Internal ISO Laboratory Quality Control Checklist

Diagnostic labs & pathology

4.1 IMPARTIALITY

Has laboratory management clearly demonstrated commitment to maintaining impartiality in all operations?

Yes No NA

Are laboratory activities structured and carried out in a way that protects impartiality?

Yes No NA

Is the laboratory free from commercial, financial, or other pressures that may compromise impartial decisions?

Yes No NA

Does the laboratory continuously assess and identify risks to impartiality?

Yes No NA

When impartiality risks are identified, can the laboratory show how they are minimized or eliminated?

Yes No NA

CONFIDENTIALITY (4.2.1 MANAGEMENT OF INFORMATION)

Does the laboratory, through binding agreements, ensure secure management of all patient information obtained or created during laboratory work?

Yes No NA

Does patient information management cover privacy and confidentiality, with advance notice to patients when data may be made public?

Yes No NA

Is all non-public information treated as proprietary and kept confidential, unless disclosure is agreed with the patient or required for complaints handling?

Yes No NA

Are staff members trained and aware of ethical conduct and confidentiality policies?

Yes No NA

CONFIDENTIALITY (4.2.2 RELEASE OF INFORMATION)

When required by law or contracts to release confidential data, is the patient informed unless restricted by law?

Yes No NA

If patient-related information comes from third parties (e.g., regulators, complainants), does the laboratory keep both the data and the source confidential unless consent is given?

Yes No NA

CONFIDENTIALITY (PERSONNEL RESPONSIBILITY)

Do all personnel (including contractors and external parties with access) maintain confidentiality of patient and laboratory information?

Yes No NA