Corrective Action Report Form

Laboratory name: _____

CLIA #: _____

Location / department: _____

Month / Year: _____

CAR #: _____

Date identified: _____

Identified by: _____

Source: [ ] QC [ ] PT [ ] Equipment [ ] Specimen/pre-analytic [ ] Complaint [ ] Audit [ ] Other

Test / instrument / area affected: _____

Description of problem: _____

Immediate action (containment): _____

Patient results affected? [ ] No [ ] Yes – date range, look-back performed, corrected reports issued:

Root cause investigation: _____

Corrective action taken: _____

Preventive action (to stop recurrence): _____

Effectiveness check (what, when, result): _____

Completed by / date: _____

Supervisor / director review / date: _____

Regulatory reference (verify against current eCFR): 42 CFR 493.1282 – the laboratory must document corrective actions taken, including when test systems do not meet performance specifications.

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Template only, not regulatory advice. Adapt to your laboratory's test menu, manufacturer instructions, and accreditor requirements. Use of this template does not by itself establish compliance.