

ISO Laboratory Accreditation Audit Checklist

Diagnostic labs & pathology

4.1 IMPARTIALITY

Has laboratory management demonstrated a strong commitment to impartiality in all activities?

Yes

No

NA

Are all laboratory operations structured and managed to safeguard impartiality?

Yes

No

NA

Is the laboratory free from commercial, financial, or external pressures that could compromise impartiality?

Yes

No

NA

Does the laboratory continuously identify and assess risks that may threaten impartiality?

Yes

No

NA

When risks to impartiality are identified, does the laboratory have a process to eliminate or minimize them?

Yes

No

NA

4.2 CONFIDENTIALITY

Does the laboratory ensure confidentiality of all customer information and test results?

Yes

No

NA

Are personnel obligated to protect confidential information even after employment ends?

Yes

No

NA

Are documented procedures available to manage confidential information securely?

Yes

No

NA

Is customer consent obtained before disclosing confidential information to third parties?

Yes

No

NA

Are IT systems and physical records safeguarded against unauthorized access?

Yes

No

NA

Is confidentiality reviewed during internal audits and management reviews?

Yes

No

NA

Do external service providers sign confidentiality agreements before accessing lab data?

Yes

No

NA

Are breaches of confidentiality recorded and investigated?

Yes

No

NA

Are personnel trained periodically on confidentiality requirements?

Yes

No

NA

Does the laboratory ensure that test subjects' personal identity is not revealed

without justification?

Yes

No

NA