

**CLIA UPDATE – June 2008**  
**Division of Laboratory Services**  
**Centers for Medicare and Medicaid Services**  
**Top 10 Deficiencies in the Nation – CMS Surveys**

| <b>Regulatory Subpart</b>                       | <b>Regulatory Cite</b> | <b>Deficiency</b>   | <b># all labs with deficiency</b> | <b>% all labs with deficiency</b> | <b># POLs with deficiency</b> | <b>% POLs with deficiency</b> |
|---|------------------------|---|-----------------------------------|-----------------------------------|-------------------------------|-------------------------------|
| Analytic Systems (D5413) STANDARD               | 493.1252(b)            | The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented. | 1,162                             | 6.34%                             | 780                           | 4.26%                         |
| General Lab Systems (D5217) STANDARD            | 493.1236(c)(1)         | At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I or this part.   | 1,151                             | 6.28%                             | 757                           | 4.13%                         |
| Analytic Systems (D5411) STANDARD               | 493.1252(a)            | Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.  | 1,077                             | 5.88%                             | 675                           | 3.68%                         |
| Analytic Systems (D5791) STANDARD               | 493.1289(a)            | The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.   | 1,067                             | 5.82%                             | 476                           | 2.59%                         |
| Analytic Systems (D5403) STANDARD               | 493.1251(b)            | The procedure manual must include the requirements for specimen acceptability, microscopic examination, step-by-step performance of the procedure, preparation of materials for testing, etc.   | 928                               | 5.06%                             | 602                           | 3.29%                         |
| General Lab Systems (D5291) STANDARD            | 493.1239(a)            | The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements in 493.1231 through 493.1236.   | 813                               | 4.44%                             | 455                           | 2.48%                         |
| Personnel Moderate Complexity (D6021) STANDARD  | 493.1407(e)(5)         | The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided.  | 801                               | 4.37%                             | 543                           | 2.96%                         |
| Analytic Systems (D5417) STANDARD               | 493.1252(d)            | Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.  | 755                               | 4.12%                             | 464                           | 2.53%                         |
| Postanalytic Systems (D5805) STANDARD           | 493.1291(c)            | The test report must indicate positive patient identification, name and address of the laboratory where the test was performed, the report date, test performed, specimen source, result and units of measurement or interpretation.  | 737                               | 4.02%                             | 430                           | 2.35%                         |
| Personnel Moderate Complexity (D6000) CONDITION | 493.1403               | The laboratory must have a director who meets the qualification requirements of 493.1405 and provides overall management and direction in accordance with 493.1407.   | 684                               | 3.73%                             | 425                           | 2.32%                         |

Total number of laboratories surveyed = 18,325

Total number of POLs surveyed = 12,087

Data based on the most current survey conducted on or after January 12, 2004

OSCAR data as of 6/10/2008

**CLIA UPDATE – June 2008**  
**Division of Laboratory Services**  
**Centers for Medicare and Medicaid Services**  
**Top 10 Conditions in the Nation – CMS Surveys**

| <b>Regulatory Subpart</b>                       | <b>Regulatory Cite</b> | <b>Deficiency</b>   | <b># all labs with deficiency</b> | <b>% all labs with deficiency</b> | <b># POLs with deficiency</b> | <b>% POLs with deficiency</b> |
|---|------------------------|---|-----------------------------------|-----------------------------------|-------------------------------|-------------------------------|
| Personnel Moderate Complexity (D6000) CONDITION | 493.1403               | The laboratory must have a director who meets the qualification requirements of 493.1405 and provides overall management and direction in accordance with 493.1407.   | 684                               | 3.73%                             | 425                           | 2.32%                         |
| Proficiency Testing (D2016) CONDITION           | 493.803                | Each laboratory performing nonwaived testing must successfully participate in a PT program approved by CMS as described in subpart I of this part for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA.   | 521                               | 2.84%                             | 342                           | 1.87%                         |
| Proficiency Testing (D2000) CONDITION           | 493.801                | Each laboratory must enroll in a PT program that meets the criteria in subpart I and is approved by HHS. The laboratory must enroll for each specialty and subspecialty, and must test the samples in the same manner as patients' specimens.   | 400                               | 2.18%                             | 267                           | 1.46%                         |
| Analytic Systems (D5400) CONDITION              | 493.1250               | Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.                  | 349                               | 1.90%                             | 187                           | 1.02%                         |
| Personnel High Complexity (D6076) CONDITION     | 493.1441               | The laboratory must have a director who meets the qualification requirements of 493.1443 and provides overall management and direction in accordance with 493.1445.   | 186                               | 1.02%                             | 46                            | 0.25%                         |
| Personnel Moderate Complexity (D6033) CONDITION | 493.1409               | The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 and provides technical oversight in accordance with 493.1413.  | 163                               | 0.89%                             | 121                           | 0.66%                         |
| Personnel Moderate Complexity (D6063) CONDITION | 493.1421               | The laboratory must have sufficient number of individuals meeting the qualifications of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.  | 139                               | 0.76%                             | 103                           | 0.56%                         |
| Hematology Quality Systems (D5024) CONDITION    | 493.1215               | If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269 and 493.1281 through 493.1299.   | 106                               | 0.58%                             | 54                            | 0.29%                         |
| Endocrinology Quality Systems (D5020) CONDITION | 493.1212               | If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.  | 78                                | 0.43%                             | 2                             | 0.01%                         |
| General Laboratory Systems (D5200) CONDITION    | 493.1230               | Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. | 70                                | 0.38%                             | 46                            | 0.25%                         |

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