Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0882284	03/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Murray Hill Urology, Pc	120 East 34 Street, New York, NY	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation of a vial of urine test strips BTNX Rapid Response Lot# URS 0040167 expiration date 07/2022 on March 15, 2022 at 10:00 AM, the laboratory failed to retain a copy of the BTNX manufacturer's packet insert. FINDINGS: The laboratory failed to retain a copy of the BTNX manufacturer's packet insert for the urine Rapid Response test strips.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) Proficiency Testing (PT) Chemistry & Endocrinology records for 2019, 2020 and 2021 and an interview with the laboratory director and testing person, the laboratory director and testing person failed to sign the attestation forms attesting that the PT samples were tested in the same manner as patient specimens.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the CAP PT 2019, 2020 and 2021 records and an interview with the laboratory director, the laboratory failed to retain copies of the attestation forms by the laboratory director and the testing person for the 2019, 2020 and 2021 test events. FINDINGS: The laboratory director and the testing person confirmed on March 15, 2022 at 10:15 AM, they failed to retain the CAP PT attestation forms for all three events in 2019, 2020 and 2021.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on direct observation of the work area in the main laboratory on March 15, 2022 at 9:45 AM, review of the plan of correction from the survey conducted on March 12, 2019 and an interview with the laboratory director, the laboratory failed to have adequate workbench space. FINDINGS: 1. The laboratory failed to implement and maintain the plan of correction from the survey conducted on March 12, 2019 to ensure adequate workbench space for conducting all phases of testing. a. The workbench spaces were cluttered with papers, manuals, reagents, supplies, safety supplies, test supply materials office supply materials and collection containers 2. The laboratory director confirmed on March 15, 2022 at approximately 9:45 AM, that the laboratory itself was not maintained to ensure the space was adequate for conducting all phases of testing. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 12, 2019.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on review of pathology & cytology test reports and an interview with the

	laboratory director, the laboratory failed to consistently retain tracking records/courier logs of patients' pathology & cytology slides, provided by the technical component laboratory with each slide delivery. FINDINGS: 1. This Physician Office Laboratory (POL) is using a technical component (TC)/professional component (PC) split for Histopathology and Cytology specimens. 2. The laboratory director confirmed on March 15, 2022 at approximately 11:30 AM that the laboratory failed to retain test requisitions/courier logs for patients' Histopathology & urine Cytology specimens, sent to processing Gene Path laboratory with each set of samples from March 1, 2019 through March 12, 2022.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the plan of correction from the survey conducted on March 12, 2019 and review of the CAP PT , result forms, and the PT summary reports in the LABDAQ Laboratory Information System (LIS) and an interview with the testing person, the laboratory failed to retain signed attestation forms and signed PT summary reports for all three test events in 2019, 2020 and 2021. FINDINGS: The plan of correction from the survey conducted on March 12, 2019 stated, "All results are entered on line and electronically for CAP. Going forward we will manually download the attestation form and sign it and keep it with the final scored records." The laboratory failed to implement and maintain the plan of correction. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 12, 2019.
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, lack of Histology & Cytology records and interview with the laboratory director, laboratory failed to establish written policies and procedures to ensure positive patient identification from specimen collection through the reporting of results (refer to D5203); failed to establish written policies and procedures for specimen collection, labeling, storage, transportation, acceptability and rejection (refer to D5311); failed to follow written policies and procedures for the annual evaluation and comparison of laboratory statistics (refer to D5629); failed to establish, reassess and document a workload limit for the Laboratory Director/Technical Supervisor (refer to D5633, D5637 and D5647); and failed to establish written policies and procedures to ensure that reports contain narrative descriptive nomenclature (refer to D5657).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232

	The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, specimen send-out log, lack of procedures for collection of biopsy specimen for Histology testing and urine collection for urine Thin-Prep Cytology and urine specimen for Fluorescence in Situ Hybridization (FISH), the laboratory failed to establish a written procedure for obtaining urology biopsy specimens and urine's specimens for Thin Prep and FISH. FINDINGS: 1. The laboratory failed to establish a written procedure for obtaining urology biopsy specimens and urine's specimens for Thin Prep and FISH. 2. The lack of the following procedures: specimen collection procedure to define the type of urology specimens obtained, identification of the urology specimens from collection, sending out specimens to reference laboratories, Histology and Cytology slides received back into the laboratory for the interpretation and diagnosis by the laboratory director and reporting the results. 3. The laboratory failed to establish a written policy or procedure for retaining test requisitions and tracking logs for the returned Histology, Cytology slides and retrieval of the test reports from the web-based computerized system.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency assessment policy and lack of competency assessment records for the calendar year 2019, 2020 and 2021 and an interview with the laboratory director, the laboratory failed to follow their written policies for competency assessment for the testing person for the calendar years 2019, 2020 and 2021. FINDINGS: The laboratory director confirmed on March 15, 2022 approximately 11:30 AM, that the laboratory failed to follow their written competency assessment polices. a. The testing person who routinely performs only chemistry and endocrinology testing failed to be evaluated for 2019, 2020 and 2021 annual competency. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 12, 2019.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the plan of correction from the survey conducted on March 12, 2019 and review of the CAP PT summary reports for 2019, 2020 and 2021 and an

	interview with the testing person, the laboratory failed to review and evaluate the Endocrinology and Chemistry PT Summary reports for all three events for 2019, 2020 and 2021. FINDINGS: The laboratory failed to implement and maintain the plan of correction from the survey conducted on March 12, 2019, which stated," All results of PT were evaluated and anything less than 100% is investigated. The test is redone using the testing material." The laboratory failed to review and evaluate the CAP PT Summary reports for the Endocrinology and Chemistry PT Summary reports for all three events for 2019, 2020 and 2021. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 12, 2019.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of a written procedures for verifying the accuracy of Histology slides, urine Cytology slides and FISH images, lack of verification records for the 2019, 2020, 2021 Histology, Cytology slides and FISH images and an interview with the laboratory director, the laboratory failed establish a written procedure and perform a verification to verify the accuracy of the 2019, 2020, 2021 Histology slides, urine Cytology slides and FISH images. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 12, 2019.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the plan of correction from the survey conducted on March 12, 2019, laboratory's Quality Assessment (QA) policies and procedures, lack of QA records for 2019, 2020, 2021 and an interview with the testing person the laboratory failed to follow and maintain the QA program, that requires and an annual review. FINDINGS: 1. The laboratory failed to implement and maintain the plan of correction from the survey conducted on March 12, 2019 which stated, "The lab will pay more attention to its established QA program." 2. The laboratory's QA policy requires an annual review for the following: patient confidentiality, patient identification & specimen integrity, compliant investigation, internal communications, personnel competency assessment, proficiency testing, safety, test requisition, procedure manual, quality control, maintenance & function checks, comparison of test results, test records, test reports and data storage & retrieval. 3. The laboratory failed to follow and maintain the QA program, that requires an annual review. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 12, 2019.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, lack of written procedures and an interview with the laboratory director, the laboratory failed to establish written policies and procedures for the following: patient preparation: specimen collection, specimen labeling to include two identifiers and specimen source, specimen storage and preservation, conditions for specimen transportation, specimen acceptability and rejection, specimen referral. FINDINGS: 1. The laboratory's procedure manual failed to establish written policies and procedures for Histology, Cytology and FISH specimen collection, specimen source, specimen storage and preservation, conditions for specimen transportation, specimen acceptability and rejection and specimen referral. a. The laboratory failed to maintain the service manuals for Gene path and Bio reference laboratories used to referral Histology and Cytology specimens. 2. The surveyor observed 28 urine specimen cups in the collection area's refrigerator at 10:30 AM labeled only with the initial of the patients first name and a last name. 3. The laboratory director confirmed on March 15, 2022, at approximately 10:15 AM, the above findings
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on lack of Histology, Cytology and FISH procedures and an interview with the laboratory director, the laboratory failed to have a complete manual to include the following criteria: requirements for type of urology biopsy and urine Cytology/FISH specimens, labeling, storage, preservation, transportation and referral of specimens,

	acceptability and rejection and reporting test results. FINDINGS: 1. The laboratory failed to establish written Histology, Cytology and FISH procedures for the following specimen collection and source, specimen labeling to include two identifiers, accessioning specimens, specimen storage and preservation, conditions for specimen transportation, specimen acceptability and rejection microscopic examination including the detection of inadequately prepared slides, specimen and slide referral, when slides are loaned for consultation and define the process for detecting diagnostic errors in Cytology annual statistical evaluations and reporting test results. 2. The laboratory director confirmed on March 15, 2022, at 10:15 AM the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the refrigerator records in the accessioning area, lack of temperature records for the main laboratory and an interview with the testing person, the laboratory failed to record the two refrigerators/freezers, room temperatures and humidity in the main laboratory and the refrigerator in the collection/accessing area for the calendar years 2019, 2020 and 2021 to survey date. FINDINGS: 1. The laboratory failed to record the two refrigerators/freezers, room temperatures and humidity for the main laboratory and the refrigerator in the collection/accessing area for the calendar years 2019, 2020 and 2021 to survey date a. The main laboratory's refrigerator /freezer are used to store control & calibration materials, patient specimens, analyzers reagents and proficiency testing samples. 2. The traceable thermometers were attached to the main laboratory's two refrigerator/freezers had an calibration outdate of 12/4/2014.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance records and an interview with the laboratory director the laboratory failed to perform an annual preventative maintenance as required by the microscope procedure. FINDINGS: The laboratory failed to perform the required, annual preventative maintenance for the microscope used for interpretation of Histology and Cytology slides. The last recorded date for the preventative maintenance was 2019.
D5433	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and an interview with the laboratory director, the laboratory failed to establish a written policy to define the frequency for the microscope maintenance after use for reviewing the Histopathology and Cytology slides. FINDINGS: The laboratory director confirmed on March 15, 2022 at approximately 10:30 AM, the laboratory failed to establish a written policy to define the maintenance frequency for the microscope used to review the Histopathology and Cytology slides.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, Pentra 400 chemistry Quality Control (QC) & calibration records and an interview with the testing person, the laboratory failed to perform the required calibration verification in 2019, 2020 and 2021. FINDINGS: The laboratory failed to follow their calibration verification procedure which requires calibration verification every six-months for those test analyte's that use two levels of QC material and calibration material that use less than three point calibrators. The laboratory failed to perform the calibration verification for the calendar year 2019, 2020 and 2021.

D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on the lack of annual Cytology statistical evaluations for 2019, 2020, 2021 and an interview with the laboratory director, the laboratory failed to establish policies and procedures to define the criteria used to evaluate the annual statistics and compare the annual statistics to detect errors in the performance of non-cytological examinations and reporting results. FINDINGS: 1. The review of the form titled " All Accounts" forms failed to define the criteria used to perform the annual statistics and a corrective action policy when the overall statically value have discrepancies. a. The form failed to include cytology cases examined, specimens type including the # of unsatisfactory for diagnostic interpretation, patient cases reported by diagnosis b. The form failed to identify and perform corrective action for the QNS-Insufficient Slide for cells - no documentation was available for QNS slides.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, lack of the six-month evaluations for 2019, 2020 and 2021 records and an interview with the laboratory director, the laboratory failed to establish a written policy and procedure to ensure the workload limit for the Laboratory Director/Technical Supervisor was reassessed every six months and adjusted when necessary in 2019, 2020 and 2021. FINDINGS: The laboratory director confirmed on March 15, 2022, at approximately 10:30 AM that the laboratory failed to establish a written policy and procedure to ensure the workload limit for the Laboratory Director/Technical Supervisor was reassessed every six months and adjusted when necessary in 2019, 2020 and 2021
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory procedure manual, plan of correction from the survey conducted on March 12, 2019 and an interview with the laboratory director, the laboratory director failed to ensure overall management of the laboratory. The laboratory director failed to a. ensure the review and evaluation of the annual statistics, refer to D6093; b. ensure that the QA program was maintained, refer to D6094; c. ensure the that the Histology and Cytology procedure manual was complete and approved, refer to D6106; d. ensure the workload list was assessed every six months, refer to D6130. THIS IS A RECITED CONDITION DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 12, 2019.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and an interview with the laboratory director, the laboratory director failed to establish a criterion to QC program. Refer to D5439 and D5637
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of the QA policy and procedures and an interview with the laboratory director, the laboratory director failed to follow and maintain the QA policy and procedures. Refer to D5209, D5211, D5217, D5291, D3031 and D3037 THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 12, 2019
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by:

	Based on review of the laboratory procedure manual and an interview with the laboratory director, the laboratory director failed to ensure the Histology and Cytology procedure manuals were completed. Refer to D5203, D5403, D5429 and D5629
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the laboratory's Histology and Cytology procedure manual and an interview with the laboratory director/technical supervisor, the laboratory director failed to ensure the workload list was assessed every six months. Refer to D5439, D5629 and D5637