STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Quality Indicators and Turnaround Time Monitoring

Governing requirement: 42 CFR 493.1299 and 493.1291(h)

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 define quality indicators, how they are measured and the action taken when targets are missed.

2. Scope

All sections and testing phases.

3. Responsibility

- Laboratory director: approves this policy, assigns responsibility for quality activities and reviews results.
- Technical consultant / technical supervisor: reviews technical aspects, investigates issues and signs off corrective actions.
- Quality lead (if assigned): coordinates records, tracking and reporting.
- All laboratory staff: follow this procedure and report problems promptly.

4. Definitions

Turnaround time (TAT): Time from **[TAT start point, e.g. receipt]** to result verification.

5. Materials, equipment and records

- LIS reports
- Indicator log

6. Procedure

1. Define each indicator, calculation, data source, target and owner.

2. Turnaround time: target for STAT tests **[STAT TAT target]** and routine tests **[Routine TAT target]**.

STAT TAT target	
Routine TAT target	

3. Specimen rejection rate: number rejected / number received.

4. Corrected report rate: corrected reports / total reports.

5. Critical value notification within **[Critical value notification target]**.

Critical value notification target	

6. Collect and plot data **[Frequency]**; investigate misses and open CAPAs.

Frequency	

7. Notify providers when results will be delayed beyond the established time frame, based on urgency (493.1291(h)).

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

• Summarize indicators for the director at quality review.

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 Subpart K: Quality system for nonwaived testing https://www.ecfr.gov/current/title-42/part-493/subpart-K

• eCFR, 42 CFR 493.1299 https://www.ecfr.gov/current/title-42/section-493.1299

• eCFR, 42 CFR 493.1291 https://www.ecfr.gov/current/title-42/section-493.1291

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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