

D5455

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§493.1256 Standard: Control procedures

(d)(3)(v) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

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

The laboratory is also responsible for following the manufacturer's instructions concerning procedure limitations for detecting nucleic acid target amplification sequences, when provided by the manufacturer.

If the laboratory suspects the presence of interfering substances (inhibitors), the laboratory is responsible for using a control material (in addition to positive and negative control materials) capable of detecting interfering substances. Patient specimens may contain substances (inhibitors) that interfere with the enzymatic reaction of a molecular amplification procedure. These interfering substances could affect the assay's sensitivity causing a false negative result. Interfering substances may include, but are not limited to components within the patient specimen or exogenous substances introduced during the preanalytic and/or analytic phase of testing.