

PCR Laboratory 2021 Acknowledgement of Review of Policies and Procedures in Title 21 Document Control System

Make sure you do the following before taking the test in MedTraining Solutions (MTS):

- I. Log in to the Department of Pathology document control system, Title 21. The link to access Title 21 is <https://wfdc.title21.com/Login/Login>
- II. Read all the policies and procedures shown below that are within the **PCR Laboratory eBinders**:

1. Equipment Manual

EventID	Title	Status	Status Date
PCR-SOP-0016: 3.0	PCR-EM-01 Instrument Equipment performance verification	Effective	3/12/2020 1:00:03 AM
PCR-SOP-0017: 3.0	PCR-EM-02 Instrument and Equipment Record Review	Effective	10/16/2020 1:00:07 AM
PCR-SOP-0018: 1.0	PCR-EM-03 Instrument Downtime Procedure	Effective	2/13/2019 12:00:00 AM
PCR-SOP-0019: 3.0	PCR-EM-04 Qubit Use and Maintenance	Effective	3/12/2020 1:00:03 AM
PCR-SOP-0020: 2.0	PCR-EM-06 Biological and Chemical Hood Use and Maintenance	Effective	2/15/2019 12:00:00 AM
PCR-SOP-0021: 1.0	PCR-EM-07 Savant SpeedVac System Use and Maintenance	Effective	2/13/2019 12:00:00 AM
PCR-SOP-0022: 2.0	PCR-EM-08 Pipette maintenance	Effective	2/15/2019 12:00:00 AM
PCR-SOP-0023: 1.0	PCR-EM-09 Refrigerator and Freezer Maintenance.docx	Effective	2/13/2019 12:00:00 AM
PCR-SOP-0024: 2.0	PCR-EM-11 Emergency Notification of Personnel for Remote Alarm Monitors	Effective	2/15/2019 12:00:00 AM
PCR-SOP-0025: 2.0	PCR-EM-12 Vortex Mixer Maintenance	Effective	2/15/2019 12:00:00 AM
PCR-SOP-0026: 1.0	PCR-EM-13 Sonicator Maintenance	Effective	2/13/2019 12:00:00 AM
PCR-SOP-0027: 1.0	PCR-EM-14 Water Bath Maintenance	Effective	2/13/2019 12:00:00 AM
PCR-SOP-0028: 1.0	PCR-EM-15 UV Stratalinker Use and Maintenance	Effective	2/13/2019 12:00:00 AM
PCR-SOP-0029: 3.0	PCR-EM-16 Centrifuge Maintenance	Effective	2/15/2019 12:00:00 AM
PCR-SOP-0030: 1.0	PCR-EM-17 Microtome Maintenance	Effective	2/13/2019 12:00:00 AM
PCR-SOP-0031: 1.0	PCR-EM-18 EZ1 BoRobot Maintenance	Effective	2/13/2019 12:00:00 AM
PCR-SOP-0032: 2.0	PCR-EM-19 Thermal Cycler Use and Maintenance	Effective	3/27/2019 12:00:00 AM
PCR-SOP-0033: 2.0	PCR-EM-20 7500 Real-Time System Use and Maintenance	Effective	3/27/2019 12:00:00 AM
PCR-SOP-0034: 3.0	PCR-EM-21 Rotor-Gene Q MDx Real-Time Cycler Use and Maintenance	Effective	3/27/2019 12:00:00 AM
PCR-SOP-0035: 3.0	PCR-EM-22 3500 Genetic Analyzer Use and Maintenance	Effective	3/27/2019 12:00:00 AM
PCR-SOP-0036: 3.0	PCR-EM-23 Roche COBAS 4800 System Use and Maintenance	Effective	3/27/2019 12:00:00 AM
PCR-SOP-0037: 2.0	PCR-EM-24 Ultraviolet Light Exposure	Effective	2/15/2019 12:00:00 AM
PCR-SOP-0038: 2.0	PCR-EM-25 NanoDrop Lite Cleaning and Maintenance	Effective	2/15/2019 12:00:00 AM
PCR-SOP-0039: 2.0	PCR-EM-27 Use and Maintenance of the Heat Block	Effective	2/15/2019 12:00:00 AM
PCR-SOP-0057: 1.0	PCR-EM-28 Use and Maintenance of the Biocartis Idylla Platform	Effective	3/22/2020 1:00:06 AM

2. Forms

EventID	Title	Status	Status Date	CodeID
PCR-FORMS-0001: 1.0	New Employee Training Checklist	Effective	1/15/2021 1:00:06 AM	PCR FORM

Please select an item to view

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3. Procedure Manual

EventId	Title	Status	Status Date	CodeID
PCR-SOP-0001: 1.0	PCR-PM-01 DNA Extraction on the E21 Biorobot	Effective	2/27/2019 12:00:00 AM	PCR.PM
PCR-SOP-0002: 3.0	PCR-PM-02 Concentrating Nucleic Acid Samples for Qualitative Assays	Effective	3/14/2019 12:00:00 AM	PCR.PM
PCR-SOP-0003: 1.0	PCR-PM-03 Formalin Fixed Paraffin Embedded Tissue DNA Extraction Procedure	Effective	2/27/2019 12:00:00 AM	PCR.PM
PCR-SOP-0004: 2.0	PCR-PM-04 RNA Extraction from Peripheral Blood and Bone Marrow	Effective	2/27/2019 12:00:00 AM	PCR.PM
PCR-SOP-0005: 2.0	PCR-PM-05 Quantifying RNA with the Qubit Fluorometer	Effective	2/7/2019 12:00:00 AM	PCR.PM
PCR-SOP-0009: 2.0	PCR-PM-09 T-Cell Receptor Gamma Gene Rearrangement Procedure	Effective	2/27/2019 12:00:00 AM	PCR.PM
PCR-SOP-0010: 2.0	PCR-PM-10 IG H Gene Clonality Procedure	Effective	2/27/2019 12:00:00 AM	PCR.PM
PCR-SOP-0011: 4.0	PCR-PM-12 BCR ABL p190 Quantitative Real-Time PCR Procedure	Effective	3/14/2019 12:00:00 AM	PCR.PM
PCR-SOP-0012: 4.0	PCR-PM-13 PML-RARA Quantitative Real-Time PCR Procedure.docx	Effective	3/14/2019 12:00:00 AM	PCR.PM
PCR-SOP-0013: 8.0	PCR-PM-14 HPV COBAS Procedure	Effective	6/9/2020 1:00:05 AM	PCR.PM
PCR-SOP-0014: 3.0	PCR-PM-15 BCR ABL1 P210 IS-MMR Quantitative Real-Time PCR Procedure	Effective	3/14/2019 12:00:00 AM	PCR.PM
PCR-SOP-0015: 1.0	PCR-PM-16 NanoDrop Lite Procedure FINAL	Effective	2/27/2019 12:00:00 AM	PCR.PM
PCR-SOP-0058: 3.0	PCR-PM-07 Itherascreen EGFR Mutation Detection Procedure	Effective	6/9/2020 1:00:05 AM	PCR.PM
PCR-SOP-0059: 1.0	PCR-PM-17 Extended RAS RAF Mutation Testing on the Idylla Platform	Effective	4/8/2020 1:00:07 AM	PCR.PM
PCR-SOP-0063: 1.0	PCR-PM-18 BRAF Mutation Testing on the Idylla Platform	Effective	4/27/2020 1:00:05 AM	PCR.PM
PCR-SOP-0065: 1.0	PCR-PM-19 v1 EGFR Mutation Testing on the Idylla Platform	Effective	8/31/2020 1:00:05 AM	PCR.PM
PCR-SOP-0066: 2.0	FLT3-ITD/TKD Mutation Procedure	Effective	12/1/2020 1:00:04 AM	PCR.PM

4. Quality Control Manual

EventId	Title	Status	Status Date	CodeID
PCR-SOP-0040: 2.0	PCR-QM-01 Molecular Diagnostics PCR Laboratory Quality Management Policy	Effective	2/7/2019 12:00:00 AM	PCR.QM
PCR-SOP-0041: 2.0	PCR-QM-02 Document Control System	Effective	2/7/2019 12:00:00 AM	PCR.QM
PCR-SOP-0042: 3.0	PCR-QM-04 Contamination Control Guidelines	Effective	2/27/2019 12:00:00 AM	PCR.QM
PCR-SOP-0043: 4.0	PCR-QM-05 Reagents and Controls	Effective	3/14/2019 12:00:00 AM	PCR.QM
PCR-SOP-0044: 2.0	PCR-QM-06 Analytic Interferences	Effective	2/15/2019 12:00:00 AM	PCR.QM
PCR-SOP-0045: 4.0	PCR-QM-07 Training, Competency Assessment, and Continuing Education	Effective	3/23/2020 1:00:07 AM	PCR.QM
PCR-SOP-0046: 2.0	PCR-QM-09 Assay Validation and Verification	Effective	2/15/2019 12:00:00 AM	PCR.QM
PCR-SOP-0047: 3.0	PCR-QM-10 Post-Validation Assay Performance Monitoring	Effective	2/7/2019 12:00:00 AM	PCR.QM
PCR-SOP-0048: 3.0	PCR-QM-11 Specimen Acceptance and Rejection Criteria	Effective	3/23/2020 1:00:07 AM	PCR.QM
PCR-SOP-0049: 1.0	PCR-QM-12 Specimen Retention	Effective	3/4/2019 12:00:00 AM	PCR.QM
PCR-SOP-0050: 2.0	PCR-QM-13 Results Reporting	Effective	2/7/2019 12:00:00 AM	PCR.QM
PCR-SOP-0051: 3.0	PCR-QM-14 Semi-Annual Instrument Comparison	Effective	3/23/2020 1:00:07 AM	PCR.QM
PCR-SOP-0052: 2.0	PCR-QM-15 Analytical Measurement Range Verification for Quantitative Assays mod 3.21.19 SSO	Effective	1/9/2019 12:00:00 AM	PCR.QM
PCR-SOP-0053: 2.0	PCR-QM-17 Accessioning Specimens	Effective	2/15/2019 12:00:00 AM	PCR.QM
PCR-SOP-0054: 2.0	PCR-QM-18 Specimen Tracking	Effective	2/7/2019 12:00:00 AM	PCR.QM
PCR-SOP-0055: 1.0	PCR-QM-19 HPV Ordering and Receiving HPV Specimens in Beaker	Effective	2/13/2019 12:00:00 AM	PCR.QM
PCR-SOP-0056: 1.0	PCR-QM-20 Alternative Performance Assessment Procedure	Effective	4/11/2019 12:00:00 AM	PCR.QM
PCR-SOP-0061: 1.0	PCR-QM-21 Hand-off Communication Procedure	Effective	4/8/2020 1:00:07 AM	PCR.QM
PCR-SOP-0062: 1.0	PCR-QM-22 Inventory Monitoring system	Effective	4/8/2020 1:00:07 AM	PCR.QM

5. SOP

EventId	Title	Status	Status Date	CodeID
PCR-SOP-0066: 2.0	FLT3-ITD/TKD Mutation Procedure	Effective	12/1/2020 1:00:04 AM	PCR.SOP

Please select an item to view

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III. Read the applicable policies and procedures found in the **Lab Compliance eBinders** listed below:

1. Poliy

LC-POL-0004: 3.0	Delegation of Duties in the Clinical Laboratory
LC-POL-0005: 1.0	Commitment to Quality Policy
LC-POL-0008: 2.0	Continuing Education Policy
LC-POL-0009: 1.0	Correction of Laboratory Records
LC-POL-0010: 1.0	Calling Critical and/or Corrected Values
LC-POL-0014: 2.0	Compliance Guidance on Laboratory Ordering Policy
LC-POL-0015: 1.0	Document Management Policy
LC-POL-0016: 2.0	Documentation of Foreign Equivalency for Laboratory Testing
Personnel	
LC-POL-0018: 1.0	Laboratory Equipment Maintenance Policy
LC-POL-0019: 1.0	Handling of Veterinary Samples
LC-POL-0021: 1.0	Laboratory Record Retention Policy
LC-POL-0023: 1.0	Limited Access to Clinical Laboratory Areas
LC-POL-0026: 1.0	Personnel File Requirements
LC-POL-0027: 1.0	Personal Electronic Devices and Internet Access
LC-POL-0031: 2.0	Quality Control (QC) Management Policy
LC-POL-0033: 2.0	Reflex Testing Policy
LC-POL-0036: 2.0	Pathology Laboratory Interim Self Inspection Procedure
LC-POL-0042: 1.0	Individual Quality Control Plan (IQCP) for the WFBMC Department of Pathology
LC-POL-0043: 1.0	Communication of Significant or Unexpected Findings
LC-POL-0047: 2.0	Critical Laboratory Values
LC-POL-0049: 1.0	List of Critical Laboratory Values
LC-POL-0050: 1.0	Reflex Tests List

2. SOP

LC-SOP-0001: 1.0	Method Validation Process NonWaived Testing
LC-SOP-0006: 1.0	Compliance with CAP Accreditation
LC-SOP-0011: 1.0	Customer Satisfaction Survey
LC-SOP-0020: 2.0	Laboratory Equipment Service Procedure
LC-SOP-0025: 1.0	Orientation and Competency Procedure
LC-SOP-0028: 3.0	CAPA Corrective Action Preventative Action
LC-SOP-0029: 2.0	Proficiency Testing Procedure
LC-SOP-0034: 1.0	Release of Laboratory Results to Patients
LC-SOP-0035: 1.0	Reporting Quality Issues in the Laboratory
LC-SOP-0041: 1.0	Laboratory Safety Manual
LC-SOP-0045: 1.0	Retrospective Color Blind Testing of Laboratory Testing Personnel
LC-SOP-0046: 1.0	Staff Certification
LC-SOP-0047: 1.0	Title 21 Document Control

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IV. Read the policies and procedures found in the **Safety eBinders** listed below:

1. Policy

The screenshot shows the 'eBinders' section of the Title 21 system. The left sidebar lists various categories like 'All - Title21 Job Aids', 'Autopsy', 'Blood Bank', etc. The main area displays a table of policies with columns for Eventid, Title, Status, and Status Date.

Eventid	Title	Status	Status Date
LC-POL-0022: 1.0	Laboratory Waste Disposal Policy	Effective	2/5/2019 12:00:00 AM
LC-POL-0032: 1.0	Reagent Labeling Policy	Effective	2/14/2019 12:00:00 AM
LC-POL-0037: 5.0	Specimen Transportation Policy	Effective	6/1/2016 12:00:00 AM
LC-POL-0039: 1.0	Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas	Effective	2/15/2018 12:00:00 AM
LC-POL-0040: 1.0	Thermometer and Timer Guideline	Effective	8/1/2018 12:00:00 AM
SAFE-POL-0001: 1.0	PPE/Hazard Assessment Policy	Effective	9/18/2020 1:00:04 AM
SAFE-SOP-0001: 1.0	Drone Delivery of Laboratory Samples	Effective	12/12/2020 1:00:04 AM

2. SOP

The screenshot shows the 'eBinders' section of the Title 21 system. The left sidebar lists various categories like 'All - Title21 Job Aids', 'Autopsy', 'Blood Bank', etc. The main area displays a table of SOPs with columns for Eventid, Title, Status, Status Date, and CodeID.

Eventid	Title	Status	Status Date	CodeID
LC-SOP-0002: 1.0	Product Recall and Alert Notifications (ECRI Alerts)	Effective	2/28/2019 12:00:00 AM	SAFE.SOP
LC-SOP-0007: 1.0	Contaminated Requisition Handling	Effective	11/1/1996 12:00:00 AM	SAFE.SOP
LC-SOP-0017: 1.0	Emergency Operating Plan (Continuity of Business Plan) – Department of Pathology	Effective	6/30/2008 12:00:00 AM	SAFE.SOP
LC-SOP-0024: 1.0	Mass Casualty Preparedness Plan for the Department of Pathology	Effective	1/22/2019 12:00:00 AM	SAFE.SOP

V. Log-in to MTS at <https://www.medtraining.org/ltac3/Secure/Login.aspx> and take the TEST to attest that you have reviewed applicable policies and procedures for the current year.