

CLIA UPDATE – December 2003
Division Of Laboratory Services
Centers For Medicare & Medicaid Services

| ENROLLMENT | Number of Labs | Number of POLs |
|--|-----------------------|-----------------------|
| Laboratories Registered (Exempt/Non-Exempt/VA combined) | 183,874 | 102,550 |
| Laboratories Registered (Non-Exempt Only) | 177,615 | 101,090 |
| By Certificate Type | | |
| Compliance (CMS Surveys) | 20,832 | 13,742 |
| Waiver | 102,123 | 49,044 |
| Provider Performed Microscopy | 38,849 | 32,332 |
| Accreditation | 15,811 | 5,972 |

| CLIA EXEMPT STATES | Number of Labs |
|---------------------------|-----------------------|
| New York (Except POLs) | 2,929 |
| Washington | 2,873 |

| CERTIFICATE OF ACCREDITATION BY ORGANIZATION (Non-Exempt only) | Number of Labs* |
|---|------------------------|
| Commission on Office Laboratory Accreditation | 6,218 |
| College of American Pathologists | 4,872 |
| Joint Commission on Accreditation of Health Care Organizations | 3,797 |
| American Osteopathic Association | 43 |
| American Association of Blood Banks | 221 |
| American Society for Histocompatibility and Immunogenetics | 126 |

*The above data represents labs whose membership with the accreditation organization has been confirmed. Some labs are accredited by more than one organization.

| MOST FREQUENT DEFICIENCIES OVER TIME | ALL LABS | | | | POLs | | | | |
|---|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | Survey | 1 st | 2 nd | 3 rd | 4 th | 1 st | 2 nd | 3 rd | 4 th |
| Quality Control – Follow manufacturers instructions (D4001) | | 30% | 11% | 7% | 5% | 35% | 11% | 7% | 5% |
| Quality Assurance – No program (7001) | | 27% | 11% | 8% | 8% | 29% | 11% | 8% | 7% |
| Quality Control – Two levels per day of testing (D4006) | | 24% | 13% | 10% | 9% | 28% | 13% | 10% | 10% |

ENFORCEMENT

Lab Registry contains 132 labs which had sanctions imposed in 2002.

Source: CMS CLIA Data Base