

Molecular Diagnostics IHC

2022 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 **Molecular Dx** (Molecular Diagnostics IHC) eBinders:

1. Equipment Manual

The screenshot shows the Title 21 health solutions eBinders interface. On the left is a navigation menu with options like Dashboard, New, My Forms, My Docs, My Tasks, Wizard, eBinders, Searches, Reports, Charts, and Favorites. The eBinders section is expanded, showing a list of categories including Accreditation, All - Title21 Job Aids, AP Support Services, Atrium Health WFB System Documents, Autopsy, Blood Bank, Cancer Center, Central Processing, Chemistry, CI Labs Administration, CLEM Allergy, CLEM Chemistry, CLEM General Lab, CLEM Hematology, CLEM Manual Testing, CLEM Phlebotomy, Critical Care Laboratory, Cytology, DAV Blood Bank, DAV Chemistry, DAV Coagulation, DAV General Lab, DAV Hematology, DAV Immunology, DAV Lab Safety, DAV Microbiology, and DAV Phlebotomy. The main content area displays a table of SOPs with columns for EventId, Title, and Status. The table lists 18 SOPs, all with a status of 'Effective'. The first few rows are: MD-SOP-0034: 5.0 - Operation of Accumet pH Meter; MD-SOP-0035: 6.0 - Glassware Cleaning; MD-SOP-0036: 6.0 - Flotation Bath and Microtome Maintenance; MD-SOP-0037: 4.0 - Pipet Calibration and Service; MD-SOP-0039: 4.0 - Eyewash Maintenance; MD-SOP-0041: 5.0 - Balance Maintenance; MD-SOP-0042: 4.0 - Thermometer Verification and Maintenance; MD-SOP-0043: 5.0 - Temperature Monitoring - MD-EM-11; MD-SOP-0045: 7.0 - Cryostat Maintenance-Leica 1850; MD-SOP-0046: 3.0 - Instrument and Equipment Record Review; MD-SOP-0047: 5.0 - Instrument/Equipment Performance Verification; MD-SOP-0048: 6.0 - Leica Coverslipper and Maintenance; MD-SOP-0049: 2.0 - Humidifier Maintenance; MD-SOP-0050: 2.0 - Remote Alarm Monitor; MD-SOP-0051: 4.0 - Weekly Decontamination of Leica CM 1850 cryostat; MD-SOP-0055: 2.0 - Certified Timer Procedure; MD-SOP-0056: 4.0 - Deionized water system-IHC lab; MD-SOP-0057: 3.0 - Leica Autostainer Programs. At the bottom of the table, it says 'Showing 1 - 18 of 18' and navigation buttons for '< Previous', '1', and 'Next >'.

EventId	Title	Status
MD-SOP-0034: 5.0	Operation of Accumet pH Meter	Effective
MD-SOP-0035: 6.0	Glassware Cleaning	Effective
MD-SOP-0036: 6.0	Flotation Bath and Microtome Maintenance	Effective
MD-SOP-0037: 4.0	Pipet Calibration and Service	Effective
MD-SOP-0039: 4.0	Eyewash Maintenance	Effective
MD-SOP-0041: 5.0	Balance Maintenance	Effective
MD-SOP-0042: 4.0	Thermometer Verification and Maintenance	Effective
MD-SOP-0043: 5.0	Temperature Monitoring - MD-EM-11	Effective
MD-SOP-0045: 7.0	Cryostat Maintenance-Leica 1850	Effective
MD-SOP-0046: 3.0	Instrument and Equipment Record Review	Effective
MD-SOP-0047: 5.0	Instrument/Equipment Performance Verification	Effective
MD-SOP-0048: 6.0	Leica Coverslipper and Maintenance	Effective
MD-SOP-0049: 2.0	Humidifier Maintenance	Effective
MD-SOP-0050: 2.0	Remote Alarm Monitor	Effective
MD-SOP-0051: 4.0	Weekly Decontamination of Leica CM 1850 cryostat	Effective
MD-SOP-0055: 2.0	Certified Timer Procedure	Effective
MD-SOP-0056: 4.0	Deionized water system-IHC lab	Effective
MD-SOP-0057: 3.0	Leica Autostainer Programs	Effective

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2. Molecular IHC Procedure Manual

EventId	Title	Status	Status Date
MD-SOP-0010: 8.0	Quality Control Procedures	Effective	5/26/2021 1:00:09 AM
MD-SOP-0011: 4.0	Quality Control - Reporting IHC, Histochemistry and Special Stain Controls	Effective	1/5/2022 1:00:07 AM
MD-SOP-0012: 6.0	Proficiency Testing Procedure	Effective	1/5/2022 1:00:07 AM
MD-SOP-0013: 3.0	Proficiency Testing Procedure - Department of Pathology	Effective	3/23/2021 1:00:04 AM
MD-SOP-0014: 6.0	Orientation/Competency Procedure	Effective	3/25/2021 1:00:04 AM
MD-SOP-0015: 5.0	H&E Slide Checking Criteria	Effective	3/23/2021 1:00:04 AM
MD-SOP-0016: 7.0	Leica AutoStainer Operation	Effective	1/5/2022 1:00:07 AM
MD-SOP-0017: 8.0	Leica Bond 3 Operating Procedure	Effective	1/5/2022 1:00:07 AM
MD-SOP-0019: 3.0	Wash Solution Procedure for Renal and Skin Biopsies	Effective	3/23/2021 1:00:04 AM
MD-SOP-0020: 5.0	Direct Immunofluorescence Staining for Renal Biopsies	Effective	3/29/2021 1:00:05 AM
MD-SOP-0021: 5.0	C4d Staining for Renal Biopsies (Frozen tissue)	Effective	3/29/2021 1:00:06 AM
MD-SOP-0022: 5.0	Immunofluorescence on Paraffin-Embedded tissues	Effective	4/14/2021 6:23:20 PM
MD-SOP-0023: 3.0	Outside Renal Biopsy Handling-MD-IHC-15	Effective	4/14/2021 6:23:20 PM
MD-SOP-0024: 6.0	Direct Immunofluorescence Staining of Skin Biopsies	Effective	4/14/2021 6:23:20 PM
MD-SOP-0025: 4.0	Submission of Skin Specimens for Direct Immunofluorescence	Effective	4/12/2021 3:43:10 PM
MD-SOP-0026: 3.0	Submission of Outside Materials for IHC and ISH	Effective	4/14/2021 6:23:20 PM
MD-SOP-0027: 3.0	Disposal of DAB	Effective	4/14/2021 6:23:20 PM
MD-SOP-0029: 4.0	Instrument Downtime Procedure – IHC	Effective	1/22/2022 1:00:05 AM
MD-SOP-0030: 5.0	Leica Bond 3 Maintenance and Cleaning Procedure	Effective	4/14/2021 7:47:31 AM
MD-SOP-0031: 5.0	Dako Autostainer Link Maintenance	Effective	4/14/2021 7:47:31 AM
MD-SOP-0033: 3.0	Comparability of Immunostainer Instruments	Effective	4/14/2021 6:23:20 PM
MD-SOP-0052: 2.0	Indirect Immunofluorescence on AGME	Effective	4/14/2021 6:23:20 PM
MD-SOP-0053: 2.0	Indirect Immunofluorescence on Split Skin	Effective	4/14/2021 6:23:20 PM
MD-SOP-0054: 2.0	Liquid Nitrogen Handling	Effective	4/14/2021 6:23:20 PM
MD-SOP-0058: 2.0	Immunohistochemistry/Immunofluorescence Specimen Collection, Identification and Rejection	Effective	1/5/2022 1:00:07 AM
MD-SOP-0059: 1.0	IHC Lab Feedback Procedure	Effective	2/19/2022 1:00:07 AM

3. Molecular Procedure Manual

EventId	Title	Status	Status Date
MD-SOP-0007: 6.0	EBER, Kappa, Lambda ISH procedure - MD-M-1	Effective	2/8/2022 1:00:06 AM
MD-SOP-0008: 6.0	Molecular Quality Improvement Monitors - MD-M-2	Effective	2/8/2022 1:00:06 AM
MD-SOP-0009: 6.0	ISH Slide Processing System Temperature Checks – MD-M-5	Effective	2/8/2022 1:00:06 AM

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4. Steroid Receptor Procedure Manual

EventId	Title	Status	Status Date
MD-SOP-0001: 5.0	Reporting IHC Results for Predictive Markers-MD-SR-1	Effective	2/25/2021 1:00:03 AM
MD-SOP-0002: 5.0	Fixation Requirements for ER, PR, Her2 - MD-SR-2	Effective	2/20/2021 1:00:03 AM
MD-SOP-0003: 4.0	CAP guidelines for reporting Her2 testing- MD-SR-3	Effective	2/2/2021 1:00:10 AM
MD-SOP-0004: 6.0	Annual Results Comparison for Predictive Markers	Effective	2/25/2021 1:00:03 AM
MD-SOP-0005: 6.0	Dako Herceptest-Automated Method-MD-SR-5	Effective	1/5/2022 1:00:07 AM

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

1. POL

EventId	Title	Status	Status Date
LC-POL-0004: 4.0	Delegation of Duties in the Clinical Laboratory	Effective	4/6/2021 3:20:58 PM
LC-POL-0008: 2.0	Continuing Education Policy	Effective	10/28/2020 1:00:05 AM
LC-POL-0014: 2.0	Compliance Guidance on Laboratory Ordering Policy	Effective	1/14/2021 1:00:05 AM
LC-POL-0015: 2.0	Document Management Policy	Effective	4/7/2021 9:16:12 AM
LC-POL-0016: 2.0	Documentation of Foreign Equivalency for Laboratory Testing Personnel	Effective	9/18/2020 2:51:39 PM
LC-POL-0019: 2.0	Handling of Veterinary Samples	Effective	4/27/2021 1:00:04 AM
LC-POL-0021: 2.0	Laboratory Record Retention Policy	Effective	4/14/2021 9:44:47 AM
LC-POL-0026: 1.0	Personnel File Requirements	Effective	1/15/2019 12:00:00 AM
LC-POL-0031: 4.0	Quality Control (QC) Management Policy	Effective	4/7/2021 1:58:00 PM
LC-POL-0042: 2.0	Individual Quality Control Plan (IQCP) for the WFBMC Department of Pathology	Effective	4/14/2021 7:00:26 PM
LC-POL-0044: 1.0	Intraoperative vs Final Diagnosis Correlation Policy	Effective	8/21/2018 12:00:00 AM
LC-POL-0048: 2.0	Anatomic Pathology/Internal Slides/Cases for External Review	Effective	4/6/2021 3:20:58 PM
LC-POL-0053: 1.0	Stored Document Verification Process	Effective	5/13/2021 1:00:02 AM
QUAL-POL-0002: 1.0	Commitment to Quality Policy	Effective	9/28/2021 1:00:07 AM
QUAL-POL-0003: 1.0	Quality Assurance Policy for Anatomic and Clinical Lab Reports	Effective	9/28/2021 1:00:07 AM
QUAL-POL-0004: 1.0	Correction of Laboratory Records	Effective	9/28/2021 1:00:07 AM
QUAL-POL-0005: 1.0	Limited Access to Clinical Laboratory Areas	Effective	9/28/2021 1:00:07 AM
QUAL-POL-0006: 1.0	Quality Assessment and Process Improvement Plan	Effective	9/22/2021 1:00:04 AM
QUAL-POL-0007: 4.0	List of Critical Laboratory Values	Effective	12/31/2021 1:00:04 AM
QUAL-POL-0008: 1.0	Critical Laboratory Values	Effective	8/27/2021 1:00:09 AM
QUAL-POL-0009: 1.0	Compliance with Synoptic Reporting	Effective	11/16/2021 1:00:09 AM
QUAL-POL-0010: 2.0	Ongoing Professional Practice Evaluation and Focused Professional Practice Evaluation Policy	Effective	2/15/2022 1:07:54 PM
QUAL-POL-0011: 1.0	Personal Electronic Devices and Internet Access	Effective	1/21/2022 1:00:05 AM
QUAL-POL-0013: 1.0	Reflex Testing Policy	Effective	2/22/2022 10:00:37 AM
QUAL-POL-0014: 1.0	Reflex Tests List	Effective	2/17/2022 9:14:18 AM

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☑	QUAL-POL-0016: 1.0	☰	Compliance with CAP Terms of Accreditation	Effective	2/22/2022 10:00:37 AM
☑	QUAL-POL-0017: 1.0	☰	Laboratory Interim Self-Inspection Process	Effective	2/28/2022 10:43:43 AM
	QUAL-POL-0020: 1.0	☰	Handling Veterinary Specimens in a Clinical Laboratory	Effective	3/4/2022 1:00:06 AM
☑	SAFE-POL-0005: 1.0	☰	Calling Critical and/or Corrected Values	Effective	3/8/2021 10:59:21 AM
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2. FORMS

EventId	Title	Status	Status Date
☑ QUAL-FORM-0001: 1.0	☰ QAPI Annual Assessment Form	Effective	9/28/2021 1:00:07 AM
☑ QUAL-FORM-0002: 1.0	☰ CAPA Fillable	Effective	8/31/2021 1:00:05 AM

3. SOP

EventId	Title	Status	Status Date
☑ LC-SOP-0001: 3.0	☰ Method Validation and Re-Validation Process for NonWaived Test	Effective	7/21/2021 1:00:05 AM
LC-SOP-0011: 1.0	☰ Customer Satisfaction Survey	Effective	1/16/2019 12:00:00 AM
☑ LC-SOP-0025: 1.0	☰ Orientation and Competency Procedure	Effective	1/31/1996 12:00:00 AM
☑ LC-SOP-0029: 3.0	☰ Proficiency Testing	Effective	5/19/2021 1:00:08 AM
LC-SOP-0034: 3.0	☰ Release of Laboratory Results to Patients	Effective	4/6/2021 3:20:58 PM
☑ LC-SOP-0046: 2.0	☰ Staff Certification	Effective	5/19/2021 1:00:08 AM
☑ LC-SOP-0047: 2.0	☰ Title 21 Document Control	Effective	6/5/2021 1:00:05 AM
☑ QUAL-SOP-0001: 1.0	☰ New Malignancy Diagnosis Confirmation Audit	Effective	11/5/2021 1:00:07 AM
☑ QUAL-SOP-0002: 1.0	☰ CAPA Corrective Action Preventative Action	Effective	9/1/2021 1:00:06 AM
QUAL-SOP-0003: 1.0	☰ Reporting Quality Issues in the Laboratory	Effective	9/28/2021 1:00:07 AM
☑ QUAL-SOP-0004: 1.0	☰ Performing an Addendum or Amendment to a Signed Out Case in AP Beaker	Effective	2/3/2022 1:27:35 PM
☑ QUAL-SOP-0005: 1.0	☰ Communication of Significant or Unexpected Findings	Effective	2/3/2022 1:27:35 PM
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IV. Read the policies and procedures found in the **Safety eBinders** listed below:

1. FORMS

EventId	Title	Status	Status Date
SAFE-FORM-0001: 1.0	PPE Assessment Template	Effective	8/19/2020 1:00:04 AM
SAFE-FORM-0002: 1.0	PPE Training	Effective	8/5/2020 1:00:03 AM
SAFE-FORM-0003: 1.0	Annual Chemical Review	Effective	11/5/2020 1:00:07 AM
SAFE-FORM-0004: 1.0	New Employee Safety Checklist	Effective	3/17/2021 1:48:54 PM
SAFE-FORM-0005: 1.0	Eyewash/Shower Flush and Maintenance Record	Effective	3/13/2021 1:00:07 AM
SAFE-FORM-0006: 1.0	Laboratory Thermometer/Timer Calibration Log	Effective	3/13/2021 1:00:07 AM
SAFE-FORM-0007: 1.0	Manual Temperature and Humidity Log	Effective	3/13/2021 1:00:07 AM
SAFE-FORM-0008: 1.0	Manufacturer Recommended Temperature/Humidity Requirement Log	Effective	3/13/2021 1:00:07 AM

2. Policy

EventId	Title	Status	Status Date
SAFE-POL-0001: 1.0	PPE/Hazard Assessment Policy	Effective	9/18/2020 1:00:04 AM
SAFE-POL-0002: 4.0	Lab Operations System Delay Notification Procedure	Effective	2/24/2022 1:00:05 AM
SAFE-POL-0003: 3.0	Laboratory Safety Manual	Effective	4/13/2021 3:47:39 PM
SAFE-POL-0004: 1.0	Department of Pathology Laboratory Equipment Maintenance Policy	Effective	4/13/2021 11:56:12 AM
SAFE-POL-0006: 1.0	Reagent Labeling Policy	Effective	2/25/2021 1:00:03 AM
SAFE-POL-0007: 1.0	Contaminated Requisition Handling	Effective	1/22/2021 1:00:05 AM
SAFE-POL-0008: 1.0	Specimen Transportation Policy	Effective	3/10/2021 1:00:10 AM
SAFE-POL-0009: 2.0	Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas (Winston)	Effective	4/6/2021 3:20:58 PM
SAFE-POL-0010: 2.0	Thermometer/Hygrometer/Timer Guidelines	Effective	4/16/2021 1:00:07 AM
SAFE-POL-0011: 1.0	Laboratory Waste Disposal Policy	Effective	4/7/2021 9:16:12 AM
SAFE-POL-0013: 1.0	Department of Pathology and Lab Services Business Continuity Playbook and Guidelines	Effective	10/21/2021 3:16:03 PM

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3. SOP

EventId	Title	Status	Status Date
LC-SOP-0045: 1.0	Retrospective Color Blind Testing of Laboratory Testing Personnel	Effective	6/25/2019 12:00:00 AM
SAFE-SOP-0001: 2.0	Drone Delivery of Laboratory Samples	Effective	4/6/2021 3:20:58 PM
SAFE-SOP-0002: 1.0	Department of Pathology Laboratory Equipment Service Procedure	Effective	1/27/2021 1:00:06 AM
SAFE-SOP-0003: 1.0	Laboratory Equipment Service Procedure	Effective	3/25/2021 1:00:04 AM
SAFE-SOP-0004: 2.0	Emergency Operating Plan (Continuity of Business Plan) – Department of Pathology	Effective	6/30/2021 1:00:04 AM
SAFE-SOP-0006: 2.0	Product Recall and Alert Notifications (MD Buyline)	Effective	2/1/2022 12:49:02 PM

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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.