the values are approximately 15 mmol/L higher than when chloride is measured directly. A patient having a sweat conductivity greater than or equal to 50 mmol/L should be referred to a specialized cystic fibrosis care center for a quantitative analysis of sweat chloride with or without sweat sodium.

REFERENCES
1) Farrell PM, *et al*. Diagnosis of Cystic Fibrosis: Consensus Guidelines from the Cystic Fibrosis Foundation. *J. Pediatr.* February 2017;181S:S4-15.
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.

*****REVISED** 08/24/2023***

CHM.30800 Sweat Test Report Disclaimer **Phase II**

If the test performed is a screening test (eg, sweat conductivity), the report includes a statement regarding the limits of clinical interpretation.

NOTE: Suggested wording for such a disclaimer might be: "This result represents a screening test for cystic fibrosis. Patients having borderline or positive results should be referred for a quantitative sweat chloride concentration."

REFERENCES
1) Rosenstein BJ, Langbaum TS. Misdiagnosis of cystic fibrosis. Need for continuing follow-up and reevaluation. *Clin Pediatr.* 1987;26:78-82
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.

PRENATAL SCREENING

TEST PANELS

Test panels include: 1) First trimester panel: total or free beta-hCG, pregnancy associated placental protein A (PAPP-A), and nuchal translucency (NT); 2) Second trimester quadruple panel: alpha-fetoprotein (AFP), unconjugated estriol (uE3), various forms of human chorionic gonadotropin (hCG), and dimeric inhibin-A (DIA); 3) Sequential and integrated panels: various combinations of first and second trimester tests. First trimester or second trimester panels may include additional markers to those listed if validated.

REQUISITIONS/CALCULATIONS/REPORTS

Requests for prenatal screening (neural tube defects, Down syndrome, etc.) must include specific information for meaningful interpretation of laboratory tests. For clinical screening purposes, analyte concentrations must be converted to multiple of the median (MoM) values, using gestational-age specific medians. The MoM value is used directly as the interpretative result for neural tube defect screening and for calculating risk for fetal trisomies. Gestational age-specific MoM values need to be adjusted for each patient, based on several variables. The laboratory must work cooperatively with the clinician to ensure that all necessary information is obtained.

A listing of published references is available with CHM.31150 (Prenatal Screen Risk Calculation) in the Master version of the checklist available for download by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists.

Inspector Instructions:

READ	• Sampling of prenatal screen policies and procedures • Sampling of prenatal screening requisitions • Sampling of records for adding or eliminating elements included in the risk calculation • Sampling of records of adjustment factors • Sampling of median value records • Sampling of records verifying calculated gestational age, maternal age and patient-specific risks • Sampling of maternal screen patient reports (demographics, clinical information, results reported in MoM, cut-off values)
ASK	• How does your laboratory verify or establish acceptable median values? • How does your laboratory monitor assay quality, appropriateness of medians and accuracy of gestational dating? • How does your laboratory monitor assay quality of nuchal translucency measurements? • What is your course of action if the requisition does not include all necessary information? • How does your laboratory verify or establish maternal weight adjustments?
DISCOVER	• Review runs that were accepted and rejected. Follow records to determine if the steps taken follow the written procedure for corrective action. • Review long term monitoring trends. Follow trends to determine if the steps taken follow the written procedure for corrective action. • Select a report with patient demographics requiring adjustment to MoM and review records for the use of correction factors for required markers

*****NEW** 12/26/2024***

CHM.31150 Prenatal Screen Risk Calculation **Phase II**

The laboratory determines which information and adjustments to include in the prenatal screening risk calculation.

NOTE: Expected elements in the prenatal risk calculation include:

- *Gestational age*
- *In vitro fertilization method, if applicable*
- *Initial or repeat testing*
- *Maternal age*
- *Maternal race or subpopulation as defined by the laboratory*
- *Maternal weight*
- *Medications to control diabetes*
- *Multiple gestation, if applicable*
- *Smoking status*

The rationale for exclusion of any expected element must be documented. Additional elements may be included in calculating the risk categorization. The rationale for additional elements must be documented.

REFERENCES

1) Wald NJ, *et al*. Maternal serum-alpha-fetoprotein measurement in antenatal screening for anencephaly and spina bifida in early pregnancy. Report of U.K. collaborative study on alpha-fetoprotein in relation to neural tube defects. *Lancet.* 1977;i:1323-1332.
2) Loughna, et al. Fetal size and dating: charts recommended for clinical obstetric practice. *Ultrasound.* 2009; 17.161-67.
3) Wald NJ, et al. Prenatal screening for open neural tube defects and Down syndrome: Three decades of progress. *Prenat Diagn.* 2010; 30:519-21.
4) Ioannou C, et al. Standardization of crown-rump length measurement. *BJOG.* 2013; 2(suppl):38-41.
5) Cuckle HS, *et al*. Estimating a woman's risk of having a pregnancy associated with Down's syndrome using her age and serum alpha-fetoprotein level. Brit J Obstet Gynecol. 1987; 94:387-402.
6) Morris JK, Wald NJ. Estimating the risk of Down syndrome in antenatal screening and the gestation at which this applies. J Med Screen. 2008; 14(1):5-7.