Immucor, Inc
510(k) application
ABS2000, Ver 2 Software
April 12, 2000
510(k) Summary of safety and effectiveness
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Clinical trial analysis: The safety and effectiveness of this device was established in clinical trials that used manual hemagglutination methods as the reference procedures of record. Data obtained in these trials shows the product performs similarly to the reference methods.

ABO/Rh typing (patient samples):

No of samples tested: 6580
Concordance with results of reference method, first pass* = 99.7%
Concordance with results of reference method, second pass (corrected)* = 100%
NTD rate = first pass, 5.2%, second pass 1.7%

Donor confirmation (donor samples):

No of samples tested: 2172
Concordance with results of reference method, first pass* = 98.9%
Concordance with results of reference method, second pass (corrected)* = 99.9%
NTD rate = first pass, 1.9%, second pass 0.5%

Two-cell antibody screen by solid phase:

No of samples tested: 5436
Concordance with results of reference method, first pass* = 98.3%
Concordance with results of reference method, second pass (corrected)* = 99.4%
Invalid rate (negative antiglobulin control test) = first pass, 0.9%, second pass 0.3%

Immediate spin crossmatch (patient-donor matches):

No of samples tested: 2729
Concordance with results of reference method, first pass* = 98.8%
Concordance with results of reference method, second pass (corrected)* = 99.6%
Failed tests due to sample preparation errors = first pass, 5.6%, second pass 2.3%

Antiglobulin (IgG) crossmatch (patient-donor matches):

No of samples tested: 2729
Concordance with results of reference method, first pass* = 95.7%
Concordance with results of reference method, second pass (corrected)* = 98.2%
Invalid rate (negative antiglobulin control test) = first pass, 0 %, second pass 0%
Failed tests due to sample preparation errors = first pass, 5.6%, second pass 2.3%

*First pass results equals the results analysis prior to correction for resolved discrepancies, sample anomalies, technologist errors unrelated to the instrument. Second pass results are results following correction of discrepancies, exclusion of improperly tested samples, etc.

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Comparison of performance to Version 1 trial results: The ABS2000 with Version 1 software (I.00.30A) is the predicate device for this instrument. Version 1 serological trials were performed in 1996. Hemagglutination methods were used as the reference standards. The outcomes of Version 2 and Version 1 trials are provided in the following table that shows the performance of the two versions are substantially equivalent. (Data derived in nonparallel evaluations.)

ASSAY	Version 1 Software		Version 2 Software	
	First Pass	Second Pass	First Pass	Second Pass
Group assay concordance	99.8%	99.9%	99.7%	100%
Group NTD rate	4.8%	3.3%	5.2%	1.7%
Donor Confirmation assay concordance	99.3%	99.6%	98.9%	99.9%
Donor Confirmation NTD	3.0%	2.1%	1.9%	0.5%
Antibody Screen assay concordance	96.7%	98.4%	98.3%	99.4%
Immediate spin assay concordance	N/A	N/A	98.8%	99.6%
IgG crossmatch concordance	98.8%	99.7%	95.7%	98.2%