

JANUARY 2021

# Virtual CAP Inspection

Two Laboratories Shared  
Perspectives



Children's Hospital Colorado  
*Here, it's different.™*



Cincinnati  
**Children's™**  
changing the outcome together



## Today's Speakers:



Kathy Good, Sr. Director Clinical Laboratory Operations  
Cincinnati Children's Hospital Medical Center



Amy Marrs, Sr. Director of Quality  
Children's Hospital Colorado



Adrienne Malta, Director Inspection Services,  
College of American Pathologists



# Presentation Agenda

1. Background and Inspection Goals
2. Inspection Timeline and Process
  - Inspection site preparations
  - Inspector pre-work
  - Inspection time!
3. Benefits and Challenges
4. Lessons Learned and recommendations for future success
5. CAP resources and tools to streamline inspections



# Background Inspection Goals

Pandemic prohibited travel to conduct normal inspection processes.

Inspection team goals:

- Conduct a thorough inspection
- Maintain staff safety
- Encourage staff learning and inspection knowledge spread

Site team goals:

- Staff to interact confidently with the surveyors
- Demonstrate the exemplary care we provide



# Inspection Timeline and Process

Discussions between Cincinnati and Colorado leadership teams lead to agreement to conduct a virtual inspection. Due to CLIA requirements, CAP instructed us that at least one inspector must go on site.

## 4 Week Process

Week 1 – Cincinnati team compiled documents requested for pre-view

Week 2 – Colorado team compiled documents requested

Week 3 – Shared materials and created a schedule for inspection meetings, inspecting laboratory to review

Week 4 – On-line meetings, review of additional and follow up items, on-site inspection



## Cincinnati Children's Preparation

1. Prepare thorough documentation list to enable standards assessment.
2. Prepare team for “new” inspection model, including web site access and virtual teams processes.
3. Thorough review of documentation provided and timely request for additional documents.
4. Build knowledge within the laboratory team.
5. Conduct a thorough assessment for the Colorado team.




## Colorado Children's goal:

1. Make a good 1<sup>st</sup> impression
2. Organized response and documentation
3. All requested materials went through the Quality Team
4. Provide all requested materials



## Site Security

- Worked with the hospital IT security team to set up a secured SharePoint site used to share materials

 Childrens of Colorado DPLM CAP Inspection SharePoint

Home	<a href="#">+ New</a> <a href="#">Page details</a>
Notebook	<h2>Children's Hospital Colorado's Department of Pathology and Laboratory Medicine (DPLM) Welcomes You!</h2> <p><b>Within the site's Documents page, folders are present for the requested documents.</b></p> <p><b>For further assistance or questions, please contact the <a href="#">DPLM Quality Team</a> or a DPLM Section Leader.</b></p>
Documents	
Pages	
Site contents	





## Security cont.

- Documentation provided includes:
  - Policies & Procedures
  - Personnel files
  - Examples of reports, maintenance, logs, PT, QC, etc.
- HIPAA compliant to share information with inspectors
- Read-only access granted to inspection team during the inspection window
- Items added to the SharePoint site by the CHCO Quality Team



# Presentation of Documentation and Materials

In the SharePoint:

- Created one folder for each laboratory section
- Within each section folder, created additional folders to sort documents by topic

## Documents



Name ▾



01. Quality Management Plan



02. Proficiency Testing



03. Competency Assessment



04. Quality Control



# Presentation of Documentation and Materials

## Document Tracker

- All requested items were put into an Excel spreadsheet for each section
- Provided requested item, folder location and the associated document

<b>Section: Lab General</b>	Cincinnati Children's Hospital Medical Center	Inspector Name:
	Children's Hospital Colorado	Email:
	Inspection Skype Meeting	Manager:
		Email:
		Give Date and Time (include all time zones)
Document Requested	Document Location - Folder	Documentation Provided
<b>Lab General Checklist:</b>		
QM Plan w/ Metrics, Review, and action plan documentation for all depts.	Policies & Procedures; Quality Reports	QLT.001 Quality Management System (QM plan on page 44); Quality Reports for Oct 2018, Dec 2019, Feb 2020
Patient & Employee Satisfaction Surveys	Survey Documents	1-Patient and Employee Satisfaction Surveys; 2018 DPLM Customer Service Survey Results
Occurrence/Incident Management Process (w/ example)	Policies & Procedures; Event Investigations	QLT.203 Communication Escalation Policy QLT.204 Event, Recall and Notification Documentation and Investigation; Event Investigation Form - LN2 Event Investigation Form - T Cells Jan 2020



# Presentation of Documentation and Materials

Spreadsheets used to:

- Provide an organized method of presenting requested documents
  - Ensures all materials are provided
  - Guide for inspectors to know where to locate answers
  - Included contact information for easy communication between lab section and inspectors
- Create a good 1<sup>st</sup> impression to inspectors

<b>Section: Lab General</b>	Cincinnati Children's Hospital Medical Center	Inspector Name:
	Children's Hospital Colorado	Email:
	Inspection Skype Meeting	Manager:
		Email:
		Give Date and Time (include all time zones)
Document Requested	Document Location - Folder	Documentation Provided
<b>Lab General Checklist:</b>		
QM Plan w/ Metrics, Review, and action plan documentation for all depts.	Policies & Procedures; Quality Reports	QLT.001 Quality Management System (QM plan on page 44); Quality Reports for Oct 2018, Dec 2019, Feb 2020
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# Inspection Time!

Inspection schedule was created with inspectors and lab staff for:

- Opening meeting
- Section inspection meetings – initial 3-hour block
- Follow up inspection meetings as needed
- Summation

	Monday		Tuesday		Wednesday		Thursday		Friday			
Denver	8/31/2020		9/1/2020		9/2/2020		9/3/2020		9/4/2020		Cincinnati	
Time (MT)	Path A	Path B	Path A	Path B	Path A	Path B	Path A	Path B	Path A	Path B	Time (ET)	
7:00 AM			Lab General/ Quality (KG and DA) <small>am, ht, sh, ty</small>	Point of Care (Dr. Steele)	Follow-Up	PDL Meeting Requested Reschedule sh	Onsite Inspection				9:00 AM	
											9:30 AM	
7:30 AM											10:00 AM	
8:00 AM	Opening Meeting			Immuno	Blood Bank (Dr. Kinney) <small>ty</small>			Chemistry (Dr. Losos, CT) <small>sh</small>	Follow-Up	Follow-Up	Follow-Up	10:30 AM
8:30 AM												11:00 AM
9:00 AM	Heme/Coag /UA (Dr. Losos, Kristy Carnevale) <small>BP</small>	AP Scheduled (Dr. R, MT, & JH) <small>sh</small>							Summation Option B		11:30 AM	
9:30 AM				LIS <small>am</small>		Follow-Up					12:00 PM	
10:00 AM												12:30 PM
10:30 AM										1:00 PM		
11:00 AM											1:30 PM	
11:30 AM												2:00 PM
12:00 PM												2:30 PM
12:30 PM	Follow-Up	Biochemical Genetics (Dr. Nicole Weaver) <small>ht</small>			Follow-Up		Follow-Up				3:00 PM	
1:00 PM											3:30 PM	
1:30 PM											4:00 PM	
2:00 PM	Follow-Up		Follow-Up	Follow-Up	Follow-Up	Follow-Up	Summation Option A				4:30 PM	
2:30 PM												



## On-line Meetings and Conversations

- Used hospital IT security approved applications for virtual meetings
- Meetings were held over Skype For Business
- Screens shared to display additional documentation



[Join Skype Meeting](#)



# On-line Meetings and Conversations

## Social Distancing

- Meetings were held in conference rooms to allow proper spacing
- CAP allowed 1 person for on-site inspection
  - Inspection limited to laboratory. Patient care areas including outpatient collection and point-of-care locations not included.
- Used Skype on laptops and cell phones to perform section walk-throughs and allow inspectors to see how processes are performed



## Benefits

- Time was not an issue
- Document review prior to inspection help build team knowledge
- No need to travel
- Meets inspection obligation during the pandemic
- Skype discussions helped to clarify and verify
- On-site inspection had a list of items based upon findings from remote teammates

## Challenges

- Missed personal connection with staff
- Lots of pre-work
- Employee records
- Requires a strong document control process
- New process for experienced inspectors
- Could be overwhelming for a smaller facility





# Lessons Learned

## Technology

- Make sure both locations have compatible and secure technology to access materials and hold virtual inspections
- IT systems/Security may not allow access to all apps (Teams, Skype, Facetime, Zoom, etc.)
- Do a test run week before scheduled meetings to make sure everything works
- Multiple monitors can assist in locating additional documentation before presenting to inspectors



# Lessons Learned

## Communication

- Establish communication process
- Make sure everyone has each others email and phone numbers
- Set expected time-lines for communication
- Ensure timely response
- If unable to meet time-line, communicate alternate ETA
- Ask everyone to mute their lines if not speaking to reduce background noise
- Define who to contact for section information AND general information prior to meetings



# Lessons Learned

## Inspection Support

- Assigned roles to assist, including:
  - Scribe during inspection meetings
  - Single point of communication for major issues and questions
  - Technical support
  - Assistance with organizing requested document
  - Assistance with scanning or uploading documents
  - Recommend individual has access to PDF Writer program (Adobe, Acrobat, etc.) to flip and delete blank pages



# Lessons Learned

## General Expectations

- Inspection process is longer than usual 1–2-day inspection process
- Inspected lab has additional time to review requested documents before presenting to inspectors – identify potential problem areas ahead of time
- Inspector has additional time to review items and ask for additional documentation
- Make the best of the learning opportunities
- Expect technical difficulties... It will happen



# Recommendations

1. CAP to establish a standard virtual inspection process
  - Standards response tool to allow documentation evidence to be tagged to the standard in question
  - Secure site for submission and subsequent review of documents
  - Local contacts to go on-site for required inspector presence
  - Consider smaller teams to go on-site if remote teams can review evidence prior to or at time of inspection
2. Use a document control tool that has an evidence room and secure on-line access outside of your hospital network
3. Be forgiving, this is new for everyone





COLLEGE of AMERICAN  
PATHOLOGISTS

# CAP Virtual Inspections

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## Tools and Tips for Successful Inspections

Adrienne M. Malta, MBA, MT(ASCP)  
Director, Inspection Services

January 13, 2021

# New Tools and Resources

- **Inspection Planning and Document Tracking Tool**
- **SharePoint Site for Document Upload**
- **Online Courses**
- **Future Plans**

# Inspection Planning & Document Tracking Tool

- **Multipurpose tool for inspectors and laboratories**
  - **Located in SharePoint Folder**
  - **Single point of reference**
    - **Inspection planning**
    - **Documents to upload**
    - **Document review findings**

	A	B
1	<b>Document Review Tracking Sheet</b>	
2	Tool designed to assist the inspection team in planning, sharing, and tracking of remote documentation requested and provided by the laboratory being inspected. This tool is intended to consolidate the review of tracking over multi site inspections.	
3	We encourage the use of this tool to ease communication of the scheduling and track progress of the inspection.	
4		
5	<b>PLEASE NOTE:</b>	
6	<b>Inspectors should only request a sampling of documents. It is not required that the lab submit all documents for a two year period.</b>	
7	<b>Tool Tabs</b>	
8	AU List - provides each AU site demographic and applicable disciplines within that AU.	
9		
10	Schedule Tab - Includes an example of a virtual inspection schedule and a guideline that provides estimate of amount of time to schedule for remote document review.	
11		
12	Director Assessment Tab - Provides each site to be inspected with the DRA checklist. Tab includes high level items for review and documentation pertaining to the DRA checklist.	
13		
14	Lab General Tab- Provides each site to be inspected with the GEN checklist. Tab includes high level items for review and documentation pertaining to the GEN checklist.	
15		
16	Discipline Specific Tab - Provides each site to be inspected with that discipline specific checklist. Tab includes high level items for review and documentation pertaining to that specific checklist as well as the high level items pertaining to the COM checklist.	
17		

◀ [ ] ▶

< > ≡ **Instructions** AU List Schedule Director Assessment Lab General CHM HEM IMM LSV MIC POC TRM URN On-site Visit

Calculation Mode: Automatic    Workbook Statistics



# Inspection Planning & Document Tracking Tool

## continued

	A	B	C	D	E	F	G	H	I
1	Estimated Time for Remote Document Review								
2									
3	Documents		<100 beds or standalone			(200 beds or greater)			
4	General/Administrative		2-3 hours			3-4 hours			
5	Proficiency Testing		1 hour			1.5 hours			
6	Core Lab (CHM, HEM, COAG, IMM, URN)		3 hours			4-5 hours			
7	POC		1 hour			2 hours			
8	TRM		1 hour (limited)			3-4 hours (full with ID)			
9	MIC		1 hour (limited)			3-4 hours (full with ID/Sens; possibly Blood Gas/Flow/COAG/URN)			
10	Blood Gas		1 hour			1.5 hours			
11	Personnel files and competency assessments		1 hour			2 hours			
12	ANP/CYP		0.5 (FS only)			2 hours			
13	Example of Schedule								
14									
15			Monday		Tuesday		Wednesday		Thursday
16	Your Laboratory		11/30/2020		12/1/2020		12/2/2020		12/3/2020
17	Time (Central)		Path A	Path B	Path A	Path B	Path A	Path B	
18	7:00 AM								
19	7:30 AM				Lab	Point of Care			
20	8:00 AM		Opening Meeting		General	(Dr. Carter)			
21	8:30 AM				(Jean Hood)		Blood	Chemistry	Presumption
22	9:00 AM		Heme/Coag/UA (Stefanie Mitchell)	ANP (Dr. Phun)		(Mike Harris)	Bank (Dr. Vital)	(Jean Hood)	(Team only)
23	9:30 AM								
24	10:00 AM								
25	10:30 AM								Summation
26	11:00 AM				Micro	Flow			
27	11:30 AM					Cytometry			

<>☰

Instructions

AU List

Schedule

Director Assessment

Lab General

CHM

HEM

IMM

LSV

MIC

- Multipurpose tool for inspectors and laboratories includes:
  - Example inspection schedule for inspection planning purposes
  - Recommended average time expectations for document review by checklists

# Inspection Planning & Document Tracking Tool

continued

- Multipurpose tool for inspectors and laboratories
  - Requested documents for laboratories to upload listed on each checklist page
  - Provides space for inspectors to take notes

A	B	C	D
1 Lab Demographics			
2 Lab Name			
3 AU Number			
4 CAP Number			
5 Contact Name			
6 Contact Info			
7			
8 Category	Comments	Comments	Comments
9	PLEASE NOTE - Document Request must be for	PLEASE NOTE - Document Request must be for	PLEASE NOTE - Document Request must be for
10	camline nurseries only.	camline nurseries only.	camline nurseries only.
11 Quality Management Program			
12 Plan/Policy			
13 Monitors			
14 Minutes of Meetings			
15 Review of Effectiveness			
16 Evaluation of Non-conforming Events/Incidents			
17 Reports/Root Cause Analysis			
18 Correction of Laboratory Records Policy			
19 Terms of Accreditation			
20 Self Inspection			
21 Policy			
22 Completed Forms			
23 Evidence of corrective action			
24 Latest Physician/Client/Patient Satisfaction Survey			
25			
26 Specimen Collection Manual			
27			
28 Water Testing/Glassware			
29 Defining of specific type of water			
30 Procedure for cleaning of glassware			
31			
32 US Manual			
33 LIS Result Verification Records Initial and after major			
34 changes			
35 Autoverification Validation Initial and after major			
36 changes			

Requested Documents

Laboratory A

Laboratory B

Laboratory C

Inspector Notes/Comments Go Here for Each Laboratory

Instructions AU List Schedule Director Assessment Lab General CHM HEM IMM LSV MIC POC TRM URN On-sit

# SharePoint Site

- Implemented in late December
- Provides secure location for laboratories to upload their files
- Allows CAP to share uploaded files securely with inspection team
- Temporary solution during the modified inspections process

# SharePoint Site

## continued

This screenshot shows the SharePoint interface for a site titled "Test" (Private group). The breadcrumb navigation shows "Documents > 1/11/2021". The document list contains one item: "II # 123456, Laboratory Name", which is a folder. A blue callout box with the text "Click link with laboratory Name" has an arrow pointing to the document name.

SharePoint

Test  
Private group

Home + New Page details Published 11/23/2020 Edit

Conversations

Documents

Notebook

Pages

Site contents

Recycle bin

Edit

Documents > 1/11/2021 See all

+ New Upload Edit in grid view Sync Export to Excel All Documents\*

Name	Modified	Modified By
II # 123456, Laboratory Name	3 minutes ago	Adrienne Malta (s)

Click link with laboratory Name

This screenshot shows the SharePoint interface for the same "Test" site, but the breadcrumb navigation is "Documents > II # 123456, Laboratory Name > 1/11/2021". The document list contains three items: a folder "SU #9876543, Core Lab", a folder "SU #1234567, Lab General", and a file "II #123456, Laboratory Name.xlsx". A blue callout box with the text "Will take you to the next page with folders for each laboratory section" has an arrow pointing to the "SU #9876543, Core Lab" folder.

SharePoint

Test  
Private group

Home + New Page details

Conversations

Documents

Notebook

Pages

Site contents

Recycle bin

Edit

Documents > II # 123456, Laboratory Name > 1/11/2021 See all

+ New Upload Edit in grid view Share Copy link All Documents\*

Name	Modified	Modified By
SU #9876543, Core Lab	2 minutes ago	Adrienne Malta (s)
SU #1234567, Lab General	2 minutes ago	Adrienne Malta (s)
II #123456, Laboratory Name.xlsx	About a minute ago	Adrienne Malta (s)

Will take you to the next page with folders for each laboratory section

# SharePoint Site

## continued

- Within each section folder are additional folders for each document category where you can save your files

The screenshot shows a SharePoint site interface. At the top is a blue header bar with the 'COLLEGE of AMERICAN PATHOLOGISTS' logo, the text 'SharePoint', a search bar, and user settings. Below the header, the site title 'Virtual Inspections' is displayed with a clipboard icon and the text 'Private group'. To the right of the title are links for 'Not following' and '40 members'. A left-hand navigation pane contains links for 'Home', 'Documents', 'Pages', 'Recycle bin', and 'Edit'. The main content area shows a breadcrumb path: '... > AU ID [redacted] Laboratory > SU ID [redacted] Lab General'. Below the path are action links: '+ New', 'Upload', 'Edit in grid view', 'Share', 'Copy link', 'Download', and 'Export to Excel'. On the right of the action links are 'All Documents' and a refresh icon. A table lists the contents of the 'Lab General' folder:

Name	Modified	Modified By
DRA- Delegation of Functions	January 4	Carmen Rea (ns)
Instrumentation	January 4	Carmen Rea (ns)
LIS Manual	January 4	Carmen Rea (ns)
Quality Management Program	January 4	Carmen Rea (ns)
Reports	January 4	Carmen Rea (ns)
Safety	January 4	Carmen Rea (ns)
Water Testing Glassware	January 4	Carmen Rea (ns)

At the bottom left is the copyright notice '© Col'. At the bottom right, the date '12 January 2021' and a small icon are visible.

# Online Courses & Resources

- **For Inspectors and Laboratories**
  - [2020 Modified Inspection Processes](#) webpage
  - [Remote Review: How CAP Inspection Document Review Just Got Easier](#) podcast describing the CAP SharePoint site
- **For Inspectors**
  - [Performing Virtual Inspections: Being the CAP's "Eyes and Ears" from Home](#) supplemental training course
  - [Inspector Training and Tools](#) within e-LAB Solutions Suite
- **For Laboratories**
  - [Navigating Your Virtual Inspection: Demonstrating CAP Accreditation Compliance in an Electronic World](#) presentation

# Future Plans

- **Modifications to Organization Profile for laboratories to upload their requested documents during reapplication**
  - **Inspectors will be able to download inspector materials and view laboratory documents**
  - **Implementation will replace SharePoint site later this year**

# Contacts

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