Washington State Medical Test Site Licensing Program
Pre-Inspection Self-Assessment Checklist
Testing In Histology and Frozen Section Laboratory

Histology / Frozen Section Pre-Inspection Checklist

Site: _____ MTS-_____

Director: _____ Contact: _____

Personnel:
The Medical Director is responsible for the overall technical supervision and management of test site personnel including policies and procedures for:

Performing, recording, and reporting tests _____
Maintaining on ongoing quality assurance program _____
Supervision of testing _____

Does the Medical Director evaluate, verify, and document the following related to technical personnel:

Education, experience, and training in test performance and reporting test results _____
Sufficient numbers to cover the scope and complexity of the services provided _____

Pathologists:

Medical license and certification as appropriate _____
Current results, education, residency and Pathology/Histology training _____
Documentation of CE activities _____
Peer group review of cases at professional meetings _____
Documentation of consult with other pathologists_____

Does the Histotech have appropriate training and certification?_____

Records:
Requisitions:

Contain patient name, identification, or other method of patient identification _____
Name and address or other suitable identifiers of person ordering test _____
Date of specimen collection, and time if appropriate _____
Source of specimen, if appropriate _____
Type of test ordered _____
Sex, and age or date of birth of patient _____
Pertinent clinical information if appropriate _____

Test Record Systems:

Consist of instrument printouts, worksheets, accession logs, etc _____
Include:

Patient Identifiers (2) _____
Date and time (if appropriate) specimen received _____
Reason for specimen rejection or limitation _____

Date of specimen testing _____
Identification of testing personnel (if appropriate) _____

Accession Logs:
Date specimen collected _____
Date specimen processed/stained _____
Date slides reviewed _____
Date reported and charted _____
System to assure that slides are back from processing laboratory if sent off-site _____

Specimen Labeling:
Adequate on tissues, blocks and slides _____
Is there a system for labeling slides? _____
Is there a system for tracking the levels of tissues and is it in writing? _____

Test Reports:
Maintained permitting identification & retrieval _____
Released to authorized personnel only _____
Include:
Name and address of testing facility _____
Patient name & identification _____
Date reported _____
Time reported (if appropriate) _____
Specimen source & limitations (if appropriate) _____
Test name test result, and units of measurement (if appropriate) _____
Signature or initials of authorized personnel (electronic acceptable) _____
Referral reports contain essential elements and duplicate copy retrieval _____
Corrected reports _____
Documentation of consultations _____

Record Retention:
Blocks (2 years from date of examination) _____
Tissues (Retain remnants of tissue specimens in an appropriate preserved state until the portions submitted for microscopic have been examined and diagnosed)_____
Reports (10 years)_____
QC/QA Documents (2 years) _____
Slides (10 years from date of examination)_____
Process to maintain records if the MTS ceases operation_____

Lot Numbers retained for:
Formalin _____
Xylene _____
Stains _____
Stain Control Slides_____

Quality Assurance:
Written Quality Assurance Plan includes policies and procedures that
Monitor, evaluate, and review QC, PT, Biannual Verification and test results _____
How to identify & correct problems _____

Establish & maintain accurate, reliable, & prompt results _____
Establish and maintain adequate and competent personnel _____
Establish and maintain the patient identification from collection to result _____
Name of patient or patient identifier _____
Case Number _____
Sequence ID of tissue and cuts _____
Maintain all slides including slide showing margins are clear _____

Quality Assurance Program must include mechanisms or systems to
Establish specimen collection criteria, acceptance & rejection _____
Notification of critical values (if appropriate)_____
Problem identification & troubleshooting _____
Evaluate correct test reporting systems _____
Issue corrected reports when indicated _____
Insure proper specimen labeling _____
Insure confidentiality _____
Provide client updates as appropriate _____

Documentation of remedial action for QA, QC, Personnel, PT problems, patient complaints _____

Facilities/Tour
Laboratory Space _____
Processing of tissue_____
Cutting (frozen section) _____
Staining and slide examination _____
Disposition and storage of report, blocks, slides, etc._____

Safety
Hazardous and infectious waste plan _____ and pick-up _____
Safety plan and MSDS _____
Is buffered formalin prepared on-site? _____
Is there a procedure and appropriate documentation the for disposal of xylene and formalin?_____
If xylene and formalin are recycled, is there a procedure and appropriate documentation?_____
Is exposure to xylene and formalin being monitored appropriately?_____
Is each open automated tissue processor operated at least 5 feet from the storage of combustible materials and from the paraffin dispenser?_____
Are microtome knives stored in original containers or by some other means to avoid personnel injury or equipment damage?_____
Are infectious tissues and other contaminated materials disposed of with a minimum danger to professional, technical, and custodial personnel?_____
Are there documented procedures for the special handling of tissues in the histology laboratory from cases in which Creutzfeldt-Jakob disease is suspected?_____
Is there documented procedures for safe disposal of used slides and paraffin blocks?_____

Is there a system to track slides that are being sent for biannual verification? _____
Are criteria available for selecting slides for biannual review and is it in writing? _____

What does the pathologist do when there is a disagreement with the verifier? _____

Policies for
- Specimen collection _____
- Handling _____
- Acceptance _____

Policies for
- Performing test _____
- Recording test _____
- Reporting tests _____
- Record retention? _____

Records of consults _____
CE activities _____
Turnaround time expectations _____
Remedial actions?

Quality Control:
Written procedures available at worksite _____
Written criteria for and maintain documentation of (if applicable)
- Temperature-controlled spaces and equipment _____
- Preventative maintenance activities _____
- Equipment function checks _____
- Procedure calibrations _____
- Method/instrument procedures _____
- Distilled water or ionized water (0.2µ particulate filter)_____

Documentation of (if applicable)
- Tissue Processor Preventive Maintenance:
  - Inspection of reagent bottles checked for leaks or any type of wear_____
  - Inspection of tissue processor retort chamber for cracks, leaks, or broken seals_____
  - Inspection of tissue processor reagent lines for clogs, leaks, and possible wear_____
  - Testing of tissue processer heaters & thermostats for proper temperature_____
  - Testing of tissue processor's pressurization pump for proper function_____
  - Testing of tissue processor's control panel for proper function_____
  - Are the staining dishes labeled accordingly? _____
  - When are changes made to the stains or reagents? _____
  - Are these stain and reagent changes recorded and maintained? _____

- Microtome Preventive Maintenance:
  - Disassembling, inspecting, cleaning, and re-assembling specimen holder_____
  - Disassembling, inspection, cleaning, and re-assembling blade holder_____
  - Removing housing, inspecting and cleaning internal gears and components_____

- Tissue Embedding Center Preventive Maintenance:
  - Inspecting controls for proper function_____
  - Test heaters to insure proper temperature in paraffin reservoir, holding tank, base mold warmer, hot work stage, forceps warmer's, and paraffin dispenser_____

Test for proper function of refrigeration components_____

Paraffin Dispenser Preventive Maintenance:

Test paraffin reservoir heater for proper function_____
Test paraffin dispenser's spout thermostat for proper function_____
Clean paraffin dispenser's spout of wax and dirt build up_____

Tape Coverslipper Preventive Maintenance:

Re-sharpen film cutting blade_____
Test all tape dispensing, slide, and slide rack sensors_____
Inspect proper dispensing of Xylene onto microscope slides_____
Inspect internal components, clean all components, and re-lubricate gears and chains_____

Glass Coverslipper Preventive Maintenance:

Inspect and maintenance of basket container, storage rack, and adjusting dispenser stroke_____
Clean vacuum pad and dispenser holder_____
Replace fuse (as appropriate)_____

Automatic Stainer Preventive Maintenance:

Inspect and test control panel for proper function_____
Inspect plumbing for proper function regarding water supplied in and water drained_____
Inspect and test robotic arm with regard to calibration and proper function_____
Clean ventilation system and replace the carbon filters_____

Microwave Device Maintenance:

Are microwave devices (if applicable) monitored at least annually to ensure that there is less than 5 mW/cm^2 leakage at a distance of 5 cm from the surface?
Are microwave devices (if applicable) periodically monitored for temperature reproducibility?_____
Are all containers used in microwave devices (if applicable) made from microwave-transparent material?_____
Are microwave devices (if applicable) properly ventilated?_____

Hood Maintenance:

Hood Function and Safety Checks (Air Exchange)_____
Safety hood vaneometer (100 lfm)_____

Review stained tissue slides to determine if they are adequate (Slides must be of adequate technical quality to be diagnostically useful. Criteria to evaluate include adequate tissue fixation, thickness of sections, absence of interfering tissue folds and tears, and good staining technique. For hematoxylin and eosin and other routine stains, the patient slide serves as the internal control to ensure staining technique.)

Are positive controls run routinely on special stains, with reactivity results documented, and are they verified for acceptability before reporting results?_____

Are the following stains of high quality, and do they satisfactorily demonstrate (on each day of use), the tissue characteristics for which they were designed and is this documented? (This list is neither all-inclusive nor exclusive of other "special stains" used in a given histology laboratory. For Gram Stain, control slides must demonstrate both Gram-positive and Gran-negative organisms.)

Acid fast organisms_____
Iron_____
Bacteria_____
Elastic tissues_____
Fungi or pneumocystis_____
Mucin_____
Connective tissue_____
Myelin_____
Nerve fibers_____
Periodic acid Schiff (PAS)_____
Glycogen_____
Reticulin fibers_____
Amyloid_____
Methyl green-pyronine (MGP)_____

Documentation of reagents, solutions, culture media, controls, calibrators, standards, reference materials and other testing materials (if appropriate) _____

Are reagents and solutions properly labeled, as applicable and appropriate, with the following?

Content and quantity, concentration or titer_____
Storage requirements_____
Date prepared or reconstituted by laboratory_____
Expiration date_____

Are all reagents, controls, and solutions used within the expiration dates:_____

Documentation of Temperatures on:

Refer _____ Incubator _____

Cryostat _____ Paraffin Bath _____

Are cryostats with digital temperature readout verified with a NIST thermometer? _____

Documentation of preventative maintenance on microscope _____