STANDARD OPERATING PROCEDURE TEMPLATE · SPECIALTY AND SUBSPECIALTY PROCEDURES

ABO/Rh(D) Typing

Governing requirement: 42 CFR 493.1271(a)

Applies to: ☐ Waived ☐ Moderate complexity ☑ High complexity

Laboratory name		**CLIA number**	
Document number		**Version**	
Effective date		**Next review due**	
Author		**Department / section**	
Approved by (laboratory director)		**Director signature**	
Approval date		**Supersedes document**	

Important: Template only. Before use, this document must be reviewed, adapted to your laboratory's instruments, test systems and the manufacturer's instructions, and approved, signed and dated by the laboratory director. Check current federal, state and accreditation requirements. Not legal advice. Sound Lab Consultants is not affiliated with or endorsed by CMS, CDC, FDA, OSHA, CAP, COLA, The Joint Commission, CLSI or any manufacturer.

1. Purpose

To determine ABO group and Rh(D) type.

2. Scope

Blood bank typing by **[Method: tube, gel or solid phase]**.

Method: tube, gel or solid phase	

3. Responsibility

- Testing personnel: perform the procedure as written and record QC and patient results.
- Technical supervisor / technical consultant: approves criteria, reviews QC and resolves problems.
- General supervisor (high complexity): provides day-to-day supervision and result review.
- Laboratory director: approves the procedure and is responsible for overall test quality.

4. Definitions

Forward type: Testing red cells with anti-A and anti-B.

Reverse type: Testing plasma with A1 and B cells.

5. Materials, equipment and records

- Antisera, reagent red cells
- Centrifuge, gel cards or analyzer

6. Procedure

1. Test red cells with anti-A, anti-B (and anti-D).

2. Test plasma with A1 and B cells.

3. Read and record reactions.

4. Resolve discrepancies before reporting; issue group O red cells if needed.

5. QC reagents each day of use per manufacturer and 21 CFR 606.

6. Confirm type on a second specimen per policy **[Second sample policy]**.

Second sample policy	

7. Quality control

• Follow the laboratory's QC policy and the manufacturer's instructions; record QC before reporting patient results.

• Stop patient testing and take corrective action when QC or acceptance criteria are not met.

8. Interpretation, reporting and documentation

• Record the activity, date, result and initials on the form or log, and have the supervisor review records **[Review frequency]**.

Review frequency	

• Keep records per the record retention SOP (at least 2 years under 42 CFR 493.1105 unless a longer period applies).

9. Limitations and cautions

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

• eCFR, 42 CFR Part 493 Laboratory Requirements (CLIA)
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

• CMS, State Operations Manual Appendix C: Survey procedures and interpretive guidelines for laboratories
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf

• Manufacturer's package insert, operator manual and safety data sheets for each test system in use

• eCFR, 21 CFR Part 606 Current good manufacturing practice for blood and blood components
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-606

• eCFR, 42 CFR 493.1271 https://www.ecfr.gov/current/title-42/section-493.1271

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

Review date	Reviewed by	Signature	Changes needed (Y/N)	Comments

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