

CENTERS FOR MEDICAID AND MEDICARE SERVICES - CLIA DATABASE INFORMATION – AS OF JANUARY 2016

| | 1993 | 1994* | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
|----------------------------|---------|---------|---------|---------|---------|---------|---------|---------|
| Total # Labs | 154,740 | 150,143 | 152,434 | 157,002 | 157,607 | 164,570 | 169,558 | 169,531 |
| Total in non-exempt states | 152,250 | 144,079 | 145,124 | 149,055 | 150,229 | 158,412 | 162,044 | 163,764 |
| Total # POLs | 90,800 | 89,344 | 82,907 | 87,832 | 88,028 | 91,600 | 93,867 | 95,069 |

| Non Exempt By Application Type** | | | | | | | | |
|----------------------------------|--------|--------|--------|--------|--------|--------|--------|--------|
| | 1993 | 1994* | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
| Compliance | 44,762 | 40,384 | 37,578 | 37,126 | 31,040 | 30,546 | 26,045 | 25,068 |
| Waiver | 67,294 | 66,235 | 65,031 | 68,127 | 74,455 | 78,825 | 84,217 | 85,944 |
| PPM | 16,443 | 18,101 | 23,089 | 25,327 | 28,931 | 31,546 | 34,782 | 35,760 |
| Accreditation | 23,751 | 19,359 | 19,426 | 18,475 | 15,803 | 17,495 | 17,000 | 16,992 |

| POLs by Application Type | | | | | | | | |
|--------------------------|------|-------|--------|--------|--------|--------|--------|--------|
| | 1993 | 1994* | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
| Compliance | NA | NA | 25,286 | 26,247 | 22,908 | 19,641 | 17,703 | 16,924 |
| Waiver | NA | NA | 28,951 | 30,267 | 32,497 | 36,950 | 39,633 | 40,990 |
| PPM | NA | NA | 19,818 | 23,399 | 25,987 | 27,831 | 29,501 | 30,210 |
| Accreditation | NA | NA | 8,852 | 7,919 | 6,636 | 7,178 | 7,030 | 6,945 |

| Accredited Labs*** | | | | | | | | |
|--------------------|------|-------|-------|-------|-------|-------|-------|-------|
| | 1993 | 1994* | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
| COLA | NA | NA | 7,528 | 7,870 | 6,836 | 7,334 | 6,773 | 6,618 |
| CAP | NA | NA | 4,933 | 4,139 | 4,241 | 4,251 | 4,352 | 4,540 |
| JCAHO | NA | NA | 6,455 | 7,161 | 6,166 | 6,481 | 4,384 | 4,416 |
| AOA | NA | NA | 161 | 53 | 48 | 60 | 52 | 56 |
| AABB | NA | NA | 2,008 | 1,716 | 1,635 | 1,666 | 1,632 | 550 |
| ASHI | NA | NA | 179 | 185 | 120 | 125 | 117 | 118 |

| | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
|----------------------------|--------|---------|---------|---------|---------|---------|---------|---------|---------|
| Total # Labs | 170996 | 174,504 | 183,874 | 186,734 | 194,734 | 198,232 | 203,939 | 206,940 | 214,875 |
| Total in non-exempt states | 165229 | 169,005 | 177,615 | 180,447 | 188,741 | 192,215 | 197,843 | 200,675 | 208,560 |
| Total # POLs | 95,879 | 97,363 | 101,090 | 104,230 | 105,914 | 106,180 | 107,937 | 108,234 | 110,925 |

| Non Exempt By Application Type** | | | | | | | | | |
|----------------------------------|--------|--------|---------|---------|---------|---------|---------|---------|---------|
| | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
| Compliance | 22,757 | 21,809 | 20,832 | 20,758 | 20,480 | 20,026 | 19,695 | 19,412 | 19,178 |
| Waiver | 88,730 | 93,129 | 102,123 | 105,138 | 113,445 | 117,418 | 122,992 | 126,219 | 134,778 |
| PPM | 36,850 | 37,755 | 38,849 | 38,884 | 39,209 | 38,814 | 39,014 | 38,783 | 38,509 |
| Accreditation | 16,892 | 16,312 | 15,811 | 15,667 | 15,607 | 15,957 | 16,142 | 16,261 | 16,095 |

| POLs by Application Type | | | | | | | | | |
|--------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
| Compliance | 15,255 | 14,522 | 13,742 | 13,718 | 13,545 | 13,184 | 12,926 | 12,696 | 12,517 |
| Waiver | 42,793 | 44,891 | 49,044 | 50,088 | 52,632 | 53,628 | 55,477 | 56,291 | 59,790 |
| PPM | 30,959 | 31,590 | 32,332 | 32,248 | 32,388 | 31,862 | 31,934 | 31,614 | 31,174 |
| Accreditation | 6,872 | 6,360 | 5,972 | 5,874 | 5,844 | 6,032 | 6,128 | 6,168 | 6,040 |

| Accredited Labs*** | | | | | | | | | |
|--------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
| COLA | 6,881 | 6,335 | 6,218 | 6,179 | 6,256 | 6,289 | 6,465 | 6,348 | 7,057 |
| CAP | 4,547 | 4,583 | 4,872 | 5,179 | 5,229 | 5,385 | 5,386 | 5,448 | 5,476 |
| Joint Commission | 4,471 | 4,397 | 3,797 | 3,467 | 3,127 | 2,928 | 2,753 | 2,730 | 2,580 |
| AOA | 53 | 49 | 43 | 34 | 49 | 62 | 73 | 81 | 77 |
| AABB | 219 | 214 | 221 | 223 | 219 | 218 | 214 | 211 | 203 |
| ASHI | 125 | 119 | 126 | 124 | 128 | 132 | 127 | 125 | 125 |

| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | | | |
|----------------------------|---------|---------|---------|---------|---------|---------|--|--|--|
| Total # Labs | 221,793 | 225,746 | 232,996 | 244,564 | 249,094 | 254,975 | | | |
| Total in non-exempt states | 215,057 | 218,944 | 225,879 | 236,882 | 241,031 | 246,650 | | | |
| Total # POLs | 113,124 | 114,461 | 116,634 | 118,837 | 119,461 | 120,919 | | | |

| Non Exempt By Application Type** | | | | | | | | | |
|----------------------------------|---------|---------|---------|---------|---------|---------|--|--|--|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | | | |
| Compliance | 19,404 | 19,319 | 19,354 | 18,959 | 18,695 | 18,385 | | | |
| Waiver | 141,994 | 146,071 | 153,568 | 165,058 | 170,404 | 177,016 | | | |
| PPM | 37,795 | 37,767 | 37,299 | 36,784 | 35,604 | 34,808 | | | |
| Accreditation | 15,864 | 15,787 | 15,658 | 16,081 | 16,328 | 16,441 | | | |

| POLs by Application Type | | | | | | | | | |
|--------------------------|--------|--------|--------|--------|--------|--------|--|--|--|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | | | |
| Compliance | 12,685 | 12,619 | 12,597 | 12,339 | 12,083 | 11,721 | | | |
| Waiver | 62,695 | 64,202 | 66,903 | 71,351 | 73,314 | 75,964 | | | |
| PPM | 30,392 | 30,312 | 29,875 | 29,289 | 28,177 | 27,467 | | | |
| Accreditation | 5,843 | 5,825 | 5,704 | 5,858 | 5,887 | 5,767 | | | |

| Accredited Labs*** | | | | | | | | | |
|--------------------|-------|-------|-------|-------|-------|-------|--|--|--|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | | | |
| COLA | 6,796 | 6,623 | 6,463 | 6,612 | 6,657 | 6,614 | | | |
| CAP | 5,580 | 5,602 | 5,728 | 5,968 | 6,169 | 6,237 | | | |
| Joint Commission | 2,458 | 2,431 | 2,380 | 2,347 | 2,278 | 2,209 | | | |
| AOA | 107 | 110 | 128 | 130 | 130 | 129 | | | |
| AABB | 215 | 219 | 218 | 225 | 216 | 206 | | | |
| ASHI | 130 | 124 | 122 | 121 | 110 | 110 | | | |
| A2LA | | | | | 1 | 1 | | | |

NA = Not available

* In the 4th quarter of 1994, CMS either deleted or terminated about 6,400 CLIA numbers because of laboratories' failure to pay CLIA certificate fees

** Proportion of labs by certificate type has changed over time due to new technology, third party payments, increase in number and type of waived and PPM tests and other influences from a dynamic health care environment

*** Accredited total By Application Type differs from Accredited Laboratory breakdown since some laboratories are accredited by more than one accreditation organization. The number of labs enrolled in each accreditation organization changed over time as duplicate enrollments were identified and eliminated