APPENDIX I

VALIDATION GUIDELINE

Laboratory Name: _____

ASHI # _____ CLIA # _____ UNOS #_____

Director/Technical Supervisor: _____

Commissioner:_____ Date of Review: _____

New Addition: _____

___ Director or Technical Supervisor previously approved for **Area of Accreditation**
If not: ___ Director or Technical Supervisor approved by DTRC

___ Laboratory previously approved for **Area of Accreditation**
If not: ___ Submit Laboratory Validation Packet

___ Director or Technical Supervisor previously approved for **Test Category** (see table)
If not: ___ Director or Technical Supervisor approved by DTRC; or,
___ Participation in Laboratory's Validation Documented

___ Laboratory previously approved for **Testing Category** (see table)
If not: ___ Log of cases reviewed and 1-2 cases with data included:

Validation Checklist

For new category or system, the following documents must be submitted to your commissioner for review.

For new method of previously approved system, the following documents must be available for the inspection but not submitted to your commissioner.

___ Summary and Interpretation of Validation - signed by Director or Technical Supervisor
___ Testing protocol – how test is to be used; purpose of test
___ Step-by-step procedure
___ Performance Specifications – summary of accuracy, precision, sensitivity, specificity, range of results, normal values, limitations of assay
___ QC procedures
___ Equipment Calibration data
___ Training checklist
___ Competence documentation for those trained to perform test
___ Enrolled in PT program

Parallel Testing – for new System Minimum of 20 tests; 10 of which must be blinded. Graded PT samples may be used to meet the blinded sample requirement. See section XXI (above) for minimum number of tests required for addition of new Testing Categories.
Acceptable performance is 80% or greater concordance.

___ Parallel Testing – for new Method, may be with previously approved method; Include worksheets if not blinded parallel study; Minimum of 20 tests.

___ Validation approved ____ Additional data requested

_____ _____

Commissioner Co-Chair

Category (What is done) Submitted Validation required	System (Assay System) Submitted Validation required	Methods (Specific assay) Internal Validation – labs should send the commissioner an email to notify
Immunogenetics: HLA Typing, MICA Typing, KIR Typing, HPA Typing, ABO/Rh Typing	High Resolution molecular Low Resolution molecular Serology Flow Cytometry	CDC (T and/or B) SSO SSP Sequencing Real time PCR Flow cytometric phenotyping
Crossmatching	Complement Dependent Cytotoxicity Flow Cytometry Other	CDC (T and/or B) AHG (T and/or B) Flow (T and/or B) Solid Phase (Class I and/or II)
Antibody Testing: HLA, HPA, ABO-A1 Titer, MICA	Antibody Detection 1. Complement Dependent Cytotoxicity 2. Solid Phase 3. Other Antibody Identification 1. Complement Dependent Cytotoxicity 2. Solid Phase 3. Other	CDC (T and/or B) AHG (T and/or B) ELISA (Class I and/or II) Flow (Class I and/or II) Microarray (Class I and/or II)
Other Testing	Molecular Immunology Flow Cytometry Cellular Chimerism/Engraftment Monitoring	STR VNTR Flow-Immunophenotyping Immune Cell Function/MLC/PLT SNP Testing Soluble Biomarker Testing