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## 42 C.F.R. § 493.1253

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### Standard: Establishment and verification of performance specifications.

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(a) *Applicability.* Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

(b)

(1) *Verification of performance specifications.* Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

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