REFERENCES
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2) Howanitz PJ, Steindel SJ. Digoxin therapeutic drug monitoring practices. A College of American Pathologists Q-Probes study of 666 institutions and 18679 toxic levels. *Arch Pathol Lab Med.* 1993;117:684-690
3) Schoenenberge RA, *et al.* Appropriateness of antiepileptic drug level monitoring. *JAMA.* 1995;274:16221626
4) Williamson KM, *et al.* Digoxin toxicity: an evaluation in current clinical practice. *Arch Intern Med.* 1998;158:2444-2499
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CHM.29025 Immunosuppressive Drug Result Reporting **Phase II**

For the reporting of immunosuppressive drug results, the patient report contains all of the following:

1. **Appropriate therapeutic ranges based on the test method used**
2. **Analytical method (all tests) and method platform (immunoassays only)**
3. **Elements required in GEN.41096**

NOTE: For immunosuppressive drugs (eg, cyclosporine, sirolimus, tacrolimus, mycophenolic acid, everolimus), the therapeutic range may depend upon the test method, type of transplant, and length of time since the transplant procedure. Results from different types of samples and different methods are not interchangeable.

Evidence of Compliance:
- ✓ Patient results showing required report elements

TUMOR MARKER TESTING

Inspector Instructions:

READ

- Sampling of tumor marker result reports
- Test reference guide or other communication to ordering providers

CHM.29050 Tumor Marker Result Reporting **Phase I**

The following information is available to clinicians for the reporting of tumor marker results:

- **Manufacturer and methodology of the tumor marker assay**
- **A statement indicating that patient results determined by assays using different manufacturers or methods may not be comparable.**

NOTE: As used in this checklist, a tumor marker is defined as any analyte that is serially measured over time primarily as an indicator of tumor burden.

Tumor marker results obtained can vary due to differences in assay methods and reagent specificity. If there is an assay change while monitoring a patient, the CAP recommends (but does not require) that the laboratory run parallel measurements with both assays.

The required information does not need to be reported with the test result if it is readily available elsewhere (eg, test reference guide).

Evidence of Compliance:
- ✓ Patient reports with required elements **OR**
- ✓ Test reference guide or other mechanism for providing ordering and interpretation information

REFERENCES
1) National Academy of Clinical Biochemistry. Sturgeon, CM, Diamandis, EP. (Eds.). *Laboratory Medicine Practice Guidelines. Use of tumor markers in clinical practice: quality requirements.* American Association for Clinical Chemistry; 2009.

SWEAT TESTING FOR CYSTIC FIBROSIS

The laboratory diagnosis of cystic fibrosis includes SCREENING and CONFIRMATORY sweat testing. Screening tests include sweat conductivity. Confirmatory tests include quantitative analysis of sweat chloride.

SPECIMEN COLLECTION AND HANDLING

Inspector Instructions:

READ	• Sampling of sweat testing policies and procedures • Sampling of records/log of insufficient sweat samples • Sampling of iontophoresis unit maintenance records
OBSERVE	• An employee performing the sweat collection procedure, if possible
ASK	• How do you ensure effective disinfection of the sweat collection equipment? • What is your course of action if the patient is receiving oxygen from an open delivery system?

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

CHM.29100 Sweat Test/Appropriate Age **Phase I**

The sweat test is offered only to patients at an appropriate age.

NOTE: To increase the likelihood of collecting an adequate sweat specimen, sweat chloride testing can be evaluated in asymptomatic newborns with a positive newborn screen result or positive prenatal genetic test when the infant is at least ten days old, greater than 36 weeks gestation, and weighs >2kg. Sweat chloride testing should be performed as soon as possible at or after 10 days of life, ideally by four weeks of age. Sweat collections acquired in newborns >3.5kg (versus >2kg) improve specimen acceptability rates by 25% and should be considered when assessing the risk of a quality not sufficient (QNS) collection versus the need to obtain diagnostic information.

In symptomatic newborns (eg, those with meconium ileus), sweat chloride can be evaluated as early as 48 hours after birth if an adequate sweat volume can be collected; although, the likelihood of an inconclusive result may be greater at this age.

REFERENCES
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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) Eng W, LeGrys VA, Schechter MS, Laughon MM, Barker PM. Sweat-testing in preterm and full-term infants less than 6 weeks of age. *Pediatr Pulmonol.* 2005;40(1):64-7.