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considerably improved the productivity of clinical laboratories fda issues final rule applying medical device rules to laboratory developed tests apr 29 2024 03 58 pm the food and drug administration april 29 issued a final rule that would phase out its general enforcement discretion approach for most laboratory developed tests over four years citing concern that some of the tests may not provide researchers point to the collection of unsuitable specimens for testing either due to inappropriate volume or quality as the most frequent source of all laboratory errors 3 specimen rejection by a laboratory can have significant clinical consequences including patient discomfort significant delay in result availability and high rate of sp several ethical issues exist within the diagnostic medical laboratory the major ethical challenges such as consent confidentiality codes of conduct conflict of interest lab utilisation proficiency and direct access testing are some times more prevalent in 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