

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

POLICIES

Oversight Policies

- Policy 1)** The Proficiency Testing Subcommittee of the Histocompatibility Committee of AFDT oversees the Proficiency Testing Program (PT). This subcommittee is composed of a Chair or Co-chairs appointed by the Histocompatibility Committee Chairs from AFDT member laboratories or individual AFDT members. The subcommittee chairs may appoint other members to the committee from AFDT member laboratories or individual AFDT members. The PT manager and one representative from each of the contract laboratories serve as ad hoc members of this subcommittee.
- Policy 2)** The policies of the PT program are established by the Proficiency Testing Subcommittee of AFDT contingent on approval by the Histocompatibility Committee of AFDT. Financial policies and membership issues must also be approved by the AFDT Board of Directors.
- Policy 3)** The Proficiency Testing Program is managed by a Proficiency Testing Manager contracted by AFDT to handle the paperwork and computerized data analysis.

Grading Policies – Cell Typing:

- Policy 1)** Grading for Class I and II will be results based: Class I and Class II typing will be graded at antigen and allelic level. Graded fields are listed in Appendix A. The labs may use either DNA and/or serology to determine the answer, but must have an answer that is consistent with consensus. Equivalents will be defined by the most recent Report on Serological Equivalents of HLA Alleles: The HLA Dictionary (see reference - Appendix B). Consensus will be 80% agreement. A minimum of 8 laboratories per region must report for a challenge to be graded.
- a) **Antigen level results** must be split at the level required by UNOS, (see UNOS HLA Equivalence Table – Attachment B).
 - b) **The graded entry** should be the final interpretation of serologic or DNA based testing expressed as the antigen level equivalent defined by the most recent Report on Serological Equivalents of HLA Alleles: The HLA Dictionary. When a group of alleles includes one or more common alleles

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

with known serologic equivalents, and other less common alleles with or without serologic equivalents, the common serologic equivalent should be reported for the purposes of this survey.

- c) **Grading of splits.** If the antigen split reaches consensus, then the specific antigen split must be reported in order to be graded as the correct response. No other splits are acceptable. Also, if the split reaches consensus, reporting the broad antigen will be a miss.
- d) **Reporting a second antigen** when no 2nd antigen is present by consensus of labs (with the consensus of the DNA labs or reference labs concurring), would result in a miss.
- e) **High resolution DNA typing will be graded.** Consensus will be 80% agreement, and a minimum of 8 laboratories must report for the challenge to be graded.

Grading Policies – PRA:

Policy 1) PRA will be graded by consensus for the presence or absence of Class I and Class II antibody, and not by methodology or percentage. Data will be collected on the percentages and the results of different methods including cytotoxic, flow and ELISA, but only one grade will be given per lab. Consensus will be 80% agreement. A minimum of 8 laboratories must report data for a challenge to be graded. There will be a data field for Class I PRA for the presence or absence of antibody (Yes or No) and a data field for Class II PRA for the presence or absence of antibody (Yes or No). Graded fields are listed in Appendix B.

Policy 2) Antibody specificity for Class I and Class II will be assessed by consensus of labs with all methods combined. The AFDT PT program will collect data on the results of different methods including cytotoxic, flow, and ELISA. Only one data field for Class I and one for Class II will be transmitted to CAP. This field should contain an interpretation of the specificity determined by all methods used in the laboratory. Graded fields are listed in Appendix B.

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

Grading Policies – Crossmatch:

Policy 1) For Crossmatching, data will be collected on multiple techniques:

- 1) No wash methods
- 2) Wash methods
- 3) Antiglobulin
- 4) Flow cytometry
- 5) Elisa

These techniques are divided into 2 categories:

- 1) T cells
- 2) B cells (B)

A separate score will be given for each category. Results may be given as positive, negative or weak. Weak will be graded as positive. Laboratories should provide data for all techniques used in the laboratory. Data will be collected on subsets of these categories, and on other techniques. The graded fields are listed in Appendix B. Consensus will be 80% agreement. A minimum of 8 laboratories must report results in order for a challenge to be graded. For crossmatching, if a situation arises where consensus results are negative for a given serum-cell crossmatch when there is a consensus positive result for a more sensitive crossmatch technique for the same serum-cell combination, reporting positive results using the less sensitive technique will be graded as correct.

Policy 2) A result that does not agree with consensus, but can be explained on the HLA antibody results may be accepted. The grading subcommittee must be assured that the antibody is in fact correct.

Graded Results:

Policy 1) **Passing grades.** Grading of all categories will be reported as pass/fail for each survey. At the end of the year, a cumulative grade which will indicate pass or failure of Proficiency testing program for the year will also be given. CLIA guidelines require 80% correct responses. All grades given will use 80% correct responses as the cutoff for passing.

- a) CLIA has mandated that a cell is an analyte, which means that a cell typed

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

for ABDR must have all antigens correctly reported to be counted as a correct response. If fewer than 80% of challenges on each send-out are typed correctly, corrective action **MUST** be taken by the laboratory.

- b) PRA challenges must be counted as correct 80% of the time. Only those challenges which reach consensus will be counted. If fewer than 80% of sera on each send-out are reported correctly, corrective action **MUST** be taken by the laboratory.
- c) Crossmatch challenges for each technique used in the laboratory must be counted as correct 80% of the time. Only those challenges which reach consensus will be counted. If fewer than 80% of the cell and serum combinations for each crossmatch technique on each send-out are reported correctly, corrective action **MUST** be taken by the laboratory.
- d) Documentation of corrective action must be available upon request of the AFDT PT committee.

Policy 2) A **FINAL** graded report will be sent to the labs at which time they will have one(1) week to submit an appeal. Acceptable reasons for an appeal would evolve around AFDT data entry errors, or misreading of submitted data.

Policy 3) **Challenge or appeal of results** - Any appeal or challenge of the results of the grading of the cell or serum exchange must be made in writing, or email, to the AFDT Proficiency Testing Subcommittee Chair(s), and it must be done within one(1) week of the **FINAL** report being sent. Testing from reference laboratories will be reviewed and each case considered individually. The laboratory may be asked to submit raw data. These data will be reviewed by the AFDT Proficiency Testing Subcommittee. If necessary, the subcommittee may request analysis of the blinded data by a consultant. The subcommittee shall make a decision as to the validity of the challenge. The subcommittee chair shall then provide a report to the laboratory explaining the reasons for upholding or altering the grade. If the laboratory does not accept the decision of the subcommittee, it may appeal the decision to the Histocompatibility Committee Co-Chairs. At the discretion of the co-chairs, the matter may be brought, in a blinded fashion, to the Histocompatibility Committee for review. The decision of the Histocompatibility Committee is final.

Policy 4) **Corrective action for PT failure** as defined in Policy 6). If a laboratory fails an analyte for the year, the laboratory must correct this by testing additional samples in a blinded fashion. The laboratory should provide the PT subcommittee chair

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

with a correction plan. The lab may request the AFDT PT program to provide additional cells (enhanced testing) to correct deficiencies. These cells will be sent out with the next regular cell exchange from the alternate region, and will be in addition to the normal cell exchange. A fee will be charged for this service. The laboratory may request a consultant visit the laboratory. AFDT may provide a list of individuals willing to serve as consultants to the laboratory, but all further arrangements and expenses will be handled and paid by the laboratory and will be by agreement between the consultant and the laboratory.

Policy 5) Remedy for receipt of inadequate sample or non receipt of sample. Upon receipt of sample, it is the responsibility of the receiving lab to inspect the shipment for any damage. If a sample is received broken or in otherwise unsuitable condition, it is the responsibility of the receiving laboratory to notify the sending laboratory, and/or the PT program manager by phone, fax, or email within 1 (one) hour of sample receipt. Documentation of the time of receipt of samples in the laboratory may be required. If the receiving laboratory does not provide notification of sample damage within 1 hour of receipt of samples in the laboratory, the receiving laboratory will be graded as incorrect due to a lack of reported results.

If notified within 1 hour of receipt of the shipment in the laboratory, the AFDT PT program will have 3 options at its discretion: 1) if feasible, replace the original sample; 2) provide a substitute sample at another time; 3) not count the missing cell or serum as a miss. If available, serum samples for the crossmatch exchange may be replaced by the sending laboratory within 24 hrs. The serum samples should then be tested for anti HLA antibody and crossmatched with cells received in the original shipment. Additional cell and serum samples will not normally be available, except for the reasons described above.

For laboratories in the continental US, if the samples are not received in the laboratory by 4 PM on Tuesday, the laboratory must notify the sending laboratory by 4:30 PM Tuesday so that tracking of the samples by FEDEX may be initiated. If samples cannot be delivered by FEDEX (or other carrier) by 2 PM on Wednesday, the options for remedy as outlined above will be utilized. In order to receive this remedy, the laboratory manager must be notified by phone, fax or email of the non-receipt of specimens by 3PM on Wednesday. AFDT cannot assure overnight delivery of samples outside of the continental US.

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

Policy 6) Reporting of grades. Each laboratory will receive a final graded report within the timeframe given in “Data Submission and Turnaround Policy 3”. Grades should be kept confidential, since they may be used for laboratory accreditation.

Grades will be reported to federal regulatory or state agencies only at the written request of the laboratory. Those laboratories that want their results directed to any accrediting or other oversight agencies must provide all pertinent information to AFDT on an annual basis. It is the responsibility of the laboratory to notify AFDT of any changes in laboratory status. As of 1999, AFDT Proficiency Testing has been accepted by the College of American Pathologists (CAP) for the purposes of the Laboratory Accreditation Program. Laboratories wishing to have AFDT PT results sent to CAP must provide AFDT with written consent and the laboratories Laboratory Accreditation Program (LAP) number.

Data Submission and Turnaround Policies

Policy 1) Attestation Statement: Each laboratory must sign an attestation statement certifying that all proficiency testing is performed in the same manner as clinical samples. The original signed version of this document is kept by the lab for presentation to official agencies, and a copy with typed names of testing personnel and Director, or designee, who reviewed the work will be mailed to AFDT. This statement must be **emailed** each set of PT results.

Policy 2) Each laboratory is responsible for timely and proper submission of data to the AFDT Proficiency Testing Program.

Policy 3) Lab data submission results are due 1 month after shipment.
Reports are sent to labs within 3 weeks after results received.
CAP report is sent 6 weeks after lab data submission of results.

Financial Policies

Policy 1) The fee structure for the AFDT Proficiency Testing Program will be determined by the Histocompatibility Committee upon the recommendation of the Proficiency Testing subcommittee, with advice from the AFDT comptroller as to expenses and revenue. The cost to member laboratories will be at a reduced rate, approximately 70% of the cost to non-member labs. Laboratories requesting participation in only the Cell Exchange or the Serum Exchange will be billed at a rate ~ 60% of the rate

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

for the full exchange. An additional fee will be assessed for any shipment made outside the continental US.

Fees for additional exchanges will be billed to the laboratory at a rate of 25% of the full annual PT fee for the laboratory.

- Policy 2)** Reimbursement to the send-out laboratories will be determined by the Histocompatibility Committee upon the recommendation of the Proficiency Testing subcommittee, with advice from the AFDT comptroller as to expenses and revenue. Any changes voted on by the Histocompatibility Committee must then be approved by the AFDT Board of Directors. The rate of reimbursement will be on a per lab basis, that is, the send-out laboratory will receive a set fee for each set of samples that is sent out to a lab.
- Policy3)** Reference labs will be selected from the participating member laboratories by the Proficiency Testing Subcommittee. Selected reference labs that perform high resolution typing of exchange cells as part of that exchange will be credited the cost of the typing portion of the Proficiency testing fee. Reimbursement to reference labs performing pretesting on sera for the crossmatch exchanges will be on a cost basis. Any and all bills for such testing should be submitted to the PT co-chairs for review. The bills will then be submitted with recommendations to the Histocompatibility Committee co-chairs for final approval and submission to the AFDT office for payment.
- Policy 4)** Payment for the Proficiency Testing Manager will be on a per laboratory basis and is established by contract with AFDT.

PROCEDURES

Send-out procedures

Send-out dates for the AFDT Proficiency Program are published on the SEOPF online site, and are also mailed to members at the beginning of each testing year.

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

Send-out laboratories will be selected by the Proficiency Testing Manager and approved by the Proficiency Testing Subcommittee from member laboratories who express a willingness to serve as such. Each of these laboratories will normally be responsible for one or more send-outs per year, on a schedule to be determined by the PT Manager, with the approval of the PT Subcommittee. The PT Manager will provide send-out labs with a list of subscriber labs to which samples should be sent. The PT Manager will 1) provide a cover letter, address and sample labels, and all other necessary information for the test samples to be shipped, 2) send a letter to each subscribing laboratory notifying them of the date of sample send-outs. Shipments must be sent to US laboratories by overnight carrier, to reach the laboratory by 10AM the next day. Samples sent outside of the continental US must be sent by the most rapid carrier service readily available. Blood samples must be packed securely to avoid breakage and must conform to all federal, state, and shipper's regulations. No reshipments will be sent, except as defined above in Grading Results Policy 5.

Cell Exchange: Cells will be selected from pre-typed, willing donors, who are known to provide a cell yield suitable to perform HLA typing. Each send-out will consist of blood from 5 donors. Blood should be drawn into ACD, with each subscribing lab receiving a 10 ml tube of whole blood for each sample.

Crossmatch Exchange: A 10cc tube of whole blood in ACD from each of 2 pretyped willing donors will be sent to each participating lab for crossmatching. The HLA type of the cells used for crossmatching will be provided by the sending lab. In addition, 5 serum samples (1.0 ml each) which have been well characterized for anti-HLA antibody by cytotoxicity, flow and ELISA will be sent for antibody analysis and crossmatching. Blood should be drawn into ACD, with each subscribing lab receiving a 10 ml tube of whole blood for each sample.

Data entry

Results will be entered by each participating laboratory into a data file. The data file format and data entry program will be provided by the AFDT PT manager. The data file will be submitted to AFDT by email. If email submission is not possible, fax submission of the results to the PT manager will be accepted. Each laboratory is responsible for the proper data entry and data entry errors made by the laboratory will be considered as misses. Data entry errors made during the processing of data by the PT Manager will be corrected back to the original submission made by the laboratory.

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

Data Analysis

Data analysis will be performed by the PT manager using software developed for this purpose. The PT manager will maintain the software and ensure that the software is up to date for the purpose of the AFDT PT program. Data analysis will be performed in a manner that conforms to the policies and procedures set forth by the AFDT PT program.

Data to Committee chairs

Processed and compiled data - The data should be compiled from the spreadsheet and sent to the PT subcommittee chairs and the Histocompatibility Chairs for review prior to reporting of grades. These data will be used along with the raw data to write a final analysis of each send-out. A final summary report prepared by the subcommittee co-chairs will be sent to each participating laboratory. This will summarize the data submitted and provide a discussion of results designed to help the laboratory interpret the data and apply it.

Raw data - A copy of the raw data should be sent to the PT subcommittee chairs and the Histocompatibility Chairs for review prior to reporting of grades.

CAP

Send-out dates. A list of send-out dates and the dates by which they will receive results on the send-outs must be sent to CAP by October 1 of the year prior to the send-out.

CAP participants. A list of CAP participants is requested by October 1. AFDT will send the names of all CAP participants from the previous year at this time unless instructed otherwise by the laboratory. New enrollees or those who newly opt to have data sent to CAP this year must be received by CAP at least 2 months before the date CAP is required to receive results (to have data for all surveys accepted by CAP, the laboratory must ensure that AFDT has received authorization for data by February 15th). Use of AFDT data for CAP accreditation requires that the laboratory provide written authorization to AFDT to transmit these data. Submission of the laboratory's CAP LAP number to AFDT will also be required for data to be transmitted to CAP.

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

Appendices

Appendices should be reviewed annually by the Proficiency Testing Committee and updated to reflect current fees, payments, sendout labs, major miss antigens, and analytes offered. These changes must be approved by the AFDT Histocompatibility Committee.

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

APPENDIX A - Analytes offered - 2006

Results entered for the following analytes will be graded and results may be sent to CAP if so requested by the laboratory. Laboratories participating in the AFDT survey should provide data for all categories for which testing is performed in the laboratory.

HLA A (antigen level resolution) (allele level)

HLA B (antigen level resolution) (allele level)

HLA DR (antigen level resolution) (allele level)

Antigen level typing of Cw, DQ, DR51,52,53

Reference for antigen equivalents:

Schreuder, G.M.T., C.K. Hurley, S.G.E. Marsh, M. Lau, M. Maiers, C. Kollman, and H. Noreen. Report on serological equivalents of HLA alleles. The HLA dictionary 1999: A summary of HLA-A, -B,-C, -DRB1/3/4/5, -DQB1 alleles and their association with serologically defined HLA-A, -B,-C, -DR and -DQ antigens. Tissue Antigens 53: 409-437, 1999.

No wash crossmatch - T

No wash crossmatch - B

Wash crossmatch - T

Wash crossmatch - B

AHG crossmatch - T

AHG crossmatch - B

Flow crossmatch - T

Flow crossmatch - B

Class I antibody (present or absent)

Class II antibody (present or absent)

Results for the following analytes are currently not graded, but results are sent to CAP as ungraded analytes if so requested by the laboratory.

Class I antibody specificity

Class II antibody specificity

Additionally, data is collected in the following categories and is made available to the participating laboratories.

- Data on PRA by method
- Data on Crossmatch by more specific methods

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

APPENDIX B – You are referred to the UNOS OPTN web site at:

<http://www.optn.org/policiesAndBylaws/policies.asp> , and to policy 3A for the most current

HLA Antigen Values and Split Equivalences

Including both:

HLA A, B, and DR Matching Antigen Equivalences

And

HLA A, B, C, DR, and DQ Unacceptable Antigen Equivalences

**POLICIES AND PROCEDURES FOR
THE AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION
(AFDT) PROFICIENCY TESTING PROGRAM
Version 2006.000**

APPENDIX C

Financial

Payment to send-out laboratories, \$65/lab serviced per send-out.

Payment to Hopkins Computing, \$14 /lab serviced per send-out.

Fees from laboratories

PT program

 \$700 per year AFDT member lab

 \$1000 per year non member lab

Cell exchange only

 \$420 per year AFDT member lab

 \$600 per year non member lab

Serum exchange only

 \$420 per year AFDT member lab

 \$600 per year non member lab

Additional cell exchange

 \$175 for AFDT labs

 \$250 for non member labs

 Additional \$50 processing fee for laboratories not participating in the AFDT PT Program

Expenses of screening sera for send-out should be billed by the provider laboratory to AFDT.