



FIGURE 480e-2 Relationship between plasma creatinine and estimated glomerular filtration rate (eGFR) using the 4-parameter Modification of Diet in Renal Disease (MDRD) equation. IDMS, isotope dilution mass spectrometry.

range for this analyte when attempting to gauge a patient's renal function. A large decrease in glomerular filtration rate (GFR) is associated with slight increases in the plasma creatinine concentration within the typical reference range provided by many laboratories (Fig. 480e-2). A 60-year-old white woman with a serum creatinine level of 1.00 mg/dL, which is well within the typical reference range, has an estimated GFR of only 57 mL/min per 1.73 m², whereas the same creatinine concentration in a 20-year-old African-American male is consistent with normal renal function. To better estimate the GFR, which is widely considered to be the most useful index of overall renal function, it has become customary to use equations that incorporate plasma creatinine with other parameters. The most widely used of these equations in current practice is the 4-parameter Modification of Diet in Renal Disease (MDRD) equation that incorporates plasma creatinine, age, gender, and ethnic group (African American or not African American). The more recent CKD-EPI equation, which uses the same 4 parameters, is beginning to replace the MDRD equation. Recommended clinical laboratory practice is to report the estimated GFR with all creatinine measurements in adults. This addition provides more useful information than would a creatinine reference range alone.

SOURCES OF ERROR IN CLINICAL LABORATORY TESTING

Errors can arise at all stages of the testing process, from specimen collection to result interpretation. An error arising at any stage may adversely affect patient care. In clinical laboratory practice, it is customary to divide the testing process into three phases: preanalytic, analytic, and postanalytic. Examples of each type of error are shown in Table 480e-3. The most common error in the testing process is specimen mislabeling, in which a specimen from one patient is placed in a container labeled with another patient's name or identifiers. Specimen mislabeling errors may have very serious consequences for a patient. For example, if erroneous typing of a patient's blood group results from specimen mislabeling and is followed by transfusion of a mismatched unit of blood, the outcome may be fatal. A mislabeled biopsy specimen can lead either to an erroneous diagnosis and inappropriate therapy or to a failure to make a diagnosis and institute appropriate therapy.

In addition to errors, many preanalytic factors can influence clinical laboratory results. Posture (i.e., recumbent versus upright), exercise, diet, recently ingested food, and use of prescribed or recreational drugs (including tobacco, alcohol, caffeine, and herbal supplements)

can influence a variety of analyte concentrations. After blood has been collected, certain analytes undergo changes in their concentration during storage or transportation. Glucose levels fall as a result of red cell metabolism. Ammonia levels rise as a result of protein breakdown. Increasing permeability and breakdown of red cell membranes leads to increases in plasma potassium and free hemoglobin levels. Bacterial contamination can lead to overgrowth of specimens. To minimize

TABLE 480e-3 EXAMPLES OF PREANALYTIC, ANALYTIC, AND POSTANALYTIC ERRORS DURING THE LABORATORY TESTING PROCESS

Preanalytic Sources of Error

Test selection
Inappropriate test for the clinical need
Lack of clinical usefulness, regardless of possible results
Test order misunderstood or not communicated
Specimen collection
Incorrect time of collection
Patient not prepared for collection (e.g., not fasting)
Incorrect specimen type (e.g., wrong anticoagulant, wrong tissue fixative)
Use of incorrect specimen container
Insufficient specimen collected
Contamination of specimen by IV fluids, drugs, or bacteria
Specimen mislabeled or unlabeled
Important clinical information not provided
Delays in transportation to the lab, leading to alterations in specimen constituents

Analytic Sources of Error

Incorrect storage conditions prior to analysis
Specimen misidentification in the laboratory
Wrong test performed
Assay interferences
Assay failure (e.g., assay out of control)

Postanalytic Sources of Error

Delay in communication of assay results
Results not communicated to correct person
Incorrect result communicated
Misinterpretation of result