
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 critical tasks.



2.1.3 Competence

Evaluation of competence shall be performed before independent performance of assigned activities and at specified intervals.*

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

*42 CFR 493.1235 and 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 24 hours of relevant continuing education biennially. 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 previously characterized DNA samples to validate the reported test. Previously characterized samples containing variants that the laboratory reports shall be available for use as detailed in Reference Standard 2.2A, Minimum DNA Resources – Red Blood Cells; Reference Standard 2.2B, Minimum DNA Resources – Platelets; and Reference Standard 2.2C, Minimum DNA Resources – Neutrophils.

2.2.1

Previously characterized samples shall have been tested by available serologic and/or molecular methods and be concordant.

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

ISBT Name (System Number)	Gene/Transcript	HGVS	Chromosome Position (GRCh38)	Nucleotide	Antigen(s)
ABO 001	<i>ABO</i>	ABO:c.261delG	9:133257521	261 delG	A/B
	NM_020469.2	ABO:c.526C>G	9:133256205	526C/G	
		ABO:c.703G>A	9:133256028	703G/A	
		ABO:c.796C>A	9:133255935	796C/A	
		ABO:c.802G>A	9:133255929	802G/A	
		ABO:c.803G>C	9:133255928	803G/C	
		ABO:c.930G>A	9:133255801	930G/A	
MNS 002	<i>GYP A</i>	GYP A:c.59C>T	4:144120567	59C/T	M/N
	NM_002099.5	GYP A:c.71G>A	4:144120555	71G/A	
		GYP A:c.72T>G	4:144120554	72T/G	
	<i>GYP B</i>	GYP B:c.143T>C	4:143999443	143T/C	S/s
	NM_002100.5	GYP B:c.230C>T	4:143997580	230C/T	
		GYP B:c.270+5G>T	4:143997535	intron 5+5g/t	U ^{var}

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