POLICY AND PROCEDURE	
SUBJECT/TITLE:	Maintenance Manual
APPLICABILITY:	Canton City Health Department Laboratory Staff
CONTACT PERSON & DIVISION:	Christina R Henning, Canton City Health Department Laboratory
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PURPOSE

This Maintenance Policy will be used to ensure the equipment, instrument, and test system performance, which is necessary for accurate and reliable test results and their reporting in the Canton City Health Department laboratory.

POLICY

The Canton City Health Department Laboratory staff will utilize available manufacturers' instructions for the maintenance of all equipment. When manufacturers' instructions are not available standard methods will be implemented. Logs will be utilized to document routine and unscheduled maintenance, documenting any repairs (including replacement parts) and calibration/verification.

BACKGROUND

Proper use and maintenance of all equipment is fundamental for assuring quality in a laboratory setting. Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing in order to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations which became effective April, 24, 2003. Together these documents provide a history of a movement toward a process of continuous improvement in order to provide consistent quality laboratory testing and results.

PROCEDURES & STANDARD OPERATING GUIDELINES

1. **General:**
    a. Each piece of equipment used in the Canton City Health Department Laboratory (CCHDL) has an individual tab inside the CCHDL Maintenance Manual. Each tab includes, if available, a copy of the most current user manual, maintenance logs, quality control monitoring instructions and (if needed) copies of logs used for regular quality control. Each tab is listed in the Maintenance Manual Table of contents (400-002-03-A_Maintenance Manual Table of Contents). Due to the size of the manual, the paper version is divided into three binders.

b. CCHDL will ensure that the testing environment (temperature, humidity, water quality) meets the manufacturer's specifications and that the manufacturer's instructions for maintenance and function checks will be followed.
c. All immediate concerns regarding equipment will be brought to the attention of either the on duty General Supervisor or Technical Supervisor.
d. All service and monthly/quarterly/annual maintenance must be recorded in the maintenance log, 400-002-02-F_Equipment Specific Maintenance and Troubleshooting Log, unless otherwise specified in the procedure. Maintenance requirements are briefly described in the Maintenance Schedule (400-002-01-A_Maintenance Schedule)
e. For new test systems, we will verify performance specifications such as accuracy, precision, sensitivity, specificity, and reference intervals.

2. AUTOCLAVE:

a. Manufacturer and Model: Market Forge Sterilmatic Model STM-EL S/n 130708, 1984
b. Routine Operation: (See manufacturer's instructions for detailed information)
    i. Prepare items to be sterilized:
        - loosen all caps,
        - put strip of autoclave tape on an item,
        - weigh and record biohazard bags, and
        - start log for current load-this includes start time, weight, description and date.
    ii. Fill the sterilizer chamber with approximately six quarts of water or just below ledge at bottom of door opening.
    iii. Load Sterilizer: Use proper sterilizer loading procedures when placing materials in sterilizer chamber. All solid containers or instruments must be placed so that water or air will not be trapped in them.
    iv. Add Maximum reading thermometer to all liquids and biohazard containing loads. Note: place thermometer as close as possible to the center of the chamber, ensuring that it has been shaken down below 100°F. CAUTION: do not place thermometer in Instrument/Fast loads. If in the middle of a cycle it is determined that a thermometer is in the chamber, immediately reset the selector to Liquids/Slow.
    v. Close Door: Grasp handle, and holding it in vertical position, pull door down until bottom of door rests in the bottom of door opening. Then rotate handle forward, engaging the lower curved portion under the horizontal rod in the casting at the bottom of the door opening. Push handle all the way down and back until door is locked securely in position.
    vi. Set Exhaust Selector: Located at center of the control housing mounted on top of the unit, to correct position. Unit is now ready to start. All items, other than solutions, may be sterilized with selector at "Instruments/Fast". Solutions require a slow exhaust. Place selector at "Liquids/Slow". Biohazard material is exhausted with the selector at "Liquids/Slow".

vii. Determine Correct Sterilization Times: (Referring to instruction manual for minimum required times in the sterilization guide and times table.) NOTE: In no case should the timer be set to less than 15 minutes. Sterilization will not be accomplished in less than 15 minutes exposure time.

viii. Turn Timer: Located at upper right front of sterilizer. Select desired length of sterilizing period. This turns power supply on and starts the cycle after pressure- temperature combination has been reached. Amber pilot light indicates that the timer is running.

ix. For all Instrument/Fast cycles record the highest temperature observed from the dial thermometer into the log book.

x. When the sterilizer chamber reaches the selected temperature, the timed exposure cycle will begin. When the exposure cycle is completed, the electric supply will be opened automatically. When the chamber pressure gauge located at the top of the control housing reads "0", the door may be opened. (Release handle and let go to avoid possible contact with remaining steam.) When opening the door, allow a few seconds for steam to escape from chamber before opening completely.

xi. Carefully remove thermometer from the chamber, let thermometer stand for 5 minutes and record the temperature in the log book.

xii. Record all other pertinent data into the log book, including the time the door was opened and tape result.

xiii. Remove load and check water level for next operation.

c. STERILIZATION GUIDE

- PACKS (Linens, gloves, etc.): Use wire basket to facilitate drying. Be sure condensate baffles are in place. Place packs on edge and arrange load in chamber, so that only minimal resistant to passage of steam through the load will exist. NOTE: Place gloves in upper two-thirds of chamber.
- JARS, CANISTERS (etc.): Place containers on side to allow for displacement of air and complete contact of steam to surfaces. Drying is also facilitated.
- PETRI DISHES, PIPETTES, and DESICCATORS (etc.): Should be inverted.
- UTENSILS: Placed on edges to facilitate drying.
- INSTRUMENT SETS: Place instruments set in trays having mesh or perforated bottoms. Place trays flat on shelves.
- PLASTIC UTENSILS: DO NOT stack or nest plastic items.
- LIQUIDS: Sterilize medium liquids separately from other supplies or materials. Set exhaust selector to proper position (liquids).
- SMALL ITEMS**:** Sterilize small items in baskets, or trays.

d. <u>Troubleshooting:</u>

i. If low water indicator light turns on during the cycle, the cycle will NOT be completed. Properly open chamber and restart operational procedures.

ii. Occasionally the door seal may not yield a tight seal. If this occurs, properly open chamber and manually adjust gasket and restart operational procedures. If this does not

correct the issue, record in maintenance log and report to management. Do not use autoclave, until the issue is resolved.

e. Precautions/Safety:
   i. Utilize extreme caution when opening the door. The unit produces steam which presents a high risk for steam and thermal burns. Additionally, allow contents to cool prior to handling or use appropriate safety personal protective clothing.

f. Routine Maintenance:
   i. Bi-Weekly or as needed if not in use:
      - Sterilizing chamber must be cleaned and drained using the following procedure. Wash wetted portion of the cylinder thoroughly by adding a mild detergent to water in cylinder.
      - Remove bottom splash baffle.
      - If a soft cloth or brush is used with the detergent and does not completely remove the surface film, a nylon soap pad should be used. After washing thoroughly rinse with clean water.
      - Dry cylinder* and leave door open overnight.

        * The Sterilmatic cylinder is constructed of corrosion resistant Alclad aluminum alloy. The protective properties of this material afforded to the interior portion of the cylinder which is exposed to water may be destroyed by allowing a film to form. Such a film can be caused by salts or other contaminants in the water. Corrosion may also occur if water is not drained regularly.
   ii. Quarterly:
      - Calibrate Thermometer and record in EPA water certification log.
      - Calibrate Timer and record in the EPA water certification log.

g. Service:
   i. Servicing is done on an as needed basis and includes replacement of door gaskets and thermo-element in steam trap as well as tightening and readjusting door latches and various nuts and bolts.

h. References:
   i. Sterilmatic Analog Electric Sterilizer, Installation-Operation Maintenance PN 14-0411. Rev a (9/14)

3. Balance:

a. Manufacturer and Model:
   i. A & D Company, FX-2000iWP, received 10/27/2011

b. Routine Operation: (See manufacturer's instructions for detailed information)
   i. Prior to use, ensure balance bubble is in the center portion of the marked circle.
   ii. Place a container on the weighing pan, if necessary.
   iii. Press the RE-ZERO key to cancel the weight (tare). The balance displays 0.00 g.
   iv. Place a sample on the pan or in the container.
   v. Wait for the stabilization indicator to be displayed. Read the value.

vi. Remove the sample and container from the pan.
vii. When the ON:OFF key is pressed with a container placed on the weighing pan, the balance displays 0.00 g and weighing is started.
viii. Move balance as little as possible.

c. Precautions/Safety:
   i. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.

d. Routine Maintenance:
   - In normal use, the exterior of the balance can be cleaned with water.
   - Do not immerse the balance in water.
   - Do not use organic solvents to clean the balance.
   - Clean the balance with a lint free cloth that is moistened with warm water and a mild detergent.
   - Do not disassemble the balance.
   - If water accumulates on the waterproof diaphragm, a weight value may be difficult to become stable.
   - Clean the diaphragm while taking much care not to deform it.

e. Troubleshooting:
   i. See page 60 of the operations manual for a list of troubleshooting codes and responses.

f. Service:
   i. Monthly:
      - Check for performance with certified calibration weights and record in the EPA water certification log.
   ii. Annually:
      - Have an outside agency perform an 8 point calibration verification and record in the EPA water certification log.

g. References:
   Manufacturer's instructions available on the internet at:
   http://www.aandd.jp/products/manual/balances/fz_fx-iwp.pdf

4. CENTRIFUGE:

a. Manufacturer and Model (2 models): Fisher Model 225, purchased 09/05/1997. Zip-IQ TT Centrifuge Mf no. 6M1810829, purchased 09/02/2019.

b. Routine Operation: (See manufacturer's instructions for detailed information)
   i. Load rotor evenly: Balance load on the head by placing tubes and sample contents of identical weight, into the head 180°apart.
   ii. Use water, as required, to balance each load within 0.5 grams.
   iii. Excessive noise and/or vibration indicates that the load is out of balance. Improper balance will consequently reduce motor life.

Fisher unit:

iv. Close lid and secure latch
v. Set SPEED control to minimum setting and then gradually rotate (clockwise rotation) SPEED control until desired speed is attained.
vi. Set TIME control to desired time interval (anywhere between 1 and 30 minutes).
vii. Allow rotor rotation to come to complete stop or depress BRAKE switch momentarily.

Zip IQ unit speed setting is preset; do not adjust for routine bloodwork.

viii. Prior to each use, ensure rotor is secure on the rotor shaft. If rotor appears loose, securely tighten using hex wrench.
ix. Ensure tubes are not hanging by caps, close and secure the lid.
x. Press the Start/Stop button to run the cycle. The unit will stop on its own, beep, and open the lid upon completion.

c. Precautions/Safety:
   i. Never exceed maximum rate head speed of 4750 rpm on the Fisher unit and 5000 on the Zip iQ..
   ii. Keep lid closed and latched when centrifuge is operating.
   iii. Do not attempt to stop head rotation with hands or objects: use BRAKE switch on Fisher centrifuge control panel.
   iv. Only use mild detergent for cleaning. Cleaning agents such as ketones, aromatic hydrocarbons or chlorinated hydrocarbons should not be used on the Fisher bowl.
   v. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.
   vi. This is a counter top unit and should not be placed on the floor.
d. Routine Maintenance:
   i. The Fisher model contains ball bearings with lifetime lubrication, and along with the Zip IQ unit requires no maintenance other than routine cleaning of exposed surfaces, rotor, and protective bowl with mild detergent. The bowl and lid should be immediately wiped clean of all chemical spills. There is no need to document regular cleaning on the Equipment Log
e. Service: (See instruction manual for how to perform service)
   i. Fisher
      - Motor Brushes: Inspect every 3 to 4 months of normal use (when in use for 1-2 days per week, inspection time can be reduced to annually). Replace the brushes if less than 0.25 inches in length.
      - Motor Replacement: install new motor as needed. Following installation always proceed to the Speed Control Limits Adjustment procedure.
      - Speed Control adjustment is only necessary when the control board is repaired or the motor is replaced.
      - The speed of rotor rotation, usually in rpm's, can be checked using a reliable tachometer. Only a photoelectric type should be used. The operator simply holds the tachometer probe over the access hole in the center of the centrifuge

lid and adjusts the speed control until the desired speed (as indicated by tachometer) is achieved. (Note the product instructions do not require speed rotation verification at any particular interval, therefore completing this performance check every 1 to 2 years would be satisfactory, based on low level of usage.). A speed of 3200 to 4500 RPM is satisfactory to produce G-force of 1000 to 2000.

ii. Zip IQ- inspect rotors monthly for wear and tear when used 5 days per week (when in use for 1-2 days per week, inspection time can be reduced to semi-annually). Replace the rotor as needed.

iii. Record ALL service on the Equipment Specific Maintenance and Troubleshooting Log

f. References:

i. Operation and Service Procedures Centrific Centrifuge, Published 6-92.

ii. Zip-IQ TT Centrifuge Instruction Manual, MKT-7.5.3-L-219 Rev 1.

5. CONDUCTIVITY METER AND PROBE:

a. Manufacturer and Model: Traceable Calibration Control Company 09-328 S/N 51159199, Probe: Fisher Scientific Catalog number 09-327-1

b. Routine Operation:

i. GENERAL INFORMATION.

- Over-range conditions are shown on the display with a "1" to the far left and a decimal point "." to the far right. No other digits are displayed.
- The automatic temperature compensation range is from 0.0 to 50.0 'C (32.0 to 122.O'F). The thermistor in the probe automatically adjusts the readout to 25.O'C. The temperature correction factor is fixed at 2% per °C.
- The instrument functions by passing a very low AC voltage across the electrode surface. Avoid working in areas where stray AC voltages may cause incorrect results, particularly in the 20 and 200 micromho range. If in doubt, shield the solution.
- Temperature has a significant effect on conductivity. To control temperature, calibration should be performed as near as possible to 25.00·C.
- Be aware that Certified Reference Material picks up contaminates from the air in a very short time. Contaminates and evaporation have a significant effect on conductivity. This effect may be minimized by using a narrow-necked container for all measurements. Keep the cap on the bottle as much as possible. Do not insert anything into this bottle.
- Do not return used solution to this bottle.
- Select a Standard as near as possible to that of the unknown. Do not standardize at 10000 and then measure unknowns at 100.

ii. INSTRUCTIONS FOR DIP CELL TYPE PROBES.

- Clean the conductivity probe with distilled/deionized water.

- Rinse the probe in a small amount of the standard, after rinsing, dispose of the rinse.
- Select a clean and dry container made out of glass or plastic that is several inches taller than the working part of the probe with a diameter of at least 1 ¾ inches. A narrow necked container is preferred to minimize air contaminants.
- Fill with a small amount of the Certified Reference Material, swirl around the sides of the container to thoroughly rinse the container. Dispose of the rinse. Then fill the container with the Certified Reference Material using at least 100mL.
- Immerse the probe in the Certified Reference Material. For approximately one minute stir the solution with the probe and move the probe up and down in the center of the solution.
- Adjust the conductivity Instrument to the correct reading while stirring. Heavily platinized probes or probes of complex geometry may require more than two minutes to achieve stable readings. Probes stored dry may also require additional time to achieve stable readings.

c. Precautions/Safety:
   i. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.

d. Routine Maintenance:
   i. After using the probe always rinse it in deionized /distilled water and replace the acrylic guard before storing it. Sample solutions which are allowed to dry on the probe will eventually block out active sites on the platinum electrodes.
   ii. The probe may be stored dry or in deionized / distilled water.

e. Service:
   i. If this Digital Conductivity Meter does not function properly for any reason, or if the letters "LO BAT" appear on the display, replace the battery with a new 9-Volt alkaline battery. Low battery power can occasionally cause any number of "apparent" operational difficulties. Replacing the battery with a new fresh battery will solve most difficulties. Incorrectly installed batteries may damage electronics. Battery life depends on the range being used. In lower ranges, battery life is extended. In the upper ranges it is shortened. Never connect an adaptor when a dry cell is in the unit, it may cause the dry cell to rupture.

f. References:
   i. Conductivity Probe Instructions, Fisher Scientific Cat. No. 09-327-1.
   ii. Traceable Expanded Range Digital Conductivity Meter Instructions, Control Company Cat. No. 4075, 2004.
   iii. Conductivity Calibration Instructions, 2008.

6. DEIONIZED WATER SYSTEM:

a. Manufacturer and Model: Western Reserve, 1.2 CF Mixed Bed Deionizer Tank and 1 Pre-Filter Activated Carbon 1.0 x 2.5.

b. Routine Operation: (See manufacturer's instructions for detailed information)

i. Utilize water only when resistivity indicator light on top of the tank is lit green.

c. Precautions/Safety:

i. None

d. Routine Maintenance:

i. Regularly inspect utility room for any leaks in tanks and piping. Notify vendor if any are found for servicing.

ii. Monthly:

- Perform conductivity testing. Conductivity should read <2.0 micromhos/cm (or us/cm)
- If needed, perform pH function check. pH should be between 5.5 - 7.5.
- Record function checks in the EPA water log.

iii. Annually:

- Have the water tested for heavy metals consistent with Ohio EPA Laboratory Manual for the Microbiological Analyses of Pubic Drinking Water requirements.

e. Service:

i. Service is performed as needed and/or when indicator light in the storage room changes from green to red. Service is performed by a contracted agent and will be automatically completed every 6 months unless called earlier.

ii. Record ALL service on the Equipment Specific Maintenance and Troubleshooting Log

f. References:

i. None

7. EMERGENCY/SAFETY SHOWER AND EYE WASH

a. Manufacturer and Model: Western Safety Shower 1992

b. Routine Operation:

i. Emergency Use Only Shower, no Routine Operation.

c. Precautions/Safety:

i. Ensure that the area surrounding the eye wash stations remains clear so that unencumbered access is always available.

d. Routine Maintenance:

i. Annually complete the Safety Equipment Minimum Performance Checklist and record in the EPA water certification log.

e. Service:

i. As needed based on Performance Checklist

f. References:

i. ANSI Z358.1-2009 Safety Equipment Minimum Performance Checklist, sourced from the following website last visited 01/05/2014:

8. **HOLOGIC:** See Hologic manual
9. **HOT PLATE:**
    a. Manufacturer and Model: Fisher Scientific, Isotemp Stirring Hotplate, cat SP88857200 Serial C3720019091648393, received 12/15/2016.
    b. Routine Operation:
        i. Reference Manual.
    c. Precautions/Safety:
        i. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.
    d. Routine Maintenance:
        i. No routine maintenance is required; reference the manual for troubleshooting error codes.
        ii. General cleaning: Wipe exterior surfaces with lightly dampened cloth containing mild soap solution.
    e. Service:
        i. No special service required.
    f. References: Fisher Scientific Operation Manual and Parts List CIC0000811 V15 02/29/16.
10. **INCUBATOR:**
    a. Manufacturer and Model: Precision Scientific Model 4EG, Gravity Convection. Installed: 02/07/1974
    b. Routine Operation: (See manufacturer's instructions for detailed information)
        i. Ensure exhaust vent shutter cab on top of the cabinet is always in the full open position.
        ii. Load unit allowing for at least 1 inch of separation between objects on shelves to maintain circulation.
        iii. The bottom of the chamber must be kept free and clear of objects.
        iv. After loading, the time required for the chamber to recover to the original stabilized temperature, will be directly related to the mass of the load.
        v. Read and record interior temperatures twice daily utilizing a properly calibrated thermometer (see section below labeled Thermometer). Record on the temperature log, 400-002-04-F_Clinic Room Incubator Temperature Chart, located on the exterior of the unit.
        vi. If the temperature is not within the range of 35°C to 37°C, actions will be taken to remedy the problem (e.g., adjust the thermostat).
            - If the thermostat is adjusted document on the temp log, 400-002-04F, recheck the temperature.
            - After allowing time for the temperature to change, read the temperature again.
            - Continue adjusting the thermostat and monitoring the temperature until an acceptable temperature is obtained and maintained.
            - If this cannot be accomplished, see the trouble shooting section below.
            - Document all temperature adjustments on the temperature chart.

- If necessary, relocate the contents of the incubator to protect them from extremely high temperatures

c. Precautions/Safety:
   i. At no time should solid shelves be substituted for the shelves that are provided.
   ii. This is a counter top unit and should not be placed on the floor.
   iii. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.

d. Troubleshooting:
   i. Loss of Heat Control: If at any time the safety thermostat assumes control of the chamber temperature, replace the control thermostat.
   ii. Temperature Variance or Fluctuation
      - Make sure the vent shutter cap is not closed. Open to maximum.
      - Test the unit when empty, if results are satisfactory, the chamber was improperly loaded. Redistribute the load.
      - Be sure to allow ample time for an empty chamber to stabilize at a temperature setting. It could take over one hour to equilibrate depending upon the difference between ambient and operating temperatures. The mass of the load can also affect stabilization time.
      - Ascertain that severe line voltage fluctuations have not occurred.
      - Make certain that all wire terminal connections are secure.
      - Make certain that an intermittent failure of the switch, thermostat, or wiring has not occurred. Isolate the cause, repair or replace.
      - Record ALL troubleshooting activities on the Equipment Specific Maintenance and Troubleshooting Log

e. Routine Maintenance:
   i. Clean interior of incubator- The interior of the unit will be cleaned as needed.
      - Empty the incubator, and clean the interior with a warm solution of water and appropriate disinfectant.
      - Rinse the interior with clean water and dry thoroughly.
      - Removable parts may be washed in warm, sudsy water. Avoid soap-filled pads or metal scouring pads.
      - Return parts and contents to the incubator.

f. Service:
   i. There is no regular service required for this unit. However, if troubleshooting fails to resolve the situation and service is required, record ALL service on the Equipment Specific Maintenance and Troubleshooting Log.

g. References:
   i. Precision Thelco Ovens and Incubators, Technical Service Department Operating Instructions Issue TS-31477-10 AC-5

11. MICROSCOPE:

a. Manufacturer and Model: Olympus BX41 System Microscope

b. Routine Operation:

Routine use of a laboratory microscope takes specialized training; therefore only general procedures are described below. Training can be obtained from in-house specialists as well as free online from the Centers for Disease Control and Prevention, Laboratory Training Branch, Basic Microscopy Course. Several Training aids from the online course can be found in the Microscope section of the Maintenance Manual.

i. Ensure light intensity is at lowest setting, this will extend bulb life.
ii. Turn on the microscope light source. Visually inspect electrical cord when powering unit on
iii. Adjust binoculars and eyepieces to your personal preference.
iv. Adjust power source for a comfortable light intensity. Be sure that Koehler illumination has been achieved.
v. Secure slide in stage slide holder.
vi. Rotate nosepiece for desired magnification objective, and raise or lower stage.
vii. With one hand, focus on specimen by using coarse- and fine-focus' knobs.
viii. With the other hand, move the slide by turning the stage drive.
ix. When reading is finished, rotate objective away from slide.
x. Release tension on slide holder, and remove slide.
xi. Eyestrain should not develop if the microscope is set up properly and the chair is at the correct height for the user.
xii. Turn light down or off.
xiii. Maintain clean microscope and note daily cleaning on the Microscope Daily Cleaning Checklist.
    - If oil was used, wipe oil from objective with lens paper.
    - When needed use lens cleaning fluid on lens tissue to wipe lenses.
    - The filter mount lens on the base is made of plastic. Do not rub it with a strong force to prevent damaging it.
    - Do not attempt to use organic solvents to clean the microscope components other than the glass components. To clean them, use a lint-free, soft cloth slightly moistened with water. If build up is noticed moisten with a diluted neutral detergent.
    - If body fluids are suspected of contacting scope, use minimal amount possible of a bactericidal disinfectant to decontaminate.
    - Do not disassemble any part of the microscope as this could result in malfunction or reduced performance.
xiv. When not using the microscope, keep it covered with a dust cover.
xv. Utilize log for any problems, deviations from daily function checks, routine maintenance, repairs and replacement parts.

c. Precautions/Safety:

i. This is a counter top unit and at no time should it be placed on the floor.
ii. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.
iii. This unit utilizes a focused light source, therefore always take caution when first using the scope and operate properly to reduce eye strain.
iv. Solvents used to clean the equipment, such as ether and alcohol are highly flammable, they must be handled carefully. Be sure to keep these chemicals away from open flames or potential sources of electrical sparks — for example, electrical equipment that is being switched on or off. Also remember to always use these chemicals only in a well-ventilated room.
v. See Safety Precautions Fig 1 in the User Manual for additional precautionary details.

d. Troubleshooting:(See detailed chart in the instruction manual)
e. Routine Maintenance:
   i. Routine maintenance of a microscope is through proper cleaning and storage. See cleaning and storage notes in operation section above and additional lab aids in the microscope section of the Maintenance manual. Additionally, detailed routine cleaning will extend the life of the microscope and should be performed on an as needed basis.
f. Service:
   i. Light bulb replacement can be done by laboratory personnel, see manufacturer's instructions for specific information.
   ii. Professional service contracts can be used on an as needed basis for all of the following: (Note CDC recommends annual service for a standard in use microscope, based on low volume usage bi-annually could be acceptable)
      - Clean all exterior frames and components,
      - clean all exterior lenses, including the bottom lense of the eyepiece and the lense above the prism in the head,
      - remove the nosepiece on the oil immersion to inspect for oil creepage,
      - re-lubricate cover on the lenses of the irises (condenser and field),
      - re-lubricate minor mechanical components as needed such as fine focus gears, shafts and prism changers,
      - adjust all fluorescent, Kohler illumination and phase for proper alignments,
      - Complete operational verification with documented check list per microscope service noting conditions bad, fair, good with notes detailing any issues or concerns.
g. References:
   i. Olympus BX41 System Microscope User Manual, AX 9853
   ii. Cleaning, Care and Maintenance of Microscope,
   iii. Microscope maintenance power point presentation prepared by the CDC

12. NEEDLES:

a. Manufacturer and Model: Beckton Dickinson Dispensing (square cut) 20G. yellow hub
b. Routine Operation: (See manufacturer's instructions for detailed information)
    i. Utilize aseptic techniques when handling the needles.
    ii. When delivering liquid from the needle, always hold in a vertical position.
    iii. To maintain clear passage for accurate drop delivery, upon completion of the tests, remove the needle from the dispensing bottle and rinse the needle with deionized/distilled water.
    iv. Do not wipe the needle since this will remove the silicone coating and may affect the accuracy of the drop of antigen being dispensed.
    v. Utilize log for any problems.
c. Precautions/Safety:
    i. Square cut needles do not pose a significant risk for puncture wounds, however use of standard needle precautions is recommended.
d. Routine Maintenance:
    i. Check the calibration of the needle each time a new needle is used, when the needle has been dropped or wiped, or when the control pattern is not met to ensure the delivery of the correct volume of antigen suspension (60 drops ± 2 drops per mL; 17 µL per drop).
        - Place a previously calibrated needle onto a 1-mL syringe (ex., TB glass syringe) or onto a 2-mL pipette. Draw 0.5 mL of RPR antigen suspension and place it in a clean dispensing bottle. Place the needle requiring calibration verification onto the dispensing bottle. Holding the dispensing bottle in a vertical position, count the number of drops delivered from the bottle containing the 0.5 mL of antigen suspension. The needle is correctly calibrated if 30 drops ± 1 drop is delivered in 0.5 mL.
        - Replace the needle if it does not meet this specification. Be sure to test the calibration of the replacement needle.
        - Always utilize the calibration log to record results.
e. Service: Not Applicable
f. References:
g. National Center for Infectious Diseases, Syphilis Procedure Manual, accessed 12/14/2014.
h. Manual of Tests for Syphilis

13. PH METER:

a. Manufacturer and Model: Fisher Corning Ph Meter Model 445. Purchased: 09/24/1998. Flat Probe, SI Analytics Model 476386 purchased 04/16/2005, Ph meter Model Thermo Scientific STARA1110 purchased 02/23/2017. Ph probe Thermo Scientific 9157BNMD purchased 09/23/2017.
b. Routine Operation: (See manufacturer's instructions for detailed information)
    - Always use a minimum of the two point calibration method.

- See specific instruction manual for detailed calibration instructions.
- Always calibrate and measure at room temperature.
- Always calibrate each day of use.
- Prior to calibrating ensure the buffer solutions are within their expiration dates.
- Samples must be in solution, dry samples cannot be tested.
- Rinse the electrode with distilled water and blot dry when transferring from one sample to another.
- Do not allow the reference chamber of the electrode to dry out. Always keep it filled with the proper fill solution. (SI Analytics probe 3M KCl and Thermo probe Ag/AgCl fill solution 900011)
- Formation of KCL salt at the tip and side of the electrode is normal and should be rinsed off with warm water.
- Leave the tip of the SI Analytics electrode in an inch of pH 7.0 buffer for short term shorage. Leave the Thermo Probe in pH electrode storage solution 91001 for short and long term storage. Do no leave it in distilled water.
- Prior to utilizing the Thermo Probe, if it has not been used in the prior two weeks, drain and replace the fill solution utilizing a disposable pipette. (Note: this is a variance from the manufacturer's instructions based on technical support call 11/20/2018). Note change on probe sticker.
- Utilize log for any problems, routine maintenance, repairs and replacement parts.
- Note: all fill and storage solutions are acceptable for use up to their expiration date, unless there are signs of contamination.

c. Precautions/Safety:
    i. The front panel is made of polyester and is not affected by most solvents. Polyester is known to be affected by some organic solvents, including toluene, xylene and methyl-ethyl-ketone.

d. Troubleshooting:
    i. If the electrode slope is off or the electrode response has become sluggish or inaccurate, change the fill solution. If that does not improve response then the pH-sensing glass and the junction have probably become coated with some of the samples being tested. See instruction manual for electrode cleaning and problem solving.
    ii. Most problems are caused by electrode faults rather than by the Model 445 but power fluctuations can corrupt calibration values being held in the meter memory. Perform a Meter Test and Reset.
    iii. Refer to instruction manual for Meter Error Code definitions and response.

e. Routine Maintenance:
    i. The Model 445 needs no maintenance except for an occasional wipe with a damp cloth. Refer to the electrode manufacturer's instructions for proper electrode care and maintenance.

f. Service: Not Applicable

g. References:

i. Corning Instruction Manual, pH meter 445, 109119-1 Rev, A, 11/96

14. PIPETS:

a. Manufacturer and Model: Eppendorf Repeater Plus Pipette, received 7/2/2007, Pipetman P1000, Eppendorf M4 put in service 12/13/2018, United/Universal PVV-100 put in service 12/13/2018.

b. Routine Operation: See manufacturer's instructions for detailed information and utilize 400-002-10-F_Pipetor Verification Calibration Instructions, for new and annual verification process.

c. Precautions/Safety:
   i. When inserting Combitips, do not press the ejection key.
   ii. When emptying the Combitip by pressing down the filling lever, always hold it vertically over a vessel to prevent splashing.
   iii. Eject the Combitip only when the filling lever has been pushed down completely.
   iv. Do not use the Repeater Plus with liquids which attack the materials ABS, ASA, PBT, PC, POM and PPS.
   v. It is essential to observe the limitations governing the stability of the materials of the Repeater Plus and to consider the chemical compatibility of the reagents used.
   vi. The recommended operating temperature for the Repeater is between +4°C and +40°C. Do not operate the device outside this temperature range.
   vii. Do not allow any liquid to enter into the Repeater Plus.
   viii. Dispose of used batteries in accordance with legal regulations.
   ix. Use only the original Eppendorf accessories

d. Troubleshooting:(See chart in the instruction manual)

e. Routine Maintenance:
   i. The Eppendorf and Pipetman pipets can be cleaned using a soft cloth softened with soap solution or disinfected with 70% isopropanol. For pipets used with the APTIMA system utilize 50/50 Bleach followed by DI water.
   ii. The PVV-100 can only be cleaned with 70% isopropanol.
   iii. The PVV-100 requires annual lubrication and inspection, see manual for details.
   iv. Do not allow any liquid to enter into the device.
   v. Check the calibrated pipette each time a new one is placed into service, when it has been dropped, AND annually.
   vi. Document calibration checks on Pipettor Delivery Form.

f. Service: (See instruction manual for how to perform service)

g. References:
   i. Repeater Plus Pipette Instruction Manual Copyright 2005.
   ii. PVV-100 Operation Manual
   iii. Rainin Pipetman instruction manual 9920-025 Rev J
   iv. The Use of Volumetric Pipets with NIST Handbook 133*, Checking the Net Contents of Packaged Goods*
   v. 400-002-08-F_Pipetor Delivery Check Form
   vi. 400-002-10-F_Pipetor Verification Calibration Instructions

15. REFRIGERATOR:

a. Manufacturer and Model: ABS Undercounter Freestanding Refrigerator ABT-HC-UCFS-0504W, SN HQ-ABS-16J 1567-1610, Received 11/07/2016.

b. Routine Operation:

i. Proper operation of the refrigerators requires it to be maintained in a level position (5 degree slope to the back is recommended) with 2 to 3 inches of space on all sides.

ii. Ambient temperature of the room where the unit is stored must be between 65 and 85°F (18 to 29°C)

iii. Only original shelving racks and drawers can be used and no solid material should be placed on the wire rack that would impede air circulation.

iv. Read and record interior temperatures twice daily utilizing a properly calibrated thermometer (see section below labeled Thermometer). Record on the temperature log, 400-002-05-F_Clinic Room Refrigerator Temperature Chart, located on the exterior of the unit. Maintain recent copies of the logs in the Daily QA Binder. Temperatures are recorded each day the health department is open for routine business.

v. If the temperature is not within the range of 2°C to 8°C, actions will be taken to remedy the problem (e.g., adjust the thermostat).

- If the thermostat is adjusted record on the daily temp log, recheck the temperature.
- After allowing time for the temperature to change, read the temperature again.
- Continue adjusting the thermostat and monitoring the temperature until an acceptable temperature is obtained and maintained.
- If this cannot be accomplished, see the trouble shooting section in the Installation and Operation Manual.
- Document all temperature adjustments on the temperature chart.
- If necessary, relocate the contents of the refrigerator to protect them from temperature fluctuations and to meet temperature control guidelines.

vi. Utilize maintenance log for any problems, routine maintenance, repairs and replacement parts.

c. Precautions/Safety:

i. Do not store flammable or explosive material in the refrigerator.

ii. The refrigerator is used for bio-hazardous products and standard precautions should be used for storage.

iii. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.

d. Routine Maintenance:

i. Perform Door Seal Check a minimum of annually and as a part of troubleshooting

- Open the door,
- Insert a strip of paper two inches wide between the door gasket and the cabinet flange and close the door,

- Slowly pull the paper strip from the outside. You should feel some resistance, and
- Repeat this test at 4 inch intervals around the door. If the door does not seal properly, replace the gasket.

ii. Defrosting

- When frost in the freezer compartment exceeds 1/4" turn the unit off and allow the ice to melt.
- Do not use an ice pick or other sharp objects. You can speed defrosting by placing a pan of warm water in the freezer compartment

e. Troubleshooting: see the trouble shooting section in the Installation and Operation Manual

f. Service:

i. Servicing is done on an as needed basis.

ii. Any handling of a refrigerant material must be done by a licensed professional.

g. References:

i. ABS Owners Guide, DY Rev,8-4-2016.

16. ROTATOR:

a. Manufacturer and Model: Fisher Scientific Clinical Rotator 14-251-200, received September 2004. LW Scientific Digital Rotator Model RTL-BLVD-241T1-B, MF no. RD1-19040356, received 09/02/2019.

b. Routine Operation: (See manufacturer's instructions for detailed information)

i. Prior to daily operation, perform and document a function/control rotation check.

- Fisher Unit:
  a. Turn the time sector to 15 minutes
  b. Hold switch should be in the down position
  c. Set Speed selector to 100 ± 1
  d. Allow time period to expire
  e. Note: this step permits Components to "warm up" so that stable oscillation speeds can be obtained
  f. Using a timing mechanism with seconds, check number of oscillations per minute.
  g. Enter function/control check results in the quality control log.
  h. If unit is operating at 100 ± 2 revolutions per minute regular operation can continue.
- LW Unit
  a. Set Speed selector to 100 ± 1
  b. Using a timing mechanism with seconds, check number of oscillations per minute.
  c. Enter function/control check results in the quality control log.
  d. If unit is operating at 100 revolutions per minute regular operation can continue.

ii. Arrange slides/cards on platform.
iii. Operate the unit
- Fisher Unit:
  a. Set SPEED selector to desired oscillations/minute.
  b. For timed operation, set HOLD switch to OFF position and turn TIME selector clockwise to desired setting.
- LW Unit:
  a. Press the power button on the front of the unit. The LED Display will show the time value that was set at last use.
  b. Setting time: Press the Time Mode button to select the operation mode (time mode or continuous mode).
     i. Press the Timer button to select the digit (hour or minute). The digit will begin flashing.
     ii. Press the Up or Down buttons to adjust tht blinking digits to the required setting.
     iii. Use Left arrow button to adjust the other digits.
     iv. Press the Timer button again and the time value will be stored into memory.
  c. Setting speed: Pres the Speed button to adjust the RPM to the required setting using the Up or Down buttons, and press the Speed button again to save the setting. The RPM value will be shown in the right LED Display.
  d. Time remaining: The remaining time will be shown on the left LED display at all times.
  e. During operation, you may press Start/Stop button to stop operation at any time.

iv. When necessary, exterior surfaces should be cleaned with a damp cloth and mild soap and disinfectant.
v. Care should be taken to prevent liquid from entering case. If possible the slide platform should be removed for cleaning.
vi. Utilize log for any problems, routine maintenance, repairs and replacement parts.

c. <u>Precautions/Safety:</u>
   i. Never place hands under or around the bottom of the platform during operation.
   ii. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.

d. <u>Routine Maintenance:</u>
   The Fisher rotator requires little maintenance other than periodic lubrication of the oscillating mechanism, and inspection of the motor brushes.
   i. Lubricating Crank Pins
      - Annually check the three crank pins on the oscillating top plate. When necessary lubricate each with a few drops of SAE-20 lubricant
      - Maintaining Motor Brushes

ii. Inspect brushes annually for wear. Replace before length is reduced to less than ¼ inch
iii. Record maintenance in Equipment Log

The LW Scientific rotator requires no routine maintenance.

e. Service: Servicing is done on an as needed basis
f. References:
   i. Fisher Scientific Clinical Rotator Instruction Manual 14577 Revision A (6/98).
   ii. LW Scientific Digital Rotator Instruction Manual, MKT-7.5.3-L-213 Rev 0

17. THERMOMETER:

a. Manufacturer and Model: Variety
b. Routine Operation: (See manufacturer's instructions for detailed information)
   i. Mercury column thermometers have a relatively thin-walled cylindrical bulb of mercury sealed to a length of capillary tubing. An increase in temperature causes the mercury in the bulb to expand and rise higher in the capillary. A temperature range and proper use depend on the type of thermometer available.
      - Periodically inspect each thermometer carefully for cracks in the capillary or bulb. Check the mercury column for separations. If separations are found, the column may be reunited by using one of the following methods:
      - Immerse the thermometer bulb in an ice-salt mixture until all mercury is drawn into the bulb. Hold the thermometer in a vertical position, tap it gently to dislodge gas bubbles, and allow it to warm at room temperature.
      - Hold the thermometer vertically in your fist so that the bulb is in the center of the palm of your hand. If the mercury begins to move, continue until column is reunited.
      - Firmly hold the thermometer horizontally at arm's length and swing it downward in a circular motion. Do not use a snapping movement. For thermometers with ring tops, attach a string and carefully swing the thermometer in a circular motion.
      - If all else fails, carefully warm the bulb over a low burner flame. Tilt the thermometer slowly back and forth so that the mercury is gradually forced into the expansion chamber.
      - Set the thermometer in a vertical position for cooling. The column should recede united.
      - After successfully reuniting the mercury column, check the accuracy of the thermometer as outlined in the following procedure.
c. Calibration of thermometers:
   i. When placed in service, the accuracy of each thermometer will be checked against an NIST-traceable thermometer. Mercury column thermometers will be calibrated annually unless the mercury separates; after reuniting the mercury column, the thermometer should be calibrated. Bimetallic thermometers will need calibration quarterly.

Correction factors should be noted on the thermometer and on the temperature chart. Recorded temperatures will be those obtained after the correction factor has been used. Thermometers with a correction factor greater than 1°C are not acceptable and will not be used.

ii. Because of the cost of a NIST thermometer, thermometers checked against a NIST will be used to calibrate laboratory thermometers. NIST-traceable thermometers may be purchased from suppliers of laboratory equipment.

- Obtain a NIST-traceable thermometer (formerly referred to as an NBStraceable thermometer).
- Place the thermometer being calibrated and the NIST-traceable in the central lab refrigerator if the thermometer will be used for cold temperature applications or the central lab incubator for temperatures above 30°C or higher temperature applications. If the thermometer is to be used for obtaining room temperatures, simply place the NIST-traceable thermometer next to the thermometer to be calibrated. Allow time for the temperature to stabilize.
- Read the temperature on both thermometers.
- Record readings on the “Calibration Record" in the Water QC Log Binder, and make note of the correction factor, if any.
- If the correction factor is greater than +1°C, the thermometer will be replaced with one that reads within +1°C of the NIST-traceable.
- Correction factors will be noted on the thermometer and on temperature charts.
- When recording temperatures, the true temperature (thermometer reading + the correction factor) will be recorded.

d. Placement of thermometers

i. Refrigerators and incubators may have “cold spots” or “hot spots”. Windows and air vents may cause these same conditions in rooms. Therefore, it is important to place thermometers in locations which reflect the most consistent temperature of the area.

- Periodically changing locations of thermometers for short periods of time is useful in locating poor areas of circulation.

e. Precautions/Safety:

i. Several of our thermometer are filled with mercury and if a mercury spill occurs refer to the Ohio EPA's Mercury Spill Response and Clean Up Guidance Document (http://web.epa.ohio.gov/ocapp/p2/mercury_pbt/mercury.pd, last accessed 12/15/2014).

f. Routine Maintenance:

i. There is no routine maintenance for thermometers. Thermometers are calibrated once a year and have the correction factor posted. See instructions for thermometer calibration above.

g. Service: (See instruction manual for how to perform service)

h. References:

i. Mercury Spill Response and Cleanup Document, http://web.epa.ohio.gov/ocapp/p2/mercury_pbt/mercury.pdf, last accessed 12/15/2014

18. TIMER:

a. Manufacturer and Model: Assorted.

b. Routine Operation:

i. Timers shall be NIST approved traceable timers capable for use in the test appropriate range.

ii. Periodically inspect each timer for obvious defects.

iii. Follow manufacturer's instructions for regular use.

iv. When placed in service including following battery replacement, the accuracy of each timer will be checked against an NIST-traceable timer.

v. When placed into service each timer will be individually identified in order to assure routine maintenance checks. Do so by numbering the inside of the battery case with a permanent marker.

vi. Timers will be individually marked with the most recent date of calibration verification.

vii. Timers for use in the STD lab will be stored and maintained in the STD room. These timers will be for use ONLY in the STD room and are not permitted for other uses.

viii. Timers for use outside of the STD lab will be stored and maintained in the central lab area or in the "food" lab area. These timers are not permitted to be placed on surfaces in the STD lab area where blood or body fluids are processed.

ix. Utilize Equipment Specific Maintenance and Troubleshooting Log for any problems, routine maintenance, and battery replacement.

c. Precautions/Safety:

i. Timers are used in spaces where they may come into contact with blood products. Therefore they should be handled as if they were contaminated despite having a clean appearance.

d. Routine Maintenance:

i. Annually check each individual timer against a NIST-traceable timer. Timers should be checked at a minimum of 1, 3, 20 and 22 minute intervals.

ii. Document all results on a maintenance function log.

e. Service: See instruction manual for how to perform service

f. References:

i. § 1910.1030 Bloodborne Pathogens, accessed on line 01/05/2015 at: https://www.osha.gov/needlesticks/needlesticks-regtxtrev.html

19. WATER BATHS:

a. Manufacturer and Model: Fisher Scientific, Isotemp 215.

b. Routine Operation:

i. Refer to instruction manual for specific instructions.

c. Precautions/Safety:

i. This is an electrical piece of equipment and all standard precautions for the use of electrical equipment apply.

d. Routine Maintenance:
   i. Annually or when water appears cloudy, drain and clean with warm soapy water and nonabrasive towel. Rinse thoroughly and refill.

e. Service:
   i. See instruction manual for how to perform service

f. References:
   i. None

CITATIONS & REFERENCES

- See equipment specific references in the procedure section above.
- Code of Federal Regulations, Title 42-Public Health, Part 493-Laboratory Requirements.
- College of American Pathologist. Laboratory Instrument Evaluation Verification and Maintenance Manual, 4th edition (ISBN 0-930304-35-7), 1989.
- National Committee for Clinic Laboratory Standards. Temperature calibration of water baths, instruments, and temperature sensors – second edition; Approved Standard.
- NCCLS Document 12-A2. Villanova, Pa.: NCCLS, 1990.Quarterly QA Checklist.
- Calibration and Calibration Verification, http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/6065bk.pdf.accessed 12/14/2014.

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APPENDICES & ATTACHMENTS

400-002-01-A_Maintenance Schedule
400-002-03-A_Maintenance Manual Table of Contents

REFERENCE FORMS

400-002-02-F_Equipment Specific Maintenance and Troubleshooting Log
400-002-04-F_Clinic Room Incubator Temperature Chart
400-002-05-F_Clinic Room Refrigerator Temperature Chart
400-002-06-F_Microscope Daily Maintenance Log
400-002-07-F_Policy Acknowledgement Signature Page
400-002-08-F_Policy Update Log Page
400-002-08-F_Pipetor Delivery Check Form
400-002-10-F_Pipetor Verification Calibration Instructions