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.

G u i d a n c e

Standard 2.0 requires that the laboratory have adequate resources. The key resources included is human resources or staffing. The laboratory should have mechanisms to ensure adequate, qualified, learned, and competent staff to carry out or deliver the product and service of 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.

G u i d a n c e

This chapter requires that an appropriate number of qualified personnel be hired. Individuals may be qualified by education, experience, or both. When defining qualifications, one should consider technical knowledge, level of decision-making (technical vs medical) needed, and amount of supervision required or available. This chapter also requires that these individuals be trained, initially and at appropriate intervals, and that the organization assesses their competence before independent performance of assigned activities and at least annually thereafter. In addition, staff must have adequate time and training to perform their jobs.

The purpose of this standard is to ensure that only qualified individuals perform activities in the laboratory. Implicit in this standard is the requirement that the laboratory defines qualifications for each job function, defines and delivers appropriate training needs, and assesses staff competence. Records of qualification, training, and competence assessments must be maintained.

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.*

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

Guidance

Competency testing assesses the ability of a specific individual to perform a specific task according to procedures. Documentation of competency assessment is completed before the individual performs the task independently and at least annually thereafter. Individuals responsible for CLIA-certified testing are evaluated for competence at least semi-annually during the first year that the person tests patient specimens and annually thereafter.

Competency assessment for any facility testing is dependent on the type of testing being performed (ie, waived, moderate complexity or high complexity) as defined by the Code of Federal Regulations in Title 42 CFR 493.5 and 493.17 and must be conducted in compliance with the CFR and the facility accrediting agency. Accrediting agencies may include but are not limited to the AABB, The Joint Commission, College of American Pathologists, Centers for Medicare and Medicaid Services (CMS; administers CLIA), and the State. CLIA lists a number of other ways an individual without a degree or a degree in something other than science can qualify as testing personnel. The facility is responsible for setting the standards for its testing personnel and those performing critical tasks. Administrative personnel will also need appropriate training and experience.

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

Guidance

In the United States, laboratory personnel requirements can be found in the Code of Federal Regulations. These provide that the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency and specific education, training, and experience.

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 serological and/or molecular methods and be concordant.

Guidance

The laboratory need have reference DNA samples relating only to those alleles for which it is reporting test results. These samples may include genomic DNA extracted from biological specimens, leukocyte reduction filters, or Epstein-Barr virus (EBV)-transformed cell lines, or they may be generated by synthetic methods. Reference samples can be validated by demonstrating: 1) concordance with a different method (eg, nucleotide sequencing), 2) concordance with a different molecular laboratory, or 3) serologic phenotype.

An exception could be made for tests that are performed using sequencing (for example, Sanger sequencing and next-generation sequencing (NGS) for which heterozygous reference samples are not required).

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	*ABO*	ABO:c.261delG ABO:c.526C>G ABO:c.703G>A ABO:c.796C>A ABO:c.802G>A ABO:c.803G>C ABO:c.930G>A	9:133257521 9:133256205 9:133256028 9:133255935 9:133255929 9:133255928 9:133255801	261 del G 526C/G 703G/A 796C/A 802G/A 803G/C 930G/A	A/B
MNS 002	*GYPA*	GYPA:c.59C>T GYPA:c.71G>A GYPA:c.72T>G	4:144120567 4:144120555 4:144120554	59C/T 71G/A 72T/G	M/N
	GYPB	GYPB:c.143T>C GYPB:c.230C>T GYPB:c.270+5G>T	4:143999443 4:143997580 4:143997535	143T/C 230C/T intron 5+5g/t	S/s U^{var}
RH 004	*RHD*			Exon 4+/- & 7+/-	D
				8 C/G 809 T/G 1154 G/C	D variant
				CNV 0/1/2	D (zygosity)
	RHDΨ	RHD:c.487-20_504dup or RHD:c.807T>G		37 bp insert in exon 4 or RHD c.807T/G	
	RHCE		1:25408709	intron 2 109bp insertion	C/c
		RHCE:307T>C		307T/C	
		RHCE:c.676C>G	1:25390874 1:25420665	676C/G	E/e
		RHCE:c.122A>G	1:25420681	122A/G	C^{W}

(Continued)