

Center for Medicaid and State Operations

Information for Laboratories

The Centers for Medicare and Medicaid Services (CMS), which administers the Clinical Laboratory Improvement (CLIA) program, recently became aware of testing circumstances that may produce erroneous results. One laboratory was identified where an operator incorrectly used a well-known pipetting system to perform HIV testing with an FDA approved HIV-1 kit that requires a micro sample of specimen. This combination, as well as poor pipetting technique, caused questionable test results. This laboratory used a root cause analysis to identify its own problem and has subsequently resolved it; however, we felt that this problem could re-occur in other laboratories under similar circumstances.

This potential problem is not a result of a malfunction of these products. Be sure to follow the manufacturer's instructions for performance.

As an added precaution and to confirm that the problem is not occurring in your laboratory, we are recommending that laboratories using this combination of test kit requiring a micro sample and dilution consider enhancing their existing QC protocol to check the system. This should be an addition to the laboratory's existing pipette checks, staff training and competency assessments, and quality assurance, etc.

Should your laboratory experience this problem, you should contact the manufacturer for technical assistance. If the problem persists, contact the Food and Drug Administration (FDA) MedWatch program at: 1-800-FDA-1088.