Tammy Theisen, BT MT(ASCP)
Saginaw County Health Department
Laboratory Director

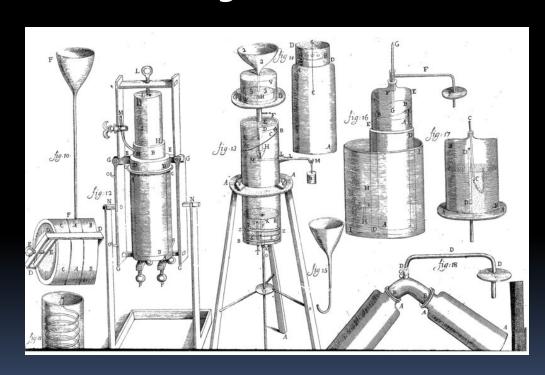
### IS THIS AUTOCLAVE WORKING?

### Today's Agenda

- History of steam sterilization
- Autoclave basic knowledge
- Biological Indicators
- Record keeping
- Tips
- Meeting the regulations with SCHD Mail-In Spore Program

## What's an Autoclave? Is it....

a bone digester



or



an Instapot??



### Ancient history

• 1450 B.C. Moses (or whomever) wrote in the books of Leviticus, Numbers and Deuteronomy the first sanitary code, involving the purification of materials by fire and boiling water. Later, around, 460-377 B.C., Hippocrates poured boiling water onto surgical instruments to clean them.





### More recent history

- 17<sup>th</sup> Century steam pressure cooker:
  - invented in 1681 by Denis Papin (1647-1712)
    - a physicist
    - one of the inventors of the steam engine
  - Bone digester
  - It was used solely for culinary reasons
- The current design of the autoclave;
  - finalized in the 1880s by Charles Chamberland
  - building up on Denis Papin's bone digester.



How it works

### Autoclave basics

- Uses steam under pressure
- High pressure enables high temperature
- Steam at 100°C has almost 7 times more heat than boiling water.
- Steam must achieve constant pressure



### How does it sterilize?

- Moist heat kills microorganisms
  - Coagulation of essential proteins
  - Vibratory motion in molecules destroy hydrogen bonds
- Sterilization requires time/temperature





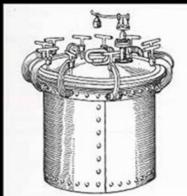




















Evolution of the Autoclave

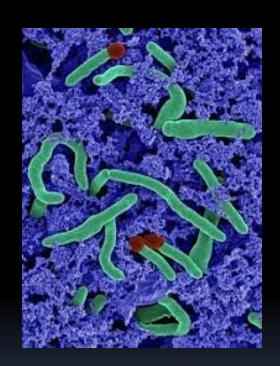
### How do I know if it's working?

**Biological Indicators** 

# What is a Biological Indicator (BI)?

- Test the system
  - Viable spores that are tough to kill
  - Geobacillus stearothermophilus and Bacillus atrophaeus





## Different Types of Biological Indicators



These are ampules that contain spores suspended in liquid



Spores that are attached to a paper strip. The dry strips are sent easily in the mail.



Other than it's the law...

### Why use BI's

Oshawa tattoo shop used dirty tools (2007)

- Health authorities suggested approximately 2,000 people to get tested for HIV, Hepatitis and ....
- Shop was closed until corrections were made
- Problem, a screw needed adjustments







https://www.thestar.com/news/gta/2007/08/10/oshawa\_tattoo\_shop\_used\_dir tv\_tools.html

https://toronto.citynews.ca/2007/08/10/health-inspectors-issue-tattoowarning-in-oshawa/

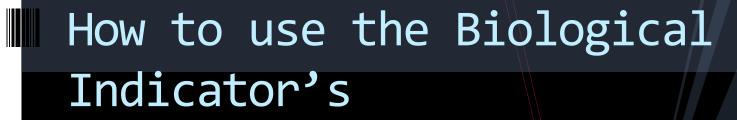
### Why use BI's

## Tattooist banned for using dirty needles (2016)

- A tattoo artist that used dirty needles has been banned by a judge from ever working again.
- Over 800 customers were tested for HIV and hepatitis B and C.
- The tattoo artist was banned from ever working in his profession again, slapped with a \$24,000 fine and handed a 16-week suspended jail term.
  - https://www.aspokesmansaid.com/shopping/stories/content-1o66o/tattooistbanned-for-using-dirty-needles







SCHD Procedure

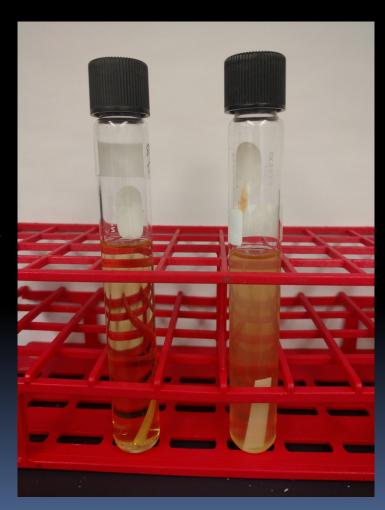
### Spore Strip Process/Procedure

- Storage
- Use spore strip(s) with a full load
- Do not open the glassine packet
- Place packet in most difficult area to be sterilized (center)
- Run sterilizer following your SOP
- Document information
- Mail in spore strip

### What happens at the Lab







### Test Report





## Record Keeping: Manufacturer's procedures



2010 PA 375; MCL 333.13101 et seq Section 15.1.8 of Requirements for Body Art

## Record Keeping: Monthly Results:

SAGINAW COUNTY HEALTH DEPARTMENT

1600 N. MICHIGAN AVENUE, ROOM 102 SAGINAW. MI 48602-5395

> Phone: (989)758-3825 Fax: (989)758-3755

### PREVIEW REPORT

COPY TO:

Specimen Number: SA18-000013

CLIA#: 23D

Date Reported: 02/06/2019 at 12:1

GENERATED AT REPORT DELIVERY
SUBMITTER: TEST BODY ART STUDIO AGENCY 1

Starlims Agency # 929594 123 TEST ROAD

SAGINAW, MI 48602

 Date Collected
 11/10/2018

 Date Received
 11/14/2018

 Specimen Type
 SPORE STRU

11/10/2018 11/14/2018 SPORE STRIP Patient Last Name PRECISION

Patient First Name 201

TEST RESULTS

STERLIZATION VERIFICATION ANALYSIS

Test Strip

\*\* GROWTH \*\*

Interpretation: FAILED - Discontinue use immediately. Call your regulatory

agency

Control Strip

GROWTH

Incubated at 55 C.

All growth checked microscopically.

1600 N. MICHIGAN AVENUE, ROOM 102 SAGINAW, MI 48602-5395

> Phone: (989)758-3825 Fax: (989)758-3755

PREVIEW REPORT

COPY TO:

GENERATED AT REPORT DELIVERY

GENERATED AT REPORT DELIVERT

SUBMITTER: TEST BODY ART STUDIO AGENCY 1 Starlims Agency # 929594 123 TEST ROAD

11:00

01/15/2019

STEAM

SPORE STRIP

SAGINAW, MI 48602

Date Collected 01/10/2019

Time Collected Date Received Specimen Type

Specimen Type Specimen Type Detail Patient Last Name PELICAN
Patient First Name 4B

Patient City LANSING

TEST RESULTS

STERLIZATION VERIFICATION ANALYSIS

Test Strip NO GROWTH

Interpretation: PASSED

Control Strip GROWTH

Incubated at 55 C.

All growth checked microscopically.

Section 15.3

Specimen Number: SA19-000001

Date Reported: 02/06/2019 at 12:12:57PM

CLIA#: 23D0374190

### **Record Keeping:**

### STERILIZATION LOG

Date	Items Processed (Lot # If Applicable)	Sterilization Time (Minutes)	Temp (°C)	Pressure	Cycle Start Time*	Sterilization Start Time**	Cycle End Time***	Indicator Change	Comments	Tech's Initials

15.1.6: .....Reactions must be recorded in a log book for each sterilization cycle



Things to consider if you received a failed test.

### User Tips: Loading Autoclave

- Proper loading ensures the sterilization and helps to maintain operational efficiency.
- Placement of items
  - Follow manufacturer's instructions
  - Direct steam contact for complete exposure time
  - No crowding
  - Place items on their edge
  - Do not stack
  - Label items before processing

### Tips: Loading Autoclave

■ Top tip: Don't over-fill or 'pack down' the load as this prevents maximum steam penetration. Spread the load evenly across the surface of the autoclave tray / shelf. If it is a mixed load with different types of products, ensure that the spread of items is even around the area of the tray / shelf.

## EXAMPLES OF AN OVERLOADED AUTOCLAVE CHAMBER (LEFT)

## AND CORRECTLY FILLED 'VALIDATED' LOAD (RIGHT)





### User Tips: Safety

- Hazards
- Prevention of Injuries
  - PPE
  - Inspect Autoclave
  - Item preparation
  - Item removal









Sterilization Verification

### Saginaw County Health Dept



# MAIL-IN SPORE STRIP TESTING PROGRAM FOR VERIFICATION OF STERILIZATION

Services available for steam/autoclave, dry heat or ethylene oxide sterilization methods

### What does SCHD Provide?

- Monthly Test Kits
  - Controls, Test Req, envelops
- Certificate of Participation
- Monthly Test Report
  - Your shop
  - Your local regulatory agency
- A phone call for a failed test (within 8 hours)
- Accurate and Reliable Results within 10 days
- Support and guidance for trouble shooting





### More Information on Program

- Call or Visit the Saginaw County Health Department, Laboratory
  - 1600 N Michigan Ave, Saginaw, MI 48602
  - Laboratory 989.758.3825
- Visit our website
  - http://www.saginawpublichealth.org/page.asp?ID=443&pID=107



### Tammy's Contact Information



# Saginaw County HEALTH DEPARTMENT

Caring experts, advocates & champions. For health. For everyone.

Tammy Theisen, Laboratory Director ttheisen@saginawcounty.com

### References/Links

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- http://www.vliz.be/docs/Zeecijfers/autoclaveoperation.pdf