
Statements of Competence for Histocompatibility Personnel

Revised 1998

- 2.E.2 Understand types and sources of antigens that can be used in ELISA testing, and their effects on testing.
- 2.E.3 Understand methods of antigen isolation and antigen adherence to plates used in ELISA testing; understand effects of solid-phase immobilization of antigen that may affect enzyme activity.
- 3. Methodology
 - 3.A Cell preparation:
 - 3.A.1 Select appropriate isolation technique for desired target cells; maintain sterility during procedure when required.
 - 3.A.2 Understand the properties of cells which influence isolation (e.g., cell density, surface immunoglobulin, adherence, cell surface receptors).
 - 3.A.3 Recognize and eliminate/neutralize components which may interfere with an assay, (e.g., RBC, platelets, PMNs, anticoagulants).
 - 3.A.4 Determine acceptability of target cell preparations, (e.g., viability staining, purity assessment).
 - 3.A.5 Perform accurate cell counts and calculations.
 - 3.A.6 Cryopreserve and thaw specimens appropriately to ensure cell function and integrity.
 - 3.B Serum preparation:
 - 3.B.1 Obtain, aliquot and store serum properly to maintain biologic activity.
 - 3.B.2 Prepare serum for testing (e.g., use of reducing reagents, cell adsorption or concentration).
 - 3.B.3 Include appropriate controls when preparing patient serum screening assays.
 - 3.C Serological assays:
 - 3.C.1 Understand differences in methods used for serological detection of class I and class II HLA antigens (e.g., direct cytotoxicity assays, direct/indirect fluorescence).
 - 3.C.1.1 Select appropriate reagents according to regulatory guidelines for class I and class II HLA antigen identification; include appropriate controls.
 - 3.C.1.2 Perform test according to established procedures regarding cell purity, addition of reagents, complement, wash steps, incubation times, temperature, vital staining.
 - 3.C.1.3 Read and record results utilizing consistent scoring criteria as per ASHI standards.
 - 3.C.1.4 Assess test for potential problems, including viability, carryover, false positive and false negative reactivity.
 - 3.C.2 Understand differences in serological methods (e.g., direct cytotoxicity assays, antiglobulin-augmentation) used to detect lymphocytotoxic antibodies.
 - 3.C.2.1 Select appropriate screening or crossmatch method (e.g., to detect HLA vs. non-HLA antibodies, IgG vs. IgM isotype, T- vs. B-cell specific) and perform test according to established procedures regarding addition of reagents, complement, wash steps, incubation times, temperature, vital staining.
 - 3.C.2.2 Select appropriate patient specimens for testing based on laboratory's established protocol, taking into account historical PRA information and sensitization events.
 - 3.C.2.3 Select appropriate target cells, taking into account type of antibody to be detected, panel size, frequency of HLA antigens and linkage disequilibrium.
 - 3.C.2.4 For patients awaiting renal transplantation, determine frequency of antibody screening testing.
 - 3.C.2.5 Read and record results utilizing consistent scoring criteria as per ASHI standards.
 - 3.D Cellular assays:
 - 3.D.1 Utilize appropriate techniques to prepare cellular assays for clinical and research applications.
 - 3.D.1.1 Utilize appropriate responder cells and inactivated stimulator cells.
 - 3.D.1.2 Select appropriate control combinations.
 - 3.D.1.3 Pipette cell mixtures into appropriate culture vessels according to established procedures and experimental design.
 - 3.D.1.4 Incubate cultures, utilizing correct CO₂ level, incubator temperature and humidity and total incubation time.
 - 3.D.1.5 Label cultures with appropriate radioisotope, considering type, amount and specific activity of isotope and duration and timing of pulse.
 - 3.D.1.6 Harvest cultures according to established procedure.
 - 3.D.1.7 Carry out scintillation counting procedure, utilizing appropriate scintillation fluid and counting time.
 - 3.E Flow cytometry assays:
 - 3.E.1 Perform appropriate methods (e.g., for immunophenotyping, HLA antigen identification, antibody screening, crossmatching), according to established procedures regarding optimum cell concentration, serum/cell ratio, wash steps, incubation times.
 - 3.E.1.1 Utilize appropriate reagents/fluorescent stains.
 - 3.E.1.2 Utilize appropriate controls.
 - 3.E.1.3 Select target cell panels to cover appropriate antigen specificities and/or major CREG groups.
 - 3.E.1.4 Assess test for potential problems, including poor cell viability, high background fluorescence, autoantibodies, false positive/false negative reactions.
 - 3.F. Molecular biology assays:
 - 3.F.1 Determine the level of molecular typing required (low, medium or high resolution).
 - 3.F.2 Verify specificity of test reagents.
 - 3.F.3 Extract nucleic acid material using methods that have been referenced in scientific literature and validated in the laboratory.
 - 3.F.3.1 Select appropriate isolation technique to provide sample of adequate quantity and quality for testing.
 - 3.F.3.2 Assess sample for integrity, quantity and quality.
 - 3.F.3.3 Prepare and store purified nucleic acid material appropriately; develop methods to validate integrity of sample under short- and long-term storage conditions.
 - 3.F.3.4 Ensure that specimens are isolated from post-amplification work areas.
 - 3.F.3.5 Understand effect of anticoagulants on extraction of nucleic acid material.
 - 3.F.4 Perform nucleic acid amplification according to established methods.
 - 3.F.4.1 Follow established guidelines for physical/biochemical barriers to prevent DNA contamination (e.g., dedicated work areas, supplies and equipment for pre- and post-amplification procedures).
 - 3.F.4.2 Monitor nucleic acid contamination within each amplification assay.
 - 3.F.4.3 Monitor quantity of specific amplification products by gel electrophoresis, hybridization with consensus probe, etc.
 - 3.F.4.4 Include controls to detect amplification failure in every amplification mixture if presence of amplified product is used as end result (i.e., SSP method).
 - 3.F.4.5 Understand how to optimize the PCR reaction to produce desired sensitivity and specificity required for testing.
 - 3.F.5 Perform gel electrophoresis of nucleic acid material using established procedures:
 - 3.F.5.1 Select appropriate-sized markers of known sequences that give discrete electrophoretic bands that span and flank entire range of system being tested.
 - 3.F.5.2 Include known human control DNA when restriction endonucleases have been used.
 - 3.F.5.3 Dispense equal amounts (mg/ml) of nucleic acid material into each lane.
 - 3.F.5.4 Optimize concentration of materials in gels used for detection of PCR products.

	3.F.6	Perform appropriate established procedure(s) necessary for allele identification (e.g., typing by sequence specific primers (SSP), sequence specific oligonucleotide probes (SSOP), restriction fragment length polymorphism (RFLP), direct sequencing) regarding specificity of primers and probes, temperature, hybridization conditions, specificity and sensitivity of labelling and detection methods.			4.A.3.4	Review patient's sensitization history in light of positive results.
	3.F.6.1	Utilize appropriate controls.			4.A.4	Interpret parentage testing results:
	3.F.6.2	Assess test for potential problems, including contamination, cross-hybridizing with closely-related alleles, amplification failure, false negative and false positive amplification, specification of acceptable limits of signal intensity for positive and negative results, weak internal control fragments and unusual amplification proteins.			4.A.4.1	Identify possible maternal and paternal haplotypes in the child.
	3.F.7	Read and record results according to established guidelines.			4.A.4.2	Determine presence of exclusion, if any, and order, e.g., first, second order.
SPEC	3.G	ELISA:			4.A.4.3	Calculate relevant inclusionary values for the HLA system at various prior probability levels and determine the need for more testing.
	3.G.1	Perform appropriate methods (e.g., for antibody screening or crossmatching), according to established procedures regarding reagent and serum concentrations, control sera, wash steps, incubation times, pH, temperature.			4.A.5	Interpret compatibility of ABO test results.
	3.G.1.1	Select target cell panels to cover appropriate specificities.			4.A.6	Identify potential HLA-compatible non-solid organ donors:
	3.G.1.2	Utilize appropriate controls.			4.A.6.1	Identify platelet donors based on patient HLA type, antibody screening results and knowledge of crossreactive antigen groups and "public" determinants.
	3.G.1.3	Assess test for potential problems, including low or high background optical density.			4.A.6.2	Identify potential bone marrow donors based on patient HLA type.
	4.	Test Result Interpretation			4.B	Cellular assays:
	4.A	Serological assays			4.B.1	Evaluate the validity of test results, taking into account stimulation and response capacity and reproducibility of replicate cultures.
	4.A.1	Interpret results of HLA class I and class II serological typing:			4.B.2	Understand how to reduce and normalize MLR and mitogen assay test results to allow for analysis and interpretation.
	4.A.1.1	Review controls (e.g., positive, negative cell viability, complement) to evaluate validity of data; recognize the need to repeat an assay based on inappropriate control results.	SPEC		4.B.3	Determine subsequent course of action if patient cells, control cells and/or medium controls do not give acceptable values and implement appropriate corrections.
	4.A.1.2	Determine antigen assignments based on patterns of serologic reactivity from manual or computer generated data.			4.B.4	MLR interpretation:
	4.A.1.2.1	Recognize appropriate antigens using monospecific and multispecific antisera.			4.B.4.1	Review reactivity of all MLR combinations with respect to HLA-Dw, DR, DQ type and identify identical, similar and disparate combinations.
	4.A.1.2.2	Recognize cross reactive groups for class I and class II HLA antigens.			4.B.4.2	Determine haplotype segregation within families and review for possible recombination and for parental haplotypes that demonstrate shared stimulatory determinants.
	4.A.1.2.3	Recognize split specificities.			4.C	Flow cytometry assays:
	4.A.1.2.4	Recognize common antigen combinations possibly due to linkage disequilibrium.			4.C.1	Review controls to evaluate validity of data.
	4.A.1.2.5	Understand and interpret reactivity patterns of "public determinants" which are shared among the "private" specificities, e.g., Bw4, Bw6, DR51, DR52, DR53.			4.C.2	Establish criteria for reporting and evaluating test results based on laboratory's established threshold for positive reactions.
	4.A.1.3	Evaluate the validity of antigen assignments and assess the need to perform additional testing; resolve any ambiguities.			4.C.3	Distinguish between calculations of linear vs. log amplification in determining fluorescence intensity.
	4.A.1.4	Assign haplotypes/genotypes, as appropriate in family studies; consider possibility of recombination.			4.C.4	Evaluate need for further testing when appropriate.
	4.A.2	Interpret crossmatch results:			4.C.5	For crossmatching, review donor/recipient match, and patient PRA and sensitization history, in light of cross-match results.
	4.A.2.1	Review controls to evaluate validity of data.			4.D	Molecular biology assays:
	4.A.2.2	Evaluate need for further testing when appropriate, (e.g., poor viability, autoantibody, weak reactivity).			4.D.1	Establish criteria for accepting or rejecting an amplification assay.
	4.A.2.3	Review donor/recipient match and patient's PRA and sensitization history in light of crossmatch results; resolve any ambiguities.			4.D.2	Establish criteria for identification of contamination of amplified nucleic acid material.
	4.A.3	Interpret results of patient antibody screening:			4.D.3	Establish acceptable limits of signal intensity for each primer mixture, probe and positive and negative controls; initiate corrective actions when these criteria are not met.
	4.A.3.1	Evaluate antibody screening data from manual or computer generated data considering linkage disequilibrium, crossreactivity of antigens and racial distribution of the panel used for testing.			4.D.4	Evaluate controls and size markers, and determine if repeat testing is required.
	4.A.3.2	Calculate panel reactive antibody (PRA).			4.D.5	Recognize primer-dimer products and differentiate bands based on size.
	4.A.3.3	Evaluate antibody specificity using statistical indices (e.g., chi square, correlation coefficient, tail analysis).			4.D.6	Use two independent interpretations of primary data whenever possible.
					4.D.7	Establish procedures for assignment of types; be able to recognize reaction patterns that may have more than one possible interpretation.
					4.D.8	Establish procedures for incorporating criteria for assignment of new alleles.
					4.D.9	Determine appropriate high resolution testing to be performed based on low resolution results.
					4.D.10	Identify and address discrepancies between molecular and serological testing results.
					4.D.11	Recognize unusual antigen association patterns and initiate additional testing if needed.
					4.D.12	Establish criteria for nucleotide assignments by direct sequencing methods.

	4.D.12.1	Determine criteria for sequencing one or both DNA strands.		5.C.3	Prepare control serum reagents utilizing appropriate methods of collection, screening, pooling, heat-inactivation, storage conditions and methods of plasma conversion.
	4.D.12.2	Determine criteria for sequencing of both DNA strands when unexpected test results are found.		5.C.4	Prepare a panel or pool of stimulating cells, selecting individual cell donors based on HLA type.
	4.D.13	Assign haplotypes/genotypes, as appropriate, in family studies; consider possibility of recombination.		5.C.5	Prepare appropriate type of scintillation cocktail with attention to safe use and storage.
SPEC	4.E. ELISA:			5.C.6	Prepare radioisotope labelling reagents (e.g., tritiated thymidine), with consideration of specific activity, concentration, appropriate storage, use and disposal.
	4.E.1	Review controls to evaluate validity of data.		5.D	Select and/or prepare reagents appropriate for flow cytometry assays:
	4.E.2	Define criteria for reporting and evaluating of test results based on laboratory's established threshold for positive reactions.		5.D.1	Prepare appropriate negative control serum/reagents.
	4.E.3	Evaluate need for further testing when appropriate.		5.D.2	Prepare appropriate positive control sera (pool of high PRA sera) and positive control reagents.
	4.F Reports:			5.D.3	Verify specificity of monoclonal antibodies.
	4.F.1	Prepare technical reports for review and signature of director using appropriate recognized nomenclature (i.e., most recent WHO publication).		5.D.4	Select appropriate reagents/fluorescent stains specific for anti-human immunoglobulin isotypes and for cell surface markers.
	4.F.2	Report results appropriately to authorized personnel in emergency situations.		5.D.5	Determine quantities of reagents to be used for each test sample.
SPEC	4.F.3	Review results of testing and issue reports to appropriate personnel; follow regulatory guidelines for inclusion of minimum required information.		5.E	Prepare reagents for molecular assays:
	4.F.4	For parentage testing, determine legal recipient(s) of report and ascertain proper authorization for release of report.		5.E.1	Prepare and/or standardize reagents for nucleic acid extraction.
	5. Reagent Selection and Preparation			5.E.2	Define specificity and sequence of all primers used.
	5.A Select and/or prepare reagents appropriate for serological assays:			5.E.3	Prepare and/or standardize primer mixtures to achieve the defined specificity for template used in testing; store under conditions that maintain specificity and sensitivity.
	5.A.1	Choose appropriate media (e.g., HBSS, PBS, RPMI, McCoy's, etc.), with required additives and supplements (e.g., sera, antibiotics, antimycotics, buffers, heparin).		5.E.4	Test each set of primers periodically for specificity, using reference nucleic acid material.
	5.A.2	Prepare and/or standardize blood cell isolation gradients, e.g., ficoll-hypaque/isopaque and percoll.		5.E.5	Prepare appropriate controls to detect technical failure and contamination with previously amplified products.
	5.A.3	Prepare control serum reagents utilizing appropriate methods of collection, screening, pooling, heat-inactivation, storage conditions and methods of plasma conversion.		5.E.6	Aliquot reagents used for amplification procedures into volumes appropriate for single use unless materials have been documented to be free of contamination at each use.
	5.A.4	Prepare cryopreservation solutions to correct concentration (e.g., DMSO).		5.E.7	Validate probes used in RFLP studies by family studies and population studies to demonstrate Mendelian inheritance of polymorphism detected.
	5.A.5	Handle serum complement appropriately:		5.E.8	Prepare and/or standardize size markers that reflect range of expected fragment sizes.
	5.A.5.1	Determine for each lot/batch number the titer and strength of reactions against each type of target cells to be tested.	SPEC	5.E.9	Define for each oligonucleotide probe and template the HLA locus and allele specificity.
	5.A.5.2	Follow precautions in the handling and storage of complement: aliquot size, maintenance temperature, thawing, dispensing, lability.		5.F	Prepare reagents for ELISA:
	5.A.6	Handle antiglobulin reagent appropriately:		5.F.1	Prepare reagent controls.
	5.A.6.1	Determine for each lot/batch number the titer and strength of reactions against each type of target cells to be tested.		5.F.2	Prepare positive control sera from pooled highly alloimmunized individuals, ensuring that the antibodies are of the appropriate isotype.
	5.A.6.2	Follow precautions in the handling and storage of antiglobulin reagent: aliquot size, maintenance temperature, thawing, dispensing, lability.		5.F.3	Prepare serum from non-alloimmunized human donor(s) for use as negative control.
	5.A.7	Prepare vital stains for cell viability determination, e.g., trypan blue, eosin, ethidium bromide, etc.		6. Instrumentation and Equipment	
	5.B Identify HLA serological reagents:			6.A	Select equipment and instruments appropriate to specific testing.
	5.B.1	Determine methods to obtain, preserve and inventory serum reagents.		6.A.1	Calibrate instruments and equipment by applying criteria established by the laboratory, manufacturer and/or accrediting and regulatory agencies.
	5.B.2	Develop a well defined panel of cells, taking into account racial distribution, crossreactive antigens, antigen frequency and linkage disequilibrium.		6.A.1.1	Calibrate flow cytometer.
	5.B.3	Characterize serum with appropriate cells.	SPEC	6.A.1.1.1	Use standards for each fluorochrome.
	5.B.4	Understand and utilize methods for the identification of reagent grade sera using methods of serum analysis (e.g., chi square, tail analysis, correlation coefficient), with or without computer assistance.		6.A.1.1.2	Compensate machine for "spill-over" of the fluorochrome signal.
	5.B.5	Request confirmation of antibody specificity for locally procured serum reagents from at least one other laboratory whenever possible.		6.A.1.1.3	Focus and align the laser.
	5.B.6	Perform testing to confirm specificity of serum reagents procured from other laboratories.		6.A.1.1.4	Establish threshold values for acceptable optical standardization for all relevant signals.
	5.C Prepare reagents for cellular testing:			6.A.1.2	For nucleic acid amplification, set number of cycles for amplification at a level sufficient to detect target nucleic acid but insufficient to detect small amounts of minor contaminants or occurrence of stochastic fluctuation.
	5.C.1	Choose appropriate media (e.g., HBSS, PBS, RPMI, McCoy's, etc.), with required additives and supplements (e.g., sera, antibiotics, antimycotics, buffers, growth factors, heparin).	SPEC	6.A.1.3	Monitor temperature of thermal cycling instruments used for DNA amplification.
	5.C.2	Prepare and/or standardize blood cell isolation gradients, e.g., ficoll-hypaque/isopaque and percoll.		6.A.1.4	Perform periodic calibration of ELISA reader.
				6.A.1.4.1	Verify that the light source produces intensity and wavelength of light required for the test system.
				6.A.1.4.2	Verify that movement of plate reader is precise.

	6.A.1.5	Perform periodic performance checks on microplate washer.	7.C.2	Participate in internal and external (e.g., ASHI/CAP Surveys) quality assurance and proficiency testing programs.
	6.A.2	Operate equipment and instruments utilizing established protocols and in accordance with criteria established by manufacturers and/or accrediting and regulatory agencies.	7.C.3	Implement program to monitor compliance to laboratory policies.
	6.A.3	Conduct and document validation and preventive maintenance programs for all instruments and equipment.	8.	General Laboratory Skills
	6.A.4	Evaluate equipment and instrument performance at prescribed intervals; recognize malfunctions, initiate and document corrective actions.	8.A	Prepare reagents according to protocols, understanding the metric system and the meaning of pH, molar, molal, % by weight or volume, normal, isotonic, picomoles, etc..
	6.A.5	Adjust and/or repair simple instruments and equipment; obtain external services when appropriate.	8.B	Maintain an accurate inventory of supplies and reagents; utilize supplies effectively while considering shelf life and expiration dates.
	6.A.6	Initiate contingency plan when malfunctions occur (e.g., power or equipment failure).	8.C	Validate, utilize and maintain computer databases of patient information and programs used for interpretation of data.
	6.A.7	Monitor and document operating conditions (e.g., temperature, CO ₂ levels, liquid nitrogen levels).	8.D	Use appropriate cleaning, decontamination and sterilization procedures for glassware, instruments and work areas.
7.	Quality Assurance		8.E	Identify and minimize laboratory hazards:
	7.A	Reagents/Equipment	8.E.1	Identify sources of biohazards and establish protective procedures for handling and disposal of such materials consistent with OSHA, CDC and mandated laboratory guidelines.
SPEC	7.A.1	Develop and maintain quality control procedures on equipment, instruments, reagents and products.	8.E.2	Correctly document, handle, store and discard radioactive materials per mandated laboratory guidelines and as dictated by the isotope's characteristics.
	7.A.2	Develop corrective action plan on quality control procedures; implement corrective action when necessary.	8.E.3	Correctly handle, store and dispose of flammables, volatile and toxic chemicals, liquid nitrogen and gas cylinders according to mandated guidelines.
	7.A.3	Choose and standardize controls appropriate to the requirements of the assay in use; maintain records in accordance with regulations.	8.E.4	Dispose of glass, syringes and needles properly.
	7.A.4	Maintain a reagent log and control system:	8.E.5	Discard venipuncture materials according to established guidelines.
	7.A.4.1	Record data on purchased chemicals, biologicals, radionucleotides.	8.F	Utilize appropriate general laboratory safety procedures:
	7.A.4.2	Label reagents with name, strength, titer or concentration, date prepared/received/opened, storage requirements, expiration date.	8.F.1	Determine location and utilization of fire extinguishers, eye wash, fire blanket, fire alarm, evacuation plans, power failure procedures, etc.
	7.A.4.3	Store, handle and dispose of all reagents properly.	8.F.2	Maintain list of personnel to be notified regarding emergencies.
	7.A.4.4	Maintain log of material safety data sheets (MSDS) and manufacturers' product inserts.	8.F.3	Recognize and be prepared to act in case of personnel or patient accident/injury.
	7.A.5	Evaluate and choose biologicals and chemicals conforming to purity, sensitivity, specificity, potency, sterility and stability required for the intended analysis.	8.F.4	Document and report personal injuries to appropriate personnel.
	7.A.6	Assess the quality of reagents by reproducibility, parallel studies, titration studies, pH, etc.	9.	General Principles
	7.A.7	Perform appropriate tests for nucleic acid, radioisotope, chemical and microbial contamination.	9.A	Demonstrate understanding of general principles of immunology:
	7.B	Documentation	9.A.1	Essential features of the immune system: types of immune responses, concepts of antigenic specificity and immunologic memory.
	7.B.1	Validate changes in testing methods by parallel or confirmatory testing.	9.A.2	Antigen: types (cellular/soluble), immunogenicity, concept of antigen vs. antigenic determinant/epitope.
	7.B.2	Maintain identity of specimen throughout testing and reporting of results, meeting processing time deadlines; address delays in result reporting.	9.A.3	Humoral immune response: immunoglobulin structure, classes and functions, dynamics of an antibody response and of the interaction between antigen and antibody, including the complement pathway of immune-mediated injury.
	7.B.3	Establish and implement policies to reject specimens when criteria of acceptability for testing are not met and to ensure that unacceptable specimens are not tested.	9.A.4	Cellular immune response: general features of cellular interaction [types of cells and characteristic phenotypes differentiating cell populations (T helper, cytotoxic/suppressor, etc.)] and cellular communication e.g., cytokines.
	7.B.4	Document incidents related to quality of testing.	9.A.5	Transplantation immunology: application of basic immunologic principles to graft rejection/acceptance, graft vs. host disease, mechanisms of tolerance, etc.
	7.B.5	Establish a system to maintain records of testing results for all subjects tested for a period of at least 2 years, depending on local regulations..	9.B	Demonstrate understanding of general principle of genetics:
	7.B.6	Establish and implement a system to report testing results in a timely, accurate and reliable manner.	9.B.1	Chromosome theory of heredity, meiosis, mitosis.
	7.B.7	Establish and implement policy to perform periodic antibody screening of patients awaiting renal transplantation.	9.B.2	Mendelian inheritance: law of segregation vs. independent assortment, allelism, recessive/dominant inheritance, homozygous/heterozygous, autosomal/sex-linked, recombination, gene conversion, etc.
	7.B.8	Maintain records of potentially sensitizing events for each patient awaiting renal transplantation.	9.C	Demonstrate understanding of general principles of immunogenetics:
SPEC	7.B.9	Establish and implement policy for repeat testing to be performed when necessary.	9.C.1	Historical background and nomenclature of the human major histocompatibility complex (MHC).
SPEC	7.B.10	Establish, implement and document corrective action procedures to deal with any inconsistency or errors in reporting of test results or problems with communication with laboratory.	9.C.2	Genetics of the human MHC
SPEC	7.B.11	Develop and implement program to regularly assess abilities of laboratory personnel to reproduce test results of previously characterized specimens.	9.C.2.1	Location of MHC genes encoding cell surface products and principles of mapping HLA loci.
SPEC	7.B.12	Validate prior to use any automated systems and computer programs used to assist in the interpretation of reaction patterns; test routinely for accuracy and reproducibility.	9.C.2.2	Principles of inheritance, concepts of HLA haplotype, genotype, phenotype including genetic recombination.
	7.C	Compliance		
	7.C.1	Maintain testing guidelines set by regulatory agencies (e.g., ASHI, UNOS, CLIA, OSHA) for procedures being performed in laboratory.		

9.C.2.3	Principle of genetic (linkage) disequilibrium between alleles of different loci on an HLA haplotype.		
9.C.2.4	Geographic and racial variations of MHC gene products, antigen and haplotype frequencies.		
9.C.3	General immunochemistry of MHC products		
9.C.3.1	Basic biochemical structure of HLA gene products.		
9.C.3.2	Serologic phenomena related to HLA antigen-antibody interaction, e.g., crossreactivity, CYNAP reactions, antibody avidity, polyclonal nature of antisera.		
9.C.3.3	Concept of multiple antigenic determinants (epitopes) on a single HLA molecule.		
9.C.4	General function of MHC gene products		
9.C.4.1	Principle of self-recognition (restriction) in host immune responses.		
9.C.4.2	HLA and association with disease, susceptibility vs. resistance, relative risk and association vs. linkage.	SPEC	
9.D	Demonstrate understanding of general principles of hybridoma technology:		
9.D.1	Basic principles of the production, standardization and use of monoclonal antibodies.		
9.D.2	Clusters of Differentiation (CD) nomenclature, CD's that are applicable to transplantation and disease states.		
9.E	Demonstrate understanding of general principles of flow cytometry:	SPEC	
9.E.1	Principles of fluorescence excitation/emission.		
9.E.2	Distribution of cell markers in various cell populations, applications of cell marker analysis.		
9.F	Demonstrate understanding of general principles of molecular biology:		
9.F.1	Theory of structural components of nucleic acids, base pairing; organization of genes, chromatin and chromosomes.		
9.F.2	Theory of gene expression including transcription and translation, and null alleles.		
9.F.3	Principles of primer and probe design.		
9.F.4	Principles of polymerase chain reaction (PCR) and its applications.		
9.F.5	Principles of molecular testing methods for major histocompatibility complex gene products (e.g., RFLP, SSOP, SSP, direct sequencing).		
9.G	Demonstrate understanding of general principles of ELISA:		
9.G.1	Principles of ELISA testing methods for antigen or antibody detection and crossmatching.		
			10. Supervisory functions/Management SPEC
			10.A Personnel:
			10.A.1 Determine levels and types of personnel appropriate for workload.
			10.A.2 Know and utilize institutional policies regarding employee selection, evaluation, benefits, counselling and grievance procedures.
			10.A.3 Schedule and supervise personnel to optimize efficiency in providing necessary level of service.
			10.A.4 Help provide continuing education for the technical personnel and others (students, physicians, etc.).
			10.A.5 Conduct training of laboratory technologists, students and physicians in techniques and procedures used in laboratory.
			10.A.6 Keep abreast of current appropriate literature and actively participate in seminars and other presentations for the instruction of laboratory and other staff.
			10.A.7 Document competency of technical personnel by job function.
			10.B Financial:
			10.B.1 Determine and choose cost effective methodologies, reagents and equipment for laboratory operation.
			10.B.2 Assist in determination of laboratory budget, considering costs and revenues.
			10.B.3 Prepare technical reports reflecting volume of work performed and procedures utilized; identify progress or adverse trends.
			10.C General:
			10.C.1 Know and implement appropriate federal, state, local, institutional and accreditation agency laws, regulations, standards and policies.
			10.C.2 Establish communications to interact effectively with patients and medical personnel both within and outside the laboratory at all levels.
			10.C.3 Assist in laboratory space allocation and design when applicable.
			10.C.4 Prepare and update laboratory manual(s) of procedures and policies.
			10.C.5 Assist in preparation of laboratory certification/accreditation applications.
			10.C.6 Prepare reports of quality assurance and proficiency testing results.
			10.C.7 Assist in development and implementation of new procedures and technologies.
			10.C.8 Validate commercial software packages for data analysis, data management, inventory systems and generation of documents and graphics.
			10.C.9 Maintain appropriate security measures of computer systems