Attachment 1

CLIA Excluded D-tags for Reporting to CO
(Please continue to report monthly to Kathy Todd)

D5441
D5445
D5447
D5449
D5451
D5453
D5455
D5457
D5459
D5461
D5463
D5465
D5467
D5469
D5471
D5473
D5475
D5477
D5479
D5481
D5485

Attachment 2

Dear Laboratory Director:

Representative(s) of the **(State Agency)** surveyed your laboratory on **(Date)** for Clinical Laboratory Improvement Amendment (CLIA) purposes. The surveyor(s) identified certain quality control (QC) requirement(s) contained in the final regulations published on January 24, 2003, and effective on April 24, 2003, that were not met.

Findings and Observations Under Revised CLIA Rules

During the exit interview of your laboratory's survey, the **(State Agency)** representative(s) discussed certain QC provisions contained in the 2003 revisions of the regulations. At present, the Centers for Medicare & Medicaid Services (CMS) is educating laboratory directors about CLIA QC regulatory requirements. Below are the requirements that were identified as not being met. We are issuing this non-compliance notice as a letter, rather than a formal enforcement action, as part of this educational effort. CMS anticipates that this educational process will allow laboratories to become more knowledgeable about QC requirements in order to make informed compliance decisions. All other applicable unmet CLIA requirements will be cited on the CMS-2567, deficiency report, and must be corrected timely.

Additionally, since the publication of the 2003 CLIA final regulations and accompanying interpretive guidelines in 2004, CMS has identified innovations in technology and received input from technical experts that may lead to further modifications of CLIA QC policies in these guidelines. CMS is currently working with the Clinical and Laboratory Standards Institute (CLSI) and experts from laboratories, industry, and government to acquire input relative to QC and technological advances so that our policies will ultimately reflect this new information. We will continue the educational process until any merited changes are incorporated into our guidelines.

Laboratories will not receive a deficiency citation if, at a minimum, the laboratory director determines that manufacturers' QC instructions reasonably monitor the accuracy of their testing and the laboratory follows these instructions, but may still receive these letters.

At the time of your survey on (**Date**) your laboratory was not in compliance with the following QC provisions contained in the revised CLIA regulations:

*************List the specific D-tags from 493.1256 not met by the laboratory here. Include a description of each regulatory citation in clear language to accompany the citation and clarify it.********

Additional information regarding these items may be found on the CMS CLIA Web site at: www.cms.hhs.gov/clia in the Interpretive Guidelines and Brochures.

The (**State Agency**) representative will be available should you have any questions regarding the areas identified during the survey. You may contact (**Name**) at (**Phone No**.) if you require further assistance.

Sincerely,

CLIA Inspector
DHSS Office of Health Facilities
Licensing and Certification

Attachment 3

CLIA EQUIVALENT QUALITY CONTROL (EQC) FACT SHEET

- The QC "exclusion" letters will continue to be used to indicate noncompliance with QC procedures at 42 CFR 493.1256 until new CLSI QC consensus documents for manufacturers and laboratories are completed and pertinent information is incorporated into the Interpretive Guidelines.
- Exclusion letters are applicable to non-compliance with D tags D5441 to D5485.
- The letters CANNOT be changed except to include the specific survey citations and surveyor contact information and whether a 2567 is included..
- The letter notifies the laboratory about QC noncompliance; on site the surveyor clarifies the regulations so the laboratory can make informed compliance decisions.
- There are 3 EQC options depending on the extent and/or presence of internal QC.

  Option I—Internal QC monitors entire analytic process**.**
  Option II—Internal QC monitors a portion of the analytic process.
  Option III—NO internal QC; STABLE.
- For non-waived laboratories EQC is a *choice* to be determined by the Laboratory Director who selects the EQC option based on written manufacturer's information regarding the extent internal QC monitors the analytic process (*operator, analysis, environment*) and the laboratory's circumstances; i.e., staff competency, turnover, device stability, etc. The laboratory may use option 1 or 2 at their discretion.
- If the laboratory chooses EQC, the surveyor can provide guidance by clarifying eligibility, and explaining the protocol and evaluation process, etc.
- EQC permits the laboratory to decrease the frequency of external QC to save costs, as long as the test system is stable, eligible, the laboratory successfully completes their evaluation process, and their quality system is functioning within acceptable limits.
- If the laboratory doesn't choose EQC, it is subject to QC procedures at 493.1256(d)(3) which requires two levels of *external* QC/day & applicable specialty requirements.
- Manufacturer's instructions which are more stringent than CLIA must be met.
- Laboratories not performing any QC or with grossly incorrect results that may harm patients, will be cited on a CMS-2567. You may also cite noncompliance specific to the requirements for laboratory director, depending on the impact and scope of the problems. If immediate jeopardy exists, then follow Standard Operating Procedures.
- If the laboratory chooses EQC for a test with specialty requirements, like coagulation or blood gases, internal QC is once/day in lieu of the specialty requirements.
- For the initial evaluation process and EQC ongoing, when the lab has a QC failure, it can only repeat the QC once. If it is an obvious problem or the QC meets expected values, EQC can be continued. If the problem isn't obvious or QC is still not meeting expected values, then the laboratory must repeat the evaluation process.
- When a QC failure occurs, the laboratory must repeat all patient testing back to the last acceptable QC result.
- To continue EQC indefinitely, the lab must ensure its quality system is functioning within acceptable limits, i.e., satisfactory proficiency testing, acceptable personnel competency, and good analytic systems quality assurance.

Attachment 4

QC DECISION TABLE

Finding	*Compliance*	*Letter*	*2567*
2 levels of external QC performed/day	Yes	No	No
EQC performed correctly	Yes	No	No
EQC done incorrectly	No	Yes	No
Lab follows manufacturer's QC instructions that are ≥ EQC or 2 external QC/day	Yes	No	No
Lab follows manufacturer's QC instructions that are < external QC or EQC	No	Yes	No
Lab uses internal QC only - may or may not meet manufacturer's instructions	No	Yes	No
Lab doesn't follow manufacturer's instructions, but does some QC	No	Yes	No
Lab does no QC or there are serious concerns about test quality or there is immediate jeopardy (real or potential harm to patients)	No	No	Yes