STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34D0664386	A. BUILDING _____ B. WING _____	C 02/08/2018

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NORTH CAROLINA BAPTIST HOSPITAL PATHOLOGY LAB	MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157

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D 000	INITIAL COMMENTS	D 000		

A complaint investigation survey was conducted at the facility February 5-8, 2018. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at approximately 4:20 p.m.

The laboratory failed to identify and correct problems in the subspecialty of histopathology. The laboratory failed to ensure the procedure manual was complete for all testing performed. The laboratory failed to ensure equipment and procedures were validated prior to use for patient testing, and failed to perform manufacturers' specified maintenance as required. The laboratory failed to monitor water quality, temperature, and humidity as required. The laboratory failed to perform and document quality control for H&E (hematoxylin and eosin) stains as required, and failed to discard expired supplies.

The laboratory director failed to provide overall management and direction for the laboratory. The laboratory director failed to ensure delegated duties were performed as required. The laboratory director failed to ensure testing personnel were trained prior to testing patients, and failed to ensure policies and procedures were established and followed for monitoring testing personnel competency.

The laboratory tests approximately 25,000 surgical pathology cases per year. As of 2/8/18, the laboratory had identified 4 cases in which erroneous histopathology test results were reported, resulting in unnecessary treatment for three patients and a delay in diagnosis for a fourth patient. Case reviews are ongoing.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D 000	Continued From page 1 Based on the severity of the deficiencies, the Immediate Jeopardy was not abated and the laboratory was placed on a 23 day revocation track.	D 000		
D5028 610H	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1273, and §§493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of policies and procedures, observation, review of 2017 laboratory records, and interview with staff 2/5/18 - 2/8/18, the laboratory failed to identify and correct problems identified during the survey in the subspecialty of histopathology. Findings: 1. The laboratory failed to ensure the procedure manual was complete for all testing performed (See D5403). 2. The laboratory failed to monitor water quality, failed to monitor and document temperature and humidity, and failed to establish temperature and humidity ranges that were consistent with manufacturers' requirements (see D5413). 3. The laboratory failed to discard expired supplies (see D5417). 4. The laboratory failed to verify performance specifications for the faxitron PathVision X-Ray	D5028		

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D5028	Continued From page 2 Analyzer prior to use in patient testing (see D5421). 5. The laboratory failed to establish performance specifications for the modified stain procedures performed on the Artisan Staining System prior to use in patient testing (see D5423). 6. The laboratory failed to perform and document manufacturers' specified maintenance for histology equipment (see D5429). 7. The laboratory failed to perform and document quality control for H&E (hematoxylin and eosin) stains as required (see D5601).	D5028		
D5209 610H	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 the laboratory's policies and procedures and interview with TP (testing personnel) 2/5/18 - 2/8/18, the laboratory failed to establish policies and procedures for monitoring the competency of testing personnel. Findings: Review of the laboratory's procedure manual for the OR (Operating Room) Pathology laboratory revealed there was no written policy or procedure which described the process for evaluating the competency of testing personnel who perform grossing of pathology specimens, including the elements evaluated, the criteria for acceptability,	D5209		

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D5209	Continued From page 3 who is responsible for performing the evaluation, and the corrective action required when competency requirements are not met. During interview 2/7/18 from approximately 12:40 p.m. to 12:55 p.m., TP #1 confirmed that the laboratory did not have a written policy or procedure for conducting competency evaluations.	D5209		
D5403 610H	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.	D5403		

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D5403	Continued From page 4 (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 review of policies and procedures and interview with TP (testing personnel) 2/5/18 - 2/8/18, the OR (Operating Room) Pathology laboratory procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual did not include step-by-step procedures for operation of the faxitron PathVision X-Ray Analyzer, including: a. requirements for specimen collection, selection, and processing; b. startup and shutdown; c. calibration, including the material used and the frequency; d. safety checks, including the documentation required and the frequency of performance; e. a description of the course of action to take if the system becomes inoperable. 2. The procedure manual did not include instructions for issuing a corrected or amended	D5403		

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D5403	Continued From page 5 surgical pathology report. During interview 2/7/18 at approximately 3:30 p.m., TP #1 confirmed that the procedure manual did not include policies and procedures for all testing performed.	D5403		
D5413 610H	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 laboratory procedures, review of 2017 deionized water testing records, review of 2017 histology laboratory temperature and humidity records, review of manufacturers' instructions and interview with the histology supervisor (assistant manager) 2/5/18 - 2/8/18, the laboratory failed to monitor water quality, failed to monitor and document temperature and humidity, and failed to define temperature and humidity requirements which were consistent with manufacturers' requirements. Findings:	D5413		

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D5413	Continued From page 6 1. Deionized Water Review of the laboratory's "Deionized Water testing Histology---SSGP-3" procedure revealed under section "2) Procedure: Deionized Water testing....A test sample of the water from the deionized water tanks in the Histology Special Stain lab must be take each month. The technician assigned to covering that lab shall be responsible for performing the following procedure at least monthly, unless > 2000 organisms is detected three months in a row. The assistant manager should be notified of this occurrence and service on the unit ordered. Then the water test must be done weekly until there is a full three-month span with no growth." Review of 2017 deionized water testing records revealed documentation that a sample was sent to the laboratory microbiology department each month for testing. There were no records to indicate what results were obtained from the monthly testing of the deionized water or if the results were reviewed to determine if weekly testing was needed. During interview 2/6/18 at approximately 11:00 a.m., the histology supervisor (assistant manager) confirmed the laboratory did not receive reports or review the results obtained from the deionized water testing. 2. Temperature and Humidity a. There were no temperature and humidity records available for review from the OR (Operating Room) Pathology laboratory. The laboratory operates two Leica cryostats and one Shandon Varistain instrument in this area.	D5413		

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D5413	Continued From page 7 During interview 2/8/18 at approximately 9:15 a.m., the histology supervisor (assistant manager) confirmed they were not monitoring or documenting the temperature and humidity for the OR Pathology laboratory. b. The Artisan staining system operators manual specifies operation in an environment with room temperature of 15-35 degrees Celsius (59-95 degrees Fahrenheit) at 15-75% relative humidity. Review of temperature and humidity logs for the Neuro IHC (Immunohistochemistry) laboratory, where two Artisan staining system instruments were operated by the laboratory, revealed a laboratory defined acceptable room temperature range of 64-104 degrees Fahrenheit and a laboratory defined acceptable humidity range of 10% - 60%. c. The ClearVue cryostat operators manual recommends a room temperature range of 15-30 degrees Celsius (59-86 degrees Fahrenheit). Under "Environmental requirements", it states "Operating temperature range (ambient temperature): 18 degrees C to 40 degrees C. All specifications related to temperature are valid only up to an ambient temperature of 22 degrees C and an air humidity lower than 60%!" Review of temperature and humidity logs for the Special Stains laboratory, where a ClearVue cryostat was operated by the laboratory, revealed a laboratory defined acceptable room temperature range of 64-104 degrees Fahrenheit and a laboratory defined humidity range of 10%-60%.	D5413		

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D5413	Continued From page 8 d. Review of the Leica Autostainer operators manual revealed, under "Technical data"....."Operating temperature range: +10 degrees C to +35 degrees C" (50-95 degrees Fahrenheit). The operators manual also specifies a "Relative humidity: max. 80% non-condensing." Review of temperature and humidity logs for the Main Histology laboratory, where the laboratory operated two Leica Autostainers, revealed a laboratory defined acceptable room temperature range of 50-86 degrees Fahrenheit and a laboratory defined acceptable humidity range of 10%-90%.	D5413		
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, review of 2016 and 2017 safety records, and interview with staff 2/5/18 - 2/8/18, the laboratory failed to discard supplies that exceeded their expiration dates. Findings: 1. During a tour of the OR (Operating Room) Pathology laboratory 2/5/17 at approximately 1:30 p.m., the surveyor observed the following expired items on the shelves behind the cryostats, available for use: a. Diff-Quik Solution I, Lot # 661616031A, Expiration Date 2017-09-30; b. Diff-Quik Solution II, Lot # 661716031A, Expiration Date 2017-09-30.	D5417		

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D5417	Continued From page 9 2. During a tour of the Neuro IHC (Immunohistochemistry) laboratory 2/7/18 at approximately 1:00 p.m., the surveyor observed the following expired items on the shelves lining the laboratory, available for use: a. Sigma Chemical Tartaric Acid, Lot # T0375, Expiration Date 11-07; b. Sodium Arsenate dibasic Heptahydrate, Lot # A6756-50C, Expiration Date 11-02-09; c. Arsenic Acid, Lot # 98H0273, Expiration Date 03-06. 3. During a tour of the Special Stains laboratory 2/7/18 at approximately 1:00 p.m., the surveyor observed the following expired item on the shelves lining the laboratory, available for use: a. Thiosemicarbazide, Expiration Date: 11/2/05. In addition, the surveyor observed that the Sodium Bisulfate received in 1998 and opened in 2013 did not include an expiration date. Review of 2016 and 2017 safety records revealed the laboratory compliance team conducted audits of the OR Pathology laboratory, the Neuro IHC laboratory, and the Special Stains laboratory 7/5/16, 1/12/17, 4/18/17, and 10/24/17. Expired supplies were noted on each of their reports. During interview 2/7/18 at approximately 2:30 p.m., the Laboratory Compliance, Safety and Quality Manager confirmed that the expired supplies were identified during routine audits and noted on the Department of Pathology General Safety Inspection reports. She verified that the laboratory was aware of the audit findings.	D5417		
D5421	ESTABLISHMENT AND VERIFICATION OF	D5421		

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D5421 610H	Continued From page 10 PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the absence of validation documentation and interview with the laboratory director and TP (testing personnel) 2/5/18 - 2/8/18, the laboratory failed to document that the faxitron PathVision X-Ray Analyzer installed in the OR (Operating Room) Pathology laboratory, achieved the performance specification standards established by the manufacturer prior to initiating patient testing. During interview 2/5/18 at approximately 3:15 p.m., the laboratory director stated that the faxitron PathVision X-Ray Analyzer had been recently purchased, and had been installed and placed into operation in December 2017. He confirmed that the laboratory had not verified the performance specifications prior to initiating patient testing, and there was no validation documentation available for review. During interview 2/5/18 at 4:00 p.m., TP #1 stated	D5421		

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D5421	Continued From page 11 that the manufacturer installed the faxitron PathVision X-Ray Analyzer analyzer in the OR Pathology laboratory on 12/22/17 and six operators were trained at that time. She stated that immediately after training, the laboratory began using the device for patient testing.	D5421		
D5423 610H	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of special stain procedures, and interview with the histology supervisor (assistant manager) 2/5/18 - 2/8/18, the laboratory failed to establish performance characteristics for modified staining procedures performed on the two Artisan Staining	D5423		

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D5423	Continued From page 12 Systems. Findings: Review of the Artisan Staining system user guide revealed special staining procedures are ".....imported from the Artisan Procedures and Libraries CD-ROM or created using the IHC Editor. The Procedure Library is the database of staining procedures that have been imported and is loaded when the system software starts. Staining procedures listed on the Program Manager screen consist of three classes: released procedures, user-defined procedures, and IHC procedures." Review of the Artisan Staining system "Procedure Manager" screen revealed modified or "user-defined" special staining procedures were designated by the symbol NCB. The following special staining procedures were modified by the laboratory and designated by the symbol NCB: 1. NCB-AFB (Acid Fast Bacteria) 2. NCB-Congo Red 3. NCB-Gram 4. NCB-Masson's 5. NCB-Mucin (Mucicarmine) 6. NCB-PAS (Periodic acid-schiff) 7. NCB-PAS-D (Periodic acid-schiff diatase) 8. NCB-Trichrome Green Review of histology laboratory records revealed no documentation that performance characteristics of the modified special staining procedures were established by the laboratory to ensure accurate and reliable results. During interview on 2/8/18 at approximately 9:15 a.m., the histology supervisor (assistant manager) confirmed that the NCB symbol indicated special staining procedures that had	D5423		

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D5423	Continued From page 13 been modified by the histology laboratory. She stated she was sure the changes must have been verified, but she was unable to provide documentation.	D5423		
D5429 610H	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 manufacturers' instructions, the absence of 2017 maintenance records, and interview with the histology supervisor (assistant manager) 2/5/18 - 2/8/18, the laboratory failed to perform and document required maintenance for equipment used in the testing process. Examples: 1. Manufacturer's instructions (user manual) for the two Leica Auto Stainers located in the Main Histology laboratory stated "Fumes are exhausted through the activated carbon filter which must be changed every three months...." There was no documentation that the carbon filter was changed every three months as specified by the manufacturer. 2. Manufacturer's instructions (user manual) for the two Artisian Staining Systems located in the Neuro IHC (Immunohistochemistry) laboratory included a list of maintenance procedures to be performed on a daily and weekly basis: "Table 11.1 - Daily and Monthly Maintenance Procedures". The table included the following daily maintenance procedures: prime bulk liquid	D5429		

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D5429	Continued From page 14 bottles, perform waste valve rinse, clean slide platform, clean reagent drip ring, check and clean spill tray. The table also included the following monthly maintenance procedures: clean bulk liquid bottles and flush bulk liquid lines with ethanol. There was no documentation that the required daily and monthly maintenance procedures were performed as specified by the manufacturer. 3. Manufacturer's instructions (user manual) for the two Leica CM1950 Cryostats located in the OR Pathology laboratory stated in the section "Instructions for changing the bacteria filter", that "The filter must be changed approx. every 3 months." There was no documentation that the filter was changed every three months as specified by the manufacturer. During interview 2/5/18 at approximately 4:00 p.m., the histology supervisor (assistant manager) stated that there is no required maintenance other than daily cleaning for any of the equipment in the histology department.	D5429		
D5601 610H	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in §493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.	D5601		

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D5601	Continued From page 15 This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2017 H&E (Hematoxylin and Eosin) quality control records and interview with the histology supervisor (assistant manager) 2/5/18 - 2/8/18, the laboratory failed to perform and document quality control to ensure predictable staining characteristics for the H&E (hematoxylin and eosin) stains performed in the OR (Operating Room) Pathology laboratory and failed to document quality control for each instrument performing H&E staining in the Main Histology laboratory. Findings: 1. The histology laboratory procedure, "Slide Checking Criteria Histology-ML-31", states " 2) Procedure: Slide Checking Criteria", "H&E (Hematoxylin and Eosin) QC (Quality Control) - A control slide for H&E staining is stained at the beginning of a run....The slide is reviewed by the histo tech. The slide is put at the beginning of the OR slides, along with a form of stain acceptability. The slide is returned along with the form back to the histology lab to be filed." There were no quality control records for the H&E staining performed in the OR Pathology laboratory available for review. During interview 2/6/18 at approximately 9:00 a.m., the histology supervisor (assistant manager) confirmed there were no quality control records for the H&E staining performed in the OR Pathology laboratory. She stated that H&E quality control for the OR Pathology laboratory was not being performed. 2. The laboratory performs H&E staining on two separate Leica stainers in the Main Histology	D5601		

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D5601	Continued From page 16 laboratory. The Leica stainers are designated #1 and #2. During interview 2/6/18 at approximately 9:00 a.m., the histology supervisor (assistant manager) stated that they use one "DAILY QUALITY CONTROL HEMATOXYLIN AND EOSIN STAIN" form each day of testing and two slides are sent with the form, labeled #1 and #2. Review of the 2017 "DAILY QUALITY CONTROL HEMATOXYLIN AND EOSIN STAIN" forms used to document the daily H&E controls for the "Main Histology Room" revealed only one form was used each day that patient H&E slides were stained. The form had a space to document acceptability of the stain, but did not include space to document acceptability for the control slide stained on each instrument (#1 and #2).	D5601		
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 policies and procedures, review of 2017 laboratory records, and interview with staff 2/5/18 - 2/8/18, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure delegated responsibilities were detailed, specific, and were performed as required by the designee (see D6079).	D6076		

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D6076	Continued From page 17 2. The laboratory director failed to ensure testing personnel were trained and the training was documented prior to testing patient specimens (see D6102). 3. The laboratory director failed to ensure competency evaluation policies were established and followed (see D6103, D6128).	D6076		
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of procedure manuals, review of personnel records, and interview with staff 2/5/18 - 2/8/18, the laboratory director delegated responsibilities to another pathologist (Surgical Pathology director), but failed to ensure the delegated duties were performed as required. Findings:	D6079		

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D6079	Continued From page 18	D6079		

Review of procedure manuals in the OR (Operating Room) Pathology laboratory, the Special Stains laboratory, and the Main Histology laboratory revealed copies of a letter of delegation dated January 1, 2014. The letter, labeled "MEMORANDUM OF INFORMATION", was signed by the current laboratory director. The letter designated the pathologist serving as the Surgical Pathology director "To sign off on and maintain documentation as required by our Regulatory Agencies." The letter did not include a specific, detailed list of duties and responsibilities.

The procedure manuals also contained a "MEMORANDUM OF INFORMATION" from the pathologist serving as the Surgical Pathology director which delegated "the authority to sign off on documentation as required by our Regulatory Agencies and to assess employee competency for the laboratory section(s) noted above" to the histology supervisor (assistant manager). This "MEMORANDUM OF INFORMATION" was also dated January 1, 2014.

Review of personnel records revealed the histology supervisor (assistant manager) does not meet the education requirements to serve as a technical supervisor or general supervisor in a high complexity histopathology laboratory. The responsibilities for review of records and testing personnel competency assessment could not be delegated to the histology supervisor (assistant manager).

The pathologist serving as Surgical Pathology director at the time of the delegation left laboratory employment in September 2017, but delegation of duties documentation had not been updated to reflect specific responsibilities

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D6079	Continued From page 19 delegated to current designees.	D6079		
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, the absence of training records, and interviews with TP (testing personnel) 2/5/18 - 2/8/18, the laboratory director failed to ensure that prior to testing patient specimens, 20 of 21 testing personnel received appropriate training and had demonstrated they could perform all testing operations reliably to provide accurate patient test results. Findings: 1. Review of personnel records for TP #2 (hired 12/29/17) who performs grossing of pathology specimens in the OR (Operating Room) Pathology laboratory revealed there was no documentation of training available for review. A document labeled "Surgical Pathology Gross Room Direct Supervision and Competency." was included with the personnel records for TP #2, but the document did not include the name of the testing personnel, the date(s) of review, or the name of the reviewer. There were no records available to document that TP #2's training was complete and she was approved to perform testing independently.	D6102		

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D6102	Continued From page 20 During interview 2/7/18 from approximately 12:40 p.m. to 12:55 p.m., TP #1 stated the document labeled "Surgical Pathology Gross Room Direct Supervision and Competency." is the training documentation for TP #2. During the interview, TP #1 also provided a log of cases that TP #2 grossed during training. TP #1 confirmed during the interview that there was no documentation available to indicate that TP #2's training was complete and she was approved by the laboratory director to perform testing independently. 2. There were no training records available for review for 19 of 19 residents (TP #3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21) who perform grossing of pathology specimens in the OR Pathology laboratory. During interview on 2/6/18 from approximately 8:30 a.m. to 9:00 a.m., TP #6 and TP #7 stated that an upper level resident works with each lower level resident during his/her first week to go over how to gross each type of pathology specimen. They stated that after the first week, the residents typically gross specimens independently, but there is a grossing manual available on the intranet for reference and the PA (pathologists' assistant) is also available if needed to answer questions. They stated they were not aware of a training form and they were unsure whether the training was documented anywhere. During interview 2/7/18 from approximately 12:40 p.m. to 12:55 p.m., TP #1 stated first year residents are trained by fourth year residents, but she was unsure whether the training is documented. TP #1 also stated she used to document training for the residents, but she is no longer responsible for that. She stated she has	D6102		

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D6102	Continued From page 21 not done it in several years.	D6102		
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures 2/5/18 - 2/8/18 and the deficiency cited at D5209, the laboratory director failed to ensure that policies and procedures were established for monitoring the competency of testing personnel in the OR (Operating Room) Pathology laboratory.	D6103		
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP (testing personnel) 2/5/18 - 2/8/18, the technical supervisor failed to perform	D6128		

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D6128	Continued From page 22 and document a competency evaluation for 1 of 21 TP (TP #1) in the OR (Operating Room) Pathology laboratory. Review of personnel records for TP #1 revealed several copies of the same document with the title "Evaluation of Skills and Abilities for Professional, Supervisory & Management Positions". Instructions at the top of the form state "Put an 'X' in the box beside the most appropriate descriptive statement of the employee's performance. Provide additional feedback in the comments section as appropriate." The form listed the following items to be evaluated: Quality of Work, Quantity of Work, Planning and Organization, Job Knowledge, Problem Solving, Teamwork, Customer Service, Initiative, Communication, Decision Making, Dependability, Attendance, Punctuality, Environmental Health and Safety, Leadership, Delegation of Work, Training and Development. The copies of the document had been filled out according to the instructions, and different comments were handwritten on the last page of each copy. The copies did not include dates that the "evaluations" were conducted, and they were not signed, so it was unclear who conducted them. During interview 2/7/18 from approximately 12:40 p.m. to 12:55 p.m., TP #1 stated that the pathologist who served as Surgical Pathology director used to evaluate her competency, but that changed in the last few years. She stated the last Surgical Pathology director did not evaluate her competency during 2016 and 2017.	D6128		