

CLIA Compliance Manual for UniCel DxC 600 System Analyzer

Table of Contents

Getting Started With the DxC 600	i
Policies and Procedures Approval Form.....	ii

TAB 1: PERSONNEL.....1-1

Laboratory Personnel Policies	1-1
Laboratory Director Responsibilities	1-1
Laboratory Director Qualifications for Moderately Complex Testing.....	1-2
Other Laboratory Personnel	1-2
Testing Personnel Qualifications.....	1-2
Testing Personnel Responsibilities	1-2
Testing Personnel Job Description	1-3
Laboratory Personnel Titles	1-3
Procedures for Laboratory Personnel Training and Evaluation	1-4
Personnel Training.....	1-4
Personnel Competency Evaluation.....	1-4
Continuing Education.....	1-4

TAB 2: PROFICIENCY TESTING (PT).....2-1

PT Policies	2-1
PT Procedures	2-1
PT Results Analysis.....	2-2
Troubleshooting Failed and 'Not Graded' PT Results.....	2-3
Retesting Retained PT Samples	2-3

TAB 3: THE LAB AREA: SAFETY AND ENVIRONMENTAL MONITORING3-1

Laboratory Safety Policies	3-1
Laboratory Safety Procedures	3-1
Safety Precautions for the Laboratory Area.....	3-1
Safety Precautions for Working With Potentially Infectious Material	3-1
Reagent Safety	3-2
Miscellaneous DxC 600 Safety Hazards.....	3-2
Procedure for Reporting Device-Related Adverse Events	3-3
Hazardous Waste Disposal	3-3
In Case of Accident.....	3-3
For More Information	3-3
The Testing Environment.....	3-4
Policy for Monitoring the Testing Environment	3-4
Procedure for Checking Water Quality.....	3-4
What to Do if Water Quality Is Out of Range	3-4
Procedures for Monitoring Temperatures	3-4
What to Do if Temperatures Are Out of Range	3-4
Phases of Testing	3-5

TAB 4: PREANALYTIC POLICIES AND PROCEDURES 4-1

Policies for the Preanalytic Phase of Testing..... 4-1
Procedures for: 4-1
 Test Requisitioning 4-1
 Handling Incomplete Requisitions 4-1
 Standing Orders..... 4-1
 Specimen Collection and Handling 4-1
 Venipuncture Procedure 4-1
 Capillary Blood Collection Procedure..... 4-3
 Specimen Transport Procedures 4-4
 Specimen Accessioning Procedures 4-4
 Specimen Handling Procedures 4-4
 Specimen Rejection Criteria..... 4-4
 Criteria for Referral of Specimens 4-4
 Verifying Performance Specifications 4-4
 Method Validation Policies 4-4
 Method Validation Procedure 4-5
 Comparing a New Test System to a Previous Method: Split Sampling 4-5

TAB 5: ANALYTIC POLICIES AND PROCEDURES 5-1

Analytic Testing Policies 5-1
Procedures for: 5-1
 Reagent Tracking 5-1
 Reagent Changing..... 5-1
 Specific Reagent Information..... 5-1
 Reagent Preparation..... 5-1
 Reagent Storage..... 5-1
 Materials, Controls and Calibrators 5-2
 Reagent, Controls, Calibration Kit Supplier..... 5-2
 Control/Calibrator Preparation 5-2
 Control/Calibrator Storage and Stability 5-2
 Instrument Maintenance 5-2
Quality Control Policies 5-3
QC Procedures 5-3
 Frequency of Testing QC..... 5-3
 Each Day of Testing:..... 5-3
 After a Complete Change of Reagents, Major Preventive Maintenance or Critical Part
 Replacement: 5-3
 Establishing Mean And Range For New Control Lot Numbers: 5-4
 Examining Control Results 5-5
 Sending QC Results to QAP..... 5-5
 QC Record Retention 5-5
Calibration Policies 5-6
Calibration Procedures 5-6
 When to Calibrate 5-6
 How to Calibrate 5-6
 Calibrator Preparation 5-6
 Verify that Calibration Is Acceptable 5-6
 Required Calibration Verification 5-6

Exceptions to the requirement for calibration verification.....	5-7
Calibration and Calibration Verification Records	5-7
Procedure for Performing Patient Tests.....	5-7
Testing Patient Samples.....	5-7
Rerunning A Test.....	5-8
Procedure Notes.....	5-8
Limitations of the Procedure	5-8
Assay Sheets.....	5-8
DxC 600 Fast Reference Sheet.....	5-9
DxC 600 Fast Reference Sheet (Cont'd)	5-10
DxC 600 Fast Reference Sheet (Cont'd)	5-11

TAB 6: POSTANALYTIC POLICIES AND PROCEDURES 6-1

Policies for Interpreting, Reporting and Recording Test Results	6-1
Procedures for:	6-1
Interpreting Results.....	6-1
Interfering Substances	6-1
Reporting Results	6-1
Reference Ranges.....	6-1
Reportable Ranges.....	6-4
Reportable Ranges	6-4
Reportable Ranges (Cont'd)	6-5
Troubleshooting Flagged Results	6-6
Documenting and Retaining Troubleshooting Records	6-6
Procedures for Supervisor Review	6-6
Turnaround Time (TAT)	6-6
Critical Value Procedures	6-6
Procedure for Reporting Results to Providers	6-7
Correcting Erroneous Test Results and Issuing Corrected Reports.....	6-7
Communications and Laboratory Complaints.....	6-8
Incident Management	6-8
Procedure for a Power Failure/ Computer Crash	6-9
Ensuring the Security of Patient Test Results	6-9
Verifying the Accuracy of Electronic Record Transmissions	6-9
Procedures for Using Alternative Methods	6-9

TAB 7: QUALITY ASSESSMENT 7-1

QA Policies	7-1
QA Procedures	7-1
Electronic Record Transmissions.....	7-4

TAB 8: FORMS 8-1

Forms Index	8-1
Lab Personnel Training Checklist	8-2
Lab Personnel Evaluation Checklist.....	8-4
Lab Testing Log	8-5
Specimen Rejection Log	8-6
PT Event Report.....	8-7
Temperature/Humidity Chart.....	8-9

Water Quality Log	8-10
Dxc 600 Maintenance / Function Checks Log.....	8-11
Monthly QA Checklist.....	8-12

TAB 9: APPENDICES.....9-1

Appendices Index	9-1
Appendix A. How To Sign Up With the CLIA Program.....	9-2
Appendix B. QAP Enrollment Form	9-6
Appendix C. Method Validation.....	9-7
Method Validation Worksheet	9-9
Appendix D.....	9-12
Split Sample Analysis Procedure	9-12
split Sample Analysis Log	9-13
Appendix E. High-Complexity Personnel Requirements.....	9-14
Appendix f. For More Information.....	9-15