ANALYTIC METHODS FOR SWEAT TESTING

Inspector Instructions:

READ

- Sweat testing method validation records
- Sampling of QC logs

CHM.30400 Sweat Test Validation **Phase II**

For sweat testing, the analytical method is validated by the laboratory prior to patient testing using specimens equivalent to the volume and concentration of patient sweat samples.

NOTE: Validation procedures must include studies of accuracy, precision, and upper/lower limits of the analytic measurement range. The laboratory should be aware that some instruments designed for serum or urine electrolyte determination may lack the sensitivity required for sweat testing.

Evidence of Compliance:

✓ Records of method validation

REFERENCES

1) Pillion DJ, Meczan E. Chloride measurement by microelectrode in cystic fibrosis and normal sweat. *Miner Electrolyte Metab.* 1987;13:196-200
2) Barnes GL, *et al.* Sweat testing by capillary collection and osmometry: suitability of the Wescor macroduct system for screening suspected cystic fibrosis patients. *Aust Paediatr J.* 1988;24:191-193
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):3707 [42CFR493.1255]
4) 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.
5) Department of Health and Human Services, Centers for Medicare and Medicaid Services Center for Disease Control and Prevention. Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; final rule. *Fed Register.* 2003 (Jan 24): Vol. 68, No. 16 [42CFR493]

CHM.30550 Sweat Chloride AMR **Phase II**

The lower limit of the sweat chloride analytical measurement range is less than or equal to 10 mmol/L.

NOTE: The lower limit of the sweat chloride analytical measurement range must be less than or equal to 10 mmol/L without any pretreatment that is not part of the usual assay procedure.

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.

CHM.30575 Confirmatory Sweat Test Report **Phase II**

If the test performed is a confirmatory test (ie, quantitative analysis of sweat chloride), the upper limit of AMR for sweat chloride results is less than or equal to 160 mmol/L.

NOTE: Even though the analytical instrument may have a higher upper limit of its AMR, sweat chloride concentrations > 160 mmol/L are not physiologically possible. Results of sweat chloride testing greater than 160 mmol/L must not be reported, and the patient must be retested.

Evidence of Compliance:
✓ Patient reports or worksheets

REFERENCES
1) Schultz IJ. Micropuncture studies of the sweat formation in cystic fibrosis patients. *J Clin Invest.* 1969;48:1470-1477

CHM.30600 Daily QC - Sweat Testing **Phase II**

The laboratory analyzes two levels of controls (one in the negative range and one in the positive range) at least once each day patient specimens are assayed.

NOTE: If sweat is collected from patients on gauze or filter paper, controls should be placed directly onto the same collection material, eluted, and treated in the same manner as a patient specimen.

For test systems with internal controls, the laboratory may limit daily quality control to the internal controls ONLY if all CAP requirements for internal controls are met, as listed in CHM.13900.

Evidence of Compliance:
✓ Records of QC results at defined frequency

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7165 [42CFR493.1255]
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.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services Center for Disease Control and Prevention. Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; final rule. *Fed Register.* 2003 (Jan 24): Vol. 68, No. 16 [42CFR493]

REPORTING OF RESULTS

Inspector Instructions:

- *Sampling of sweat analysis reports (appropriate reference intervals and disclaimer if applicable)*

***REVISED** 08/24/2023*
CHM.30700 Sweat Test Reporting **Phase II**

The laboratory report indicates the specific analytes measured in the sweat analysis, and applies the appropriate reference intervals and/or decision levels to patient results.

NOTE: The laboratory report must clearly indicate the analytes measured in the sweat test, and apply the appropriate reference intervals and/or decision levels to patient results.

The following table includes the Cystic Fibrosis Foundation reference intervals for chloride (Farrell PM et al 2017):

Test	Result	Interpretation
Sweat Chloride	≤29 mmol/L	CF unlikely
Sweat Chloride	30-59 mmol/L	Intermediate
Sweat Chloride	≥60mmol/L	Indicative of CF

Conductivity is a nonselective method for sweat analysis that has its own unique set of reference intervals. When sweat conductivity is expressed as units of aqueous sodium chloride solution,