Individualized
Quality Control Plans

Diagnostic laboratories using non-CLIA waived test systems with fewer than two levels of external controls every day of patient testing have until January 1, 2016 to decide how they will run controls for that test system. Examples of eligible tests include:Triage Cardiac Markers and D-Dimer; Qualigen FastPak; strep culture disks and media; nonwaived flu tests, pregnancy tests and mono tests run on serum or plasma, and non-waived analytes (e.g. CRP) run on the Piccolo. Pathology, histopathology, oral pathology, and cytology are not eligible for IQCP.

The two choices for laboratories beginning Jan. 1, 2016, are:

1. Use the CLIA default control requirement of running two levels of controls every day of patient testing.

2. Implement an effective Individualized Quality Control Plan (IQCP) after completing the required study. This study begins with a risk assessment of the laboratory's policies and history of any failures: specimen collection and handling, environmental specifications, reagents and test system, training and competency of testing personnel. The assessment must include an evaluation of whether the risks discovered are acceptable. The laboratory must then develop its quality control plan based on the risk assessment. This may mean a more controls or higher frequency of controls that are required by the CLIA default.The third facet of an IQCP is including the IQCP in the ongoing quality assessment monitoring, evaluating the effectiveness of the ICQP at least annually.

This week's tip provided by:

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