



CHEMISTRY DOCUMENT

PENNSYLVANIA DEPARTMENT OF HEALTH
BUREAU OF LABORATORIES
DIVISION OF LABORATORY IMPROVEMENT

CLIA #:		LABORATORY ID #:	
NAME OF LABORATORY:			
DATE OF SURVEY:	START TIME:	EXAMINER:	
PERSON(S) INTERVIEWED:			
NAME:		TITLE:	
COMMENTS:			
DEFICIENCIES:			
DIRECTOR PRESENT AT EXIT INTERVIEW? Y N			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS																																																																														
ADMINISTRATIVE																																																																																		
	A. What is the extent of services provided?																																																																																	
	1. Routine chemistry?																																																																																	
	2. Endocrinology?																																																																																	
	3. Toxicology?																																																																																	
	4. Other?																																																																																	
PROFICIENCY TESTING																																																																																		
	A. Which program is the laboratory enrolled in?																																																																																	
D2000	B. Is the lab enrolled for all regulated analytes (including waived tests for State purposes)?																																																																																	
	<p>REGULATED ANALYTES:</p> <table border="0"> <tr> <td><u>Routine Chemistry:</u></td> <td><u>Endocrinology:</u></td> <td><u>Toxicology:</u></td> </tr> <tr> <td>ALT/SGPT</td> <td>Cortisol</td> <td>Alcohol (blood)</td> </tr> <tr> <td>Albumin</td> <td>Free Thyroxine</td> <td>Blood lead</td> </tr> <tr> <td>Alkaline phosphatase</td> <td>HCG (non-waived)</td> <td>Carbamazepene</td> </tr> <tr> <td>Amylase</td> <td>T3 Uptake</td> <td>Digoxin</td> </tr> <tr> <td>AST/SGOT</td> <td>Triiodothyronine</td> <td>Ethosuximide</td> </tr> <tr> <td>Bilirubin, Total</td> <td>TSH</td> <td>Gentamicin</td> </tr> <tr> <td>Blood gas</td> <td>Thyroxine</td> <td>Lithium</td> </tr> <tr> <td>Calcium, Total</td> <td></td> <td>Phenobarbital</td> </tr> <tr> <td>Chloride</td> <td></td> <td>Phenytoin</td> </tr> <tr> <td>Cholesterol, Total</td> <td></td> <td>Primidone</td> </tr> <tr> <td>HDL</td> <td></td> <td>Procainamide</td> </tr> <tr> <td>Creatine kinase</td> <td></td> <td>(And metabolite)</td> </tr> <tr> <td>CK isoenzymes</td> <td></td> <td>Quinidine</td> </tr> <tr> <td>Creatinine</td> <td></td> <td>Theophylline</td> </tr> <tr> <td>Glucose (non-waived)</td> <td></td> <td>Tobramycin</td> </tr> <tr> <td>Iron, Total</td> <td></td> <td>Valproic Acid</td> </tr> <tr> <td>Lactate dehydrogenase</td> <td></td> <td></td> </tr> <tr> <td>LDH isoenzymes</td> <td></td> <td></td> </tr> <tr> <td>Magnesium</td> <td></td> <td></td> </tr> <tr> <td>Potassium</td> <td></td> <td></td> </tr> <tr> <td>Sodium</td> <td></td> <td></td> </tr> <tr> <td>Total Protein</td> <td></td> <td></td> </tr> <tr> <td>Triglycerides</td> <td></td> <td></td> </tr> <tr> <td>Urea Nitrogen</td> <td></td> <td></td> </tr> <tr> <td>Uric Acid</td> <td></td> <td></td> </tr> </table>	<u>Routine Chemistry:</u>	<u>Endocrinology:</u>	<u>Toxicology:</u>	ALT/SGPT	Cortisol	Alcohol (blood)	Albumin	Free Thyroxine	Blood lead	Alkaline phosphatase	HCG (non-waived)	Carbamazepene	Amylase	T3 Uptake	Digoxin	AST/SGOT	Triiodothyronine	Ethosuximide	Bilirubin, Total	TSH	Gentamicin	Blood gas	Thyroxine	Lithium	Calcium, Total		Phenobarbital	Chloride		Phenytoin	Cholesterol, Total		Primidone	HDL		Procainamide	Creatine kinase		(And metabolite)	CK isoenzymes		Quinidine	Creatinine		Theophylline	Glucose (non-waived)		Tobramycin	Iron, Total		Valproic Acid	Lactate dehydrogenase			LDH isoenzymes			Magnesium			Potassium			Sodium			Total Protein			Triglycerides			Urea Nitrogen			Uric Acid					
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D2006	C. Are proficiency testing (PT) specimens handled like patient specimens?																																																																																	

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	1. Do reagents and instrumentation used for PT match those used for patient testing?			
D2007	2. Are PT specimens integrated within the routine workload and analyzed by personnel who routinely test patient specimens?			
D2128 D2129	D. Is corrective action taken for unsatisfactory or unsuccessful PT results?			
	1. Is corrective action documented?			
D6018 D6091	E. Are PT results reviewed by and discussed with the director? Documented?			
D7047	F. How are tests for which no PT is available evaluated at least every 6 months? Documented?			
	G. Does the lab perform the same tests at more than one location or by more than one method?			
D7043	1. If yes, do they compare test results at least twice a year? Documented?			
PATIENT TEST MANAGEMENT				
D6031 D6106	A. Does the laboratory have a procedure manual available in the work area?			
	B. Does the procedure manual contain:			
D4046 D4048	1. Patient preparation, specimen collection and processing, including criteria for specimen rejection?			
	c. Is the reason for specimen rejection documented in the patient report or QA record?			
D4049	2. Microscopic exam procedures?			
D4050	3. Step-by-step procedure with calculations and interpretations of results?			
D4051	4. Preparation/storage of materials used for testing?			
D4052	5. Calibration and calibration verification?			
D4054	6. Reportable ranges?			
D4055	7. Control procedures?			
D4056	8. Remedial action when quality control is unacceptable?			
D4057	9. Limitations, including interfering substances?			
D4058	10. Normal ranges or reference ranges?			
D4059	11. Panic values?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	a. Are criteria established for immediate notification of a physician or other clinical personnel when results exceed critical limits?			
D4060	12. References?			
D4061	13. Specimen storage and preservation?			
D4062	14. System for reporting patient results (including protocol for reporting critical values)?			
	a. Does the manual include procedures for reporting test results when they exceed the reportable range established by the lab?			
D4063	15. What to do if the test system is inoperable?			
D4064	16. Criteria for specimen referral?			
D4065	C. Is there documentation of an annual review of procedures by the director or a designee?			
D4066 D4067	D. If a test was added, has the procedure been reviewed and approved by the director?			
D4068	E. If a test was discontinued, are procedures available for 2 years?			
	F. Do test records include the following information:			
D3037	1. Patient name or unique identifier?			
D3038	2. Date and time specimen was collected/received?			
D3040	3. Reason for specimen rejection?			
D3041	4. Date of test performance?			
D3043	5. Identity of the personnel performing the test(s)?			
D3034	G. Does the laboratory keep all records for at least 2 years (including instrument print-outs)?			
AUTOMATED INSTRUMENTS				
	A. Does the lab have a written verification procedure to determine the precision, accuracy and other pertinent performance characteristics of each new test method or instrument?			
	New instrument(s) or test method(s):			
	Date(s) in-use:			
D4074	1. Are verification procedures complete? Documented?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS	
		INSTRUMENT			
	Routine Chemistry, Endocrinology, TDM:				
	Analytes performed:				
D4043	B. Is the procedure manual complete?				
D4101	C. Are manufacturer's calibration procedures being followed?				
	D. Is there a mechanism to link the patient identifier to test run and analyzer position?				
	1. Are all results verified prior to release?				
D4057	E. Are criteria established for parameters which warrant further investigation (repeat and verify)?				
	F. Does the lab verify its reportable range of patient test results every 6 months (HIGH COMPLEXITY ONLY)?				
D4006	G. Are at least one normal and one abnormal control material run each day of testing (or at the frequency specified by the manufacturer, if more stringent)?				
D4055	H. Is an acceptable QC protocol defined (e.g. Westgard)?				
D4182	I. Do QC records include:				
	1. The date the material was run?				
	2. All control results, whether in range or not?				
	3. Ranges of acceptable control values?				
	4. Documentation of corrective action, if necessary?				
	5. Indication of date of opening?				
	6. Lot numbers and expiration dates?				
D7033	J. Does the laboratory perform QC review?				
	1. Is documentation available?				
D4084	K. Are maintenance/function checks performed as per manufacturer's specifications? Documented?				

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
BLOOD GASES				
D4043	A. Is the procedure manual complete?			
	B. Are calibration and calibration verification procedures performed as per manufacturer's instructions?			
	C. Is one control material run each 8 hour shift?			
	D. Does the lab run both a low and a high calibrator/control material each day of testing?			
	E. Does the lab include one sample of calibrator/control material each time patients are tested (unless automated instrument internally verifies calibration at least every 30 minutes)?			
	F. Do quality control records contain:			
	1. The date the material was run?			
	2. All control results, whether in range?			
	3. Ranges of acceptable control values?			
	4. Documentation of corrective action?			
	5. Indication of date of opening?			
	6. Lot numbers and expiration dates?			
	G. Does the laboratory perform QC review?			
	1. Is documentation available?			
	H. Are maintenance/function checks performed as per manufacturer's specifications? Documented?			
RADIO IMMUNO ASSAYS (RIA)				
	A. Are gamma counters calibrated each day of use?			
	B. Is background radioactivity determined each day of use?			
	1. Are there written criteria for acceptable background levels?			
DRUGS OF ABUSE				
	A. Are drug screen results used to determine a state of health or to initiate or modify a course of treatment?			
	1. If yes, is the lab licensed by the state for DOA testing and does the lab participate in the state's PT program for DOA testing?			
	B. Instrument used:			
	1. Are manufacturer's calibration procedures being followed?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	2. Are at least one normal and one abnormal control material run each day of testing (or at the frequency specified by the manufacturer, if more stringent)?			
	3. Are quality control records complete?			
	4. Are maintenance/function checks performed as per manufacturer's specifications? Documented?			
	C. Does the lab perform thin layer chromatography?			
	1. Are standards included on each plate?			
	2. Is a control included in each run?			
	3. Are reagents prepared fresh, as needed?			
	D. Does the lab use gas chromatography or GC mass spectrometry?			
	1. Does the lab follow written procedures for calibration, operation, and maintenance of all GC equipment?			
	2. Are sensitivity and linearity determined for each quantitative procedure?			
	E. Does the lab use drugs of abuse test kit systems (e.g. Triage)?			
	1. Are manufacturer's instructions followed for verifying these unit test systems? Documented?			
ELECTROPHORESIS				
	A. Does the laboratory perform electrophoresis testing (e.g. serum proteins, isoenzymes, hemoglobin)?			
	1. Are control samples run with each batch of patient samples for all electrophoresis procedures for which controls are available?			
	2. If patients are quantitated, are controls quantitated?			
MISC. EQUIPMENT CHECKS				
D4025	A. Are temperatures checked daily as needed (e.g. water baths, heating blocks, ovens, fridge, freezer, etc.)? Documented?			
	1. Are acceptable ranges defined for all temperature dependent equipment?			
	2. Is corrective action documented if temperature ranges are exceeded?			
	B. Are pipettes periodically checked for accuracy?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	C. Are colorimeters, spectrophotometers, flame photometers calibrated and maintained according to manufacturer's instructions?			
	D. Are centrifuges cleaned and maintained? Documented?			
	1. Are operating speeds periodically checked?			
PERSONNEL ASSESSMENT				
D6030 D6102	A. Have all personnel received appropriate training prior to testing patient specimens? Documented?			
	1. If a computer system (LIS) is used in the lab, have individuals been properly trained in the use of the system? Documented?			
D6031 D6103	B. Does the laboratory have a policy and procedure for assuring personnel competency? Are competency checks documented?			
QUALITY ASSURANCE				
D7001	A. Does the laboratory have a written quality assurance policy and does the lab conduct periodic quality assurance reviews?			
D7062 D7065	1. Does the lab utilize the data obtained from the quality assurance reviews to identify problems and improve lab performance?			