

## Laboratory Diagnostics - Appendix 6

### Surge Capacity Plan for Specimen Receipt and Disposal

#### Specimen Receipt

All specimens submitted to the PHEL are accessioned by the Specimen Receiving Laboratory. PHEL currently uses a software program called “Harvest”, a product of Orchard Corporation, as a tool to record samples as received by the institution and as a vehicle to send reports to submitters and relevant parties, eg. Communicable Disease Service.

The Specimen Receiving Unit is currently staffed by 14 individuals who are responsible for sample accessioning and data entry. To meet workload demands during a pandemic the director of the Public Health Laboratory could reassign staff to this unit as conditions warrant.

#### Specimen Disposal

Current PHEL policy dictates that samples be archived for 90 days after which time they are discarded according to policies/standard operating procedures established by the division. Included is a document entitled “Sample Storage and Retrieval Policy” which outlines specimen retention times. Please find attached the current Autoclave Policy authored by the QAP for the general manner in which all autoclavable material is to be treated. In addition please find attached QC Requirements for Autoclave Runs” as a protocol and containing detailed criteria for all facets of sterilization of waste material, including samples being discarded. All laboratory personnel have been trained in the operation of the autoclaves.



**To:** Distribution Listserv  
**From:** Rose Ann La Fisca  
Director, Office of Policy, Planning and Regulatory  
Compliance  
Public Health and Environmental Laboratories (PHEL)  
**Date:** November 14, 2006  
**Subject:** Sample Storage Policy (REVISED)

# MEMO

## Laboratory Diagnostics - Appendix 6 – Attachment A

### Sample Storage and Retrieval Policy

Effective January 1, 2007, Public Health Laboratory Services (PHLS) will appropriately retain positive isolates for no more than ninety (90) days after final identification in programs that historically have currently been holding them for two (2) years. Retention of specimens for longer periods of time is permitted when part of a special project or when they possess unique biochemical/morphological/molecular characteristics or antibiotic patterns of interest or value to a particular laboratory program.

Programs with retention times dictated by state and/or federal regulations or agency Memoranda of Agreement should advise this office regarding these specific requirements and maintain compliance with same.

To ensure standardization, the Quality Assurance Program (QAP) is available to guide laboratory program supervisors in the development of a system for sample retention, retrieval and disposal. A high-quality sample storage protocol must provide appropriate environmental conditions, security, convenient tracking and methodical disposition of outdated materials. Stored samples must be clearly labeled with a unique identifier and careful documentation maintained regarding their exact location and any subsequent movement of the sample for reasons of retrieval, disposition and/or chain of custody. A disposition schedule must be created, assigned to staff, either on a standing or rotational basis, and enforced by the laboratory supervisor to eliminate needless storage in the Division.

The laboratory should maintain chain of custody where appropriate, including food samples, from the time of receipt in the laboratory. If the laboratory uses a sample submitted for testing in its entirety, this fact should be documented on the worksheet.

The walk-in freezer (B8), located in the basement of the laboratory building, has been designated for storage for the PHLS. One person and one backup individual from Microbiology, Virology and Clinical Services must be designated as "gatekeeper" to manage access and chain of custody on the stored materials. All plans for use of this freezer must include a sign in and sign out requirement for deposition, retrieval or disposal of specimens.

Each program must provide updated storage/retrieval plans to the QAP in accordance with the initial "Sample Storage and Retrieval Policy" issued June 6, 2005 and provide them to Sr. Management Assistant Sandy Rice, of this office. **Updated plans will be reviewed for completeness by the QAP and approved by the PHLS Director. Once the specimen storage and retrieval plan is approved it must immediately be provided to the technical staff for implementation by the effective date of this policy.**

**Include this policy in your Standard Operational Procedures Manual**

## Laboratory Diagnostics - Appendix 6 - Attachment B

### QC Requirements for Autoclave Runs

1. **Materials Needed for Autoclave run QC**
2. **QC Criteria for Autoclave runs with the New Package Insert for the Biological Indicators**
3. **Instructions for Biological Indicator Card**
4. **Incubation of Biological Indicators**
5. **Acceptable QC Results**
6. **Documenting QC Readings-** QC for Chemical Integrator, Sterilizer Tape, and Maximum Read Thermometer and Biological Indicator BT Sure QC Forms
7. **Room Location for 24 Hour Hold of Sterilized Autoclave Material**

#### 1. Materials Needed:

- BT Sure Biological Indicators
- 3M™ Comply™ SteriGage™ Steam Chemical Integrators
- Calibrated Maximum Read Thermometer
- Autoclave tape (Sterilizer tape)
- Petri dish, beaker, etc.
- Erlenmeyer flask

#### 2. QC Criteria for Autoclave runs with the New Package Insert for the Biological Indicators

- Biological indicators, steam chemical integrators, autoclave tape, and maximum read thermometer will be used as QC measures. Biological indicators, chemical steam integrators, and autoclave tape will be referred to as a QC set in this document.
- Biological indicators and steam chemical integrators are to be placed in a container, e.g. Petri dish, beaker, etc. The container used must be the container that has been validated in your autoclave validation. Make sure that the biological indicators are placed in a horizontal position.
- **Note:** It has been observed that a beaker with a small opening does not give acceptable results because the air gets trapped. A Petri dish will give the best results, but if a beaker with a small opening is used for the validation then it must also be used for a run on a normal working day. It is recommended that if a beaker is used that it must be a large beaker, i.e. at least 250ml.
- A piece of autoclave tape must also be included; this can be placed across the opening of the container being used.
- In addition, a calibrated maximum read thermometer must be placed in a large erlenmeyer flask (at least 1000ml) filled quarter to halfway with water with each autoclave run. Make sure to take the reading of the maximum read thermometer 5 minutes after it has been placed at room temperature. After taking the reading, the maximum read thermometer must be shaken down before the next run.
- In accordance with the new package insert for the BT Sure Biological Indicators, it is recommended that at least two biological indicators be used per cycle.
- Therefore, for an autoclave run the above mentioned QC set will be placed in 2 different locations in the autoclave along with the maximum read thermometer:
  - One QC set will be placed near the drain.
  - A second QC set will be placed next to the materials being autoclaved, e.g. if an autoclave bag is placed in a metal container, then place the QC set next to the metal

## Laboratory Diagnostics - Appendix 6 - Attachment B

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## Laboratory Diagnostics - Appendix 6 - Attachment B

- container. If a metal container is not used the QC set must be placed in the center of the materials being autoclaved. Do not place the QC set inside the metal container or an autoclave bag.
- Label all QC sets with the location prior to placing them in the autoclave, e.g. near the drain and next to the load.
  - Since the load can not be released for discard or re-use until the 24 hr observation reading for the biological indicators is completed and deemed acceptable you must assign the load a unique ID# so it can be tracked. Assign the load a unique ID#. The **Load ID#** consists of the following: **autoclave unit ID – MMDDYY – load#**, where “MM” is the month, “DD” is the day, and “YY” is the year. **Autoclave unit ID:** this is the new assigned ID # for your autoclave listed in Appendix #1 of this document. **Load #:** since there might be more than one load per day, the first load of the day will be labeled “A”. If a second load is processed on the same day using the same autoclave, the load # will be “B”. The next day’s load would start with A again, then B, then C etc.
  - An example of a Load ID# is, from autoclave #1, on November 05, 2006, first load of the day = 01-110506-A. If a second load is processed on the same day using the same autoclave the Load ID # would be 01-110506-B. The next day’s load would start with A again, then B, then C etc.
  - All contents should be tagged with this ID and it should be recorded on the appropriate QC forms discussed below.

### 3. Instructions for Biological Indicator Card

- A separate card must be filled out for each biological indicator before it is placed in the autoclave.
- The following information must be recorded on the Biological Indicator card:
  - Autoclave Number** = the assigned number of your autoclave
  - Run Date** = the date of the run
  - Lot #** = lot# of the biological indicator
  - Expiration Date** = expiration date of the biological indicator
  - Time** = sterilization time of the cycle in minutes, e.g. 60min
  - Temp (°C)** = record the temperature that has been set for your autoclave, e.g. 121°C
  - Pressure (PSI)** = record the pressure that has been set for your autoclave, e.g. 15psi
  - Tech** = the initials of the tech performing the autoclave run**In addition**, document the cycle type, the location of the biological indicator, and the load ID# somewhere on the card.
- **NOTE:** The cards for each BI must be retained by the Special Bacteriology staff for at least 2 years.

### 4. Incubation of Biological Indicators

- After sterilization, all biological indicators with the biological indicator cards, completely filled out, must be taken to Special Bacteriology Laboratory (L-429) for incubation immediately, with the exception of Modular Facility autoclave material.
- Take an unsterilized BI also for each autoclave run. Make sure that this BI has the same lot# and expiration date as the autoclaved BIs.

## Laboratory Diagnostics - Appendix 6 - Attachment B

- **NOTE:** Do not crush the glass ampoule; this will be done by the laboratory staff in Special Bacteriology.
- **NOTE:** Do not place the BIs in the incubator; give them to staff in Special Bacteriology Laboratory or leave them on their bench.

### For Special Bacteriology Laboratory:

- After sterilization, the contents of the biological indicator are hot. Always allow the biological indicator to cool for at least 10 minutes before crushing the glass ampoule inside.
- Once the biological indicator is cooled, crush the glass ampoule inside by squeezing the bottom of the biological indicator.
- An unsterilized biological indicator will serve as the positive growth control; also crush the glass ampoule of this control biological indicator.
- Make sure that all biological indicators used during the sterilization run and the ones used for the control are from the same lot #.
- Immediately after crushing the BIs, incubate all biological indicators from each sterilization run in addition to an unsterilized biological indicator between 55°C to 60°C for 24 hours.
- **NOTE:** If BIs from several runs are incubated at the SAME time, only one unsterilized BI should be used as the positive growth control. However, if BIs from autoclave runs are incubated at different times then one unsterilized BI must be included for each time.
- Record the result after 24 hours on the “Biological Indicator (BT Sure)” QC form. Do not incubate the biological indicators for 48 hrs.
- **NOTE:** Biological Indicators must be autoclaved before disposal.
- The laboratory to which the autoclave load belongs will be notified of the 24 hour result of the biological indicator by the laboratory staff in Special Bacteriology. The load can not be released for discard or re-use until the 24 hr reading of the biological indicators is completed and deemed acceptable.

### 5. Expected QC Results

**Steam Chemical Integrator-** A black line that crosses the acceptable range area on the indicator strip.

**Maximum Read Thermometer-** Temperature equal to or above 121°C.

**Pressure-** Reading  $\geq$  15psi.

**Autoclave Tape (Sterilizer Tape Result) -** Heat sensitive tape which exhibits a change in color after adequate exposure to sterilization process.

**Autoclaved BI (Biological Indicator from the Sterilization run) -** Color remains purple after 24 hour incubation.

**Unsterilized BI (Control BI, positive growth control) -** Color changes from purple to yellow after 24 hour incubation.

For any unacceptable QC results consult the Quality Assurance Program.

### 6. Documenting QC Readings

- The reading from the maximum read thermometer must be taken 5 minutes after it has been placed at room temperature.
- The steam chemical integrators, autoclave tapes, and the temperature from the maximum read thermometer are to be read after the autoclave run is completed.

## Laboratory Diagnostics - Appendix 6 - Attachment B

- Record results on the QC form, “**QC for Chemical Integrator, Sterilizer Tape, and Maximum Read Thermometer**”.
- For an autoclave run you will document two steam chemical integrator and autoclave tape results on two separate rows.

**Autoclave Number** = the assigned number for your autoclave (Appendix #1)

**Autoclave Location** = the floor where autoclave is located and the laboratory using it.

**Sterilizer Run Date** = the date of the run

**Sterilizer Run Time (min)** = sterilization time of the Cycle being used

**Pressure (PSI)** = record the pressure that has been set for your autoclave, e.g. 15psi

**Temp (°C)** = record the temperature that has been set for your autoclave, e.g. 121°C

**Chemical Integrator Lot Number** = the Lot # of the steam chemical integrator

**Chemical Integrator Exp. Date** = the expiration date of the steam chemical integrator. The first 4 numbers of the lot# are for the year and the next 2 numbers following that are for the month. The last 2 letters of the lot# do not pertain to the expiration date. An example of the lot# and expiration date is: Lot# =201011AG, Exp. Date =11/2010.

**Chemical Integrator Result** = a black line that crosses the acceptable range area on the indicator strip is an acceptable result. Refer to the “Result” legend on the bottom of the form on how to record this result.

**Sterilizer Tape Result** = heat sensitive tape which exhibits a change in color after adequate exposure to sterilization process is an acceptable result. Refer to the “Result” legend on the bottom of the form on how to record this result.

**Max Read Thermometer Temp. (°C)** = record the actual temperature from the maximum read thermometer.

**Tech Initials** = initials of the person recording the information; must be the same person who did the run on the autoclave.

**Comments** = Additional information about the steam chemical integrators will be documented here. Since the sterilizer run time is being documented in the respective column, in the comments column you will have to write the type of cycle, the location of the steam chemical integrator, and the load ID# for that sterilizer run time. Additional comments can also be written here, e.g. if a QC was out of range you can write “Quality Event Form” filled out.

- The steam chemical integrators and the autoclave tapes from the runs are to be saved by stapling or taping them on a sheet of paper. In addition, the autoclave printout from each run needs to be saved by stapling it to this sheet of paper; it can be printout can be torn off, otherwise save the roll of tape. The autoclave printout from each run must be labeled with the load ID# and initialed and dated with the current date. The following information must be included on this sheet of paper: **locations of the QC set, type of cycle, the load ID#, the date of the run, and initials and date** of the person recording the information. This must be the same person who did the run on the autoclave.

## Laboratory Diagnostics - Appendix 6 - Attachment B

- The Biological Indicator QC will be recorded on the "**Biological Indicator BT Sure**" QC Form.

**BI Lot#** = this is the lot# of the biological indicator. The lot# must be checked for each BI before recording the QC on the form. Since the BIs are ordered in a large quantity and the lot# of the BIs is mostly the same for each shipment, the lot# doesn't have to be written each time. However, when recording the QC for the BI, check the lot# of each BI to make sure it is the same as the lot# that has been already documented on the QC log. If the lot# is not the same as the one documented, record the QC on a new Biological Indicator BT Sure" QC Form.

**BI Expiration Date** = this is the expiration date of the biological indicator.

**Autoclave Location/Unit ID#** = Autoclave Unit ID# is the assigned number for your autoclave, refer to Appendix #1 (Autoclave Unit ID#). Autoclave location refers to the floor where the autoclave is located.

**Laboratory** = the name of your laboratory

**Run Date** = the date of the autoclave run.

**Load ID#** = assign the load a unique ID#: (autoclave unit ID – MMDDYY – load).

**Incubation Time (In and Out)** = this is the incubation time for the BI. The BI must be incubated immediately after it is crushed.

**“In”** is the actual time that the biological indicator was placed in the incubator for incubation. **“Out”** is the actual time the biological indicator was taken out of the incubator. The incubation time (in and out) must be 24 hour time frame.

**Autoclaved BI Result** = expected reaction is color remains purple after 24 hour incubation. Refer to the “Expected Reaction” legend on the bottom of the form on how to record this result. Since the package insert for the biological indicators has been revised by the manufacturer, only a reading after 24 hrs incubation is required. There are two locations for the biological indicators, **Location 1** is for the BI placed near the load, **Location 2** is BI placed near the drain.

**Unsterilized BI Result** = This is the control BI. Expected reaction is color changes from purple to yellow after 24 hour incubation. Refer to the “Expected Reaction” legend on the bottom of the form on how to record this result. Since the package insert for the biological indicators has been revised by the manufacturer, only a reading after 24 hrs incubation is required.

**QC/Test Assessment** = This is the assessment of both autoclaved and unsterilized (control) biological indicators. The QC/Test Assessment is “Acceptable” when the autoclaved and unsterilized BIs yield the expected results. The QC/Test Assessment is “Unacceptable” if any BIs do not yield the expected results.

**Tech Initials/Date** = initials and date of the person recording the results for the BIs after 24 hours.

**Comments** = Additional information about the biological indicators will be documented here. Additional comments can also be written here, e.g. if a QC was out of range you can write “Quality Event Form” filled out.

## Laboratory Diagnostics - Appendix 6 - Attachment B

### 7. Room Location for 24 Hour Hold of Sterilized Autoclave Material

Since the sterilized load can not be released for discard or re-used until the 24 hr observation reading for the biological indicators is completed and deemed sterile, these are the following room locations to hold the sterilized autoclave material:

- 1<sup>st</sup> Floor- L-118
  - 2<sup>nd</sup> Floor- L-229B? (Need to Discuss)
  - 3<sup>rd</sup> Floor- L-307
  - 4<sup>th</sup> Floor- L-438
  - 5<sup>th</sup> Floor- L-518
- 
- The sterilized autoclave material in the Modular Facility will be saved in a designated area in the Modular facility.

**NOTE:** The laboratory to which the autoclave load belongs will be notified of the 24 hour result of the biological indicator by the laboratory staff in Special Bacteriology via email. The load can only be released for discard or re-use after the 24 hr observation reading for the biological indicators is completed and deemed acceptable. If the 24 hour reading is not acceptable, do not release the load, contact QAP. The current package insert for the BI will be provided by email and subsequent updated package inserts will be provided by QAP.



**Attestation Statement**

Laboratory: \_\_\_\_\_

**QC Requirements for Autoclave Runs**

I acknowledge that I have read the “QC requirements for autoclave runs” in its’ entirety and I fully understand and will perform the practices outlined in this document.

Employee Name	Signature and Date
1.	
2.	
3.	
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12.	
13.	
14.	
15.	

Laboratory Diagnostics - Appendix 6 - Attachment B



Autoclave Unit ID#

Autoclave Unit ID	Location: H&A	Model	Program User / Load type
#1	5th floor, Rm 522	Amsco 3034S	TB, BT
#2	5th floor, Rm 528	LBR	TB back up, Virology, BT/MDS
#3	4th floor, Rm 438	LBR	STD, Enterics, Special Bacteriology, Special Immunology, and Sanitary Bacteriology
#4	3rd floor, Rm 301	Amsco 3021	Glassware
#5	3rd floor, Rm 301	Amsco 2351	Glassware
#6	3rd floor, Rm 301	Amsco 2351	Media
#7	3rd floor, Rm 307	LBR	Trash
#8	3rd floor, Rm 330	Amsco 3024 C ISO	Media
#9	2nd floor, Rm 230	Amsco 3021	West Nile, HIV, Specimen Services, Clinical Services
#10	2nd floor by cage washer	24x36 x36 To be installed	Trash
#11	1st floor, Rm 118 (Agriculture)	LBR 2038	Media Not Applicable for PHLS
#12	1st floor, Rm 118 (Agriculture)	LBR 2460	Trash
#13	BSL-3 Mod Lab	Steris Amsco Renasissance Reman 3023	BT
#14	Mod Lab	Portable R2D2	BT

**NOTE: Please use this table as a reference to document the Autoclave Unit ID#/Autoclave # on the QC forms used to document QC for the autoclaves, e.g. "Biological Indicator BT Sure", "QC for Chemical Integrator, Sterilizer Tape, and Maximum Read Thermometer", Biological Indicator Card, etc.**