### I. General Laboratory Skills – 6 items

A. Specimen Collection and Handling
   1. Ship and receive samples (e.g., packaging, labeling, transport)
   2. Verify and maintain sample identity
   3. Verify requisition documentation
   4. Perform venipuncture

B. Understand and follow laboratory safety and cleaning information and procedures (e.g., sharps, flammables, corrosives, volatiles, infectious agents)

C. Monitor and maintain supply inventories

D. Maintain patient records (paper or electronic)

E. Perform basic laboratory math (e.g., calculate totals, concentrations or dilutions based on counts, percentages or molarity)

### II. Histocompatibility and Immunogenetics Testing – 48 items

A. Prepare, process, and store specimens (e.g., cryopreservation, target cell selection, DNA extraction, centrifugation, DTT treatment, adsorption, Pronase treatment, viability, concentration, sterility)
   1. Theory (e.g., know how things work and why they are or are not appropriate in a particular case)
   2. Application (e.g., know how things are done and when they are recommended or required)

B. Prepare, label, and store reagents (e.g., reconstitution, pH, sterility, lot number, expiration dates)
   1. Theory (e.g., know how things work and why they are or are not appropriate in a particular case)
   2. Application (e.g., know how things are done and when they are recommended or required)

C. Test Selection
   1. Ensure the assay selected is appropriate for the intended purpose (e.g., level of resolution, sensitivity, limitations, variations)
      a. Theory (e.g., know how the assay works and why it is or is not appropriate in a particular case)
      b. Application (e.g., know how to perform an assay and when it is recommended or required)
   2. Ensure the assay components are appropriate for the intended purpose (e.g., panel selection, primer and probe design, fluorescent markers, secondary antibody)
      a. Theory (e.g., know how a component or process works and why it is or is not appropriate in a particular case)
      b. Application (e.g., know how to perform or use a component or process and when it is recommended or required)

D. Ensure that the selection and use of equipment and materials are appropriate for the intended purpose (e.g., pipettors (adjustable ranges), plastic ware (composition), centrifuge rotors (style, radius), flow cytometers (PMT settings and filters, compensation, log or linear mode))
1. Theory (e.g., know how the equipment and materials work and why they are or are not appropriate in a particular case)

2. Application (e.g., know how to use the equipment and materials and when they are recommended or required)

E. Cell Associated Analytes

1. Assay for cell components that characterize or predict immunological status
   a. Perform typing for transplantation, transfusion, disease association, or pharmacological applications (e.g., HLA Class-I & II, ABO, MICA, KIR)
   b. Identify genes defining alleles of secreted factors (e.g., IFN, TNF)
   c. Identify genes or loci driving cell processes (e.g., siRNA)

2. Assay for cell processes that characterize or predict immunological status (e.g., cell stimulation assays)

F. Secreted Analytes

1. Assay for secreted factors that characterize or predict immunological status
   a. Identify and characterize antibodies (e.g., HLA Class-I & II, MICA, autoantibody, presence, absence, isotype, titre, PRA, specificity, crossmatch)
   b. Identify and characterize Cytokines
   c. Identify and characterize soluble forms of cell associated components (e.g., sHLA, sCD30)

G. Quality Control and Assurance

1. Evaluate and document the acceptability of specimens (collected, processed, or stored)
2. Evaluate and document the acceptability of reagents (prepared, labeled, or stored)
3. Evaluate and document the acceptability of individual assays or batch runs
4. Adhere to policies and guidelines to ensure assay integrity (e.g., maintain physical separation, avoid carry-over)

III. Test Results and Reporting – 51 items

A. Interpret or calculate results
   1. assign genotype, phenotype, haplotype
   2. determine presence, absence, specificity, titre, isotype (e.g., HLA antibody, cytokine levels)
   3. assess compatibility (e.g., crossmatch, HLA, GVH, HVG, KIR)
   4. calculate results (e.g., PRA, cPRA, chi-square, r-value, engraftment/chimerism, relative risk)

B. Recognize common factors affecting interpretation (e.g., impact of linkage disequilibrium, null alleles, allele frequencies, CREGs, primer dimers, therapeutic agents)

C. Identify and address ambiguous results

D. Identify and address atypical results (e.g., possibility of technical error)

E. Identify and address differences between the current assay results and other results or clinical information

F. Results Reporting
   1. Review reports for complete and required (i.e., reporting requirements specific to HLA) information
   2. Review reports for accuracy

IV. Histocompatibility and Immunogenetics Testing Principles and Theory – 16 items

A. Understand nomenclature

B. Understand relevant biological and therapeutic processes, mechanisms, and strategies
C. Understand the biological roles and characteristics of the analytes detected (e.g., properties of alleles, isotypes or subtypes, differences between MHC Class-I & II including antigen presentation, distribution, and structure)

D. Understand the clinical significance of assay results (e.g., disease associations, vaccines, drug sensitivity, determination of unacceptable antigens)

V. Quality Systems – 19 items

A. Perform and document QC, QA and compliance activities (not covered in II.G above) as mandated by relevant law and regulatory agencies.

1. Understand and comply with regulations (e.g., HIPPA, CLIA, ASHI, OSHA)
2. Perform routine monitoring of instruments and temperatures
3. Maintain licensure and continuing education
4. Perform competency assessments (of technical ability)
5. Create and maintain procedure manuals
6. Ensure compliance with laboratory safety requirements
7. Ensure compliance with general clinical specimen collection and handling requirements
8. Ensure compliance with general clinical reporting requirements when reporting results
9. Perform assay validation
10. Utilize quality indices (e.g., turnaround times, retest rates, Levey-Jennings)
11. Participate in risk management and assessment activities (e.g., perform or generate error tracking, occurrence reports, root cause analysis)

VI. Supervisory Functions and Management – 10 items

A. Participate in the creation or monitoring of work schedules and duty assignments

B. Participate in the hiring and discipline of laboratory staff and utilize institutional and regulatory policies regarding employee selection, job descriptions, performance evaluations (in the “business sense”), benefits, counseling and grievance procedures

C. Participate in the training and education of laboratory staff or other medical professionals

D. Participate in the budgeting process

E. Participate in the allocation of space or laboratory design