



Maximizing In-House Laboratory Testing:

Navigating New 2025 Lab Director Regulations, Ensuring Compliance, and Enhancing Profitability

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Speakers

- **Verlin K Janzen, MT(ASCP), MD, FAAFP**
 - FP Physician – retired from Hutchinson Clinic – Hutchinson KS
 - Family Physician, Occupational Medicine
 - Medical Director – Laboratory, Population Health, Informatics
 - COLA Board member: 1992-2001, 2006-present
- **Andy Gill, MT(ASCP)**
 - Laboratory Consultant
 - Hospital Lab Manager Duke Healthcare System
 - Established the LSU Drug Testing Program

Objectives

1. Understand how the new CLIA (Clinical Laboratory Improvement Amendments) regulations will affect the ability to operate outpatient office laboratories.
2. Choose the laboratory tests, testing equipment and personnel that are most appropriate for the needs of your outpatient office.
3. Analyze the potential revenue and costs associated with outpatient office laboratory testing to optimize financial viability.
4. Discuss quality testing required in outpatient office laboratories.

Why are we doing this session?

1. Recent regulatory changes that could affect physician offices that are currently doing testing
2. Encourage MORE offices to consider doing testing – especially MODERATE complexity testing
 - Good for patients – rapid results, efficient use of time
 - Good for physicians – efficient use of time, revenue enhancement

Overview

- Goal – to have successful laboratory in physician office serving practice's patients and physicians
- To be successful – all 3 legs must be in place and working



“Three-Legged Stool” of Successful Lab



Analytic

- Analyzer selection
- Personnel qualifications
 - Lab Director
- Installation
- Validations
- Training
- Support
- QC

Regulatory

- CLIA ID
- Lab Director qualifications
- Policy/Procedure Manuals
- CLIA or COLA
- QA/QC/PTM/PT/ Personnel

Economic

- Credentialing
- CLIA ID
- NPI
- Medicare Provider #
- Billing/Reimb
- Instruments
 - Buy-Lease-CPR
 - Reagents
 - Personnel (MT, MLT, MA)



Navigating New CLIA Regulations: Ensuring Compliance for Outpatient Office Laboratories

- Overview CLIA regulations
- Test complexity model
- Surveys
- 2025 Regulatory Changes – how to survive

What is CLIA?

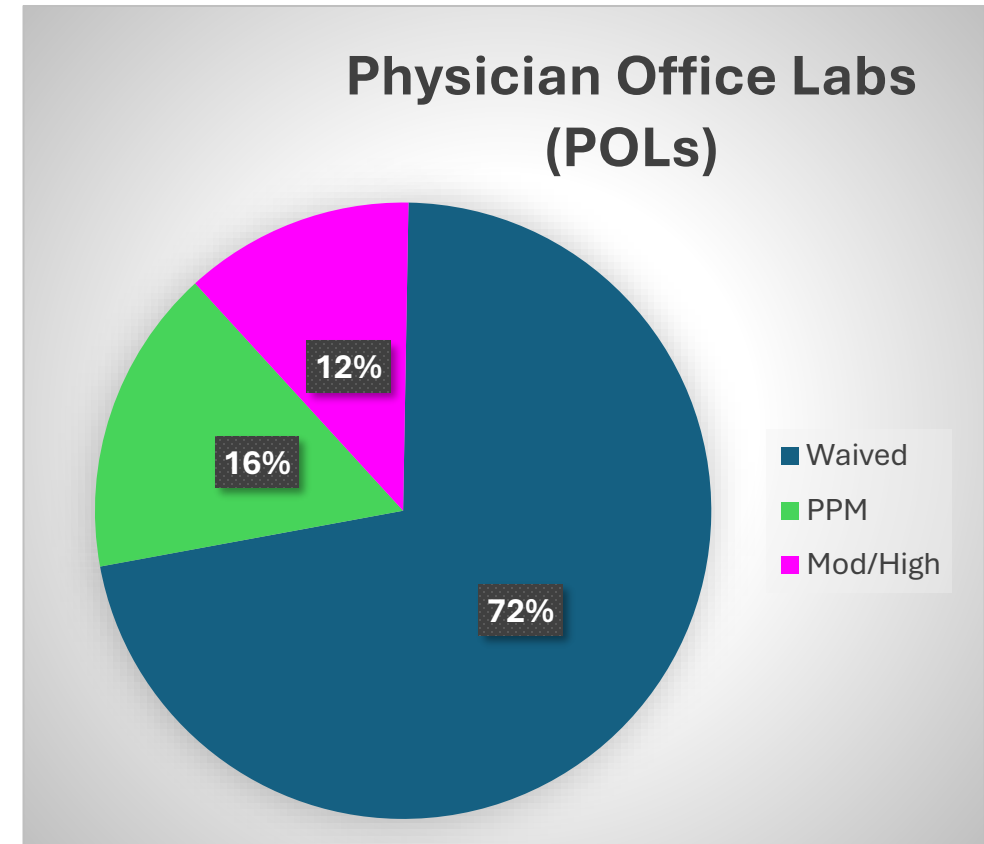
- **C**linical **L**aboratory **I**mprovement **A**ct/**A**mendments
 - 1967 (Act) – large labs w/interstate testing (hospitals, reference labs)
 - 1992 (Amendments) – other labs including POLs (physician office labs)
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 - December 28, 2024 – changes that will particularly affect POLs

CLIA covers ...

- All labs examining “materials derived from the human body for purposes of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of health of, human beings”
- Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing ARE NOT considered laboratories

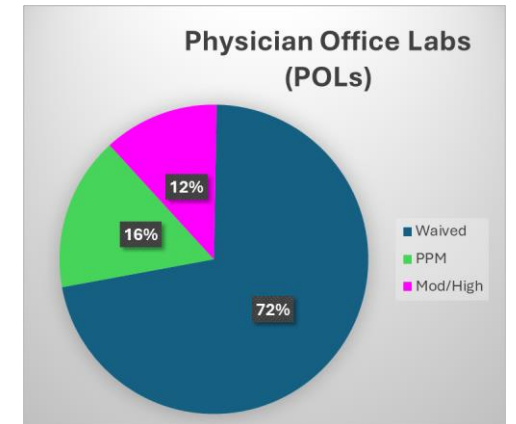
CLIA regulates based on test complexity

- Waived
 - Moderate complexity
 - Provider-performed microscopy
 - High complexity
-
- Requirements for each test is based on its complexity
 - Your lab's certificate to test is based on the MOST complex test you perform



Test complexities *in general*

- **Waived** – simple tests, ‘no harm’⁽¹⁾ if done incorrectly – kits, point-of-care tests
- **Moderate** – most tests
 - **PROVIDER PERFORMED** microscopy (PPM) – KOH/wet mount, microscopic UA, pinworm exam, fern test, nasal smear eos, fecal leukocyte, qualitative semen analysis
- **High** – non-automated tests, microbiology cultures, most gram stains, abnormal WBC differentials, uncategorized tests



(1) Per CLIA Law - <https://www.govinfo.gov/content/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partF-subpart2-sec263a.pdf>

Waived tests (2024)

148 Analytes (15,428 test systems) now waived

Comprehensive Metab Profile

Lipids – total chol, HDL, trigs

FSH, TSH, LH, urine hCG

BNP

A1c, microalbumin, fructosamine

Ionized calcium

Ketones – blood & urine

Platelet aggregation

CBC w/3-part differential, platelet count

Cannabinoids, cocaine, cotinine, benzo-diazepines, ethanol, fentanyl, norfentanyl, 6-acetylmorphine, meth-amphetamines, morphine, opiates, oxazepam, propoxyphene, PCP, secobarbital, tramadol, tricyclics

Lyme disease

H pylori antibodies

Herpes simplex

Hepatitis C antibody

Mono, influenza a/b, Grp A strep, RSV, adenovirus (eye)

Trichomonas

Protime

Adenovirus (conjunctival fluid)

Bacterial vaginosis

Ferning in saliva (ovulation)

Lithium

Male fertility (motile sperm > 10M)

Syphilis

SARS-CoV-2 & other respiratory viruses

CLIA Requirements by Test Complexity

	Facility	Quality Systems	Personnel	Proficiency Testing	Routine Inspections
Waived	Register – follow manufacturer instructions – allow unannounced surveys – notify of changes in ownership/director/menu				
PPM	✓	✓	✓	✓	
Moderate	✓	✓	✓	✓	Q 2 yrs
High	✓	✓	✓	✓	Q 2 yrs

Facility Administration

- Space, ventilation, utilities
- Minimize contamination
- Sufficient instrument/supplies for type & volume of testing
- Compliance with Federal, State, and local laboratory requirements
 - OSHA, Hazmat, etc
- Safety (physical, chemical, biological, electrical, biohazard)
- Record retention guidelines
- Transfusion Service requirements

Quality Systems

- Quality control (QC) – internal controls to be sure system is working correctly
- Calibration, preventive maintenance
- Quality Assurance (QA)
- Test ordering & resulting
- Specimen handling
- Reagent storage
- Complaints

Proficiency Testing (PT)

- External controls to be sure providing accurate results
 - Quality control = internal controls
- Lab purchases CHALLENGES that are sent to them 2-3 times per year for tests done in the lab
 - Lab tests and reports to PT company
 - PT company sends report to lab AND to CMS/Accreditor
 - Passing for most is 4/5 (80%)

Personnel Requirements*

Personnel Category	Test Complexity		
	PPM	Moderate	High
Lab Director	MD, DO, DPM, NP, PA	Pathologist, or PhD, MS, BS w/20 hr course + varying experience , or MD/DO with 1 yr experience + 20 hr course	Pathologist or PhD with 20-hr course + experience, or MD/DO with 2 yr experience w/20 hr course
Technical Consultant	--	Pathologist, MD, DO, PhD, MS, BS	--
Technical Supervisor	--	--	Pathologist, MD, DO, PhD, MS, BS
General Supervisor			MD, DO, PhD, MS, BS, AD
Clinical Consultant		MD, DO, PhD	MD, DO, PhD
Testing Personnel	MD, DO, DPM, NP, PA	Minimum - HS Grad	Minimum - AD w/science degree

* Very high-level summary – see CLIA regs for more detail

Importance of Training & Competency Requirement

- Training is required for ALL personnel
 - If laboratorian – on your instruments, your policies/procedures
 - Non-laboratorian (HS grad, nurse, MA, etc) may test with appropriate training
 - Training as above **PLUS** basics of lab science (QC, PT, calibration, etc)
 - EVEN down to point of “importance of accurate results”
 - Performed by MT or Manufacturer’s Rep
- COMPETENCY – required by CLIA
 - At 6 mo, 1 yr, then annually thereafter
 - SIX categories of competency review

Importance of Training & Competency Requirement cont'd

Six Categories of Competency Review

1. **Direct observations** of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
2. **Monitoring** the recording and reporting of test results;
3. **Review** of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
4. **Direct observations of performance** of instrument maintenance and function checks;
5. **Assessment of test performance** through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. **Assessment of problem-solving skills.** Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform.

So WHY don't you just do waived testing?

Waived tests (2024)

148 Analytes (15,428 test systems) now waived

Comprehensive Metab Profile	Lyme disease
Lipids – total chol, HDL, trigs	H pylori antibodies
FSH, TSH, LH, urine hCG	Herpes simplex
BNP	Hepatitis C antibody
A1c, microalbumin, fructosamine	Mono, influenza a/b, Grp A strep, RSV, adenovirus (eye)
Ionized calcium	Trichomonas
Ketones – blood & urine	Protime
Platelet aggregation	Adenovirus (conjunctival fluid)
CBC w/3-part differential, platelet count	Bacterial vaginosis
Cannabinoids, cocaine, cotinine, benzo-diazepines, ethanol, fentanyl, norfentanyl, 6-acetylmorphine, meth-amphetamines, morphine, opiates, oxazepam, propoxyphene, PCP, secobarbital, tramadol, tricyclics	Ferning in saliva (ovulation)
	Lithium
	Male fertility (motile sperm > 10M)
	Syphilis
	SARS-CoV-2 & other respiratory viruses

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>

CLIA Requirements by Test Complexity

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PPM	✓	✓	✓	✓	
Moderate	✓	✓	✓	✓	Q 2 yrs
High	✓	✓	✓	✓	Q 2 yrs

Pros of Waived testing

- Less complex – BUT still risk for problems/errors
- Less regulation

Cons of Waived testing

- Cost of waived test \geq reimb
- Accuracy may be less

Surveys

CLIA Requirements by Test Complexity

	Facility	Quality Systems	Personnel	Proficiency Testing	Routine Inspections
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PPM	✓	✓	✓	✓	
Moderate	✓	✓	✓	✓	Q 2 yrs
High	✓	✓	✓	✓	Q 2 yrs

- CMS – survey by state health department
- Accreditation
 - COLA
 - CAP
 - Joint Commission

- Routine – every 2 yrs
 - Only moderate/high complex labs
- Non-routine
 - Complaints
 - Follow-up problem
 - Validation (done by CMS to check on accreditor)

IMPORTANT

Tips - Recommendations

- **No matter the lab complexity SOMEONE in the office/lab MUST**
 - **Be in the know about regs, requirements**
 - **Oversee reimbursements / write-offs / insurance rules**
- Labs that have problems
 - Uninvolved lab director
 - Turn-over of personnel
 - Poor or absent training programs
 - Non-laboratorian testing personnel with little knowledge of good testing practice

Laboratory consultant

- Viable option if you don't have the expertise
- Level of involvement – variable, tailored to what you need
- Uses
 - Training
 - Financial oversight / recommendations
 - Technical oversight
 - Instrument selection
 - Test menu evaluation
- Where/how to find
 - Word of mouth
 - Local hospital

Regulatory Changes in 2025



- Fee increases / changes
- Provider performed microscopy (PPM) lab directors must now evaluate competency of staff (all 5 components CMS specifies)
- Moderate complex lab directors New in 2025
 - Non-pathologist physicians must be licensed in the state and have 20 hr CME course covering LD responsibilities **PLUS 1 year of documented experience supervising or directing non-waived testing ****
 - Must be on-site @ least once every 6 months with at least 4 months between visits if only 2 visits in year
 - Must document visits and what was done regarding required LD responsibilities

** LDs serving in their role at the end of 2024 and continuously since then – can continue without meeting the new requirement.

Evaluating Competency (for PPM LDs)

IMPORTANT

New in 2025

Evaluate and document the performance of individuals responsible for PPM testing at least **SEMIANNUALLY** during the first year the individual tests patient specimens and at least **ANNUALLY** thereafter. This must include:

1. Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing;
2. Monitoring the recording and reporting of test results;
3. Review of test results or worksheets;
4. Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and
5. Assessment of problem-solving skills

Why are these changes a potential big deal

- Many POLs have no one in-waiting (training + experience) if something happens to current qualified lab director
- Now takes **DOCUMENTED ONE YEAR of experience** to qualify
 - so could be without LD or need to find alternative solution for interim
- Recommend – having another person serve as ‘assistant LD’ for one year – document (officially name, meeting minutes, co-signing documents, etc)
- ALSO recommend – getting documentation of your experience on letterhead from someone in authority to place in your file – in case needed years later

Why are these changes a potential big deal

- Many POLs have no one in-waiting (training + experience) if something happens to current qualified lab director
- Now takes DOCUMENTED ONE YEAR of experience to qualify
- Alternatives
 - Pathologist certified in anatomic or clinical pathology licensed in the state
 - PhD, MS, or BS (chemical, biology, clinical or medical laboratory science or medical technology)* with 20 hr CME course covering LD responsibilities PLUS
 - 1 (PhD, MS) or 2 yrs (BS) training/experience in non-waived testing PLUS
 - 1 (PhD, MS) or 2 yrs (BS) of supervisory experience in non-waived testing

*CLIA specifies course content

20-hr CME on LD Responsibilities

- COLA on-line courses – <https://education.lms.cola.org/catalog/info/id:133>
- COLA in-person LD course – May 6-8, 2025 (Chandler, AZ)
 - <https://web.cvent.com/event/5c9db922-76c0-4439-a162-fa7aebdf5ae1/websitePage:6f1a4579-d430-49fc-99d8-fc86bf7d3e27>
- University of Iowa - <https://uiowa.cloud-cme.com/course/courseoverview?P=0&EID=66153>
- LabUniversity – <https://labuniversity.org/lab-director-cme-program/#programcourses>
- College of American Pathologists - <https://education.cap.org/clialabdir>

For up-to-date list of course options – see <https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/training>

Lab Director Responsibilities - summary

- **OVERALL OPERATION** including employing competent personnel and compliance with regulations
- If qualified – TC, CC, testing personnel – or delegate
- Must be accessible – up to 5 labs – onsite @ least every 6 months – document activities
- Testing systems provide quality services
- Safety – OSHA, EPA, nuclear, electrical, fire
- Testing methods – provide quality results, verify accuracy/precision/etc, performance by staff
- Proficiency testing – enroll, review, correct
- QC/QA – establish, maintain effective program
- Analytic Performance – establish, maintain
- Report contents/Consultation
- Personnel – number, training, competency, monitor
- Procedure Manual – LD must approve
- Specify responsibilities/roles in writing



Selecting the Right Lab Equipment & Tests – Tailoring Solutions for your Outpatient Laboratory

- Test Menu Considerations
- Instrument Options
- Reporting - LIS

Test Menu Considerations

- Reasons for testing
 - Turn-around-time (TAT)
 - Patient satisfaction – more complete office
 - Result quality
 - Revenue for practice
- Need vs want
- Might you test even if break-even or test @ \$\$ loss?

Test Menu Considerations

- Common tests/panels by specialty
 - FP/IM – CBC, lipids, chem panels, thyroid, UA, rapid tests (flu, strep, mono)
 - Rheumatology – sed rate, CRP, Rheumatoid factor, CBC, renal function
 - OB-GYN – CBC, urine dipsticks (4 parameter)
 - Endocrinology – A1c, thyroid function, chemistries, etc
- Look @ send-out reports
- Look @ proficiency testing reports – for commonly done tests

Test Menu Considerations

- Payor considerations
 - Reimbursement - Payor mix
 - Guidelines – medical necessity, covered dx, frequency
 - Are you in-network?
 - Are you preferred site?
 - Do they pay for testing done in office?

Test Menu Considerations

- Lab considerations
 - Will it take NEW instrument/kit?
 - NEW proficiency testing?
 - Personnel requirements – CLIA qualifications, volume
 - Space – instrument, reagent storage
 - Is the test soon to become obsolete or replaced?
 - Batching option – defeats TAT purpose, but may make it \$\$ viable
 - LIS / EMR interface

Typical POL Menu

5 Typical Testing Categories

1. **Hematology/Coag:** CBC w/Diff, ESR, PT/INR
2. **Chemistry:** Gen Chem Panels- CMP, BMP, Lipids, etc
3. **Immunoassay:** Thyroids, Cancer Markers
4. **Urinalysis-** Biochemical Dipstix, maybe Microscopic
5. **Waived/Kit Tests:** FOB, Strep A, Flu A&B, RSV, Covid



Recent Top 10 by Frequency

- | | |
|------------------------|---------------------|
| 1 CBC w/AUTO DIFF | 6 Vitamin D |
| 2 CMP Comprehensive MP | 7 BMP Basic Metabol |
| 3 TSH (3rd Gen) | 8 PT/INR maybe? |
| 4 Lipid Panel | 9 Renal Function |
| 5 Hgb A1c % | 10 Magnesium |

Analytical Options

- Waived vs Moderate complexity
- Instruments: Floor vs Bench Top
- Batching vs Real-time Random Access
- Water System?
- Wet Chemistry vs Dry Slide

Analytical Options con't

- Selecting the appropriate analyzer
 - Menu - Throughput (Theoretical vs Actual), Maintenance, PT
 - Training and operations - complexity matching personnel
- Working with sales reps...Timing counts..."Blue Moon"
- Talk to other users – references
- Reporting - LIS vs EMR vs paper
- Options for LIS

EMR LIS Modules

- EMRs generally REPORT results
 - Instrument results → LIS → EMR
- They generally DO NOT have LIS functionality
 - Connecting to instruments for results
 - Data analysis - Reports
 - Financials
 - Billing
 - Testing statistics

Ask the Experts: Q & A

4:05-4:20

Put your question in the chat box – and we'll answer as many as we can

Break – resume @ 4:35



Financial Analysis for Outpatient Laboratories: Maximizing Revenue and Managing Costs

Andy Gill, MT(ASCP)

Objective

At the conclusion of your presentation, learners should be prepared to:

- Perform a physician office laboratory financial analysis that takes into account cost-effective and convenient patient point-of-care testing

Financial Considerations

30,000 ft Flyover Financial Considerations

- Importance of tracking revenue & expenses
 - Revenue - by payor
 - Write – offs – by payor
- Expenses
 - Personnel + Benefits
 - Instrument Costs: Analyzer, Service Agreements,
 - Analyzer Procurement: Lease, Purchase, cost-per-test, cost-per-reportable
 - Reagents, QC, calibration frequency, calibration verifications
 - Proficiency Testing
 - Medical Waste
 - PPE

Financial Considerations con't

- Regulatory Fees based on Specialties and Annual Test Volumes
- Practice Size vs viability of laboratory- “Size Matters” but....
- Reference Laboratories- You will always need one
 - Recommend 2 if large enough – competition helps
- Proficiency Testing: Waived, Now 5 Samples, or Split Samples

Other Considerations

- Should you consider a Lab Consultant? Maybe?
 - if you want a lab and don't have the expertise
 - Just like a plumber for plumbing or an Ortho for a Knee Replacement
- Services provided: Full Menu or Ala Carte
 - Manuals, PT, QC, Hiring, Training, Regulatory, Inspection Prep
- Costs
- Finding a good consultant- Word of Mouth, References, Hospital
- <https://www.myconsultantcentral.com/find-a-consultant/>
- Check references

Financial Considerations

- Staffing - # of personnel- grow into business...
 - Drivers: # specialties, volumes, drawing, processing, performing
 - Lab Tech “extenders”
 - LIS (1-2 FTE’s)
 - optimum analyzer choices (throughput, calibration frequencies, maintenance, etc)
- Options - MT, MLT, nurses, MA’s, HS grads, etc.
- ALERT!!! There is shortage of quality trained personnel – harder to find and more expensive to hire
 - HS grad Moderate Complexity - cheaper....however....
 - The LESSER the training the GREATER the need for oversight
 - You become their laboratory education and training
 - Use of nurses - how that works



Case Studies

- Small 3-5 physician practice
- Medium 10-12 physician practice

Objective

At the conclusion of your presentation, learners should be prepared to:

- Appropriately staff a physician office laboratory to best meet patient needs

Goal of this section

~~Impossible~~

1. **If you have a lab** - should be at least break even – should really be a profit center
2. **If you don't have lab** – YOU CAN and maybe should

Case Study 3-5 Docs

<i>Economic Analysis Worksheet</i>	<i>LABORATORY INFORMATION</i>
Practice name	Internal Medicine Associates of xxx
Address	123 Medical Drive
City/State	Somewhere , TX 79106
Case description	Lab Audit (5 Docs)
% Medicare	75%
Other Payer Rev. as % of Medicare	from Revenue Anal. worksheet

Case Study 3-5 Docs

Laboratory Equipment	Cost:	Equipment Description
Chemistry	\$35,000	Refurb Mid Vol Floor Model or New Benchtop)
Hematology	\$30,000	New CBC 5-Diff 3 yr
Immunoassay	\$42,000	
PT (hand held)	\$16,000	
U/A Strip reader	\$1,000	
Other		
Other		
LIS System	\$20,000	
Total Capital Required	\$144,000	
Lease/Amortization factor		<i>see leasing chart in instruction manual</i>
Monthly Lease/Amortization	\$2,640	per month
Service Contracts	\$409	per month
Total Equip. & Maint.	\$3,049	per month

Case Study 3-5 Docs

Q/A & CLIA Costs	Tests on Menu	Avg. Reag. Cost/Test	Avg. Control Cost/Test	AvgCals/Ctrls Test per Day	Days of Oper. per Week	Cost per month
Routine chemistries	18	\$0.71	\$1.75	4	5	\$1,158.80
Special chemistries	7	\$3.94	\$2.50	4	5	\$2,406.40
Hematology	1	\$0.35	\$0.50	3	5	\$51.00
Immunoassay	8	\$3.00	\$3.00	4	5	\$2,160.00
Coagulation (PT, PTT)	2	\$0.65	\$3.00	0	5	\$0.00
TOTAL						\$5,776.20
CLIA/COLA fees	\$1,525	Annual cost				\$127
Proficiency testing	\$750	Annual cost				\$63
Personnel						Total Cost per Month: \$5,965.78
Benefits	20%	of annual salary				

Case Study 3-5 Docs

<i>Position Description</i>	<i>FTE's</i>	<i>Hourly Rate</i>	<i>Total Salaries</i>	<i>Benefits</i>	<i>Total Cost</i>	<i>Monthly Cost</i>
Testing (MT)	1.00	\$35.00	\$72,800	\$14,560	\$87,360	\$7,280
Phlebotomy	1.00	\$11.00	\$22,880	\$4,576	\$27,456	\$2,288
Supervision			\$0	\$0	\$0	\$0
Other (MLT)	0.50	\$22.00	\$22,880	\$4,576	\$27,456	\$2,288
Totals	2.50		\$118,560	\$23,712	\$142,272	\$11,856
Office rent & utility costs	\$2,400	Annual cost				
Overhead costs	\$9,000	Annual cost				

Internal Medicine Associates of xxx		% Medicare Beneficiaries: 75%		Fixed Costs:		Monthly	Annual	FTE's:		Testing
123 Medical Drive		Total Capital Investment \$144,000		Salaries/Personnel Costs		\$11,856	\$142,272			Phlebotomy
Somewhere , TX 79106				Equipment/Maintenance Costs		\$3,049	\$36,592			Supervision
Lab Audit				Control/CLIA Compliance Costs		\$5,966	\$71,589			Other

TESTS PERFORMED IN OFFICE LABORATORY (Annually)				Other Rev. as % of Medicare			
Test/Panel Descriptor	CPT	Tests per Procedure	Number of Procedures	Billed to Medicare	Billed to Other Payers	Reagent Costs	Medicare Reimb.
Basic Metabolic Panel	80048	8	3,540	2,655	885	\$0.87	\$11.83
Comp. Metabolic Panel	80053	14	3,084	2,313	771	\$5.29	\$14.77
Hepatic Function Panel	80076	6	1,464	1,098	366	\$0.96	\$11.42
Lipid Panel	80061	3	3,852	2,889	963	\$8.47	\$18.72
Electrolyte Panel	80051	4		0	0		
Amylase	82150	1		0	0		
Iron & TIBC	83540/50	2		0	0		
Magnesium	83735	1		0	0		
Ferritin	82728	1		0	0		
Glucose	82947	1	48	36	12	\$0.12	\$5.48
LDL- Direct	83721	1	1,044	783	261	\$6.73	\$13.33
HDL Chol.	83718	1	792	594	198	\$1.15	\$11.44
Single chemistry	various	1	4,008	3,006	1,002	\$0.20	\$7.25
U/A with micro	81000	2	2,004	1,503	501	\$0.74	\$4.43
CBC	85024	1	3,240	2,430	810	\$0.27	\$11.83
PT	85610	1	2,088	1,566	522	\$0.65	\$5.49
MicroAlbumin	82044	2	372	279	93	\$3.50	\$6.39
Sed Rate	85651	1	288	216	72	\$0.38	\$4.96
Free T4	84439	1		0	0		
TSH	84443	1	2,424	1,818	606	\$4.18	\$23.47
Total T4	84436	1	804	603	201	\$1.97	\$9.61
Digoxin	80162	1		0	0		
A1c	83036	1		0	0		
	84153	1	508	441	147	\$10.33	\$25.70
				9	3	\$2.80	\$14.24
					0		
						\$1.30	\$4.54

Case Study 3-5 Docs

POL Profit & Loss Detail**Annual Revenue from POL Testing**

Medicare Beneficiaries	\$	284,041
Other Payer Patients	\$	239,607
Draw Fee Revenue (Medicare)	\$	30,686
Draw Fee (Other Payers)	\$	-
	\$	554,335

Annual Revenue from Reference Lab Testing

Other Payer Revenue	\$	-
Total Annual Revenue	\$	554,335

Annual Variable Costs:

POL Direct Costs (reagents and supplies)	\$	87,351
Draw Fee Costs	\$	-
Reference Lab Costs	\$	-
Total Annual Direct Costs	\$	87,351

Annual Fixed Costs:

Salaries/Personnel Costs	\$	142,272
Equipment/Maintenance Costs	\$	36,592
Rent and Overhead Costs	\$	11,400
Controls/CLIA Compliance Costs	\$	71,589
Total Annual Fixed Costs	\$	261,854

Total Annual Costs:	\$	349,205
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POL Profit	\$	205,130	Profit Margin:	37%
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Case Study 10-12 Docs

<i>Economic Analysis Worksheet</i>	<i>LABORATORY INFORMATION</i>
Practice name	Lab Audit Example
Address	
City/State	Little Town, MS
Case description	(10 Doc)
% Medicare	74%
Other Payer Rev. as % of Medicare	95% from Revenue Anal. worksheet

Case Study 10-12 Docs

Laboratory Equipment	Cost:	Equipment Description
Chemistry	\$75,000	Refurb Floor Model
Hematology	\$35,000	Hematology
Immunoassay		
PT (hand held)	\$16,000	Coag
U/A Strip reader	\$1,500	Urinalysis
Other	\$4,750	Set up
Other		
LIS System	\$20,000	LIS
Total Capital Required	\$152,250	
Lease/Amortization factor		<i>see leasing chart in instruction manual</i>
Monthly Lease/Amortization	\$2,791	per month
Service Contracts	\$1,269	per month
Total Equip. & Maint.	\$4,060	per month

Case Study 10-12 Docs

<i>Position Description</i>	<i>FTE's</i>	<i>Hourly Rate</i>	<i>Total Salaries</i>	<i>Benefits</i>	<i>Total Cost</i>	<i>Monthly Cost</i>
Testing (MT)	1.50	\$35.00	\$109,200	\$0	\$109,200	\$9,100
Phlebotomy	1.00	\$11.00	\$22,880	\$0	\$22,880	\$1,907
Supervision			\$0	\$0	\$0	\$0
Other (MLT or LA)	1.00	\$22.00	\$45,760	\$0	\$45,760	\$3,813
Totals	3.50		\$177,840	\$0	\$177,840	\$14,820
Office rent & utility costs	\$6,000	Annual cost				
Overhead costs	\$9,500	Annual cost				

Case Study 10-12 Docs

Q/A & CLIA Costs	Tests on Menu	Avg. Reag. Cost/Test	Avg. Control Cost/Test	AvgCals/Ctrls Test per Day	Days of Oper. per Week	Cost per month
Routine chemistries	24	\$0.75	\$1.75	4	5	\$1,580.00
Special chemistries	5	\$3.75	\$2.50	4	5	\$1,700.00
Hematology	1	\$1.00	\$0.65	3	5	\$99.00
Immunoassay	8	\$3.95	\$3.00	4	5	\$2,768.00
Coagulation (PT, PTT)	1	\$1.25	\$2.00	2	5	\$130.00
TOTAL						\$6,277.00
CLIA/COLA fees	\$1,800	Annual cost				\$150
Proficiency testing	\$850	Annual cost				\$71
Personnel					Total Cost per Month:	\$6,497.83
Benefits		of annual salary				

Economic Analysis Worksheet				OFFICE LABORATORY TESTS			
Lab Audit Example				Fixed Costs:	Monthly	Annual	FTE's:
0		% Medicare Beneficiaries:	74%	Salaries/Personnel Costs	\$14,820	\$177,840	Testing 1.50
Little Town, MS		Total Capital Investment	\$152,250	Equipment/Maintenance Costs	\$4,060	\$48,720	Phlebotomy 1.00
0				Control/CLIA Compliance Costs	\$6,498	\$77,974	Supervision 0.00
							Other 1.00

TESTS PERFORMED IN OFFICE LABORATORY (Annually)							Other Rev. as % of Medicare
Test/Panel Descriptor	CPT	Tests per Procedure	Number of Procedures	Billed to Medicare	Billed to Other Payers	Reagent Costs	Medicare Reimb.
Basic Metabolic Panel	80049	7	3,317	2,455	862	\$0.92	\$11.83
Comp. Metabolic Panel	80054	13	12,870	9,524	3,346	\$5.29	\$14.77
Hepatic Function Panel	80058	6	2,213	1,638	575	\$0.96	\$11.42
Lipid Panel	80061	3	5,257	3,890	1,367	\$4.25	\$14.36
CBC	85024	1	16,651	12,322	4,329	\$1.00	\$10.40
Ferritin	82728	1	687	508	179	\$0.28	\$6.43
TSH	84443	1	5,949	4,402	1,547	\$2.28	\$21.47
A1c	83036	1	7,556	5,591	1,965	\$1.10	\$13.16
Thyroid Panel w/TSH	80092	3		0	0		
Electrolyte Panel	80051	4	307	227	80	\$0.52	
Amylase	82150	1		0	0		
Iron & TIBC	83540/50	2		0	0		
Magnesium	83735	1		0	0		
Glucose	82947	1		0	0		
Cholesterol	82465	1		0	0		
HDL Chol.	83718	1		0	0		
Single chemistry	various	1		0	0		
U/A with micro	81000	2		0	0		
PT	85610	1	1,041	770	271	\$1.10	\$4.32
Hgb & Hct	85014/18	2		0	0		
Sed Rate	85651	1		0	0		
T4	84436	1		0	0		
Theophylline	80198	1		0	0		
Digoxin	80162	1		0	0		
PSA	84153	1	521	386	135	\$3.22	\$12.18
Strep	87430	1		0	0		
Preg.	84703	1		0	0		
Occult blood	82270	1	389	288	101	\$2.22	\$11.63
Routine Cult.	87087	1		0	0		
Other				0	0		
Other				0	0		
Cuvettes			0	0	0	\$0.65	
Total # of Procedures			56,758	42,001	14,757		
Total # of tests performed:			253,600				
Specimen collection:	CPT		Total Number	Billed to Medicare	Billed to Other Payers	Test Cost	Medicare Reimb.
Venipunctures	G0001		24,677	18,261	6,416		\$3.00

POL Profit & Loss Detail**Annual Revenue from POL Testing**

Medicare Beneficiaries	\$	555,155
Other Payer Patients	\$	185,302
Draw Fee Revenue (Medicare)	\$	54,784
Draw Fee (Other Payers)	\$	-
	\$	795,241

Annual Revenue from Reference Lab Testing

Other Payer Revenue	\$	-
Total Annual Revenue	\$	795,241

Annual Variable Costs:

POL Direct Costs (reagents and supplies)	\$	138,165
Draw Fee Costs	\$	-
Reference Lab Costs	\$	-
Total Annual Direct Costs	\$	138,165

Annual Fixed Costs:

Salaries/Personnel Costs	\$	177,840
Equipment/Maintenance Costs	\$	48,720
Rent and Overhead Costs	\$	15,500
Controls/CLIA Compliance Costs	\$	77,974
Total Annual Fixed Costs	\$	320,034

Total Annual Costs:	\$	458,199
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POL Profit	\$	337,042	Profit Margin:	42%
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Ask the Experts: Q & A

5:35-5:50

Put your question in the chat box – and we'll answer as many as we can