

§493.1495 Standard; Testing personnel responsibilities

(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

***Interpretive* Guidelines §493.1495(b)(5):**

If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite §493.1445(e)(12) under the director responsibilities.

Some examples of problems that may adversely affect patient test results may include:

- A pleural fluid that is mislabeled as a urine specimen and, therefore, is cultured as a urine culture;
- Performing a potassium on a hemolyzed sample; or
- Tests are incubated at 37°C when the manufacturer's instructions require 25°C

incubation.