2. RESOURCES

2.0 Resources

The laboratory shall have policies, processes, and procedures to ensure the provision of adequate resources to perform, verify, and manage all activities in the laboratory.

2.1 Human Resources

The laboratory shall have a process to ensure the employment of an adequate number of qualified (by education, training, and/or experience) individuals. Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.

2.1.1 Qualification

Personnel performing critical tasks shall be qualified on the basis of appropriate education, training, and/or experience.

2.1.2 Training

The laboratory shall have a process for identifying training needs and shall provide for the training of all personnel performing activities affecting quality.

2.1.3 Competence

Evaluation of continued competence shall be performed at specified intervals.*

2.1.3.1 Action shall be taken when competence has not been demonstrated.

*42 CFR 493.1235, 42 CFR 493.1451(b)(8)(9).

2.1.4 Continuing Education
Employees performing and/or reviewing specific testing methods as defined by Standards 5.3, and 5.4 shall participate in a minimum of 12 hours of relevant continuing education on an annual basis. The laboratory director shall define the continuing education needs of these personnel.

2.1.5 Personnel Records
Personnel records for each employee shall be maintained.

2.1.5.1 For those authorized to perform or review critical processing steps, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

2.2 DNA Resources

The laboratory shall use appropriate reference DNA to validate and control the reported test. Reference DNA containing the target polymorphisms that the laboratory reports shall be available for use as detailed in Reference Standards 2.2A, 2.2B, 2.2C and 2.2D.

2.2.1 Reference samples shall have been tested by available serological and/or molecular methods and be concordant.

2.2.1.1 When serologic testing is not possible, molecular results shall be confirmed by another method or by an external laboratory.

Reference Standard 2.2A—Minimum DNA Resources – Red Blood Cells*

ISBT Name (System Number)	Gene†	Target Nucleotide‡	Predicted Antigen or Phenotype	Comments
ABO 001	*ABO*	261 del G 467C>T 703G>A 802G>A 1096G>A		Targets for non-O1 alleles may vary and multiple targets or sequencing is required for accurate determination of subgroups.
MNS 002	*GYPA*	59C>T 71G>A 72T>G	M/N	It may not be necessary to interrogate all three depending on the assay design.
	GYPB	143T>C 230C>T intron +5g>t	S/s	
			U+^{var}	Homozygote for rare when available.
RH 004	*RHD*	Exon 4 & 7	D+/D-	Prediction of weak D and partial D requires analysis of additional targets.
	RHDΨ	37 bp insert in exon 4 or RHD c.807T>G		
	RHCE	intron 2 109bp insertion 307T>C	C/c	
		676C>G	E/e	
		122A>G	C^W-/C^W+	Homozygote for rare when available.
		106G>A	C^X-/C^X+	Homozygote for rare when available.

(Continued)