Kansas Department of Health and Environment
Amended Permanent Regulations
Interpretive guidelines as in effect 12/31/97

28-33-12	General Provisions (a) Definitions	INTERPRETATIVE GUIDELINES
	(1) "Department" means the department of health and environment.	
	(2) "Division" means the division of Kansas health and environmental laboratory (DHEL).	
	(3) "Laboratory director" means the person responsible for the professional, administrative, organizational, and educational duties of a laboratory.	
	(4) "Laboratory supervisor" means the individual responsible for providing day-to-day supervision of testing personnel, including the proper performance of all laboratory procedures and reporting of test results.	
	(5) "Testing personnel" means individuals responsible for specimen processing, test performance, and reporting test results.	Specimen processing does **NOT** include: specimen collection, specimen transportation, specimen accessioning, initial centrifugation, or entry of requests into computers Test reporting does **NOT** include: entry of results into computers, dispersement of results to authorized individuals, or handling of customer service requests.
	(6) "Test for controlled substance" means a procedure to evaluate a specimen for compounds identified in schedule I or II of the Kansas controlled substance act, K.S.A. 1995 Supp. 65-4105 and 65-4107.	Copies of Schedule I and II can be obtained from the State Pharmacy Board or from: Secretary of State Publications State Capitol Building, 2nd Floor Topeka, KS 66612
	(7) "Threshold" means a defined drug or metabolite concentration which is established at a level such that: (A) a concentration at or above this level defines a positive result; and (B) a concentration below this level defines a negative result.	
	(8) "Screening test" means a test designed to eliminate true negative specimens from further consideration. Threshold limits used for screening tests shall conform to the mandatory guidelines for federal work place drug testing programs established by the substance abuse and mental health services administration of the department of health and human services in the federal register, volume 59, number 110, page 29921, published June 9, 1994.	Screening Cutoffs which must be used are: Amphetamines---1,000 ng/ml Cannabinoids/THC---50 ng/ml Cocaine and Metabolites---300 ng/ml Opiates---300 ng/ml Phencyclidine---25 ng/ml
	(9) "Confirmatory test" means a mass spectrometry analytical procedure used to specifically identify the presence of a drug or drug metabolite. Threshold limits used for confirmatory testing shall conform to the mandatory guidelines for federal work place drug testing programs established by the substance abuse and mental health services administration of the department of health and human services in the federal register, volume 59, number 110, page 29921-22, published June 9, 1994.	Confirmatory Cutoffs which must be used are: Amphetamines---500 ng/ml Cannabinoids/THC---15 ng/ml Cocaine and Metabolites---150 ng/ml Opiates---300 ng/ml Phencyclidine---25 ng/ml

	(10) "Unsatisfactory performance" means a score for any analyte of less than 80% as determined by the proficiency testing provider.	DHEL will not "regrade" proficiency testing results.
	(11) "Unsuccessful participation" means unsatisfactory performance for the same analyte in two consecutive or two out of three consecutive proficiency testing events.	
	(12) "CLIA" means the clinical laboratory improvement amendments of 1988, Public Law 100-578, as implemented by 42 CFR part 493, issued February 28, 1992, as amended and in effect on April 24, 1995.	Copies of the CLIA Interpretative Guidelines may be obtained from: National Technical Information Services US Department of Commerce 5285 Port Royal Road Springfield, VA 22161
KAD 001	(b) Approval procedure. (1) Except as provided in subsection (k), each laboratory located in Kansas seeking approval of the department to perform tests on biological specimens for controlled substances, as defined in schedule I and II of the Kansas controlled substance act, K.S.A. 1995 Supp. 65-4105 and 65-4107, shall be a laboratory which the division director or director's designee determines meets the requirements for certification under CLIA for the type and complexity of the tests being performed.	Laboratories <u>not</u> holding valid CLIA certificates must follow CLIA regulations as defined in (12) above.
	(2)(A) Except as set out in paragraph (C), each laboratory seeking approval to test biological specimens for the following drugs or their metabolites shall meet the requirements set out in paragraph (B): (i) amphetamines; (ii) cannabinoids or tetrahyrocannabinoids (THC), (iii) cocaine; (iv) opiates; and (v) phencyclidine.	"Biological specimens" means: human blood, human urine, human saliva, and human gastric contents.
	(B) In addition to meeting requirements for certification under CLIA, each laboratory seeking approval under paragraph (A) shall: (i) submit a completed application on standard forms furnished by the division; and (ii) submit documents demonstrating successful performance in one testing event using a proficiency testing program approved by the division.	
KAD 002	(C) Any laboratory facility testing specimens for emergency diagnosis and treatment may test for drugs listed on schedule I or II of the Kansas controlled substance act, K.S.A. 1995 Supp. 65-4105 and 65-4107, without meeting the requirements of paragraph (B), if test results are used only for diagnosis and treatment.	Testing for medical purposes may be performed without DHEL approval. However, laboratories performing medical testing must hold a valid CLIA certificate for the type and complexity of tests performed. Laboratories performing post-mortem testing must be approved by DHEL [see section (b)].
	(c) Upon receipt of a laboratory's application for approval, the laboratory shall be inspected by a representative of the division. The laboratory shall be evaluated to determine compliance using the following criteria:	Routine inspections will be announced in advance.

Kansas Department of Health and Environment
Amended Permanent Regulations
Interpretive guidelines as in effect 12/31/97

KAD 003	(1) Screening test methods shall screen for the following five classes of drugs: (A) amphetamines; (B) cannabinoid or THC metabolites; (C) cocaine metabolites; (D) opiates; and (E) phencyclidine.	Test methods must screen individually for the five classes of drugs.
KAD 004	(2) Each test procedure shall be performed in accordance with a written protocol.	
KAD 005	The protocol shall be approved by the laboratory director.	
KAD 006	The protocol shall require that a blank control containing no drug and a control fortified with a known analyte concentration greater than the threshold limit for each analyte are included with each batch of specimens tested. At least one fortified control shall be at or near the threshold cut off.	"Near" means the weighed in value of the control must be within plus or minus 25% of the cutoff.
KAD 007	The protocol shall insure that carry-over between specimens does not occur.	
KAD 008	(3) A laboratory quality assurance program shall be developed and implemented. The program shall contain the following components: (A) requirements for sample collection which adhere to the criteria of the division director or the director's designee, or a signed statement that the specimen was properly collected according to these criteria, if collection is at a location other than the laboratory performing the test;	A copy of the division's requirements for sample collection can be obtained from: Kansas Department of Health and Environment Laboratory Certification and Improvement Forbes Field, Building 740 Topeka, KS 66620-0001
KAD 009	(B) identification and chain of custody procedures for specimens;	
KAD 010	(C) procedures for assuring the security of the testing area, test records, and test reports;	Laboratories must have a mechanism for assuring that computers and other electronic data are secure. Paper records must be maintained in a secure area. Specimens must be maintained in a secured area under chain-of-custody.
KAD 011	(D) confirmation procedures for all positive screening tests unless evidenced by documentation that: (i) testing is performed for medical purposes on a hospital inpatient or patient currently undergoing treatment in a hospital emergency room; (ii) testing is performed on a specimen from an individual currently under treatment for substance abuse; or (iii) testing is performed for a correctional facility solely for the purpose of internal management of persons as defined in regulations promulgated by the secretary of corrections; as defined in regulations promulgated by the secretary of corrections;	It is the responsibility of the testing laboratory to assure that all necessary confirmation procedures are performed. Documentation must be maintained by the testing laboratory detailing the exception used if confirmation procedures are not performed.
KAD 012	(E) a policy stating that only confirmed positive results shall be reported as positive;	
KAD 013	(F) procedures for an internal quality control program that monitors the accuracy and precision of laboratory performance;	
KAD 014	(G) procedures for an instrument maintenance program which, at a minimum, conforms to the manufacturer's specifications;	
KAD 015	(H) provision for retention of all confirmed positive specimens for at least one year;	Specimens must be maintained by the confirming laboratory under chain-of-custody in a secured area.
KAD 016	(I) policies requiring disposal of all medical wastes in accordance with K.A.R. 28-29-27; and	

	(J) documentation of adherence to the foregoing policies and procedures.	
KAD 017	(4) Equipment required by the test system shall meet the specifications of the test system's manufacturer.	
KAD 018	(5) Reagents, controls, and any other required materials for the procedure being performed shall be available and shall be stored according to the manufacturer's specifications.	
	(d) During the inspection by the division, one or more testing personnel may be required to demonstrate performance of the procedure under consideration.	
	(e) Except as provided in subsection (k), each approved laboratory located in Kansas shall be inspected by the division biennially. A follow-up inspection of any approved laboratory may be conducted by the division at any time.	All laboratories will be inspected by DHEL once every two years. Biennial inspections will be conducted concurrently, whenever possible, with CLIA inspections performed by the department. Follow-up or complaint inspections will be conducted on an unannounced basis.
KAD 019	(f) Each laboratory performing tests for controlled substances shall have an individual serving as laboratory director who holds one of the following credentials: (1) current licensure as a physician in the state where the laboratory is located with additional training in pharmacology, toxicology, clinical pathology or forensic pathology; or (2) an earned doctoral degree from an accredited institution in a chemical or biological science and at least two years of laboratory experience in chemistry or analytical toxicology.	Documentation of credentials required: 1. Copy of current state license as a physician; or 2. Copy of diploma with stated field of education or transcript indicating field of study in which the degree was conferred. Written documentation of experience is also required. Resumes are self-documenting and therefore not acceptable.
KAD 020	(g) Each laboratory performing tests for controlled substances shall have an individual or individuals serving as a laboratory supervisor. Each laboratory supervisor shall hold one of the following credentials: (1) an earned doctoral degree from an accredited institution in a chemical or biological science and at least two years of laboratory experience in chemistry or analytical toxicology; or (2) an earned baccalaureate degree from an accredited institution in a chemical or biological science or medical technology and at least four years of experience in chemistry or analytical toxicology.	Copy of diploma with stated field of education or transcript indicating field of study in which the degree was conferred. Written documentation of experience (two years for PhD or four years for BS/BA degree) is also required. Resumes are self-documenting and therefore not acceptable.
KAD 021	(h) Each laboratory performing tests for controlled substances shall have one or more individuals serving as testing personnel who hold one of the following credentials: (1) an earned baccalaureate degree from an accredited institution in a chemical or biological science or medical technology; or (2) an earned associate degree from an accredited institution in a chemical or biological science or medical technology. (3) have achieved a satisfactory grade in the health and human services written clinical laboratory technologist examinations offered between March 7, 1975 and August 28, 1987 by the professional examination service.	Copy of diploma with stated field of education or transcript indicating field of study in which the degree was conferred or copy (front and back) of HEW or HHS card.
	(A) The laboratory director shall document that testing personnel performing tests have been adequately trained in each test procedure being performed.	
KAD 022	(B) Records of educational credentials and training shall be maintained for each individual qualified under subsections (f), (g) or (h) of this regulation.	Educational credentials for each individual performing testing must be on file prior to that individual reporting patient results. Records must be maintained for at least two years after the last date of employment.

Kansas Department of Health and Environment
Amended Permanent Regulations
Interpretive guidelines as in effect 12/31/97

KAD 023	(i) One copy of each test requisition, test record, and test report shall be maintained in a readily retrievable manner by the laboratory for a period of two years.	Test records include, but are not limited to: calibration records, preventative maintenance records, quality control records, quality assurance records, and proficiency testing records. Electronic data systems may be used. Instrument tape(s) must also be kept.
KAD 024	(j) Proficiency program. Each laboratory shall enroll and participate in an approved external proficiency testing program for opiates, cocaine, cannabinoids or THC, amphetamines, and phencyclidine. A list of approved proficiency testing programs shall be available from the division.	The list of approved PT (proficiency testing) programs will be available from DHEL by November 1 of each year.
KAD 025	(1) The results of each laboratory's performance in the proficiency testing program shall be sent directly from the approved program provider to the division.	It is the responsibility of the testing laboratory to notify the PT provider to send results to DHEL.
KAD 026	(2) The approval for any laboratory may be revoked by the director of the division or the director's designee when the laboratory meets the criteria for unsuccessful participation in an approved external proficiency testing program.	
KAD 027	(3) Each laboratory shall undertake an investigation and institute corrective action for all incorrect responses identified in the proficiency testing program. The laboratory shall maintain documentation of the investigation and corrective action for a period of two years.	
	(k) (1) Any laboratory which is not located in the state of Kansas may apply for approval. Such a laboratory shall be added to the list of approved laboratories if it meets the following conditions.	
	(A) The laboratory shall be certified or approved by federal, state or independent agency having standards that are determined by the director of the division, or the director's designee, to be generally equivalent or more stringent than the standards set out in subsections (b) through (j) of this regulation.	Those agencies currently determined to have equivalent standards are: Substance Abuse and Mental Health Services Administration of the US Dept. of Health and Human Services (SAMHSA).
	(B) The laboratory seeking approval shall submit the following documentation for inspection by the department: (i) a completed application on standard forms furnished by the division; (ii) a report of the most recently completed on-site inspection by the approving agency addressing subsections (c) through (e); (iii) proficiency testing results from the most recently completed proficiency challenge; (iv) documents demonstrating that the laboratory personnel meet the qualifications set forth in subsections (f), (g), and (h); and (v) any other documentation deemed necessary by the division.	The PT results submitted must be from a Kansas approved PT program and submitted directly to the State of Kansas by the PT program.
	(2) Any laboratory located in Kansas may seek approval under this subsection in lieu of following approval procedures in subsection (b) and meeting the on-site inspection requirements in subsections (c) through (e).	On site inspections of Kansas laboratories seeking approval under (k)(1)(B) above will not be conducted.
	(l) List of approved laboratories. A current list of approved laboratories shall be maintained by the division. Each laboratory shall be approved biennially.	

	(m) Removal from approved list. (1) A laboratory shall be removed from the approved list after voluntarily terminating or after notice and an opportunity for a hearing. All orders of revocation shall become final 15 days after service unless an appeal is filed in writing. All appeals shall be conducted according to the Kansas administrative procedure act, K.S.A. 77-501 et seq. and amendments thereto. (2) Notification of removal of a laboratory from the approved list shall be made by certified mail. (Authorized by K.S.A. 1995 Supp. 65-1,107; implementing K.S.A. 1995 Supp. 65-1,107, 65-1,108, and 65-1,108a; effective Oct. 2, 1989; amended May 3, 1996).	