

AFDT

Proficiency Testing Program

Report

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AFDT Proficiency Testing Results – March 3, 2008

SUMMARY REPORT Cell Sendout:

The March 2008 AFDT (American Foundation for Donation and Transplantation) Proficiency Testing challenges were graciously sent out by Dr. Sandra Helman and her Medical College of Georgia staff in Augusta, Georgia. AFDT Proficiency Testing sends out 5 anti-coagulated whole blood samples per challenge. AFDT Proficiency Testing (AFDT-PT) will, as closely as possible, send proficiency testing (PT) samples that most represent actual patient samples that are received by labs for clinical testing. Federal regulations require that all PT samples must be handled and tested exactly like those clinical samples that are received in each laboratory on a routine basis. This will more accurately assess and predict how a clinical Histocompatibility lab functions on a day-to-day basis. We feel that these AFDT Proficiency Testing Samples meet all mandates and guidelines. The results obtained and graded are therefore more relevant and indicative of actual clinical situations and thereby in keeping with the intent of CLIA, UNOS, ASHI and CAP standards. Labs may test by any methods employed and report results as they would normally do on a clinical report.

AFDT will **grade** any methods entered in to the data fields. If a lab does not want any particular data field be graded, **NT** must be entered into that field, in order to be excluded. Labs must contact their accrediting agencies, (ASHI, CAP, UNOS, NMDP) etc to determine what loci and alleles need to be submitted for grading.

The updated AFDT Grading Criteria 2008

I. HLA Typing

Consensus = 80%

Each locus will be graded if consensus is reached for that locus; if a laboratory does not wish to be graded for a particular locus (ex. Bw4/6, Cw), they must enter NT (not tested) in result fields.

Class I typing will be considered an analyte. A miss for any Class I locus will be considered a miss for the sample.

Class II typing will be considered an analyte. A miss for any Class II locus will be considered a miss for the sample.

Satisfactory Performance: 80% concordance for each analyte (Ex. Four of five samples must agree with consensus for each graded locus for the analyte being graded)

Successful Performance: Must have Satisfactory performance for two out of three Typing Exchanges for each analyte

Structure: Five samples sent out for HLA typing three times per year (15 samples per year)
Results can be entered for Serological Typing, Low resolution DNA typing, and High resolution DNA typing
Results obtained from serological and/or DNA typing are used to enter the Antigen level typing.

A. Antigen Results Table – used for Grading Low resolution

1. Enter the Antigen level result. The level of resolution must meet requirements for HLA typing entered in UNET. (Ex, A9 must be split into A23, 24; B15 must be split into B62, B63, etc.)
2. Results for the Antigen Result can be based on Serology and/or DNA typing.
3. The results entered in the Antigen table must be the “serological equivalents” of the Low resolution results. The DNA typing must be able to call the common HLA splits required by UNOS.
4. Cw will not be graded for the “serology only” labs for the Cw antigens that do not have a serological equivalent.

B. Serology typing – *graded for educational purposes only*

1. Enter results in Serology Table.
2. Enter in Antigen Result Table also, if Serology is the only method used in the laboratory. Only results entered in the Antigen Table will be used for grading purposes.
3. Serology Results will be assessed if consensus is $\geq 80\%$ with other serology labs.

4. Serology results entered in the Serology Results Table must be based ONLY on serological tray reactions for accurate comparison of serological methods and should **not** be “serological equivalents” of DNA typing.

C. Low-intermediate resolution DNA typing-
graded for educational purposes only

1. Enter results in Low resolution DNA table.
2. Results will be assessed if consensus is $\geq 80\%$ with other DNA labs entering results in Low resolution DNA table.
3. The computer program will indicate discrepancies based on the first two digits of results entered on the Low resolution table.
4. Enter “serological equivalent” of Low resolution typing in the Antigen table. This is done in order to meet the UNOS requirement that DNA labs be able to reach at least the resolution of serology typing.
5. Antigen level results must be split at the level required by UNOS.

D. High resolution typing – used for grading High resolution

1. Enter results in High resolution tables. (Also enter serological equivalents in Antigen table)
2. High resolution will be graded based on the first four digits entered in the high resolution table.
3. Results will be graded if consensus is $\geq 80\%$ with other DNA labs entering results in the high resolution table.
4. For PT purposes, labs doing high resolution should enter the most probable result based on typing Exon 2 and 3 for Class I and Exon 2 for Class II. If an ambiguity involves a rare allele, then the most probable result should be reported for PT purposes. Ambiguities involving alleles that are not rare (as defined by ASHI), must be resolved by the laboratory if the polymorphism is in Exon 2 or 3 for Class I and Exon 2 for Class II.
5. If a laboratory does high resolution for some (but not all of the alleles), the result should be entered as NT (not tested) for the locus for which high resolution was not performed. (Example, a lab may not do high resolution for DRB3, but does high resolution for DRB1). Results entered as “NT” will not be graded.
6. However, a laboratory must do high resolution for at least 80% of the alleles on the PT for a given locus in order to be considered as capable of doing “high resolution” for that locus.

7. Occasionally, low resolution testing may produce an “allelic result”. Results should not be entered in the High Resolution Typing Results Table unless the laboratory is using a method that is designed to provide high resolution typing (ex. Sequencing, high resolution SSP panels, etc.)

II. Crossmatch

Structure: Two exchanges per year consisting of 5 sera with 2 cells (10 XM each exchange; 20 XM per year).

Methods graded: Cytotoxicity- T cell
 AHG-T cell
 Cytotoxicity- B cell

 Flow Cytometry- T cell
 Flow Cytometry- B cell

 Solid phase – Class I
 Solid phase – Class II

T cell crossmatch (or Class I XM) is considered a separate analyte from B cell (or Class II XM).

Satisfactory Performance: 80% concordance for each analyte (Ex. 8 of 10 crossmatches must agree with consensus for each method being graded).

Successful Performance: Must have Satisfactory Performance for two out of three Typing Exchanges for each analyte.

1. Results will be graded when there is consensus \geq 80% for the methods, as grouped in the tables described above.
2. Enter P (pos), N (neg), or NT (not tested) for each method performed.
3. If a lab gets a FP compared to other labs for a particular method, but the same serum-cell combination reaches consensus positive by a more sensitive method, the discrepancy will not be counted as a miss.
4. A final interpretation (Compatible, Incompatible, More Info needed) will be compared between laboratories. This will be for educational information only and will not be graded. The interpretation should be based upon all the information available (all methods of XM, all methods of PRA, and donor type).

III. PRA

1. There will be three main divisions for PRA testing that will be graded separately: Serological Methods, Solid Phase - multiantigen panel, and Solid Phase-single antigen panel. Class I and Class II specificities will be graded separately for each category.

Serology: (includes all serological methods- lab will choose method(s) used.
CDC-Class I
CDC-Class II

Solid Phase - Multiantigen - Includes Flow, ELISA, Luminex, Microarray, etc.
Lab will click on specific method(s) used.

Solid Phase-Class I (multiantigen panel)
Solid Phase-Class II (multiantigen panel)

Solid Phase - Single antigen-Includes Flow, ELISA, Luminex, Microarray, etc.
Lab will click on specific method(s) used

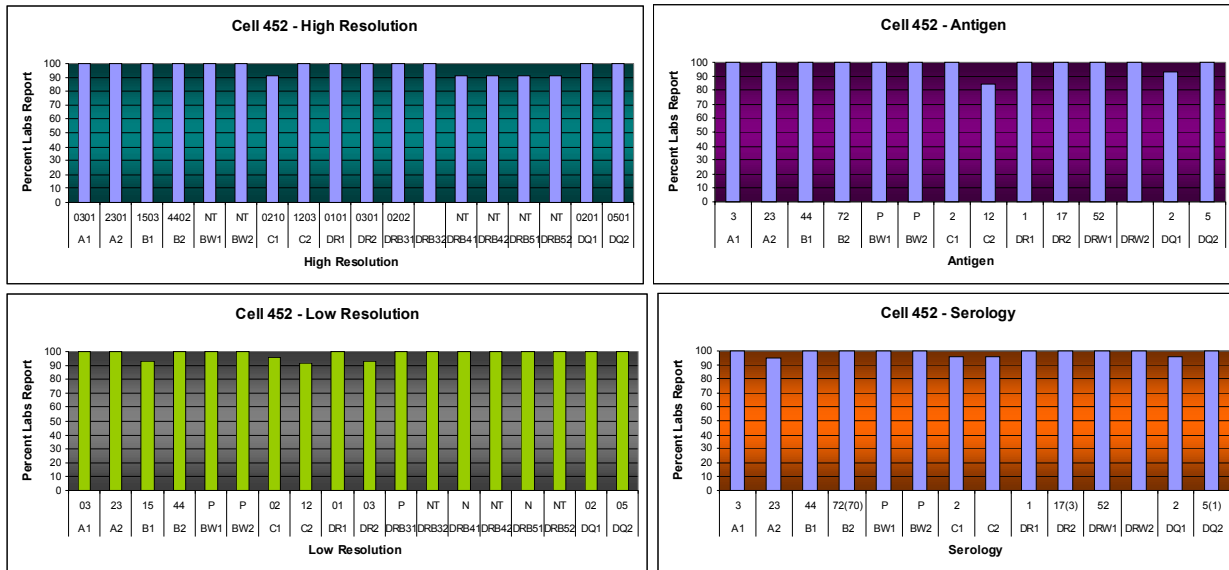
Solid Phase- Class I (single antigen panel)
Solid Phase-Class II (single antigen panel)

2. Report will show the Antigens reported that reached 50% consensus or greater. Only those that actually reached 80% will be graded. A result will be flagged (and may be considered a miss in the future) if less than 10% of the labs reported it.
3. Screening – report Pos, Neg or Not tested (we really do not care that much about the % PRA since that will be calculated by UNOS based on specificity).
4. Specificity – All specificities that reach 80% consensus will be graded. Partial credit will be given for the specificities that are correctly called for each sample. (Ex. If 5 specificities are called for a particular serum, but the lab only called 4 of them, then they will get 0.8 credit for that sample. Based on 5 sera in the exchange and assuming they got the other four correct, and then their final grade will be 4.8 out of 5 or 96% for the exchange.
5. The broad specificities will not be an option (as this makes computer analysis very difficult. The lab will need to click each split or each member of a CREG group that is identified.

Faxed results are no longer acceptable and electronic data entry is required. Please contact AFDT if there are any problems with data submissions. All communication will be done electronically so please carefully watch for any announcements from AFDT regarding changes and sendout information from AFDT Proficiency Testing Committee. Paper copies of reports will no longer be sent to labs, either.

The report below is a complete summary of the March 3, 2008 results. Note that each cell is presented separately and the methods displayed in charts and graphs that will describe the antigens and alleles that were reported. Each lab can compare their results with those of other labs that participated in this exchange.

CELL A452 – Black

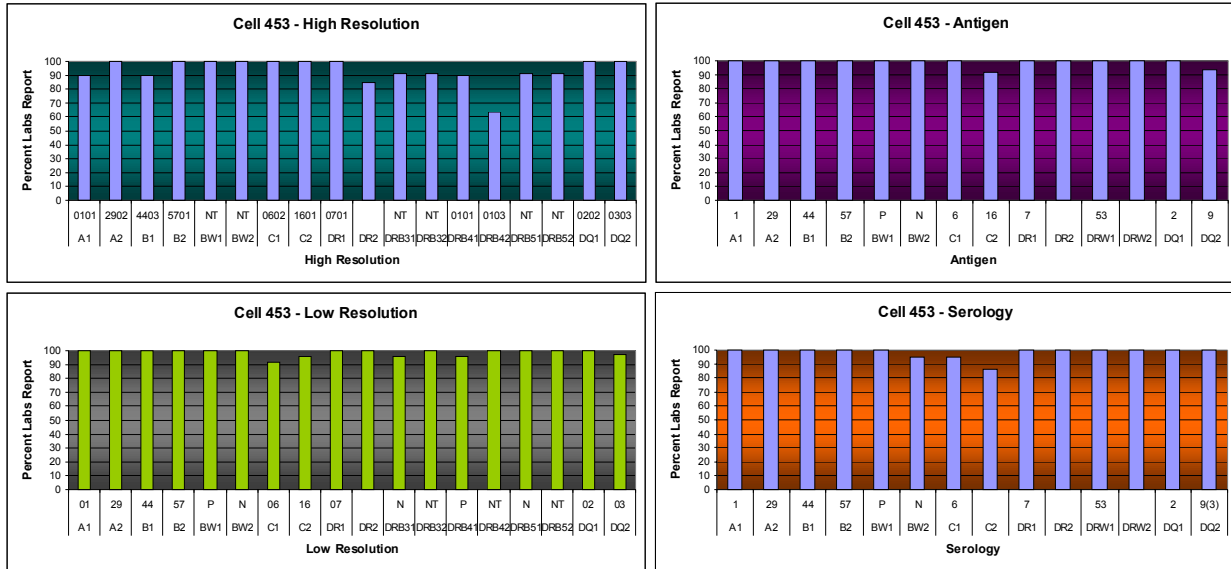


CELL 452 (Black) Antigen Level: **HLA: A3, A23; B44, B72, (Bw4, Bw6); Cw2, Cw12); DR1, DR17; DR52; DQ2, DQ5**

CELL 452 (Black) High Resolution: **HLA: A*0301, A*2301; B*1503, B*4402, Cw*0210, Cw*1203; DRB1*0101, DRB1*0301; DRB3*0202; DQB1*0201, DQB1*0501**

Cell 452 is from a Black donor. All alleles met consensus in this cell by serology, low resolution, antigen level and high resolution methods.

Cell A453 – Caucasian

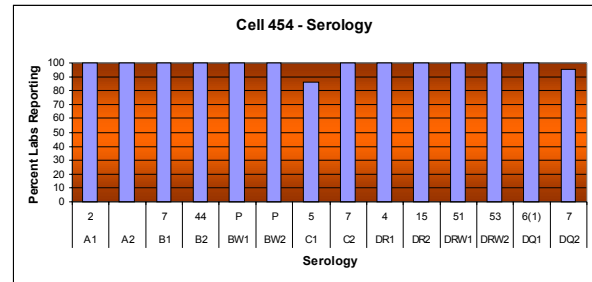
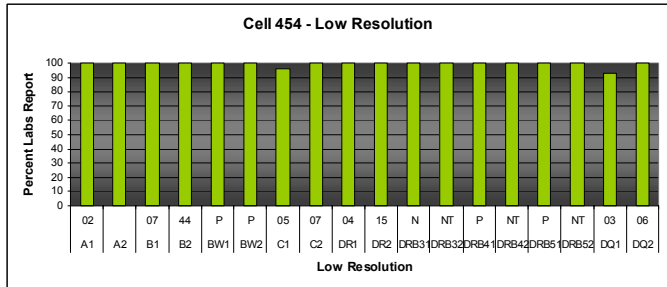
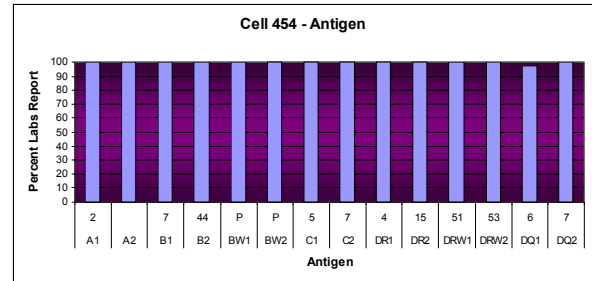
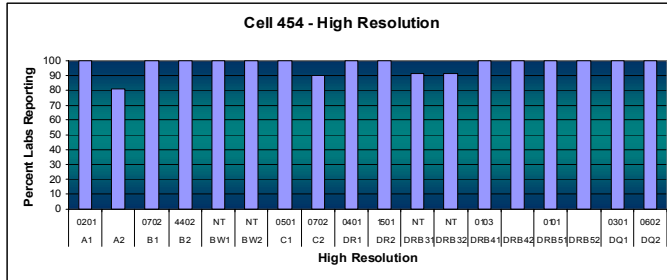


CELL 453 (Caucasian) Antigen Level: **HLA: A1, A29; B44, B57, (Bw4); Cw6, Cw16; DR7, DR-; DR53; DQ2, DQ9**

CELL 453 High Resolution: **HLA: A*0101, A*2902; B*4403; B*5701; Cw*0602, Cw*1601; DRB1*0701; DRB4*0101, DRB4*0103; DQB1*0202, DQB*0303**

This cell is from a Caucasian donor, also reached consensus for Class 1 and Class 2 antigens, by all methods for all alleles.

Cell A454 – Caucasian

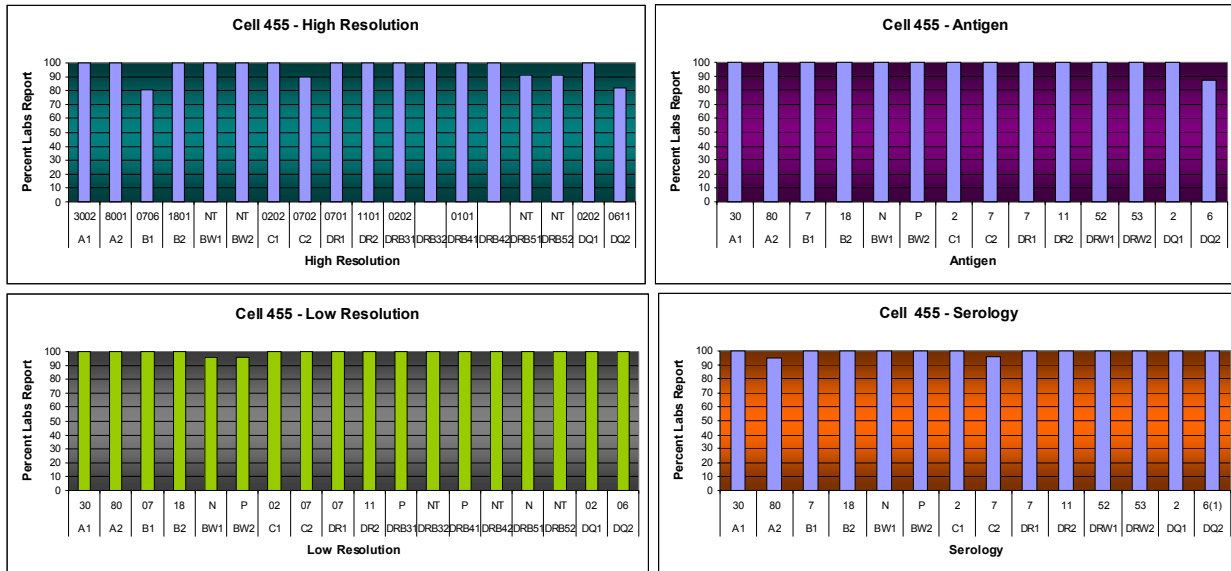


CELL 454 (Caucasian) Antigen Level: **HLA: A2, A-; B7, B44 (Bw4, BW6); Cw5, Cw7; DR4, DR15; DR51,DR53; DQ6, DQ7**

CELL 454 (Caucasian) High Resolution: **HLA: A*0201; B*0702, B*4402; Cw*0501,Cw*0702-; DRB1*0401, DRB1*1501; DRB4*0103, DRB5*0101; DQB1*0301, DQB*0602**

This Caucasian donor also reached consensus for Class 1 and Class 2 antigens, at the serology, low-resolution, high resolution and antigen level for all loci. High resolution results indicate that this cell is probably homozygous for A*0201.

Cell A455 - Black

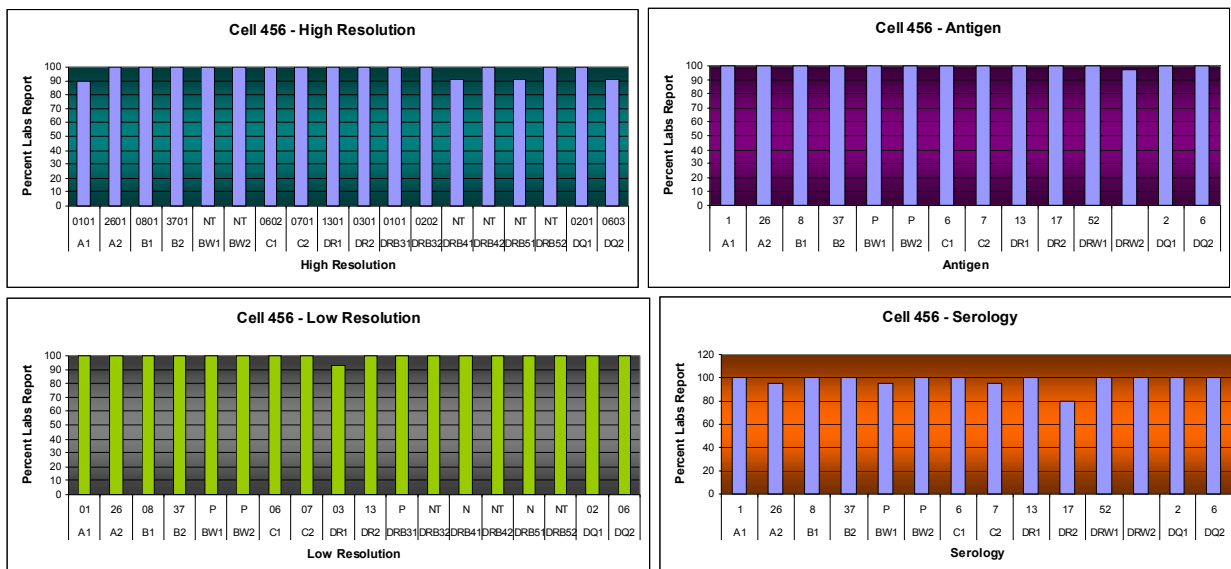


CELL 455 (Black) Antigen Level: HLA: A30, A80; B7, B18; Bw6; Cw2, Cw7: DR7, DR11; DR52, DR53; DQ2, DQ6

CELL 455 (Black) High Resolution: HLA: A*3002, A*8001; B*0706, B*1801; Cw*0202, Cw*0702; DRB1*0701, DRB1*1101; DRB3*0201, DRB4*0101; DQB1*0202, DQB1*0611

This interesting cell is from a Black donor and appears to have an unusual B7. B*0706 was reported by 81% of the labs by high resolution methods. This barely met consensus.

Cell A456 - Caucasian



CELL 456 (Caucasian) Antigen Level: **HLA: A1, A26; B8, B37; Bw4, Bw6; Cw6, Cw7; DR13; DR17; DR52, DR-, DQ2, DQ6**

Cell 456 High Resolution: **HLA: A*0101, A*2601; B*0801, B*3701; Cw*0602, Cw*0701; DRB1*1301, DRB1*0301; DRB3*0101; DRB3*0202; DQB1*0201, DQB1*0603**

Cell 456 is also from a Caucasian donor. All alleles met consensus.

Conclusions: As seen in past exchanges, most laboratories continue to employ a combination of serological and molecular techniques to assign serological, antigen level and low and high resolution results. AFDT is anxious to provide a PT program that is beneficial to you individual situations and your input is always welcomed.

A very special Thanks goes to Marilyn Langan, who has completely rewritten the AFDT data base and data entry portions for the PT program. The new 2008 grading rules were incorporated into the PT program and approved by the AFDT PT committee, but are largely due to Dr. Deborah Crowe's tireless support of the AFDT Histocompatibility Committee. Arlene Skinner (skinner@seopf.org) is the AFDT PT Manager. Dod Stewart (dods@bellsouth.net) will continue to provide technical support.

The AFDT Histocompatibility Specialist's Course will be held in Palm Springs, CA from June 20- 28, 2008. Information about the course can be obtained by contacting Arlene Skinner (skinner@seopf.org) or through the AFDT website www.seopf.org or by the link http://www.seopf.org/Specialist_Brochure.htm. The very important course is ABHI approved for Technologists and Director level participants.

The next AFDT challenges will be Crossmatch/PRA Typing from Emory University in Atlanta – May12, 2008.