Sweat Collection by Macroduct Pilocarpine Iontophoresis

Purpose

This procedure provides instructions for SWEAT COLLECTION BY MACRODUCT PILOCARPINE IONTOPHORESIS. Do not attempt sweat collection without thorough familiarity with this procedure. The Wescor Macro-duct sweat collection system utilizes fully automatic battery powered pilocarpine iontophoresis through an electrical potential gradient; the drug is transported through a limited area of skin to the sweat gland where it has a stimulating effect on eccrine secretion. This method is the approved guideline for the collection of sweat for the quantitative measurement of chloride in the diagnosis of cystic fibrosis.

Policy Statements

- Sweat testing is performed on patients who are > 48 hours old
- Sweat testing is not performed on patients receiving oxygen by an open delivery system
- The Laboratory and Infection Control annually review policies regarding disinfection of equipment and facilities. Documentation of the review is maintained in the Chemistry Groupwise Procedure Review folder
- Children's Biomed department annually inspects battery units for current leakage and current control. Biomed maintains the documentation.
- The incidence of insufficient sweat samples is monitored routinely

Sunquest Test Code

SWCL: sweat chloride
SWCD: sweat chloride collection duration

Records/Forms/ Documents

Maintenance Log for Wescor collector system

Materials

Reagents	Supplies	Equipment
• Pilocarpine gels	• Alcohol prep pads • Gauze • Deionized water • Hospital-approved Disinfectant wipes • Sweat Collectors • Sealable containers	Wescor Macroduct system containing • Various sizes of Velcro straps for collectors • Red and black electrodes • Velcro straps • Webster battery pack sweat inducer • Nippers

Safety & Precautions

- Pilocarpine may cause inflammation. Do not ingest. See MSDS for more information.
- Burn possibilities are reduced by using undamaged pilogel disks, appropriate strap pressure so disks are not crushed, and leaving the skin moist where the electrode is to be placed.
- Always use PPE when working with or handling blood and body fluids.

Sample

Patients suitable for sweat collection are:

- > 48 hours of age, preferably > 10 days old and > 2 Kg weight if asymptomatic
- Well-hydrated
- Clinically stable
- Free of acute illness
- Not receiving mineralocorticoids
- Not on oxygen by open delivery (headbox or nasal prong is OK)
- Free of diffuse skin inflammation, such as eczema, which can increase contamination of sweat with serous fluid after stimulation.

Postpone sweat collection on patients that do not meet these criteria. Consult patient's provider.

Procedures:

Sweat Inducer Maintenance

Step	Action	Related Document
1	Clean the stainless steel electrode fascia with an alcohol pad each day of use.	
2	Inspect the battery pack for tight fittings.	
3	Inspect the electrodes and wires for continuity.	
4	Check the low battery light after the unit is turned on. (Refer to Section 4 in the Wescor Instruction Manual.)	
	If / **Then**	
	Low battery light is lit / Replace batteries	
	Consistently low sweat volumes are observed / Replace batteries, even if light is not yet on	
5	To troubleshoot a malfunctioning inducer, place 3 quarters between the red and black electrodes. Connect the fitting to the battery pack. Switch the toggle to "on."	
	If / **Then**	
	Green light comes on. / Current check OK.	
	Light does not come on. / Check the batteries, cord and battery housing to make sure all points are connected.	
6	For additional troubleshooting, refer to manufacturer's instruction manual and/or Children's Biomed department.	

Infection Control

Step	Action	Related Document
1	After each patient collection, use a hospital-approved disinfectant wipe to clean the switch and surfaces of the sweat inducer, the cables, the nippers, the Velcro bands, and any other re-usable equipment. Document on Daily Maintenance Log.	
2	Leave the collection tray outside the patient's room if the patient is in transmission-based precautions. Take only the required supplies into the patient's room.	
3	Patient rooms and facilities are maintained according to organizational policy.	Org Policy #1201.09 *Worksite Cleanliness for Infection Prevention and Control.*

Patient and Family Preparation

Step	Action	Related Document
1	Prior to stimulation educate the patient and family about the procedure and possible risks involved. • A sweat-inducing drug called pilocarpine is delivered through the surface of the skin to the sweat glands by means of a small electric current. • Most children will exhibit sensitivity to pilocarpine that manifests as “redness” under the electrodes. • Occasionally one or more blister like welts may form as a reaction to the pilocarpine and will disappear in 2-3 hours. • Although the incidence is very rare (less than 1 in 50,000), minor skin burns are a possibility with this procedure. • You or your child may be referred to Children’s Emergency Department after consulting your physician in the event of a reaction.	
2	Please direct ALL questions regarding CF disease and diagnosis to the patient’s physician. Refrain from discussing anything other than the collection procedure with the family.	
3	Advise families that have concerns about the procedure to consult with their physician before proceeding with the sweat stimulation.	

Stimulation

Step	Action	Related Document
1	Always wear powder-free gloves to prevent contamination.	
2	Attach electrodes to the sweat inducer.	
3	Place one pilocarpine gel firmly into each of the red and black electrodes. Do not use disks that have been frozen or are cracked.	
4	Choose the site to stimulate collection. The lower arm or upper leg is to be used for collection sites, and the skin must be intact and free from diffuse inflammation or rash. Avoid areas where tendons or bone are prominent. Iontophoresis current must not cross the heart.	
5	Cleanse the site thoroughly using alcohol, and then Clinical Laboratory Reagent Water (CLRW) on gauze. Some patients’ skin is resistant to stimulation; scrub the site to remove dry skin.	

6	Apply the electrodes containing the gels firmly to the site using the color-coded Velcro bands. a. Leave the skin moist after cleaning to reduce the possibility of burns and to insure good contact ***or*** b. Place a drop of DI water on the skin or surface of the gel before attaching. c. The red electrode should be placed on the inner flexor surface of the forearm, or the inner thigh, in an area that will accommodate the collection device following stimulation. d. The black electrode should be placed next to, but not touching the red electrode. Make sure it is not wet between the two electrodes, or bridging will occur and the patient will not sweat properly.	
7	Begin the induction by turning the switch on the battery unit to the "RUN" position and hold until a "beep" is heard. The green light will become bright. The instrument is programmed to deliver 1.5 mA of current for 5 minutes. When it is complete an audible tone will alert the operator.	
8	If a continuous alarm sounds, it indicates the circuit has been broken. Turn switch to STOP, correct fault, and begin again. Refer to Section 4.1 in the Wescor Instruction Manual.	
9	Remove the electrode and gels when the tone sounds.	
10	Wash the arm with distilled reagent grade (CLRW) water, and dry using clean gauze.	
11	Do not dispose of gels in patient care areas. Pilocarpine is a POISON.	See MSDS for more information.

Collection

Step	Action	Related Document
1.	Attach an appropriate sized Velcro strap to the collection device, threading it through the end slits. Avoid touching the collecting surface of the coil, which could contaminate the sample. Gloves should be used to prevent contamination.	
2.	Fasten the collector directly over the iontophoresed area (red electrode) securing the device by threading the other end of the strap through the remaining slit. Firmly tighten while spreading the skin under the collector so as not to pinch, and secure the Velcro strap.	
3.	Record the start of each collection on the patient's label to document collection duration	
4.	The collector may be further held in place by use of an elastic bandage.	
5.	Encourage the patient to sit quietly. Use of a blanket or infant warmer while monitoring the patient's temperature, or feeding or nursing the baby can increase sweat production.	

6.	Sweat should be collected for a ***maximum of 30 minutes***. The minimum sample volume collected must be **15uL**, or **3 complete revolutions** in the microbore tubing. The collector can be removed once there are at least 4 complete revolutions, and before the maximum time of 30 minutes.	
7.	To remove the collection device, press down firmly on the device while lifting off the plastic cover and carefully prying up the free end of the tubing slightly. With the nippers, snip the other attached end of the tubing as close to the base as possible. This is to prevent loss of specimen under the device.	
8.	Do not attempt to remove the entire collector assembly from the patient before separating the tubing. Vacuum could cause a loss of specimen.	
9.	Record the actual time each collector is removed on the patient's label. Make sure each specimen is adequately marked to ensure proper identification.	
10.	Label the collection with the patient's name, and transport promptly to the lab in a **sealed plastic bag** to prevent evaporation and minimize exposure to air. NOTE: In St Paul Outpatient Lab, if there are many patients waiting to be drawn and time does not allow for transport to the lab, call the Operations Supervisor or main lab number and ask someone to pick up the specimens.	
11.	Two collections should be attempted for quality assurance. If one of the collections produces a visually inadequate volume, attempt one more collection to gain 2 adequate samples.	
12.	If **neither of the first two collection attempts** produce 3 full revolutions of sweat ***(samples are both less than 2 revolutions)***, postpone further attempts until the patient is better hydrated, and have another technologist perform the subsequent repeat collection if possible. ***Notify the patient's provider if both collection attempts are obviously unsuccessful.***	
13.	The chemistry lab tech must evaluate samples and cancel any inadequate specimen(s). Submit all collection devices to lab in a **sealed plastic transport bag**, appropriately labeled with patient information and times collections were started and stopped.	
14.	Inform families that inquire about results, "*You can speak with your physician or the genetics counselor at your appointment today about the availability and meaning of the sweat chloride results*."	

15.	In Sunquest function CVIS, at each of these PROMPTS: PHLEB.WORKLOAD: enter SWC for Sweat Collection RECEIVE TIME: enter the time received in the lab COLL TIME/CREDIT/PARTIAL: enter the time the sample was collected MODIFY ORDER: enter Y TEST-2: SWCD (order the test code SWCD) BEGN1: enter the time the first collection device was placed on the patient BEGN2: enter the time the second collection device was placed on the patient END1: enter the time the first collection device was removed from the patient END2: enter the time the second collection device was removed from the patient This difference between the Begin Time and End Times must not exceed 30 minutes.	
16.	Credit SWCL in OER ***only*** if no collection is attempted.	

Limitations

1. Repeat testing may be performed when practical, even the same day. The rate of sweating varies from day to day.
2. Burn possibilities are reduced by using undamaged pilogel disks, appropriate strap pressure so disks are not crushed, and leaving the skin moist where the electrode is to be placed (or adding a drop of water to the disks.)
3. While allergic reactions to Pilocarpine iontophoresis are unusual, if diffuse inflammation, burns, or urticaria (hives) occurs:
    a. Immediately discontinue the procedure
    b. Contact the patient's physician
    c. Notify the Pharmacy.
    d. Complete an on-line Patient Safety Report, and include a description of the appearance of the area, and any conversation with the family.
    e. Do not assay the sweat sample due to possible contamination with serous fluid.
4. If the patient is experiencing discomfort during the iontophoresis, it is probably due to an uneven current distribution. This can be corrected by tightening the bands to apply even pressure across the gel.
5. Collections from more than one site should never be pooled.
6. Iontophoresis current must never cross the patient's trunk.
7. The minimum rate of sweating is 1 gm/m^2/minute. A longer collection time would require a larger volume of sweat. The 15 μL sample size corresponds to a maximum 30-minute collection time for the area stimulated by the Macroduct system.
8. The incidence of insufficient samples must be measured, investigated and resolved if it exceeds 5% for ages >90 days, and if it exceeds 10% for ages <90 days. Only when there are 2 QNS samples in one collection will it be counted in the collection failure rate, per CLSI and CF Foundation guidelines.
9. If one arm yields an acceptable sweat collection volume but the other arm is <15uL or unable to perform, run and report the acceptable sweat collection. It is not required to have two acceptable collections in order to perform testing.

References

1. College of American Pathologists, Chemistry and Toxicology Checklist, revised January 4, 2012.
2. Cystic Fibrosis Foundation Sweat Testing guidelines.
3. Clinical and Laboratory Standards Institute (CLSI). Sweat Testing: Sample Collection and Quantitative Chloride Analysis; Approved Guideline-Third Edition. NCCLS document C34-A3. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PN, 19087, 2000.
4. Macroduct Sweat Collection System Model 3700 SYS, Instruction/Service Manual, Wescor, Inc., M 2551-7 rev A, © 2004.
5. Macroduct Supply Kit Product Insert, Information for Parents, Wescor, Inc. 370 West 1700 South, Logan, UT 84321, 6/13/2008

Appendices

8.07 Sweat Chloride Collection Training Documentation

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1 (MPLS)	Minneapolis	January 1991	Initial Version

1 (SYSTEM)	Kristine Carlson	October 13, 1998	Chloride, Sweat Collection and Assay
2.	Kristine Carlson	March 8, 1999	Macroduct System
3.	L. Lichty	April 16, 2002	Sweat Stimulation and Collection
4.	L. Lichty	February 5, 2004	Sweat Collection
5.	L. Lichty	July 6, 2005	
6.	L. Lichty	January 4, 2006	Notify Pharmacy and complete Patient Safety Report for reaction to pilocarpine.
7.	L. Lichty	September 11,2007	Sweat Collection, added inform family of burn risk, and conditions of iontophoresis
8.	L. Lichty	February 21, 2011	New format. Added safety section, revised infection control, revised procedural risk, renumbered from CH 0.23
9.	L. Lichty	January 7, 2013	Notify patient physician in case of burn or reaction, storage conditions
10.	L. Lichty	November 17, 2014	Added CVIS steps to collection, revised Infection Control language.
11.	L. Lichty	September 30, 2015	Added SWCD test code to document collection duration
12.	L. Lichty	8/1/2016	Notify provider of collection failure
13.	Erin Bartos	3/1/2017	Changes to Patient and Family Preparation. Deliver patient specimen in a sealed plastic bag. Changes to crediting, and QNS failure rate counting. Changes to who cancels testing. All samples should be submitted to lab.