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| **FACILITY:** | **HELEN KELLER HOSPITAL CLINICAL LABORATORY** | | | | **START DATE:** | | | | **COMPLETION DATE:** | | |
| **DEPARTMENT:** | **CHEMISTRY** | **SYSTEM: COBAS 6000** | | | | | **JOB TITLE:** | | | | |
| **POPULATION [AGE GROUP] SERVED: NEONATE PEDIATRIC ADOLESCENT ADULT GERIATRIC** | | | | | | | | | | | |
| **REASON FOR VALIDATION:**  1. BEFORE PERFORMING PATIENT TESTING  2. SEMI-ANNUALLY DURING THE FIRST YEAR  3. ANNUALLY | | | **METHOD OF VALIDATION:**  **O**- OBSERVATION (DIRECT OBSERVATION OF TESTING)  **R**- RECORD REVIEW (MONITORING RESULT REPORTING,REPORTING OF CV)  **D**- DIRECT OBSERVATION OF INSTRUMENT CHECKS  **C**- COGNITIVE (WRITTEN TEST/EVALUATION OF PROBLEM SOLVING SKILLS)  **B**- BLIND TESTING (PROFICIENCY TESTING/INTERNAL SAMPLES)  **Q**- MONITORING OF QUALITY CONTROL  **P**- POLICY/PROCEDURE REVIEW | | | | | | | | **SKILL NOT VALIDATED:**  **U-** NO OPPORTUNITY DURING  EVALUATION TIME FRAME.  **NP-** NEEDS MORE PRACTICE.  **NA**-EMPLOYEE DOES NOT  PERFROM THIS PARTICULAR  TASK. |
| **SKILL/PROCEDURE** | | | | **DATE OF VALIDATION** | | **INITIALS OF EVALUATOR** | | **DEMONSTRATED METHOD OF VALIDATION** | | **COMMENTS** | |
| READ CHEMISTRY MANUAL | | | |  | |  | |  | |  | |
| **PRE-ANALYTIC** | | | |  | |  | |  | |  | |
| DAILY MAINTENANCE | | | |  | |  | |  | |  | |
| WEEKLY MAINTENANCE | | | |  | |  | |  | |  | |
| MONTHLY/AS NEEDED MAINTENANCE | | | |  | |  | |  | |  | |
| CALIBRATIONS | | | |  | |  | |  | |  | |
| QUALITY CONTROL | | | |  | |  | |  | |  | |
| RECEIVING SPECIMENS | | | |  | |  | |  | |  | |
| REAGENT STORAGE/PREPERATIONS | | | |  | |  | |  | |  | |

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| **SKILL/PROCEDURE** | **DATE OF VALIDATION** | **INITIALS OF EVALUATOR** | **DEMONSTRATED METHOD OF VALIDATION** | **COMMENTS** |
| **ANALYTIC** |  |  |  |  |
| SAMPLE INTEGRITY |  |  |  |  |
| HEMOLYSIS, LIPEMIC AND ICTERIC DOCUMENTATION |  |  |  |  |
| DILUTIONS |  |  |  |  |
| AMR LIMITS |  |  |  |  |
| CRR LIMITS |  |  |  |  |
| SAMPLE PROCESSING (SURC) |  |  |  |  |
| SYSTEM ERRORS/FLAGS |  |  |  |  |
| PROFICIENCY/BLIND SAMPLES |  |  |  |  |
| **POST-ANALYTIC** |  |  |  |  |
| DELTA CHECKS |  |  |  |  |
| VALIDATION OF RESULTS |  |  |  |  |
| AUTOVERIFICATION |  |  |  |  |

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| **SKILL/PROCEDURE** | **DATE OF VALIDATION** | **INITIALS OF EVALUATOR** | **DEMONSTRATED METHOD OF VALIDATION** | **COMMENTS** |
| DI INTERFACE |  |  |  |  |
| PRINTING REPORTS |  |  |  |  |
| FAXING REPORTS |  |  |  |  |
| ENTERING COMMENTS |  |  |  |  |
| CRITICAL RESULT DOCUMENTATION |  |  |  |  |
| FILING SAMPLES |  |  |  |  |

1. WHAT WOULD YOU DO IF YOUR QUALITY CONTROL RESULT IS OUT OF RANGE?

2. HOW DO YOU TURN OFF AUTOVERIFICATION?

3. WHAT KIND OF SPECIMEN DO YOU NEED FOR AN AMMONIA LEVEL?