



Indianapolis, IN 46202

Unplanned Deviation Report

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| PART 1: REPORT | | |
| Reported by: | Discovered Date/Time: | Date/Time Occurred: |
| Patient name/MRN and/or DIN | | |
| Description of Deviation Identified (attach any supporting documentation and indicate who was involved, if known): | | |
| How discovered: <input type="checkbox"/> Client/Physician Inquiry/Complaint <input type="checkbox"/> Audit/Review/Pending <input type="checkbox"/> Other: | | |
| Description of Immediate Action Taken (short-term solution): Please attach additional documentation if available | | |

Print form and submit to management for Root Cause Analysis and CAPA

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| Part 2: Root Cause Analysis | | | | |
| Severity of Incident or Error (check one): <input type="checkbox"/> (4) Catastrophic <input type="checkbox"/> (3) Major <input type="checkbox"/> (2) Moderate <input type="checkbox"/> (1) Minor | | | | |
| Results of Investigation: | | | | |
| Key Quality Indicators (check all that apply): | | | | |
| Materials <input type="checkbox"/> Supply defect <input type="checkbox"/> Sample Collection <input type="checkbox"/> Sample Transport <input type="checkbox"/> Sample Handling <input type="checkbox"/> Reagent/Kit Defect <input type="checkbox"/> Other: | Methods <input type="checkbox"/> SOP inadequate <input type="checkbox"/> Form inadequate <input type="checkbox"/> Other: | Machines <input type="checkbox"/> Calibration <input type="checkbox"/> Preventative Maintenance <input type="checkbox"/> General failure <input type="checkbox"/> IT/LIS Problem <input type="checkbox"/> Other: | Environment <input type="checkbox"/> Distraction <input type="checkbox"/> Temperature <input type="checkbox"/> Other: | Personnel <input type="checkbox"/> Failure to follow SOP <input type="checkbox"/> Inattention <input type="checkbox"/> Training/Competence <input type="checkbox"/> Documentation error <input type="checkbox"/> Communication <input type="checkbox"/> Other: |
| Part 3: Corrective and Preventative Action (check all that apply): | | | | |
| <input type="checkbox"/> Reported defect to vendor/nursing/courier <input type="checkbox"/> Other: | <input type="checkbox"/> Revised SOP <input type="checkbox"/> Revised form <input type="checkbox"/> Other: | <input type="checkbox"/> Performed calibration <input type="checkbox"/> Performed PM <input type="checkbox"/> Requested/performed equipment repair <input type="checkbox"/> Opened ticket <input type="checkbox"/> Other: | <input type="checkbox"/> Removed distraction <input type="checkbox"/> Corrected temperature <input type="checkbox"/> Other: | <input type="checkbox"/> Retrained <input type="checkbox"/> Counseled <input type="checkbox"/> Corrected document <input type="checkbox"/> Other: |
| Corrective Action Additional Comments: | | | | |
| Staff Member(s) Response Comments: | | | | |
| Staff Signature: | | | Date: | |
| Supervisor Signature | | | Date: | |

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| PART 4: QUALITY IMPROVEMENT REVIEW | |
| Reviewed by: | Date: |