrap-up
2. Paperwork

Protecting PHI

Discarding all documents

3. Soliciting and providing feedback to CAP
 1. *Provided to inspectors during summation*
 2. *Collected and sent to CAP*
 3. *Expectations? Reinforcement? Affirmation?*
 4. *Remain auditable by CLIA*

Plus/Delta of Virtual Inspections



Safety - Social distancing
A more planned process
Increased document and personnel records review time for scrutiny
Increased number of inspectors, particularly pathology residents and those not typically able to travel
Accommodation of busy schedules



Lack of spontaneity; reduced or inhibited interactions with lab staff
Decreased opportunities for personal collaboration
Increased time required to search/find evidence of compliance within policies and procedures
Disruptions/distractions while multi-tasking with primary work
Reduced visualization of operations



Thank You and Q&A

Thank you for joining our webinar. We hope this webinar will prove to be beneficial to you as you prepare for your virtual inspection experience.

We will now provide answers and feedback to your submitted questions