D5453
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§493.1256 Standard: Control procedures

(d)(3)(iv) Each test system that has an extraction phase, include two control

materials, including one that is capable of detecting errors in the extraction process; and

Interpretive Guidelines §493.1256(d)(3)(iv)

Bacteriology:

For direct antigen systems, laboratories may use bacterial cell suspensions to meet the requirement for control organisms since the cell suspensions are subjected to both the extraction and reaction phases of the test. However, a matrix similar to patient specimens is preferred. For example, for direct antigen tests for group A streptococcal antigen, commercially prepared, dried (solid-shafted) swabs, one containing group A streptococcus (S. pyogenes) as a positive control and another with non-group A streptococcus and/or Staphylococcus aureus as a negative control may be used.

Additionally, if the manufacturer's instructions do not specify what the positive control contains, the laboratory should contact the manufacturer to ensure that the positive control contains a cell suspension of the organism. Otherwise, the laboratory must have an alternative mechanism for meeting this requirement (e.g., laboratory suspension stock American Type Culture Collection (ATCC) organism, commercially prepared organism controls).

Toxicology:

For comprehensive broad spectrum qualitative drug screening, procedures using gas chromatography, a control material containing one or more drugs representative of each drug class reported (e.g., tricyclic antidepressants, barbiturates), must go through each test phase, including the extraction process.

NOTE: For gas chromatography and mass spectrometry used for drug confirmations, an analyte-specific control is required for both qualitative and quantitative tests.