December 7, 2018

Celeste Philip, MD, MPH
Surgeon General and Secretary
4052 Bald Cypress Way
Tallahassee, Florida 32399

Dear Dr. Philip:

Attached is our audit report # A-1718DOH-020, *County Health Departments' Ordering and Shipping of Clients' Lab Work*. This report summarizes our independent evaluation of the county health departments' compliance with laws, regulations, policies and procedures related to the ordering and shipping of clients' laboratory testing.

The audit was conducted by Ashlea Mincy, CIGA, and supervised by Mark H. Boehmer, CPA, Director of Auditing.

Management agreed with the findings identified in the report and has completed corrective actions on seven of 11 recommendations. We will provide you a status update in six months detailing the progress management has made toward addressing the remaining four proposed corrective actions included in Appendix A of this report.

If you wish to discuss this report, please let me know.

Sincerely,

Michael J. Bennett, CIA, CGAP, CIG
Inspector General

MJB/akm
Enclosure

cc: Eric Miller, Chief Inspector General, Executive Office of the Governor
Lisa Norman, Office of the Auditor General
Cindy Dick, MBA, CPM, Chief of Staff
Michele Tallent, Deputy Secretary for Operations
Paul D. Myers, Deputy Secretary for County Health Systems
Marsha Lindeman, ARNP, MSN, Assistant Deputy Secretary for Health
Carina Blackmore, DVM, PhD, Dipl ACVPM, State Epidemiologist, Director, Division of Disease Control and Health Protection
Patty Lewandowski, Chief, Bureau of Public Health Laboratories

FLORIDA DEPARTMENT OF HEALTH
OFFICE OF INSPECTOR GENERAL

COUNTY HEALTH DEPARTMENTS' ORDERING AND SHIPPING OF CLIENTS' LAB WORK

Report # A-1718DOH-020 • December 7, 2018

Purpose of this project:
Following a series of lost shipments of laboratory (lab) specimens from county health departments (CHDs) to the Department of Health's (Department, DOH) Laboratories, the Office of Inspector General (OIG) initiated this project related to ordering and shipping of clients' lab specimens due to the risk of Personally Identifiable Information (PII) and Protected Health Information (PHI) exposure when shipments are lost.

We wanted to review and evaluate processes used by CHDs to prepare and ship clients' lab specimens for testing. We also wanted to determine whether CHDs, to protect PII and PHI, use available systems to prepare labels with barcodes for clients' specimens when ordering and shipping lab work.

What we examined:
We observed on June 6 and June 8, 2018, the opening of a total of 78 shipments of lab specimens from 40 CHDs received at the Department's Jacksonville Laboratory (Laboratory).

Summary of Results:
We identified the following issues that management should address:

- CHDs included unnecessary PHI in shipments to the Laboratory.
- Specimen container labels that were printed from e-Lab included clients' PHI.
- Policies and procedures for specimen submission have not been developed.
- Some packages of lab specimens were not properly identified with UN 3373 labels.
- Lab specimens were not consistently shipped.
- CHD staff did not always appropriately affix labels so barcodes could be scanned at the Laboratories.
- Requisitions and specimen container labels were completed by hand and submitted via mail.

Additional details follow below. Final reports will include management's response in **Appendix A**.

BACKGROUND

The Bureau of Public Health Laboratories (BPHL), pursuant to Section 381.0202(1), *Florida Statutes* (*F.S.*), provides clinical and environmental lab services to the 67 counties for the protection of public health, with labs in Jacksonville, Miami, and Tampa.

CHDs' use of the Department's *Health Management System* (HMS) includes client registration, scheduling, care coordination, electronic lab test ordering, and test results. Each client's electronic medical record is maintained in HMS. The electronic lab test ordering and results function (e-Lab) in HMS was procured from Change Healthcare Solutions, LLC (vendor).

With proper use of the e-Lab function, an ordering provider electronically creates, modifies, and submits lab orders when a need for microbiological and chemical analyses is identified. The e-Lab creates an electronic requisition form and a specimen container label with corresponding

barcodes. The label is to be affixed to the specimen container. The creation of requisitions and labels in e-Lab, and affixing the label to the specimen reduces the need for clients' PHI in shipments to the Laboratories. There is no need for additional documentation in the shipment. The shipment would not include discernable client PII or PHI, should it be opened by someone other than authorized Laboratory staff. Upon receipt at the Laboratories, the barcode located on the label is scanned, providing staff access to the electronic order. Once lab testing is complete, providers can then access test results in e-Lab.

DETAILED RESULTS AND RECOMMENDATIONS

Criteria for the detailed results below, unless otherwise stated, include:

- All PII contained in the Department's records relating to an individual's personal health services is confidential. - Section 119.0712(1), *F.S.*
- The identity of a person upon whom a HIV test has been performed is confidential. - Section 381.004(2)(f), *F.S.*
- Personal information is defined as an individual's first name or first initial and last name in combination with data elements that include any information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnoses by a health care professional; or an individual's health insurance policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual. - Section 501.171(1)(g), *F.S.*
- The Department defines PHI as health information that contains information such that an individual person can be identified as the subject of that information. – DOH Policy (DOHP) 380-1-13, *Health Record Policy*.

BPHL offers voluntary *Infectious Substances Packaging and Shipping* training to hospital and CHD lab personnel. Staff from 51 CHDs attended the training between January 1, 2017 and June 1, 2018.

Our audit identified the following opportunities for improving effectiveness and efficiencies in operations:

1. CHDs included unnecessary PHI in shipments to the Laboratory.

- Sixty-one (61) of the 78 shipments (or 78%) we inspected sent from CHDs to the Laboratory included manifests and/or hard copies of the requisition forms in addition to the specimen containers' labels (See table at **Exhibit 1**). The information on the manifests and requisitions duplicated the information on the labels while also including the client age, gender, address, phone number, and insurance information.
- Including the client name, date of birth, and test description increases the likelihood that clients PHI will be disclosed in the event of a shipment being lost, damaged, or misdelivered. Also, the information listed above plus the client's addresses, phone numbers, insurance information, etc. could be used to commit identity theft.
- As discussed in Background above, printing a label with a barcode reduces the amount of PII and PHI needed in a specimen shipment to the Laboratories.

We recommend the Office of County Health Systems require CHDs use only labels with barcodes when shipping specimens to the Laboratories, except where paperwork, such as manifests and/or requisitions, is required.

2. *Specimen container labels that were printed from e-Lab included clients' PHI.*

- e-Lab labels attached to specimen containers shipped to the Laboratories included the client name, date of birth, test description (what is being tested for), requisition number, and collection date (See example at **Exhibit 2**).
- 42 *CFR*[1] 493.1241 provides that specimen labeling must include either "[t]he [client's] name or unique client identifier."
- HMS already assigns a unique identifier to registered clients, in most instances, that could be used on the e-Lab label. The client's PII and PHI could then be referenced in e-Lab, rather than being included in the shipment.
- Including the client name, date of birth, and test description increases the possibility clients' PII and PHI will be disclosed in the event of a shipment being lost, damaged, or misdelivered.
- Listing a client's name and date of birth on a label with a HIV test description increases the likelihood of violating Section 381.004(2)(f), *F.S.*

We recommend the Bureau of Clinic Management and Informatics in collaboration with BPHL evaluate the information included on the e-Lab labels. Information on the label should be minimized to the greatest extent possible, to protect the client's PII and PHI from improper disclosure.

3. *Policies and procedures for specimen submission have not been developed.*

- The Department has not developed and provided CHDs written uniform procedures for proper labeling, packaging, and shipment of specimens.
- 42 *CFR* 493.1242(a), requires that a laboratory establish and follow written policies and procedures for each of the following, if applicable:
  1. Client preparation.
  2. Specimen collection.
  3. Specimen labeling, including client name or unique identifier and, when appropriate specimen source.
  4. Specimen storage and preservation.
  5. Conditions for specimen transportation,
  6. Specimen processing.
  7. Specimen acceptability and rejection.
  8. Specimen referral.
- CHD staff may not properly label and package specimens for shipment to the Laboratories without written uniform procedures and sufficient training.
- It was brought to our attention blood spills have occasionally occurred when specimens are not properly packaged (See pictures at **Exhibit 3**).
- One shipment we inspected from a CHD included lab specimens and requisitions intended to be shipped to a private lab. Laboratory staff explained it is a common occurrence for CHDs to include shipments required to go to a private lab, in shipments to the Laboratory. Laboratory staff must then forward the requisitions and specimens to the private lab, resulting in inefficient use of staff time and increased cost.

[1] *Code of Federal Regulations*

- We identified the Department does not have a monitoring process to quickly identify possible lost shipments sent to, but not received by the Laboratory. These incidents are only identified when the ordering provider attempts to access the results.
- It is not clear whether the CHD sender or the Laboratories are responsible for completing an *Incident Report*.

We recommend the BPHL develop written uniform guidance regarding packaging and shipping in accordance with 42 CFR 493.1242(a). Additionally, we recommend BPHL and the Office of County Health Systems together develop a monitoring process so CHD shipments not received by BPHL are timely identified and reported.

4. Some packages of lab specimens were not properly identified with UN 3373 labels.

- 49 *CFR* 172.400(b) requires packages that contain hazardous materials, including infectious substances, be affixed with labels specified for the material. This identifies to handlers the package contains a Category B infectious substance, which could be either a diagnostic, clinical specimen, or biological substance.
- 49 CFR 173.199 requires shipments containing Category B infectious substances to be labeled on the outside of the package with a UN 3373 label (Example at **Exhibit 4**). This CFR also requires persons who ship such specimens to receive "General Awareness" hazardous materials training and "Infectious Substances" training. Those who prepare and ship specimens fitting the criteria for UN 3373 are required to know the requirements for proper transport.
- Packages we inspected from two CHDs did not include the required UN 3373 label on the outside of the package.
- The Department is subject to monetary penalties for failing to properly ship specimens without required labels. 49 CFR 107.329 explains each person who knowingly violates a requirement of Federal hazardous material transportation law is liable for a civil penalty up to $75,000 per violation. The penalty can be up to $175,000 per violation if the result is a serious illness.
- Laboratory staff were not aware of the responsibility to complete an *Incident Report* each time a noncompliant shipment is received.

We recommend the Office of County Health Systems develop requirements to help ensure CHDs properly label shipments of lab specimens, in accordance with 49 CFR 173.199.

We recommend BPHL staff prepare an Incident Report to notify Department management and the OIG each time a noncompliant shipment is received.

5. Lab specimens were not consistently shipped.

- 49 *CFR* 173.199 requires category B infectious substances to be packaged in a triple packaging consisting of a primary receptacle, a secondary packaging, and a rigid outer packaging. The primary receptacles must be packed in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. The secondary packaging must be secured in rigid outer packaging with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging. Absorbent material must be placed between the primary receptacle and secondary packaging when the substance is a liquid. The absorbent material must be of sufficient quantity to absorb entire

contents of the primary receptacles and not compromise the integrity of the cushioning material or the outer packaging. The triple packaging must be designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. The triple packaging must be capable of successfully passing the drop tests at a height of at least 1.2 meters (3.94 feet). Following the drop tests, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging.

- BPHL provided shipping units to CHDs to use when shipping specimens to the Laboratories (see example at **Exhibit 5**). These were tested to ensure compliance with 49 *CFR* 173.199. A unit is comprised of a metal cylinder to be placed in a cylinder made of rigid cardboard. The cylinders are secured with lids. The inner cylinder's lid is equipped with a rubber gasket ensuring an airtight and waterproof seal. The unit also includes absorbent material and cushioning placed in the inner cylinder. CHD staff need only remove the lids, place the specimen in the inner cylinder, and replace the lids to properly ship the specimens.
- Shipments from one CHD, including a Tuberculosis (TB) sputum culture, were not packaged in the shipping containers provided by BPHL (See **Exhibit 6**). A shipment we inspected on June 6, 2018, included the specimens packaged in the inner cylinder, but the rigid cardboard cylinder was not used. Another shipment we inspected June 8, 2018, included specimens packaged in specimen bags, which did not have sufficient absorbent material. Immediately upon our notification, the CHD directed its lab staff to exclusively use the units provided by BPHL.
- As previously mentioned in Finding 3, the Department has not developed and provided CHDs written uniform procedures for proper labeling, packaging, and shipment of specimens.

We recommend BPHL develop written procedures regarding packaging and shipping of specimens to comply with 49 CFR 173.199 requirements for Category B infectious disease specimens. We also recommend BPHL in collaboration with the Office of County Health Systems train all CHD employees responsible for packaging and shipping of Category B infectious disease specimens to ensure consistency.

6. *CHD staff did not always appropriately affix labels so barcodes could be scanned at the Laboratories.*

- e-Lab labels created and placed on the specimen containers were not always printed of a size and/or properly placed on the specimen container to allow scanning of the barcode.
- The Department has not specified the print size or proper placement of the label on the specimen container, so the barcode may be easily scanned by Laboratory staff. Some labels were either printed too small or wrapped around the specimen container covering parts of the barcode, making them unable to be scanned.
- Laboratory staff were forced to use magnification tools to determine the client's name and test(s) ordered, rendering the process inefficient and increasing the possibility of an error.

We recommend the Bureau of Clinic Management & Informatics collaborate with the Vendor to specify a minimum size for printing of barcodes to be scanned.

We recommend BPHL develop written procedures, which includes instructions regarding the agreed-upon minimum size and how to properly affix the label to the specimen container.

7. Requisitions and specimen container labels were completed by hand and submitted via mail.

- Some CHDs and community partners, when conducting community events (e.g., health fairs), submit requisitions and labels that are hand-written. These are sent directly to the Laboratories and not submitted via e-Lab, resulting in misspelled client names and information not written in a consistent format.
- Having to verify and input information for these requisitions and labels takes time away from processing those shipments with proper labeling. The process increases the possibility for error. Additionally, lab requisitions not submitted using e-Lab requires testing results be returned to the ordering provider via mail, increasing the risk client results will be compromised.
- BPHL has developed a web portal to accommodate providers unable to electronically prepare and submit lab orders using pre-printed labels with barcodes, and retrieve results via e-Lab. The web portal is in production and functional for both Ordering and Reporting as of May 26, 2018 and was being piloted.

We recommend that where CHDs submit lab specimens from community events, the Office of County Health Systems require CHDs submit all lab requisitions using e-Lab.

ADDITIONAL COMMENT

It was brought to our attention during the audit that in May 2018, BPHL changed the way reports of lab results were printed. This change resulted in the "attention to" field being removed from the mailing address. The result was that lab results reports were sent via mail to an address and not to the attention of a specific person, increasing the likelihood clients' results would be opened, viewed and passed around by individuals without a business need to know. Immediately upon being notified by recipients, BPHL reverted to the old system, correcting the issue.

SUBSEQUENT EVENT

The Office of Inspector General received an *Incident Report*[2] September 19, 2018, of a breach of PII and PHI. A TB specimen was collected by a CHD and shipped to the Laboratory in a shipping container. The specimen container was affixed with a label that included the client's name, date of birth, test description (what is being tested for), requisition number, and collection date. In addition to the label, the shipment included a hard copy of the requisition form with the client's age, gender, address, phone number, and insurance information (See example at **Exhibit 2**). Due to human error, the specimen container was not properly secured when preparing the shipping container. As a result, the shipping container arrived empty at the Laboratory, the specimen container and requisition form locations unknown. As identified in Findings 1 & 2 the client's PII and PHI may have been improperly disclosed.

[2] No. 20180919001

SUPPLEMENTAL INFORMATION

Section 20.055, *Florida Statutes,* charges the Department's Office of Inspector General with responsibility to provide a central point for coordination of activities that promote accountability, integrity, and efficiency in government.

Ashlea K. Mincy, CIGA, Senior Management Analyst II, conducted the audit under the supervision of Mark H. Boehmer, CPA, Director of Auditing.

Our methodology included reviewing applicable law, rule, policy, and operational procedures; inspecting shipments of specimens; and interviewing management and staff.

This audit was conducted in conformance with *International Standards for the Professional Practice of Internal Auditing*, issued by the Institute of Internal Auditors, as provided by Section 20.055(6)(a), *Florida Statutes*, and as recommended by Quality Standards for Audits by Offices of Inspector General (*Principles and Standards for Offices of Inspectors General*, Association of Inspectors General).

We want to thank management and staff in the Department's Bureau of Public Health Laboratories, the Office of County Health Systems, and the Bureau of Clinic Management and Informatics for their cooperation and assistance throughout the project.

Copies of all final reports are available on our website at **www.floridahealth.gov** **(search: internal audit**). If you have questions or comments, please contact us by the following means:

Address:
4052 Bald Cypress Way, Bin A03,
Tallahassee, FL 32399

Email:
inspectorgeneral@flhealth.gov

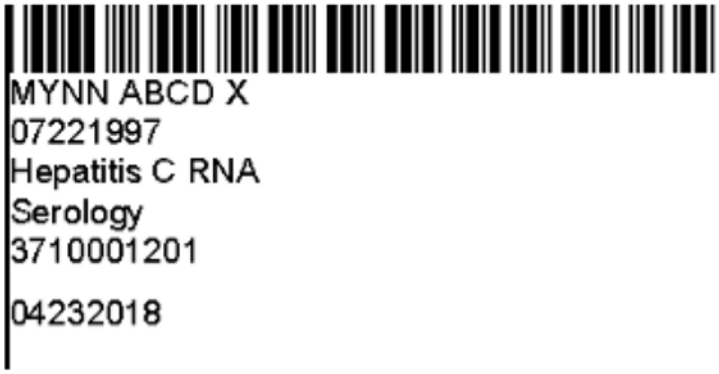
Phone:
850-245-4141

EXHIBIT 1

Shipment Observation

CHD	Total Observed	Included Manifests	Included Requisitions	Only Label and/or HIV Gold Form
Alachua	4		4	
Brevard	5	4	2	
Broward	2	1	1	
Charlotte	2		2	
Citrus	2	1	1	
Clay	2	2		
Collier	3	3	3	
Columbia	1	1	1	
De Soto	2			2
Escambia	1			1
Flagler	2	1		1
Gadsden	2		2	
Hardee	1		1	
Hendry	4	4	1	
Hernando	1		1	
Highlands	1		1	
Holmes	3	2	3	
Indian River	1		1	
Jackson	1	1	1	
Jefferson	1			1
Lake	4	3		1
Leon	2			2
Liberty	1			1
Manatee	1			1
Marion	1			1
Martin	1	1	1	
Miami-Dade	1	1		
Orange	7	1	2	5
Osceola	1		1	
Pasco	2	1	2	
Pinellas	2	1	1	
Polk	4	1	3	
Putnam	1		1	
Saint Lucie	1	1		
Santa Rosa	1			1
Seminole	1	1	1	
Sumter	1	1	1	
Union	2	1	2	
Volusia	1	1		
Wakulla	2		2	
Totals	**78**	**34**	**42**	**17**
Percentage of Shipments		**44%**	**54%**	**22%**

EXHIBIT 2



Specimen Container Label

BUREAU OF LABORATORIES-JAX

Account #: **020100** Req #: **3710001201**

Requisition
(Bill to THIRD PARTY)

020100 Central Health Clinic
2585 Merchants Row Boulevard
Tallahassee, FL 32399
(850)555-1212

Patient Information
MYNN, ABCD X JR
123 Happy Rd
Saint Petersburg, FL 33701
(727)323-5555

Collection Date: **4/23/2018 14:45EDT**
Lab Reference #: Fasting:
Ref Physician: **Eileen M Bray**
Ref Physician #: **1114108404**
U.P.I.N:
Physician NPI: **1114108404** Prepaid:
Call Results to:
Fax Results to: ☐ **STAT**

Patient ID: **5296183141**
DOB: **7/22/1997** Age: **20** Sex: **Female**

Guarantor: **Self** DOB: **7/22/1997** Phone: **(727)323-5555**
ABCD X MYNN
123 Happy Rd
Saint Petersburg, FL 33701

Primary Ins: **Self**	Secondary Ins: **Self**	Tertiary Ins: **Self**
ABCD X MYNN	**ABCD X MYNN**	**ABCD X MYNN**
123 Happy Rd	**123 Happy Rd**	**123 Happy Rd**
Saint Petersburg,FL 33701	**Saint Petersburg,FL 33701**	**Saint Petersburg,FL 33701**
(727)323-5555	**(727)323-5555**	**(727)323-5555**
DOB: **7/22/1997**	**7/22/1997**	**7/22/1997**
Policy #: **123121111**	**123235447587**	**3647567567**
Group #:		
Bill Code: **DEFAULT**	**DEFAULT**	**DEFAULT**
AMERIGROUP MCD HMO 61010	**AAA LIFE INS CO 1000**	**MEDICAID**
Attn Medicaid Claims	**Accident Claims**	**Po Box 7072**
Virginia Beach,VA 23466	**Lake Mary,FL 32746**	**Tallahassee,FL 32314**

TEST CODE/DESCRIPTION		DIAGNOSIS CODES
	Serology	
1) **0390**	**Hepatitis C RNA**	***A06.0**

Pregnancy Status:	
Date of Onset Symptoms:	
Special Project:	
Fasting Indicator:	
Priority:	
Specimen Source:	**Blood arterial**
Specimen Type:	**Blood**
Special Handling:	

Requisition

EXHIBIT 3

Example of a shipment that lacked sufficient amount of absorbent material, and the primary and secondary packagings were not leak proof.

Insufficient cushioning resulting in broken primaries.

*Photos provided by BPHL.

EXHIBIT 4

Proper UN 3373 label*

Incorrectly sized UN 3373 label*

Boxes not properly labeled*

*Photos provided by BPHL.

EXHIBIT 5

Shipping Unit*

Components of one Shipping Unit*

*Photos provided by BPHL.

EXHIBIT 6

Shipment of TB specimens not shipped in a Shipping Unit provided by BPHL.

APPENDIX A: MANAGEMENT RESPONSE

	Recommendation	Management Response
1	*We recommend the Office of County Health Systems (CHS) require county health departments (CHD) use only labels with barcodes when shipping specimens to the Laboratories, except where paperwork, such as manifests and/or requisitions, is required.*	We concur. Management action completed. In partnership with CHS, the Bureau of Public Health Laboratories (BPHL) has determined it can develop a more user-friendly protocol or Standard Operating Procedure (SOP) regarding packaging and shipping in accordance with 42 Code of Federal Regulations (*CFR)* 493.1242(a). A draft copy of said SOP was provided, via email, to the Office of Inspector General (OIG) by the BPHL on Tuesday, October 16, 2018. With a more robust SOP in place, CHS and BPHL agreed to partner to ensure standards are communicated and adhered to, and that appropriate training is available for all relevant CHD personnel. *Contact:* Beth A. Paterniti *Anticipated Completion Date:* N/A (Completed)
2	*We recommend the Bureau of Clinic Management and Informatics in collaboration with BPHL evaluate the information included on the e-Lab labels. Information on the label should be minimized to the greatest extent possible, to protect the client's Personally Identifiable Information (PII) and Protected Health Information (PHI) from improper disclosure.*	We concur. BPHL has reviewed the finding and determined BPHL can still meet federal regulations while minimizing patient PHI included on the e-Lab labels. BPHL contacted the Bureau of Clinic Management and Informatics to request removal of patient names on the e-Lab labels. *Contact:* Tom Herring *Anticipated Completion Date:* April 15, 2019
3.1	*We recommend the BPHL develop written uniform guidance regarding packaging and shipping in accordance with 42 CFR 493.1242(a).*	We concur. Management action completed. BPHL created a SOP for packaging and shipping in accordance with 42 *CFR* 493.1242(a). *Contact:* Patty Lewandowski *Anticipated Completion Date:* N/A (Completed)
3.2	*Additionally, we recommend BPHL and CHS together develop a monitoring process so CHD shipments not received by BPHL are timely identified and reported.*	We concur. BPHL created a SOP for packaging and shipping regarding packaging and shipping in accordance with 42 *CFR* 493.1242(a), including policies and procedures for specimen submission. Monitoring Process: • CHDs will include a redacted manifest in each shipment, track each package, and verify receipt by delivery confirmation. • BPHL must provide to the courier one all-inclusive signature for all packages delivered for one shipment/delivery. After receipt of packages, BPHL will reconcile for every package by reviewing the tracking number list provided at shipment along with the included manifest. For any missing packages, BPHL will promptly notify the CHD. *Contact:* Patty Lewandowski *Anticipated Completion Date:* December 31, 2018

4.1	*We recommend the CHS develop requirements to help ensure CHDs properly label shipments of lab specimens, in accordance with 49 CFR 173.199.*	We concur. Management action completed. In partnership with CHS, BPHL determined it can develop a more user-friendly protocol or SOP regarding packaging and shipping in accordance with 42 *CFR* 493.1242(a). A draft copy of said SOP was provided, via email, to the OIG by the BPHL on Tuesday, October 16, 2018. With a more robust SOP in place, CHS and BPHL agreed to partner to ensure standards are communicated and adhered to, and appropriate training is available for all relevant CHD personnel. *Contact:* Beth A. Paterniti *Anticipated Completion Date:* N/A (Completed)
4.2	*We recommend BPHL staff prepare an Incident Report to notify Department management and the OIG each time a noncompliant shipment is received.*	We concur. Management action completed. BPHL will prepare an Incident Report to notify Department management and the OIG each time a noncompliant shipment is received that would constitute a potential risk or harm to the recipient of the packages. Additionally, BPHL will track and tally other noncompliant shipments and provide this information to the originating entity for training or re-training purposes. *Contact:* Patty Lewandowski *Anticipated Completion Date:* N/A (Completed)
5.1	*We recommend BPHL develop written procedures regarding packaging and shipping of specimens to comply with 49 CFR 173.199 requirements for Category B infectious disease specimens.*	We concur. Management action completed. BPHL created a more user-friendly guidance or SOP regarding packaging and shipping in accordance with 42 *CFR* 493.1242(a), with policies and procedures for specimen submission, as well as procedures regarding packaging and shipping of specimens, to comply with 49 *CFR* 173.199 requirements for Category B infectious disease specimens. *Contact:* Patty Lewandowski *Anticipated Completion Date:* N/A (Completed)
5.2	*We also recommend BPHL in collaboration with CHS train all CHD employees responsible for packaging and shipping of Category B infectious disease specimens to ensure consistency.*	We concur. BPHL will provide limited training to CHD staff responsible for packaging and shipping of Category B infectious disease specimens. BPHL is awarded funding from the Public Health Emergency Preparedness grant to provide this training to sentinel laboratory staff and will allow CHD staff to attend when there are available slots. Additionally, BPHL will provide information regarding online training that is available for all CHD staff responsible for packaging and shipping of Category B infectious disease specimens. *Contact:* Patty Lewandowski *Anticipated Completion Date:* April 15, 2019

6.1	*We recommend the Bureau of Clinic Management & Informatics collaborate with the Vendor to specify a minimum size for printing of barcodes to be scanned.*	We concur. Management action completed. BPHL created a more user-friendly guidance or SOP regarding packaging and shipping in accordance with 42 *CFR* 493.1242(a), with policies and procedures for specimen submission, as well as procedures regarding packaging and shipping of specimens, to comply with 49 *CFR* 173.199 requirements for Category B infectious disease specimens. *Contact:* Patty Lewandowski *Anticipated Completion Date:* N/A (Completed)
6.2	*We recommend BPHL develop written procedures, which includes instructions regarding the agreed-upon minimum size and how to properly affix the label to the specimen container.*	We concur. Management action completed. BPHL created a more user-friendly guidance or SOP regarding packaging and shipping in accordance with 42 *CFR* 493.1242(a), with policies and procedures for specimen submission, as well as procedures regarding packaging and shipping of specimens, to comply with 49 *CFR* 173.199 requirements for Category B infectious disease specimens. *Contact:* Patty Lewandowski *Anticipated Completion Date:* N/A (Completed)
7	*We recommend that where CHDs submit lab specimens from community events, CHS require CHDs submit all lab requisitions using e-Lab.*	We concur. After review of the report and follow up with BPHL, it is unclear if there are sufficient tools in place to facilitate the mandatory use of e-Labs for CHDs' submission of lab specimens from community events. BPHL developed a web portal to accommodate providers unable to electronically prepare and submit lab orders using pre-printed labels with barcodes, and retrieve results via e-Lab. The web portal is in production and functional for both Ordering and Reporting as of May 26, 2018, and was being piloted. CHS has met with the Office of the Deputy Secretary for Health on the findings of this report and requested a formal review and status update on the implementation of the web portal in production. A follow up meeting is scheduled between CHS, BPHL, and the Assistant Deputy Secretary for Health in early December 2018. *Contact:* Beth A. Paterniti *Anticipated Completion Date:* January 31, 2019