New York State's Experience with Assessment of Waived Testing and PPMP Practices: Are We Ready for Waived HIV Antibody Tests?

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BACKGROUND

NYS, a CLIA-exempt state, conducted a study as part of the CDC's Laboratory Medicine Sentinel Monitoring Network to assess testing practices among sites designated as Limited Service Laboratories (LSLs). These are point of care testing sites, other than physician offices, that are limited to waived assays or provider performed microscopy procedures (PPMP). Although NYS has provided regulatory oversight to comprehensive clinical laboratories since 1965, it is only since 1996 that the program began registration and assessment of LSLs.

OBJECTIVES

To determine the type and extent of oversight necessary, practical and feasible for waived and PPMP sites.

METHODS

Selection criteria included geographic location, facility type, test volume and affiliation or lack of affiliation with a NYS-permitted laboratory. Data were collected using questionnaires developed to obtain information describing testing and QA practices.

RESULTS

Between September 2000 and January 2002 on-site surveys were conducted in 609 of the nearly 3,000 LSLs. Greater than half of the sites consisted of nursing facilities and clinics; nurses performed more than 80% of the testing. The five waived assays most frequently performed were blood glucose (83%), urinalysis (62%), occult blood (48%), urine hCG (39%) and strep antigen (23%). A large proportion of sites lacked adequate procedural and QA practices. Among non-affiliated LSLs, 39% and 65% did not perform manufacturer's recommended QC for glucometer and urinalysis testing, respectively.

Implications for Programs/Policy

Findings raise concern for the quality of waived testing performed in settings not typically staffed by professional laboratorians and also underscore the need to provide adequate oversight and training opportunities. The desire to increase access by promoting waiver of additional tests, including HIV antibody tests, heightens the need to reassess current regulatory requirements for waived tests.

Implications for Research

The findings support the need to identify and implement training and oversight strategies that will effectively raise the level of QA practices in these settings.

Table 1
Limited Service Laboratory (LSL's)
Registered by the New York State
Department of Health

Facility Type	**Registered N = 2,837**	**Surveyed N = 609**
Community Clinic	549	138
Ancillary Testing Site	544	96
Nursing Home	568	150
Home Health Agency	232	46
Student Health Service	217	36
Industrial/Insurance	133	49
Correctional Facility	81	1
End Stage Renal Dialysis Center	92	19
WIC Clinic	62	1
Ambulance	73	15
Ambulatory Surgery Center	55	12
HMO	8	2
Hospice	15	3
Hospital	32	7
Other	176	34

Table 2
Individuals Performing Tests in
New York State Limited Service
Laboratories

Personnel Category	**Facilities N=609**
Registered Nurse	7,236
Licensed Practical Nurse	4,303
Medical Doctor	621
Nurse Practioner	300
Clerical Staff	289
Physician's Assistant	67
Medical Laboratory Technician	34
Medical Technologist	18
Other (includes security personnel, podiatrists, phlebotomists, counselors, emergency medical technicians, medical assistants and nutritionists)	840

Table 3
Selected Safety Citations

Expectation	Percentage of sites meeting expectation	
	Affiliated[a] N=157	**Non-affiliated N=452**
	%	**%**
Employ adequate personal protective equipment	98	99
Comply with eating/drinking/smoking restriction	100	99
Follow proper sharps disposal practices	97	92
Comply with regulated medical waste requirements	99	99

[a] Facility has a formal affiliation with a New York State-licensed laboratory

Table 4
Whole Blood Glucose

Expectation	Percentage of sites meeting expectation	
	Affiliated[a] N=122	Non-Affiliated N=382
	%	%
Use adequate specimen collection/labeling practices	97	97
Follow required reagent storage recommendation	89	79
Assess and document reagent expiration date and lot number	84	48
Perform recommended calibration	95	87
Perform recommended QC	96	61
Have a policy for reacting to failed QC	89	45
Have a policy for correcting report errors	84	59

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Table 5
Urine Dipstick Analysis

Expectation	Percentage of sites meeting expectation	
	Affiliated[a] N=126	Non-Affiliated N=253
	%	%
Use adequate specimen collection/labeling practices	99	94
Follow required reagent storage recommendation	85	81
Assess and document reagent expiration date and lot number	82	40
Perform recommended QC	91	35
Adhere to test time limitations	99	93
Have a policy for reacting to failed QC	86	40
Supervisor actively reviews QC	86	50
Have a policy for correcting report errors	81	54

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Table 6
Fecal Occult Blood

Expectation	Percentage of sites meeting expectation	
	Affiliated[a] N=88	Non-Affiliated N=205
	%	%
Use adequate specimen collection/labeling practices	98	93
Follow required reagent storage recommendation	88	88
Assess and document reagent expiration date and lot number	63	45
Perform recommended QC	86	69
Adhere to test time limitations	98	97
Have a policy for reacting to failed QC	83	50
Supervisor actively reviews QC	86	61
Have a policy for correcting report errors	82	60

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Table 7
Urine hCG

Expectation	Percentage of sites meeting expectation	
	Affiliated[a] N=94	Non-Affiliated N=146
	%	%
Use adequate specimen collection/labeling practices	99	97
Follow required reagent storage recommendation	85	85
Assess and document reagent expiration date and lot number	88	49
Perform recommended QC	95	61
Adhere to test time limitations	99	95
Have a policy for reacting to failed QC	86	43
Supervisor actively reviews QC	86	60
Have a policy for correcting report errors	78	64

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Table 8
Strep Group A Antigen

Expectation	Percentage of sites meeting expectation	
	Affiliated[a] N=62	Non-Affiliated N=76
	%	%
Use adequate specimen collection/labeling practices	95	97
Follow required reagent storage recommendation	85	82
Assess and document reagent expiration date and lot number	87	62
Perform Recommended QC	95	68
Adhere to test time limitations	100	99
Have a policy for reacting to failed QC	89	50
Supervisor actively reviews QC	89	75
Have a policy for correcting report errors	79	74

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Table 9
PPMP (KOH)

Expectation	Percentage of sites meeting expectation	
	Affiliated[a] N = 44	Non-affiliated N = 66
	%	%
Written collection procedure	80	77
Microscope maintenance	91	79
Written testing procedure	77	76
Written reporting policy	77	79
Supervisory review (results)	75	77
Corrective action (reports)	64	56
Competency assessment	68	41

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Table 10
Provider-Performed Microscopsy Procedures (Wet Mount)

Expectation	Percentage of sites meeting expectation	
	Affiliated[a] N = 78	Non-affiliated N = 105
	%	%
Have a written collection procedure	87	78
Perform microscope maintenance	92	86
Have a written test procedure	83	78
Have a written reporting policy	83	77
Supervisor actively reviews (results)	77	77
Have a policy for correcting report errors	68	57
Conduct staff competency assessment	67	40

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