



URINALYSIS 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. Dipsticks only?			
	2. Dipsticks plus microscopic?			
	3. Automated strip reader?			
	Instrument used:			
PROFICIENCY TESTING				
	A. Which program is the laboratory enrolled in?			
	B. Are proficiency testing (PT) specimens handled like patient specimens?			
	1. Do reagents and instrumentation used for PT match those used for patient testing?			
	2. Are PT specimens integrated within the routine workload and analyzed by personnel who routinely test patient specimens?			
	C. Is corrective action taken for unsatisfactory or unsuccessful PT results?			
	1. Is corrective action documented?			
	D. Are PT results reviewed by and discussed with the director? Documented?			
	E. How are tests for which no PT is available evaluated at least every 6 months? Documented?			
	F. Does the lab perform the same tests at more than one location or by more than one method?			
	1. If yes, do they compare test results at least twice a year? Documented?			
PATIENT TEST MANAGEMENT				
	A. Does the laboratory have a procedure manual available in the work area?			
	B. Does the procedure manual contain:			
	1. Patient preparation, specimen collection and processing, including criteria for specimen rejection?			
	a. Are procedures available for proper collection of a clean-catch voided specimen?			

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	b. Are written instructions provided for proper collection of timed specimens?			
	c. Is the reason for specimen rejection documented in the patient report or QA record?			
	2. Microscopic exam procedures?			
	3. Step-by-step procedure with calculations and interpretations of results?			
	4. Preparation/storage of materials used for testing?			
	5. Calibration and calibration verification?			
	6. Reportable ranges?			
	7. Control procedures?			
	8. Remedial action when quality control is unacceptable?			
	9. Limitations, including interfering substances?			
	10. Normal ranges or reference ranges?			
	11. Panic values?			
	a. Are criteria established for immediate notification of a physician or other clinical personnel when results of a dipstick or other qualitative urine test exceed critical limits?			
	12. References?			
	13. Specimen storage and preservation?			
	a. Are specimens examined within 1 hour of collection?			
	b. Is there a procedure defining urine preservation for all tests when analysis is to be delayed?			
	14. System for reporting patient results (including protocol for reporting critical values)?			
	15. What to do if the test system is inoperable?			
	16. Criteria for specimen referral?			
	C. Is there documentation of an annual review of urinalysis procedures by the director or a designee?			
	D. Do test records include the following information:			
	1. Patient name or unique identifier?			
	2. Date and time specimen was collected/received?			
	3. Reason for specimen rejection?			

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	4. Date of test performance?				
	5. Identity of the personnel performing the test(s)?				
	E. Does the laboratory keep all records for at least 2 years (including instrument print-outs)?				
REAGENTS AND CONTROLS					
	Dipstick manufacturer:				
	Control material used:				
	A. Are all reagents properly labeled as to content, concentration, and the date prepared or received?				
	1. Is a record kept of the date of opening, lot numbers, and expiration dates?				
	B. If dipsticks are read visually, is a positive control run each week of patient testing and when a new lot number is put into use for each dipstick constituent reported? Documented?				
	C. For qualitative tests other than multi parameter chemistry dipsticks, are a positive and a negative control run with each new lot number, or more frequently, if specified by the manufacturer? Documented?				
	D. Is an acceptable QC protocol defined (e.g. Westgard)?				
	E. 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?				
	F. Does the laboratory perform QC review?				
	1. Is documentation available?				
INSTRUMENTS AND EQUIPMENT					
	A. If an automated or semi-automated system is used for dipstick analysis:				
	1. Is it calibrated according to manufacturer's instructions?				

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	2. Are positive and negative controls run each day of testing? Documented?			
	B. If the lab uses a refractometer or urinometer for measuring specific gravity, is it calibrated each week of use with both a high and a low material? (Distilled water = 1.0000 and NaCl = 1.0225)			
	C. Does the lab have a routine maintenance schedule for all instruments and equipment in urinalysis? Documented?			
	D. Are temperatures checked daily as needed? Documented?			
MICROSCOPIC EXAMINATION				
	A. Are microscopic examinations of urine sediment performed as part of routine urinalysis testing, or are there specific, documented criteria defining the circumstances under which the microscopic exam may be omitted?			
	B. Does the lab follow a standardized procedure for urine microscopic exams (e.g. standardized volume, centrifugation, etc.)?			
	C. Are reference materials available to assist in the microscopic identification of sediment constituents?			
	D. Does the lab have a defined system to ensure that all personnel report microscopic data in a similar fashion?			
	E. Are microscopically identified constituents in the sediment correlated with macroscopic results (e.g. RBC's in sediment=positive blood on dipstick)?			
MORPHOLOGY SYSTEMS				
	A. Is an automated imaging system used for microscopic urinalysis? System in use:			
	B. Is there documentation to indicate that the automated method was evaluated in the lab against manual microscopic analysis before it was put into use?			
	C. Are cell count controls performed? Documented?			

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PERSONNEL ASSESSMENT				
	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?			
	B. Does the laboratory have a policy and procedure for assuring personnel competency?			
	1. Are personnel competency checks documented?			
QUALITY ASSURANCE				
	A. Does the laboratory have a written quality assurance policy and does the lab conduct periodic quality assurance reviews?			
	1. Does the lab utilize the data obtained from the quality assurance reviews to identify problems and improve lab performance?			
SAFETY				
	A. Are warning labels affixed to collection containers when acid preservatives are used?			