Catalog Number SS-150
GLASS ENCAPSULATED SWEAT CONTROLS FOR CYSTIC FIBROSIS TESTING
For In Vitro Diagnostic Use
Lot No:
Expiration Date: 28 February 2009

Analyte / Instrument	**LEVEL 1** (Source lot 19141) Normal	**LEVEL 2** (Source lot 19142) High Normal / Equivocal	**LEVEL 3** (Source lot 19143) Abnormal
Chloride Chloridometer[1]	34 ± 6 mmol/L	68 ± 11 mmol/L	137 ± 21 mmol/L
Conductivity Wescor® Sweat•Chek™ 3100 and 3120	42 ± 5 mmol/L	77 ± 6 mmol/L	142 ± 12 mmol/L
Osmolality Wescor® Model 5520 Vapor Pressure Osmometer	74 ± 12 mmol/kg	139 ± 12 mmol/kg	281 ± 22 mmol/kg

[1] Mean calculated using data from Labconco Digital Chloridometer (Labconco Corp., Kansas City MO 64132).

Intended Use
Wescor Sweat Controls for Cystic Fibrosis Testing are assayed controls intended as a means of validating the measurement of conductivity[A], osmolality, or chloride in patient samples.

Product Description
Wescor Sweat Controls for Cystic Fibrosis Testing are liquid, ready to use, and require no reconstitution or dilution. They are supplied in three levels, representing normal, high normal/equivocal, and abnormal electrolyte concentrations. There are 36 ampules per box, 12 x 0.75 mL of each level. They are prepared in an aqueous simulated human sweat matrix[B] to which preservatives, including 0.05% sodium azide have been added.

Warnings and Precautions
The Wescor Sweat Controls for Cystic Fibrosis Testing do not contain any human source material. No special precautions are required in handling the product other than those routinely used in the laboratory. Dispose of properly. Sodium azide may form metal azides in plumbing and pose a threat of explosion.

Storage and Stability
1. The Sweat Controls should be stored at room temperature.

Each ampule contains 0.75 mL of solution. This volume adequately mitigates evaporative concentration for a few hours after the ampule is broken. Ampules are intended for one-time use only.

Instructions for Use
1. Invert gently to ensure homogeneity of the contents.
2. Before opening, flip the neck of the ampule or tap the bottom of the ampule against a hard surface to clear solution from the neck.
3. Place the ampule in the ampule organizer in the position marked for breaking ampules.
4. Place the safety sleeve over the neck of the ampule.
5. Holding the ampule organizer down against the counter, grasp the neck of the ampule firmly between thumb and forefinger and snap the neck off.
6. Sample directly from the ampule, use a fresh Sweat Chek™ take up tube, micropipettor tip, or other sample loading device each time to avoid contamination of the solution.
7. Treat the controls as you would a patient sample in accordance with the manufacturer's requirements of the test method for each type of analysis: Chloride, Sodium, Conductivity, Osmolality.

Expected Values
The expected values have been established in the laboratory and from interlaboratory data using the listed manufacturer's instruments. Use of control materials having known component concentrations are an integral part of diagnostic procedures. Monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method. Each laboratory should establish its own quality control standards for the test method used.

Limitations
Any future changes made by the manufacturer of a test method may give a different value from the one indicated. Limitations of the test method are included in the information provided by the instrument manufacturer.

References

[A] Hammond KB, Turcios NL, Gibson LE. Clinical Evalualuation of the Macroduct Sweat Collection System and Conductvity Analyzer in the Diagnosis of Cystic Fibrosis. Pediatrics 1994; 124: 255-260.

[B] Emrich HM, Stoll E, Colombo JP, Richterrich R, Rossi E: Sweat Composition in Relation to Rate of Sweating in Patients with Cystic Fibrosis of the Pancreas, Pediatric Research, 2: 464-478 (1968).

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