MDM
LAB CONSULTING

MOLECULAR EXPERTISE.
OPERATIONAL EXCELLENCE.
MEASURABLE IMPACT.

MOLECULAR LABORATORY
INSPECTION READINESS CHECKLIST

CAP | CLIA | COLA

Use this checklist to ensure your laboratory is inspection-ready every day of the year.

1. VALIDATION DOCUMENTATION
FOR EVERY ACTIVE ASSAY

NOTES

- ☐ Approved validation plan with acceptance criteria
- ☐ Medical Director approval
- ☐ Validation report completed and approved
- ☐ Accuracy study (including method comparison)
- ☐ Precision: repeatability and reproducibility
- ☐ Analytical sensitivity (LOD/LOQ)
- ☐ Analytical specificity
- ☐ Reportable range / reference interval (if applicable)
- ☐ Linearity (if applicable)
- ☐ Interfering substances (e.g., blood, bilirubin, lipemia)
- ☐ Carryover (if applicable)
- ☐ Specimen stability
- ☐ Shipping study (CLIA requirement)
- ☐ Statistical analysis and data interpretation
- ☐ All raw data available and traceable

2. QUALITY MANAGEMENT SYSTEM

NOTES

- ☐ Quality indicators reviewed and trended
- ☐ KPIs monitored and documented
- ☐ CAPA log current and complete
- ☐ Nonconforming events documented
- ☐ Root cause analyses completed
- ☐ Corrective actions verified effective
- ☐ Internal audits performed
- ☐ Management review meetings conducted
- ☐ Risk assessments up to date
- ☐ Proficiency testing results reviewed
- ☐ PT failures investigated with corrective actions
- ☐ Alternative assessments (if needed) documented

3. PERSONNEL & COMPETENCY

NOTES

- ☐ Job descriptions current and signed
- ☐ Initial competency assessments complete
- ☐ Ongoing competency (semiannual/annual)
- ☐ Training records complete and current
- ☐ Continuing education documented
- ☐ Licensure / certifications current
- ☐ Annual policy review acknowledgments
- ☐ Personnel files complete and organized
- ☐ Staff know SOP locations and key workflows

4. STANDARD OPERATING PROCEDURES (SOPS)

NOTES

- ☐ All SOPs current and in use
- ☐ Version control maintained
- ☐ Obsolete versions archived
- ☐ Medical Director approvals current
- ☐ SOPs reflect current laboratory practice
- ☐ Staff trained on current procedures
- ☐ Critical SOPs easily accessible

5. EQUIPMENT & ENVIRONMENTAL MONITORING

NOTES

- ☐ Equipment inventory complete
- ☐ IQ/OQ/PQ or installation documentation (as applicable)
- ☐ Calibration records up to date
- ☐ Preventive maintenance performed
- ☐ Service records available
- ☐ Temperature monitoring logs complete
- ☐ Instrument comparisons / Verifications
- ☐ Environmental monitoring (if applicable)
- ☐ Maintenance logs complete and reviewed

MDM CONSULTANT INSIGHT

Inspectors don't expect perfection.
They expect evidence that your laboratory recognizes issues, investigates them appropriately, and implements sustainable corrective actions.

INSPECTION DAY ESSENTIALS

- ☑ Conference room prepared
- ☑ Inspection binder ready
- ☑ Key documentation organized
- ☑ Staff notified of schedule
- ☑ QC completed and reviewed
- ☑ Temperature logs printed
- ☑ Laptop and network access ready
- ☑ Coffee

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