*concentrations of naturally occurring opiates (morphine and codeine) and for the semisynthetic opioids (oxycodone, hydrocodone) when compared to the 2000 ng/mL cutoff.*

*It is recommended that the laboratory review the package insert for its opiates immunoassay for cross-reactivity with the semisynthetic opioids (eg, oxycodone, hydrocodone). Specific immunoassays for the detection of semisynthetic and synthetic (eg, buprenorphine, fentanyl) opioids are available and should be used when reliable detection of those drugs is required; alternative targeted methods such as mass spectrometry may also be appropriate.*

*If cutoff values different than those defined by the manufacturer are used, the laboratory must perform appropriate validation studies to support the modification.*

**Evidence of Compliance:**

✓ Patient reports with cutoffs appropriate for the clinical setting

REFERENCES

1) Magnani BJ, Kwong TC, McMillin G, Wu AHB., eds Clinical Toxicology Testing: A Guide for Laboratory Professionals. 2nd ed. Northfield, IL: CAP Press; 2020.

# THERAPEUTIC DRUG MONITORING

## Inspector Instructions:

| | |
|---|---|
|   | • Sampling of TDM policies and procedures<br>• Sampling of TDM patient reports (dosage, time of drug administration) |
|   | • How is the clinician able to link TDM laboratory results to the dosage and time the patient received the drug? |

**CHM.28900 Specimen Collection/Drug Dosing** **Phase I**

**As applicable, information is available to clinical personnel for the optimal specimen collection time in relation to drug dosing.**

**Evidence of Compliance:**

✓ Test reference guide **OR** other mechanism for providing guidance for specimen collection for therapeutic drug testing

REFERENCES

1) Nicholson PW, *et al.* Ideal sampling time for drug assays. *Br J Clin Pharm.* 1980;9:467470
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;274:1622-1626
4) Williamson KM, *et al.* Digoxin toxicity: an evaluation in current clinical practice. *Arch Intern Med.* 1998;158:2444-2499

**CHM.29000 TDM Results** **Phase II**

**Where applicable, TDM results are reported in relation to patient dosing and/or timing information.**

*NOTE: The intent is to have a mechanism whereby the clinician can easily and accurately link TDM results from the laboratory to the dosage and time of drug administration. Ideally, the test result, dose and administration time would be reported in juxtaposition on the patient chart. This may be the responsibility of the laboratory, or an integrating function of reported laboratory analytic data with clinical information from other sources.*

REFERENCES
1) Elin RJ. Computer-assisted therapeutic drug monitoring. *Clin Lab Med.* 1987;7:485-492
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
5) Steele BW, *et al*. An evaluation of analytic goals for assays of drugs. A College of American Pathologists therapeutic drug monitoring survey study. *Arch Pathol Lab Med.* 2001;125:729-735

**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