

D5451

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§493.1256 Standard: Control procedures

(d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;

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

For tests in which patient results are reported in terms of graded reactivity (1+, 2+, 3+, etc.) control(s) of graded reactivity must be used. For tests in which patient results are reported as a titer, controls of known titer must be used.

EXCEPTIONS:

A negative control is not required for anti-streptolysin O titer, anti-hyaluronidase titer tests. A positive control is not required for the cold agglutination test. For radial immuno-diffusion, one control or calibration material is required on each plate.