Reference Standard 2.2B. Additional Resources (Continued)

ISBT Symbol	System or Collection No./Antigen No.	Antisera	No. of Examples	RBCs	No. of Examples
JMH	026 / 001	JMH	1	JMH–	2
I	027 / 001	I	1	i_{adult}	2
GLOB	028 / 001	P	1	P–	1
JR	032 / 001	Jr^a	1	Jr(a–)	2
LAN	033 / 001	Lan	1	Lan–	2
VEL	034 / 001	Vel	2	Vel–	2
AUG	036 / 002	AUG2	1	AUG:-1,-2	2
COST	205 / 001	Cs^a	1	Cs(a–)	2
Ii	207 / 002	i	1		
AnWj	901 / 009	AnWj	1	AnWj–	2
Sd^a	901 / 012	Sd^a	1	Sd(a–)	2

Other Resources	Name
Enzyme	• Trypsin • α-chymotrypsin • Pronase
Enhancement Media	• Polybrene
Substances	• Lewis substance • P1 substance
Other	• Drug antibodies • Drug-treated red cells • Recombinant blood group protein

3. EQUIPMENT

3.0 Equipment

The laboratory shall identify the equipment that is critical to the provision of immunohematology reports and testing services. The laboratory shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conform to these *IRL Standards* and other specified requirements.

3.1 Selection of Equipment

The laboratory shall have a process to define the selection criteria for equipment.

3.2 Qualification of Equipment

All equipment shall be qualified for its intended use. Equipment repairs and upgrades shall be evaluated and equipment requalified, as appropriate, based on the facility's policies and manufacturer recommendations.

3.2.1 Installation Qualification

Equipment shall be installed per the manufacturer's specifications.

3.2.2 Operational Qualification

The functionality of each piece of equipment and each component of a computer system shall be verified before actual use, and shall meet the manufacturer's operational specifications.

3.2.3 Performance Qualification

The laboratory shall demonstrate that equipment performs as expected for its intended use.

3.2.3.1 Performance specifications established by the manufacturer shall be met.

3.3 Use of Equipment

Equipment shall be used in accordance with the manufacturer's written instructions.

3.4 Unique Identification of Equipment

Equipment shall have unique identification.

3.5 Equipment Monitoring and Maintenance

The laboratory shall have a process for scheduled monitoring and maintenance of all equipment that at a minimum is in accordance with manufacturer's written instructions and applicable laws and regulations. The process shall include: frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.

3.5.1 Calibration of Equipment

Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be performed:

1) Before use.
2) After activities that may affect the calibration.
3) At prescribed intervals.

3.5.1.1 There shall be safeguards to prevent equipment from adjustments that would invalidate the calibrated setting. Standard 5.1.3 applies.

3.5.1.2 Calibration procedures shall follow the manufacturer's written instructions, and shall include:

1) Instructions for performing calibrations.
2) Acceptance criteria.
3) Actions to be taken when unsatisfactory results are obtained.