VALIDATION CHECKLIST

Laboratory Name: _____

ASHI # _____ CLIA # _____ UNOS #_____

Director/Technical Supervisor: _____

Commissioner:_____ Date of Review: _____

New Addition: _____

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

___ Director previously approved for **Technology** (see table on page 2)
If not: ___ Log of case reviews submitted

___ Laboratory previously approved for **Testing Category** (see table on page 2)
If not:
Log of cases reviewed and 1-2 cases with data included:
___ 50 HLA typings, ___ 10 Cellular assays
___ 20 HLA crossmatch tests, ___ 10 Engraftment studies
___ 50 HLA Ab screens/IDs, ___ 10 Flow Phenotype cases
___ 50 Parentage Testing cases
___ Test data included different types of testing material if applicable (PB, LN, Spleen)

Validation Checklist (required for all additions)

___ Summary and Interpretation of Validation - signed by Director
___ 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
___ Parallel Study – for new Method, may be with previously approved method; Include worksheets if not blinded parallel study;
Minimum of 20 tests or equal to 1 yr PT
(Blinded parallel testing required if New Technology or Testing Category)
___ Training checklist
___ Competence documentation for those trained to perform test
___ Enrolled in PT program
___ **On-site inspection required if New Technology or Testing Category**

___ Validation approved ____ Additional data requested

_____ _____
Commissioner Co-Chair

Technologies:	**Testing Categories:**	**Methods included under Technology:**
Serology/Solid Phase	HLA Typing Crossmatching HLA Antibody Screen/ID Parentage Testing	Cytotoxicity, ELISA, Microarray
Molecular-Polymorphism analysis	HLA Typing Parentage Testing	SSO, rSSO, SSP, RFLP
SBT / Fragment Analysis	HLA Typing Chimerism/Engraftment Parentage Testing	Sequencing, STR, VNTR, Heteroduplex
Flow Cytometry	Crossmatching HLA Antibody Screen/ID Immunophenotyping	Methods for Quantitation, Direct Labeling, Indirect Labeling, Internal Labeling, External Labeling
Cellular	Immune Cell Function	MLC, PLT, CTL, Mitogen or Antigen stimulation, and measuring thymidine incorporation or ATP production
ABO/Rh		ABO grouping, Rh typing, anti-A1 titers