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Successful Validation of an Automated Cell Washer for pRBCs in Different Additive Solutions (AS) by a Hospital-based Transfusion Service

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Background

Support of a long-standing cell washer (COBE 2991 Terumo Lakewood, CO) used routinely by transfusion services (TS) will be ending in 2028. An alternate cell washer, designed to wash red cell units (pRBC) for patient transfusion, is suitable for washing CPDA-1 and CPD/AS-1 pRBC per the manufacturer. However, the TS inventory includes other anticoagulant additive solutions,AS-3 and AS-5. A validation protocol was designed to confirm acceptable post-wash parameters for AS-1, AS-3 and AS-5 units. To utilize the hospital clinical analyzers for testing patient plasma samples, methods suitable for blood product storage solution samples were identified to ensure acceptable results for validation samples. Knowledge of these methods may be useful to facilities designing similar validations.

Methods

Fourteen in-date, prestorage leukocyte-reduced pRBC units were selected for the validation: 6 AS-1 , 5 AS-3 and 3 AS-5 units. Washing was performed on the ACP 215 (Haemonetics® Braintree, MA) per manufacturer's instructions using 0.2% dextrose 0.9% NaCl processing solution. Samples obtained pre and post wash were tested for supernatant potassium (K+), total protein(TP), albumin(Alb), and IgA. Unit weights and Hcts were recorded and used to calculate % recovery=[net post-wash weight x post-wash HCT) ÷ (net pre-wash weight x pre-wash HCT) x 100]. TP and Alb were performed on Siemens Atellica Chemistry Analyzer (Malvern, PA) using the urine channel, which provided the analytical measurement ranges (AMR) for microalbumin 0.3 - 38.0 mg/dL and protein 3.0 - 250 mg/dL for blood product supernatant samples. Supernatant K+ (AMR: 0.5 to 25.0 mmol/L) was performed on the ABL 800 Flex blood gas analyzer (Radiometer America, Inc.). IgA levels were tested with Siemens BN™ II nephelometric analyzer (AMR: 6.28-287mg/dL with <6.28 mg/dL being below the negative threshold for the assay).

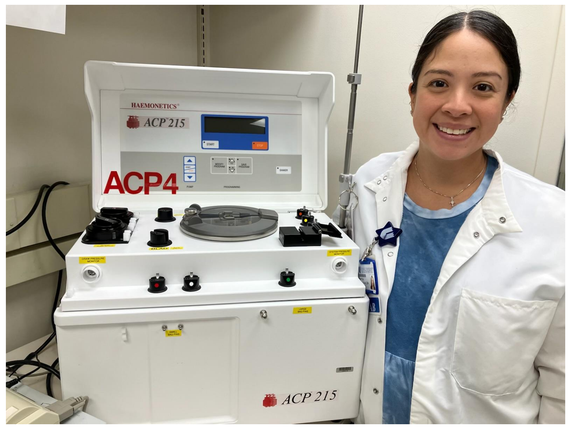
Results

The validation data is summarized in Table 1. Acceptable post-wash parameters were: RBC recovery ≥85%, supernatant K+ < 0.5mmol/L, TP and Alb >90% decrease, and IgA below negative threshold for the assay. Mean TP decrease post-wash was 97.5 ± 2.57%. Mean Alb decrease post-wash was estimated at 97.6 +3.5% using 380 mg/dL as the pre-wash value when result was above upper limit for the assay.

Table 1. Validation Results

Anticoagulant	Count	Wash status	HgB g/dL	HCT %	RBC Recovery %	K mmol/L	Total protein mg/dL	Albumin mg/dL	IgA post <6.28 mg/dL **
AS-1	1	PRE	19.6	63.5		26.4	851.3	359.4	
		POST	19.8	62.8	87.4	<0.5	37.5	3.4	Y
	2	PRE	19.6	63.0		21.4	637.2	300.2	
		POST	20.1	62.3	86.1	<0.5	43.7	2.9	Y
	3	PRE	19.6	63.9		18.4	454.2	221.7	
		POST	18.5	58.2	90.4	<0.5	31.0	1.6	Y
	4	PRE	20.0	63.3		21.1	NA*	NA*	
		POST	20.0	61.8	87.1	<0.5	NA*	NA*	Y
	5	PRE	20.8	68.9		42.6	558.9	245.6	
		POST	20.4	66.5	89.6	0.5	40.0	1.8	Y
	6	PRE	18.5	60.7		28.9	425.4	197.5	
		POST	16.5	54.5	92.9	<0.5	1.1	23.4	Y
AS-3	7	PRE	19.0	59.6		37.5	1518.5	>380	
		POST	16.2	52.0	92.4	<0.5	38.2	1.4	Y
	8	PRE	19.6	58.7		43.5	1436.2	>380	
		POST	17.2	53.1	92.9	<0.5	36.3	4.3	Y
	9	PRE	18.1	57.8		41.4	1316.3	>380	
		POST	15.5	50.8	92.0	<0.5	26.4	3.7	Y
	10	PRE	18.7	57.4		42.3	1291.3	>380	
		POST	17.5	55.0	94.0	<0.5	34.8	5.1	Y
	11	PRE	18.9	59.0		21.6	1372.3	>380	
		POST	16.6	54.0	96.1	<0.5	7.5	35.4	Y
AS-5	12	PRE	18.6	63.5		39.4	571.1	260.3	
		POST	19.0	67.3	95.7	<2.0	40.0	2.0	Y
	13	PRE	17.2	58.7		33.9	965.0	>380	
		POST	17.2	60.0	97.7	<2.0	74.2	3.3	Y
	14	PRE	18.6	63.4		39.7	665.7	315.1	
		POST	17.5	60.5	88.8	<2.0	34.4	2.4	Y

*Data not available, **Below the negative threshold for the assay



Conclusions

The validation of AS-1, AS-3, and AS-5 units was acceptable for deployment of washing RBCs with the ACP 215 device for clinical use in the TS. Percent RBC recovery and in-vitro post- wash parameters were consistently observed. Future validation of deglycerolizing frozen RBCs on this device is planned. However, with the sunset of the COBE 2991, novel methods for automated platelet washing and stroma preparation are needed.