CHM.29150 Biennial Review Equipment Disinfection **Phase I**

The laboratory reviews the procedures employed for disinfection of equipment and facilities used for sweat collection at least biennially.

NOTE: The purpose of this review is to assure continued effectiveness. One suggested approach is biennial evaluation by the infection control department of the institution.

CHM.29200 Sweat Collection and Analysis Procedure **Phase II**

The laboratory follows generally accepted procedures for sweat collection and analysis, including steps to minimize sample evaporation or contamination.

NOTE: Because sample evaporation and contamination can have significant impact on the validity of test results, laboratories must incorporate the following steps into their procedure and/ or follow manufacturer's recommendations:

When using gauze or filter paper collection pads:

1. *Use gauze and/or filter paper that is low in electrolyte content*
2. *Wash the patient's skin thoroughly with distilled or deionized water, then dry before stimulation. Repeat after stimulation and before collection*
3. *Do not touch the weighing vial, wax film, collection site, or collection pad. Always use forceps or powder-free gloves*
4. *Use two pieces of waterproof adhesive tape on all sides of the paraffin wax film or wrap with a disposable stretch bandage to produce an airtight seal*
5. *Blot back into the collection pad any condensate that may have formed on the wax film during collection. Failure to collect the condensate can result in false positive test results*
6. *After collection, quickly transfer the specimen pad to the weighing vial and reweigh promptly*

When collecting sweat into Macroduct coils:

1. *Wash the patient's skin thoroughly with distilled, deionized water. Leave the skin slightly wet after washing the area where the electrode will be attached or add a drop of distilled or deionized water to either the skin or the Pilogel surface (after installation in the electrode). Repeat after stimulation and before collection*
2. *Avoid touching the collecting surface of the coil*
3. *Fasten the collector to the extremity with firm strap pressure. Test for proper attachment after sweat appears in the coils*
4. *Do not attempt to remove the entire collector assembly from the patient's extremity before separating the coil from the main body. Loss of specimen may occur*
5. *Do not contaminate the nippers or sweat dispensing needle with sweat sample*

When collecting and analyzing sweat using the Nanoduct system:

1. *Wash the patient's skin thoroughly with distilled, deionized water. Leave the skin slightly wet after washing the area where the electrode will be attached or add a drop of distilled or deionized water to either the skin or the pilogel surface (after installation in the electrode). Repeat after stimulation and before collection*
2. *Avoid touching the collecting surface of the device*

REFERENCES

1) Scott MG, *et al.* Electrolytes and blood gases, In Burtis C and Ashwood E (eds), Tietz textbook of clinical chemistry. Philadelphia: WB Saunders, 4th edition, 2006
2) Clinical and Laboratory Standards Institute (CLSI). *Sweat Testing: Specimen Collection and Quantitative Chloride Analysis.* 4th ed. CLSI guideline C34. Clinical and Laboratory Standards Institute, Wayne, PA, 2019.

CHM.29300 Sweat Stimulation **Phase II**

Sweat is stimulated and collected from the patient's lower arm or upper leg, using a site that is free from diffuse inflammation or rash.

NOTE: Sweat must not be stimulated or collected from the head or trunk. Sweat must not be stimulated or collected from an area of diffuse inflammation, such as a rash or eczematous lesion, because of the likelihood of contamination by serous fluid.

REFERENCES
1) Liebke C, *et al.* Sweat electrolyte concentrations in children with atopic dermatitis. *Lancet.* 1997;350:1678
2) Clinical and Laboratory Standards Institute (CLSI). *Sweat Testing: Specimen Collection and Quantitative Chloride Analysis.* 4th ed. CLSI guideline C34. Clinical and Laboratory Standards Institute, Wayne, PA, 2019.

CHM.29400 Pilocarpine Grade **Phase II**

If the laboratory prepares the pilocarpine solution for iontophoresis, the source of the pilocarpine is USP grade or equivalent.

CHM.29500 Electrode Placement **Phase II**

Electrodes used for stimulation are placed such that iontophoretic current never crosses the patient's trunk.

NOTE: The protocol must specify that electrodes used for stimulation be placed so that current does not cross the patient's trunk. This is to avoid the possibility of current crossing the heart, which results in cardiac depolarization.

CHM.29600 Iontophoresis Conditions and Equipment Maintenance **Phase II**

Iontophoresis conditions and maintenance requirements are defined.

NOTE: For safety reasons, the iontophoretic current source must be battery-powered, to avoid the possibility of patient exposure to line voltage. For manually controlled devices, iontophoresis must be performed for no more than five minutes at a current less than 4 mA, to prevent burns. The iontophoresis unit must be tested by qualified personnel (such as engineering personnel) for current leakage and current control at defined frequencies and records retained.

CHM.29700 Iontophoresis Oxygen **Phase II**

Iontophoresis is not performed on patients receiving oxygen by an open delivery system.

NOTE: While the possibility of an explosion due to the generation of an electrical spark is remote, it cannot be ignored. Often, these patients can temporarily receive oxygen via a facemask or nasal cannula, in which case sweat testing can be done.

CHM.29800 Iontophoretic Stimulation **Phase II**

The area of iontophoretic stimulation is equivalent to the area of sweat collection.

NOTE: Sweat electrolyte concentration is related to sweat rate. At low sweat rates, sweat electrolyte concentration decreases. The average sweat rate should exceed 1 g/m^2/min.

To ensure adequate sweat stimulation and accurately reflect sweat electrolyte concentration, a minimum acceptable sweat volume or weight is required. This requirement is based on the size of the electrode and stimulation area, the type and size of collecting media, and the duration of sweat collection. To standardize the process, the stimulation and collection area should be equivalent, and the time of collection consistent. For example, for the positive electrode, use a 1.5 x 1.5 inch (3.8 x 3.8 cm) electrode over a 2 x 2 inch (5.1 x 5.1 cm) gauze pad saturated with pilocarpine for stimulation, then collect sweat onto a 2 x 2 inch pre-weighed gauze pad.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Sweat Testing: Specimen Collection and Quantitative Chloride Analysis.* 4th ed. CLSI guideline C34. Clinical and Laboratory Standards Institute, Wayne, PA, 2019.