

C Quality Assurance

C1.000 Facilities, Equipment Maintenance and Function Checks

C1.100 The laboratory must provide sufficient space for all procedures to be carried out without crowding personnel to the extent that errors may result. The laboratory must have adequate and easily accessible facilities for refrigerator and freezer storage of reagents and specimens.

C1.200 The laboratory must provide adequate lighting and ventilation.

C1.300 Refrigerators and freezers must be monitored to ensure maintenance of optimal temperatures for storage of each type of sample or reagent. The laboratory's storage and maintenance of both critical reagents and relevant transplant candidate sera must use an audible or centrally located temperature alarm system. An emergency plan for alternative storage must be in place. In laboratories where liquid nitrogen is utilized for storage of frozen cells, the level of liquid nitrogen in the cell freezers must be monitored at intervals that will ensure an adequate supply at all times. Ambient temperature and/or the temperatures of incubators in which test procedures are carried out must be monitored each day of use to ensure that these procedures are carried out within temperature ranges specified in the laboratory's procedure manual.

C1.400 The laboratory must establish and employ policies and procedures for the proper maintenance of equipment, instruments and test systems by 1) defining the preventive maintenance program for each instrument and piece of equipment, and by 2) performing and documenting function checks on equipment with at least the frequency specified by the manufacturer. Instruments requiring calibration must be verified at least every 6 months.

C1.500 Adequate facilities to store records must be immediately available to the laboratory. Records must be available onsite for a minimum of two years and readily retrievable thereafter for at least the time period specified by local, State and Federal Regulations.

C1.600 The laboratory must comply with all applicable Federal, State and local laws that relate to laboratory employee health and safety; fire safety; and the storage, handling and disposal of hazardous chemical, biological and radioactive materials.

C1.700 The laboratory must have documented validation of all computer software programs used for patient data analysis to ensure that computer-assisted analyses are accurate before results are issued.

C2.000 Specimen Submission and Requisition

C2.100 The laboratory must have available and follow written policies and procedures regarding specimen collection.

C2.200 The laboratory must perform tests only at the written or electronic request of an authorized person. The laboratory must ensure that the requisition includes: 1) the test subject's name or other unique identifier; 2) the name and address or other suitable identifiers of the authorized person who ordered the test; 3) date of specimen collection; 4) time of specimen collection, when pertinent to testing; and 5) the tests ordered. Oral requests for laboratory tests are permitted only if the laboratory subsequently obtains written authorization for testing within 30 days of the request.

C2.300 Each container of a blood or tissue sample submitted for testing must be individually labeled with the name or other unique identification number for the individual and the date of collection.

C2.400 The laboratory must maintain a system to ensure reliable specimen identification throughout collection, processing, testing and reporting to ensure that accurate test results are recorded.

C2.500 The laboratory must have criteria for specimen rejection and a mechanism to ensure that unacceptable specimens are not tested.

C2.600 If the laboratory draws blood samples, it must use a procedure that ensures minimal possibility of infection of the donor or contamination of the sample. All needles and syringes must be disposable.

C2.700 Laboratory personnel must handle and transport all blood and tissue samples with the understanding that they could transmit infectious agents.

C2.800 The laboratory must document that anticoagulant and preservation solutions do not interfere with test performance. The anticoagulant/preservation medium used must preserve sample integrity for the length of time and under the storage conditions the laboratory procedures permit between sample collection and testing.

C3.000 Reagents

C3.100 The laboratory must properly label and store all reagents according to manufacturers' instructions or locally specified conditions to maintain optimal reactivity and specificity. Any deviation from a manufacturer's set conditions for reagent storage and any locally established storage conditions must be validated by the laboratory.

C3.200 Reagents, solutions, culture media, controls, calibrators and other supplies, as appropriate, must be labeled to indicate 1) identity and, when significant, titer, strength or concentration; 2) recommended storage requirements; 3) preparation and/or expiration date and other pertinent information.

C3.300 Laboratories must have a policy for quality control of each lot and shipment of reagents, and must adhere to their policy.

C3.400 Reagents from different lots of commercial kits must not be mixed. The appropriate performance of each lot and shipment of reagent must be documented before results using these reagents are reported.

C3.500 There must be a documented system in place for identifying which lots of reagents were used for an assay.

C4.000 Laboratory Procedure Manual

C4.100 All procedures in use in the laboratory must be detailed in a procedure manual that is readily available where the procedures are carried out. The use of product inserts provided by manufacturers is not acceptable in place of a written procedure.

C4.200 The laboratory director must review the procedure manual at least annually and written evidence of this review must be in the manual. The director must approve any new procedures or changes in existing procedures and this approval must be evident in the manual at the time those changes are initiated.

C5.000 Proficiency Testing and Competency Evaluation

C5.100 The laboratory must participate in at least one external proficiency testing program, if available, for each analyte (e.g., HLA phenotype or alloantibody). If an external proficiency program is not available, the laboratory must use other procedures that meet CLIA requirements to validate performance at least semi-annually for each analyte.

C5.200 The laboratory must determine and document the cause for each unsatisfactory proficiency test result. If a laboratory's performance in an external proficiency testing program is unsuccessful (i.e., less than 80% correct for an entire year for a specific analyte or within a single survey, or having two out of three consecutive surveys graded as unsuccessful), the laboratory must participate in an enhanced proficiency testing program in that area until performance is deemed satisfactory.

C5.300 The laboratory must test proficiency samples in a manner comparable to that for testing clinical samples.

C5.400 The laboratory must document annual competency testing for each individual in the laboratory who performs clinical testing for each test performed.

C5.500 The Director/Technical Supervisor or designee must evaluate the competency of each technologist and technician annually.

C5.600 The Director/Technical Supervisor and technical staff must participate in continuing education in histocompatibility, immunogenetics and/or clinical transplantation at least to the minimum requirements established for accreditation by national, state, and local regulatory agencies.

C6.000 Quality Assurance Evaluation of Test Management Systems

C6.100 The laboratory must establish and employ policies and procedures, and document actions taken when test systems do not meet the laboratory's established criteria for assuring the quality of patient testing. The laboratory must promptly notify the authorized person ordering or utilizing the test results of any errors or discrepancies when detected, issue corrected reports, and maintain copies of both the original and the corrected report for a minimum of two years or the interval required by local, state and federal regulations.

C6.200 The laboratory must have an ongoing mechanism for monitoring and evaluating the quality assurance program including an ongoing mechanism to evaluate corrective actions taken. The laboratory must document and assess problems identified during quality assurance reviews, discuss them with the staff, and take corrective actions necessary to prevent recurrences. Ineffective policies and procedures must be revised based on the outcome of the evaluation.

C6.300 The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken, for a minimum of two years or the interval required by local, state, federal and UNOS regulations.

C6.400 If a laboratory performs the same test using different methodologies or instruments or performs the same test at multiple sites, the laboratory must perform a parallel comparison of the test results at least twice a year.

C6.500 The laboratory must verify or establish for each method the performance specifications for accuracy, precision, analytical sensitivity and specificity and, if applicable, the reportable range of patient test results, the reference ranges, or any other applicable performance characteristic, which may influence test results prior to reporting patient test results.

C6.600 The laboratory must include appropriate controls for each test to evaluate test performance.

C7.000 Client Service Evaluation

C7.100 All complaints and problems reported to the laboratory must be documented. The laboratory must investigate complaints and take corrective action when necessary.

C7.200 The laboratory must have a system in place to document problems that result from breakdowns in communication between the laboratory and the authorized individual who orders tests or receives results.

C7.300 The laboratory must, upon request, make available to clients a list of the test methods employed by the laboratory, a list of performance specifications for each method (including normal ranges, if applicable) and a list of interfering factors that could affect interpretation of test results. Pertinent updates on testing information must be provided whenever changes occur that affect test results or the interpretation of test results.

C8.000 Records and Test Reports

C8.100 The record system must provide documentation of the following: test requisition, subject identification number, accession number or unique identification of the specimen, the tissue source of the specimen, the dates of specimen collection and receipt, the time of specimen receipt, if relevant, the condition and disposition of the specimens that do not meet the laboratory's criteria for acceptability, the records and dates for specimen testing including the personnel that performed the tests, the type of specimen used for testing, tests data and results, legally reproduced copies of preliminary and final reports and the documented review of these by the Director/Technical Supervisor or designee who meets at a minimum the requirements of General Supervisor.

C8.200 Records may be saved in computer files provided that back-up files (either electronic or hardcopies) are maintained to ensure against loss of data.

C8.300 The laboratory must have adequate systems in place to report results in a timely, accurate reliable and confidential manner. The laboratory must ensure subject confidentiality throughout those parts of the total testing process that are under the laboratory's control.

C8.400 The report must contain:

- a. The name and address or other unique identifier of the laboratory and/or Institution.
- b. The date of collection of sample.
- c. The date(s) of testing of the sample when pertinent to the interpretation of the test.
- d. The name or unique identifier of each individual tested.
- e. The date of the report.
- f. The test results.
- g. The units of measurement if applicable.

C8.500 Reports must be reviewed by the Director/Technical Supervisor or a designee who at least meets the minimum requirements of a General Supervisor prior to release. STAT reports (e.g., deceased donor HLA typing or crossmatch reports) must be reviewed by one of the above individuals during the next day of regular laboratory operation.

C8.600 Laboratories must have a mechanism in place for addressing any discrepancies in HLA typing results as reported by different laboratories or at different times for the same individual.

C8.700 All UNOS histocompatibility laboratories must review and verify the Waiting List histocompatibility data for every patient whose test results the laboratory was responsible for. Documentation of such review must be kept for at least three years or the interval required by local, state and federal regulations, whichever is the longer, and must be available for audit by UNOS.

C9.000 Subcontracting

C9.100 A UNOS approved laboratory may engage another laboratory to perform testing by subcontracting the work to that laboratory. In that event, if histocompatibility and/or transplantation immunology testing is referred, the subcontracting laboratory must be CLIA certified/exempt and either UNOS approved or ASHI accredited for that testing. If other testing is subcontracted, the subcontracting laboratory must document expertise and/or accreditation in those tests. The results must be returned to the referring laboratory and are to be released only after the review and approval of the director of that laboratory. The identity of the subcontracting laboratory and that portion of the testing for which it bears responsibility must be noted in the report of the UNOS laboratory. A copy of the testing laboratory's report must be kept on file by the laboratory receiving the results. Proficiency testing must not be referred to another laboratory.