Describe briefly the most recent revision made to this policy, procedure or protocol & why:
New Procedure

Purpose/Policy Statement:
As part of our performance monitoring process, proficiency testing is performed for each test in order to monitor and evaluate testing processes for accuracy and reliability of analytic results.

Definitions:
• n/a

POLICY CONTENT

With most tests performed this monitoring is achieved through the purchase of external proficiency test samples. If external proficiency samples are not available, alternative methods will be used to evaluate and monitor performance. All tests performed will be monitored. Proficiency test list includes: HQIP, MK, HER2, HQIPBX and PM2.

STEPS / KEY POINTS

External proficiency testing samples are purchased through the College of American Pathologists or through an acceptable vendor for each test/method performed in the laboratory.

Proficiency samples are tested using the same procedures/processes as used for patient samples.

Proficiency samples will be rotated among all appropriate staff working in the testing area across all shifts of operation. This rotation of staff includes technical processing of the samples and pathologists interpretation.

If external proficiency samples are not available for a test/method, an alternative performance assessment system is used. Semi-annual assessment is to be performed.

Alternatives when external proficiency samples are not available include:
Split sample sent to reference lab using comparable methodology
Testing performed independently by two different technologists
Blind testing of samples with known results
Other equivalent system approved by medical director

Results from alternative methods are compared and evaluated using the same format as used with external proficiency testing samples.

All results of alternative or external proficiency testing are reviewed by technical supervisor and pathologist.
There will be no communication with any other laboratory about proficiency testing samples prior to submission of data for grading. No proficiency testing samples will be referred for testing to another laboratory. Also, this laboratory will not perform PT testing from any other laboratory.

All results, external or alternative, will be reviewed including those which indicate:
- a lack of consensus
- that the lab submitted its results after the deadline cutoff.
- that the lab submitted an inappropriate method code
- that the lab did not submit results
- educational challenges

If a result is unacceptable, or if acceptable results show bias or trend, as determined through comparison of results, a complete review of the testing system is conducted.

The cause of the failure should be determined and systems modified as needed to prevent reoccurrence. This investigation and review is documented detailing all the steps reviewed with findings and any system changes. This is reviewed and signed by pathologist.

Investigation of a failure may include any combination of the following:
- Check of sample preparation, testing and reporting of results.
- Review of all-participant report received from the PT provider.
- Review of QC performance, instrument calibration and reagent performance prior to, during and after the original analysis of the PT challenge.
- Change reagent lot numbers of instruments.
- Verify that the PT material was processed in the correct instrument mode and the correct code was entered.
- Retest the PT specimen if possible.
- Seek assistance from the instrument manufacturer.

Corrective action after a PT failure may include, but is not limited to:
- Modification of QC range (narrow).
- Increase in the frequency of calibration.
- Performance of instrument function verification.
- Revision of the analytic process.
- Design of a process to verify clerical entries prior to PT result submission.
- Retraining of personnel with regard to sample preparation, testing and reporting.

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**Equipment/Supplies** (If Applicable):

n/a

**Form Name & Number or Attachment Name** (If Applicable):

Histo29.01

**Author Position**:

Lead Histologist

**Review/Revision Authority** (Position Not Individual Name):

n/a

**Expert Consultant Position/s** (Not Individual Name/s):

n/a

**References** (Required for Clinical Documents):

n/a

**Is there a Regulatory Requirement?** Yes ☐ No ☐

If yes, insert requirement information here:
Review History (No Changes):
n/a

Revision History (Note changes in area under header):
n/a

Computer Search Words:
n/a

Policy, Procedure or Protocol Cross Reference Information:

n/a