

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

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

<b>CLIA EXEMPT STATES</b>	<b>Number of Labs</b>
New York (Except POLs)	2,929
Washington	2,873

<b>CERTIFICATE OF ACCREDITATION BY ORGANIZATION (Non-Exempt only)</b>	<b>Number of Labs*</b>
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.

<b>MOST FREQUENT DEFICIENCIES OVER TIME</b>	<b>ALL LABS</b>				<b>POLs</b>				
	<b>Survey</b>	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>
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**

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**CERTIFICATE OF COMPLIANCE LABORATORIES**  
**BY CERTIFICATE SCHEDULE**

<b>Certificate Schedule</b>	<b>ANNUAL TEST VOLUME</b>	<b>ALL</b>		<b>POLs</b>	
TOTAL LABS		20,832		13,742	
Low Vol A	2,000 or fewer	8,997	43.2%	7,057	51.4%
<b>A</b>	2,001 – 10,000	5,048	24.2%	3,824	27.8%
<b>B</b>	2,001 – 10,000	1,144	5.5%	637	4.6%
<b>C</b>	10,001 – 25,000	1,534	7.4%	886	6.4%
<b>D</b>	10,001 – 25,000	853	4.1%	318	2.3%
<b>E</b>	25,001 – 50,000	1,325	6.4%	472	3.4%
<b>F</b>	50,001 – 75,000	652	3.1%	212	1.5%
<b>G</b>	75,001 – 100,000	373	1.8%	104	0.8%
<b>H</b>	100,001 – 500,000	778	3.7%	213	1.5%
<b>I</b>	500,001 – 1,000,000	74	0.4%	18	0.1%
<b>J</b>	more than 1,000,000	54	0.3%	1	0.1%

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**LABORATORIES BY TYPE OF FACILITY**

Type Of Laboratory	Number	Percent
Ambulatory Surgical Centers	3,002	1.6
Community Clinic	6,646	3.6
Comp. Outpatient Rehab Facility	197	0.1
Ancillary Testing Site in Health Care Facility	2,710	1.5
End Stage Renal Disease Dialysis Facility	3,574	1.9
Health Fair	477	0.3
Health Maintenance Organization	656	0.4
Home Health Agency	7,899	4.3
Hospice	1,177	0.6
Hospital	8,713	4.7
Independent	5,070	2.8
Industrial	1,600	0.9
Insurance	50	0.03
Intermediate Care Facility for Mentally Retarded	841	0.5
Mobile Laboratory	1,085	0.6
Pharmacy	2,280	1.2
School/Student Health Facility	1,772	1.0
Skilled Nursing Facility/Nursing Facility	14,803	8.1
Physician Office	102,550	56.0
Other Practitioner	2,154	1.2
Tissue Bank/Repositories	33	0.02
Blood Banks	371	0.2
Rural Health Clinic	922	0.5
Federally Qualified Health Center	187	0.1
Ambulance	1,690	0.9
Public Health Laboratories	114	0.06
Other	13,301	7.2
<b>Total</b>	<b>183,874</b>	<b>100</b>

**Source: CMS CLIA Data Base**

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CLIA Surveys: Top Deficiencies  
First, Second, Third, and Fourth Cycle

Regulatory Subpart	Regulatory Cite	Deficiency	All Labs				POLs			
			1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>
Quality Control (D4006)	493.1202(c)(4)	The lab must perform and document at least 2 levels of controls each day or testing.	6,361 30%	1,435 10.5%	929 6.8%	703 5.1%	4,992 35%	958 10.5%	634 7.0%	446 4.9%
Quality Assurance (D7001)	493.1701	The lab must establish and follow a comprehensive, written quality assurance program to monitor its overall operation.	5,645 27%	1,483 10.8%	1,112 8.1%	1,070 7.8%	4,266 29%	997 11.0%	703 7.7%	672 7.4%
Quality Control (D4001)	493.1202(c)(1)	The lab must follow the manufacturer's instructions for instrument operation and test performance.	5,124 24%	1,719 12.5%	1,307 9.5%	1,223 8.9%	4,050 28%	1,132 12.5%	920 10.1%	872 9.6%
Personnel (D6032)	493.1407(e)(14)	The lab director must specify in writing the responsibilities and duties of all personnel.	3,853 18%	587 4.3%	336 2.4%	288 2.1%	2,821 20%	428 4.7%	261 2.9%	201 2.2%
Quality Control (D4022)	493.1202(c)(2)	The lab must have a procedure manual.	2,903 14%	723 5.3%	454 3.3%	355 2.6%	2,219 15%	526 5.8%	360 4.0%	267 2.9%
Quality Assurance (D7047)	493.1709(b)	The lab must have a system for verifying accuracy and reliability twice each year for tests not covered under the lab's PT program.	NA	1,292 9.4%	1,023 7.5%	930 6.8%	NA	671 7.4%	607 6.7%	535 5.9%
Proficiency Testing (D6018)	493.1407(e)(4) iii	All PT reports received are reviewed by appropriate staff to evaluate lab's performance and identify any problems that require corrective action.	NA	566 4.1%	653 4.8%	554 4.0%	NA	462 5.1%	488 5.4%	415 4.6%
Proficiency Testing (D2000)	493.801	The lab must enroll in a PT program approved by HHS for each specialty and subspecialty of tests it performs.	NA	456 3.3%	249 1.8%	288 2.1%	NA	356 3.9%	168 1.8%	202 2.2%
Proficiency Testing (D2015)	493.801(b)(5)	Laboratory must keep lab proficiency records a minimum amount of time.	NA	744 5.4%	640 4.7%	653 4.8%	NA	510 5.6%	462 5.1%	438 4.8%
Total Number of Laboratories with First, Second, Third and Fourth surveys			21,224	13,715			14,391	9,084		

NA = Not Available