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

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{A 000}	INITIAL COMMENTS A complaint investigation was conducted jointly with members of DHSR CLIA staff February 5, 2018 through February 8, 2018 to determine the facility's compliance with the Federal Medicare Conditions of Participation for Hospitals. The complaint investigation resulted in identification of an immediate jeopardy to the health and safety of patients as evidenced by the Governing Body and Medical Staff's failure to provide oversight and ensure laboratory specimens were appropriately processed with accurate results for medical interventions. Pursuant to 482.12 Governing Body and 482.22 Medical Staff, facility staff failed to provide oversight of Laboratory Services, in particularly the subspecialty of histopathology. The facility's administrative staff was notified on February 8, 2018 at 1620 of the identification of the immediate jeopardy. 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	{A 000}		

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

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{A 000}	Continued From page 1	{A 000}		

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 February 8, 2018, the laboratory identified four (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.

Based on the severity of the deficiencies and action the immediate jeopardy was not abated and determined to be on-going.

A follow-up survey was conducted at the facility March 21, 2018 through March 23, 2018, and March 26, 2018. Based on follow-up survey findings, the Immediate Jeopardy was abated and conditions remain uncorrected.

As of March 26, 2018, the laboratory had identified a total of 9,291 histopathology cases requiring review, and reviews had been performed for 1,422 of the cases. During reviews conducted since the February 5-8, 2018 complaint investigation survey, the laboratory had identified an additional 25 cases in which erroneous histopathology test results were reported. The erroneous histopathology test results resulted in unnecessary treatment for 3 patients and a potential delay in treatment for 3 other patients. For the other 19 patients, treatment was not impacted. Case reviews are ongoing.

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{A 043}	Continued From page 2	{A 043}		
{A 043}	GOVERNING BODY CFR(s): 482.12 There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ... This CONDITION is not met as evidenced by: Based on review of hospital laboratory policies and procedures, testing personnel files, and testing personnel interviews February 5, 2018 through February 8, 2018, the Governing Body failed to provide oversight of Laboratory Services and ensure laboratory specimens were appropriately processed with accurate results for medical interventions, in particularly the subspecialty of histopathology. Findings include: The hospital laboratory failed to be in compliance with CFR 493.... as referenced in the report of survey conducted by Clinical Laboratory Improvement Amendment (CLIA) staff February 5, 2018 through February 8, 2018. D5028: Histopathology : CFR 493.1219 D5403: Procedure Manual : CFR 493.1251(b) D5421: Establishment and Verification of Performance: CFR 493.1253(b)(1) D5429: Maintenance and Function Checks: CFR 493.1254(a)(1) D6076: Laboratory Director Responsibilities: CFR 493.1441 D6079: Laboratory Director Responsibilities: CFR 493.1445(a)(b) D6102: Laboratory Director Responsibilities:	{A 043}		

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{A 043}	Continued From page 3 CFR 493.1445(e)(12) A) The laboratory tests approximately 25,000 surgical pathology cases per year. As of February 8, 2018, 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. B) The laboratory director delegated responsibilities to another pathologist (Surgical Pathology Director), but failed to ensure the delegated duties were performed as evidenced by the following: 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.	{A 043}		

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{A 043}	Continued From page 4 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 delegated to current designees. C) The laboratory director failed to provide overall management and direction for the laboratory. D) 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. 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 as evidenced by the following: 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...."	{A 043}		

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{A 043}	Continued From page 5 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 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. E) The laboratory failed to monitor water quality, failed to monitor and document temperature and	{A 043}		

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{A 043}	Continued From page 6	{A 043}		

humidity, and failed to establish temperature and humidity ranges that were consistent with manufacturers' requirements as evidenced by the following :

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.

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

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{A 043}	Continued From page 7	{A 043}		

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.

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

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{A 043}	Continued From page 8 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%. 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%. 3. Observation, review of 2016 and 2017 safety records, and interview with staff 2/5/18 - 2/8/18, revealed the laboratory failed to discard supplies that exceeded their expiration dates. Findings include:	{A 043}		

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{A 043}	Continued From page 9 1. During tour of the OR (Operating Room) Pathology laboratory 2/5/17 at approximately 1:30 p.m., the following expired items were observed 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. 2. During a tour of the Neuro IHC (Immunohistochemistry) laboratory 2/7/18 at approximately 1:00 p.m., the following expired items were observed 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 following expired item was observed on the shelves lining the laboratory, available for use: a. Thiosemicarbazide, Expiration Date: 11/2/05. Observation revealed 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.	{A 043}		

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{A 043}	Continued From page 10 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. F) The laboratory failed to ensure the procedure manual was complete for all testing performed. G) 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 as evidenced by the following: 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. 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	{A 043}		

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{A 043}	Continued From page 11 complete and she was approved to perform testing independently. 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	{A 043}		

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{A 043}	Continued From page 12 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 not done it in several years. H) The laboratory failed to verify performance specifications for the faxitron PathVision X-Ray Analyzer prior to use in patient testing. I) The laboratory failed to establish performance specifications for the modified stain procedures performed on the Artisan Staining System prior to use in patient testing In summary the Governing Body failed to provide oversight and ensure the Laboratory Director provided overall management and direction for the delivery of quality laboratory services. As a result, laboratory specimens were processed with erroneous results. As of March 26, 2018, the laboratory had identified a total of 9,291 histopathology cases requiring review, and reviews had been performed for 1,422 of the cases. During reviews conducted since the February 5-8, 2018 complaint investigation survey, the laboratory had identified an additional 25 cases in which erroneous histopathology test results were reported. The erroneous histopathology test results resulted in unnecessary treatment for 3 patients and a potential delay in treatment for 3 other patients. For the other 19 patients, treatment was not impacted. Case reviews are ongoing.	{A 043}		
{A 115}	PATIENT RIGHTS CFR(s): 482.13	{A 115}		

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{A 115}	Continued From page 13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on review of hospital laboratory policies and procedures, testing personnel files, and testing personnel interviews February 5, 2018 through February 8, 2018, the hospital staff failed to provide oversight of Laboratory Services and ensure laboratory specimens were appropriately processed with accurate results for medical interventions, in particularly the subspecialty of histopathology. Thereby, the hospital failed to provide patients with appropriate care, treatment and services. Findings include: A. Based on review of hospital laboratory policies and procedures, testing personnel files, and testing personnel interviews February 5, 2018 through February 8, 2018, the Medical Staff failed to provide oversight of Laboratory Services and ensure laboratory specimens were appropriately processed with accurate results for medical interventions, in particularly the subspecialty of histopathology. Medical Staff failed ensure to the hospital's Laboratory Director provided oversight to ensure the delegated responsibilities assigned to another pathologist (Surgical Pathology Director), were performed as required. ~ Cross Reference, §482.22 Medical Staff : A-338 B. Based on review of policies and procedures, review of 2017 laboratory records, and interview with staff February 5, 2018 through February 8, 2018, the laboratory director failed to provide overall management and direction for the laboratory. The laboratory failed to have	{A 115}		

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{A 115}	Continued From page 14 systems implemented to ensure specimens were appropriately processed with accurate results for medical interventions, in particularly the subspecialty of histopathology. ~ Cross Reference, §482.27 Laboratory Services: A-576 In summary the Governing Body, Medical Staff failed to provide oversight and ensure the Laboratory Director provided overall management and direction for the delivery of quality laboratory services. As a result, laboratory specimens were processed with erroneous results which impacted medical interventions rendered to patients.	{A 115}		
A 263	QAPI CFR(s): 482.21 The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on review of laboratory procedures,	A 263		

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A 263	Continued From page 15 manufacturer's instructions, laboratory equipment maintenance records, review of 2017 H&E (Hematoxylin and Eosin) quality control records, lab personnel files, ad staff interviews, the laboratory failed to develop and implement quality improvements to promote the delivery of quality laboratory services with appropriately processed accurate results for medical interventions. Pursuant to 482.12 Governing Body and 482.22 Medical Staff, facility staff failed to provide oversight of Laboratory Services, in particularly the subspecialty of histopathology. Findings include: As of March 26, 2018, the laboratory had identified a total of 9,291 histopathology cases requiring review, and reviews had been performed for 1,422 of the cases. During reviews conducted since the February 5-8, 2018 complaint investigation survey, the laboratory had identified an additional 25 cases in which erroneous histopathology test results were reported. The erroneous histopathology test results resulted in unnecessary treatment for 3 patients and a potential delay in treatment for 3 other patients. For the other 19 patients, treatment was not impacted. Case reviews are ongoing.	A 263		
{A 283}	QUALITY IMPROVEMENT ACTIVITIES CFR(s): 482.21(b)(2)(ii), (c)(1), (c)(3) (b) Program Data (2) [The hospital must use the data collected to -.....] (ii) Identify opportunities for improvement and changes that will lead to improvement. (c) Program Activities	{A 283}		

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{A 283}	Continued From page 16 (1) The hospital must set priorities for its performance improvement activities that-- (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety, and quality of care. (3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, manufacturer's instructions, laboratory equipment maintenance records, review of 2017 H&E (Hematoxylin and Eosin) quality control records, lab personnel files, ad staff interviews, the laboratory failed to develop and implement quality improvements to promote the delivery of quality laboratory services with appropriately processed accurate results for medical interventions. Pursuant to 482.12 Governing Body and 482.22 Medical Staff, facility staff failed to provide oversight of Laboratory Services, in particularly the subspecialty of histopathology. Findings include: A) 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,	{A 283}		

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{A 283}	Continued From page 17 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 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. B) 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 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	{A 283}		

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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 been modified by the histology laboratory. She stated she was sure the changes must have been verified, but she was unable to provide documentation.

C) Based on review of manufacturer's 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

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{A 283}	Continued From page 19 required maintenance for equipment used in the testing process as evidenced by the following: 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 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.	{A 283}		

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{A 283}	Continued From page 20 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. D) 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	{A 283}		

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{A 283}	Continued From page 21 performed. 2. The laboratory performs H&E staining on two separate Leica stainers in the Main Histology 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). In summary, the laboratory tests approximately 25,000 surgical pathology cases per year. As of February 8, 2018, the laboratory identified four (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 since the initial identification in September 2017.	{A 283}		
{A 338}	MEDICAL STAFF CFR(s): 482.22 The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the	{A 338}		

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hospital.
This CONDITION is not met as evidenced by:
Based on review of hospital laboratory policies and procedures, testing personnel files, and testing personnel interviews February 5, 2018 through February 8, 2018, the Medical Staff failed to provide oversight of Laboratory Services and ensure laboratory specimens were appropriately processed with accurate results for medical interventions, in particularly the subspecialty of histopathology. Medical Staff failed ensure to the hospital's Laboratory Director provided oversight to ensure the delegated responsibilities assigned to another pathologist (Surgical Pathology Director), were performed as required. Findings include:

A) 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

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{A 338}	Continued From page 23 dated January 1, 2014. B) Review of personnel records revealed the histology supervisor (assistant manager) did 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). C) The pathologist serving as Surgical Pathology director at the time of the delegation left laboratory employment in September 2017, and delegation of duties documentation had not been updated to reflect specific responsibilities delegated to current designees. D) 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. As evidenced by the following: 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	{A 338}		

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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.

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

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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 not done it in several years.

E) Review of the laboratory's policies and procedures 2/5/18 - 2/8/18 and survey findings, 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 as evidenced by the following: .

1) Review of personnel records and interview with TP (testing personnel) 2/5/18 - 2/8/18, the technical supervisor failed to perform and document a competency evaluation for 1 of 21 TP (TP #1) in the OR (Operating Room) Pathology laboratory.

2) 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

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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.

3) 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.

F) Interview on 02/05/2018 at 1200 with MD #11, the Chief Medical Officer, revealed "We've had a work flow/work force imbalance." Interview revealed there had been corrective actions and changes in the anatomical pathology laboratory as a result of expressed concerns. "There were reasons that led to a change in leadership as a result of feedback the organization received. We are deep in the midst of a complex and deep review to see if we have a quality issue." The interview revealed "We've internally and externally reviewed and found our care did not meet our standards." The hospital was now in a review process and were re-reviewing "100 percent" of the breast cancer cases. The interview revealed the organization had not reached a "summative conclusion" and they had disclosure meetings with all patients involved, they had "attempted to put more qualified individuals into the workflow," new leadership, and upregulated the process of dual reads (already had dual reads on all outside cases). Interview revealed there was no evidence to date that the organization had a problem other than

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{A 338}	Continued From page 27 the work by MD #7, "who is now gone." G) Interview on 02/05/2018 at 1245 and on 02/08/2018 at 1415 with MD #10, the Chair of the Pathology Department, revealed he had been in his position since August of 2017. Interview revealed he was asked to chair after the previous Chair (MD #7) separated from the organization. Interview revealed the hospital had recently "as of last Monday," hired a new Director of Surgical Pathology. Interview revealed they implemented a mandatory second review for all new breast biopsies to be documented on the pink sheets. The interview revealed "the nexus was clearly on breast biopsies, and the "new breast cancer policy (mandatory second review for all new breast biopsies) was implemented January first. Interview revealed any new breast cancer diagnosis, whether in house or external, was now to be reviewed by two Pathologists. Interview revealed "pink sheets" were created to ensure a second reading for all the newly diagnosed breast cancer specimens. Interview revealed the "ultimate goal" would be to add a second reading for all positive malignancies. When asked about monitoring the "pink sheets" for compliance with the two reads, MD #10 replied they were only in the first month and his plan was "to wait a few months then identify all the breast cancers, then see if we have a pink sheet." MD #10 stated he wanted to "allow for implementation before collecting data."	{A 338}		
{A 576}	LABORATORY SERVICES CFR(s): 482.27 The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all	{A 576}		

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{A 576}	Continued From page 28	{A 576}		

laboratory services provided to its patients are performed in a facility certified in accordance with Part 493 of this chapter.

This CONDITION is not met as evidenced by:
Based on review of policies and procedures, review of 2017 laboratory records, and interview with staff February 5, 2018 through February 8, 2018, the laboratory director failed to provide overall management and direction for the laboratory. The laboratory failed to have systems implemented to ensure specimens were appropriately processed with accurate results for medical interventions, in particularly the subspecialty of histopathology. Findings include:

A) The hospital laboratory failed to be in compliance with CFR 493.... as referenced in the report of survey conducted by Clinical Laboratory Improvement Amendment (CLIA) staff February 5, 2018 through February 8, 2018.

D5028: Histopathology : CFR 493.1219
D5403: Procedure Manual : CFR 493.1251(b)
D5421: Establishment and Verification of Performance: CFR 493.1253(b)(1)
D5601: Histopathology: CFR 493.1273(a)(f))
D6076: Laboratory Director Responsibilities: CFR 493.1441
D6079: Laboratory Director Responsibilitie: CFR 493.1445(a)(b)
D6102: Laboratory Director Responsibilities: CFR 493.1445(e)(12)

B) The laboratory director delegated responsibilities to another pathologist (Surgical Pathology director), but failed to ensure the delegated duties were performed as required. The laboratory failed to identify and correct

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{A 576}	Continued From page 29 problems in the subspecialty of histopathology. 6079 C) The laboratory director failed to provide overall management and direction for the laboratory. D) 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. E) The laboratory failed to monitor water quality, temperature, and humidity as required. F) 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. G) The laboratory failed to ensure the procedure manual was complete for all testing performed. Review of the Operating Room (OR) Pathology laboratory procedure manual was not complete and current for the testing performed as evidenced by the following: 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.	{A 576}		

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{A 576}	Continued From page 30 2. The procedure manual did not include instructions for issuing a corrected or amended surgical pathology report. During interview February 7, 2018 at approximately 3:30 p.m., TP #1 confirmed that the procedure manual did not include policies and procedures for all testing performed. H) 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. I) The laboratory failed to verify performance specifications for the faxitron PathVision X-Ray Analyzer prior to use in patient testing. 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 surgical pathology report. 3. 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	{A 576}		

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{A 576}	Continued From page 31 testing performed. J) The laboratory failed to establish performance specifications for the modified stain procedures performed on the Artisan Staining System prior to use in patient testing' 1. 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. 2. 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%. K) The laboratory tests approximately 25,000 surgical pathology cases per year. As of February 8, 2018, 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. 1. The laboratory director failed to ensure delegated responsibilities were detailed, specific, and were performed as required by the designee. 2. The laboratory director failed to ensure testing personnel were trained and the training was documented prior to testing patient specimens. 3. The laboratory director failed to ensure competency evaluation policies were established	{A 576}		

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{A 576}	Continued From page 32 and followed. As of March 26, 2018, the laboratory had identified a total of 9,291 histopathology cases requiring review, and reviews had been performed for 1,422 of the cases. During reviews conducted since the February 5-8, 2018 complaint investigation survey, the laboratory had identified an additional 25 cases in which erroneous histopathology test results were reported. The erroneous histopathology test results resulted in unnecessary treatment for 3 patients and a potential delay in treatment for 3 other patients. For the other 19 patients, treatment was not impacted. Case reviews are ongoing.	{A 576}		
{A 582}	ADEQUACY OF LABORATORY SERVICES CFR(s): 482.27(a) The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets the requirements of part 493 of this chapter. This STANDARD is not met as evidenced by: Based on review of facility policies, facility's Medical Staff Bylaws, medical record review, and interview, the facility laboratory failed provide oversight of Laboratory Services and ensure laboratory specimens were appropriately processed with accurate results for medical interventions, in particularly the subspecialty of histopathology for sampled patients (Patient #1, Patient #2, Patient #3, Patient #4). The findings include: A) The laboratory tests approximately 25,000 surgical pathology cases per year. As of February	{A 582}		

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{A 582}	Continued From page 33 8, 2018, 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. B) Review of the facility policy "Breast Cancer Case Reviews Prior to Initiating Therapy," effective 01/02/2018, revealed "The pathology department provides diagnostic services that are critical to successful treatment of cancer patients. The pathologist's interpretations and review of specimens are critical to determining appropriate treatment for all cancer patients, and thus they are important members of the treatment team and are a significant component of quality care for [the facility] ... It is therefore the policy of [name of facility] to ensure that all breast biopsies and other surgical procedures performed by an outside facility are reviewed by Pathology prior to the patient receiving the first course of treatment." C) Review of the "MEDICAL STAFF BYLAWS, POLICIES, AND RULES AND REGULATIONS OF [NAME OF FACILITY]," revealed "...5.E. PERFORMANCE IMPROVEMENT FUNCTIONS (1) The Medical Staff is actively involved in the measurement, assessment, and improvement of at least the following: (a) patient safety, including processes to respond to patient safety alerts, meet patient safety goals, and reduce patient safety risks;...(f)operative and other invasive procedures, including tissue review and review of discrepancies between pre-operative and post-operative diagnoses;..." D) Review of Patient #3's medical record revealed a female patient status post a mammogram screening on May 17, 2017. The	{A 582}		

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radiology report revealed calcifications in the medial central left breast, middle third and documented "additional imaging evaluation needed with magnification views." On 06/05/2017 the patient had a diagnostic mammogram with left digital breast tomosynthesis (a new screening and diagnostic breast imaging process to improve the early detection of breast cancer). The radiology report documented "mildly suspicious," and "recommend a needle biopsy." On 06/13/2017, a stereotactic left breast biopsy (a procedure that uses mammography to precisely identify and biopsy an abnormality within the breast), was performed.

The pathology result for the 6/15/2017 biopsy of the left breast by MD #7, revealed invasive ductal carcinoma (a cancer that is not contained and grows through the duct walls into the surrounding breast tissue), and ductal carcinoma in situ ([DCIS] cancer contained in the mammary ducts). A surgical consult was recommended, and on 07/18/2017, the patient underwent left sentinel node biopsies of four areas. A left lumpectomy (a surgical procedure where cancerous breast tissue and a small area of surrounding healthy tissue is removed). The pathology report by MD #7, revealed no carcinoma (cancer) in the lymph nodes, and for the lumpectomy, "ductal carcinoma in-situ, intermediate grade ..." of the left breast. Patient #3 underwent radiation treatments to the left breast from 08/24/2017 through 09/15/2017. Review revealed an amended report for the final pathologic diagnosis dated 01/04/2018. "This case has been re-reviewed and also reviewed at [name of external facility (1/4/2018)];" Documentation on 01/20/2018, from MD #10, the Pathologist who re-reviewed the pathology documented "The Final

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Pathologic Diagnosis is revised ...BREAST, LEFT, LUMPECTOMY: Focal atypical ductal hyperplasia ... within a background of sclerosis with usual ductal hyperplasia, see COMMENT." The comment revealed the "focus of atypia in the biopsy and lumpectomy was concerning," but it did not meet criteria for DCIS. The diagnoses for the sentinel lymph node biopsies was "unchanged."

Interview on 02/05/2018 at 1200 with MD #11, the Chief Medical Officer, revealed "We've had a work flow/work force imbalance." Interview revealed there had been corrective actions and changes in the anatomical pathology laboratory as a result of expressed concerns. "There were reasons that led to a change in leadership as a result of feedback the organization received. We are deep in the midst of a complex and deep review to see if we have a quality issue." The interview revealed "We've internally and externally reviewed and found our care did not meet our standards." The hospital was now in a review process and were re-reviewing "100 percent" of the breast cancer cases. The interview revealed the organization had not reached a "summative conclusion" and they had disclosure meetings with all patients involved, they had "attempted to put more qualified individuals into the workflow," new leadership, and upregulated the process of dual reads (already had dual reads on all outside cases). Interview revealed there was no evidence to date that the organization had a problem other than the work by MD #7, "who is now gone."

Interview on 02/05/2018 at 1245 and on 02/08/2018 at 1415 with MD #10, the Chair of the Pathology Department, revealed he had been in

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his position since August of 2017. Interview revealed he was asked to chair after the previous Chair (MD #7) separated from the organization. Interview revealed the hospital had recently "as of last Monday," hired a new Director of Surgical Pathology. Interview revealed they implemented a mandatory second review for all new breast biopsies to be documented on the pink sheets. The interview revealed "the nexus was clearly on breast biopsies, and the "new breast cancer policy (mandatory second review for all new breast biopsies) was implemented January first. Interview revealed any new breast cancer diagnosis, whether in house or external, was now to be reviewed by two Pathologists. Interview revealed "pink sheets" were created to ensure a second reading for all the newly diagnosed breast cancer specimens. Interview revealed the "ultimate goal" would be to add a second reading for all positive malignancies. When asked about monitoring the "pink sheets" for compliance with the two reads, MD #10 replied they were only in the first month and his plan was "to wait a few months then identify all the breast cancers, then see if we have a pink sheet." MD #10 stated he wanted to "allow for implementation before collecting data."

Review of an email sent "To all SP [Surgical Pathologists] and Cyto [cytopathology] Faculty, SP & Cyto Fellows, and Residents, on December 28, 2017 at 0853, revealed "Starting January 2, 2018 (next week): * ... Briefly, all outside pathology (breast biopsies, etc.) must be reviewed here prior to initiating therapy. I recognize that this is largely in the purview of oncologists (medical & radiation) and surgeons but you may come across such patients. * In addition, we need internal confirmation, using the

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attached form [pink sheet], for all newly diagnosed breast cancers. This includes both internal and external cases."

Interview on 02/07/2018 at 1000 with Staff #1, the Manager of Laboratory Compliance, Quality Assurance, Point of Care and Safety, revealed "It was mentioned to me on a need to know basis that there were some issues with some pathology reports and they were in the hands of Risk Management to be handled." Interview revealed she was the one who wrote the "Breast Cancer Case Reviews Prior to Initiating Therapy," policy effective 01/02/2018. Interview revealed the policy stated any case that comes in as an outside consult had to be reviewed by an internal source before we treated patients ... Interview revealed "The policy references only outside cases." The Manager of Laboratory Compliance was unaware of a new policy put in place by MD #10, requiring a second read on both internal and external biopsies indicating new breast cancer. Interview revealed the January 2018 data had not been compiled yet since there had not been enough time to process the information. Interview revealed the tracking of the "pink sheets" had not been added to QA (Quality Assurance) yet. Interview revealed the "pink sheets" were taking the policy a "step forward" to start collection process. "When everyone else is allowed to know about the problem, then everyone else can know and they can write a new policy." Interview revealed the incorrect lab reporting was "so highly guarded and so highly confidential it was not shared with anyone in the lab." Interview revealed MD #10 met with the Pathology staff during the Pathology Department meeting on January 2, 2018 at 1200 and presented the pink form requiring a second reading on all new breast

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{A 582}	Continued From page 38 biopsies. Interview on 02/07/2018 at 1020 with Staff #2, revealed she could not begin compiling data for monthly QA meetings until after the seventh of each month. Interview revealed the monthly QA meetings occurred the last Wednesday of each month. As the new process of a second read for all new breast cancers was initiated the first of January, the data has not been added to the QA yet, but would be part of the February QA meeting. Interview revealed all "pink sheets" come directly to her mailbox. Interview revealed she will review, track and monitor for compliance. Interview on 02/05/2018 at 1400 with the Chief of Physics for Radiation Oncology and the Radiation Safety Officer, revealed they discovered in December of 2017, after the Patient #3 had received a full course of radiation therapy, the diagnosis was incorrect. "The Pathologist said they had breast cancer, we went through our standard of care." Interview revealed, after Patient #3's treatment, it was discovered she did not have cancer. Interview revealed the Director of Radiation Oncology, the facility Safety Officer, and the North Carolina Division of Health Service Regulation were notified, and the situation was immediately investigated. Interview revealed the treatments were done properly, and there were no errors or deviations. The Radiation compliance section from the State came on site, reviewed the cases in detail and took a full report. No issues of non-compliance were identified in the radiology department. Interview revealed the Radiation Oncologist conducted a "thorough review of hundreds of cases." Interview revealed "Moving forward, we are looking into possibly doing a step to verify there are two sign offs in pathology."	{A 582}		

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{A 582}	Continued From page 39 Interviews on 02/05/2018 at 1505, 02/06/2018 at 1050 with the Director of Risk Management, revealed in September of 2017, Risk Management was made aware of concerns regarding 10 patients of MD #7. Interview revealed the concerns were brought to the Director's attention as a result of several complaints by employees from the laboratory. Interview revealed Risk Management started reviewing cases and getting ready to have them externally reviewed. The cases were internally re-reviewed and sent for external review as well. Risk Management's review of the 10 patients' case files revealed 4 of the 10 patients' plans of care would be affected with an incorrect diagnosis, which included Patient #3. After re-reviewing the breast cancer cases, and the "confirming reports" from external reviews, received on December 15, 2017, it was found that the diagnosis of breast cancer was incorrect for Patient #3. Interview revealed Risk Management "immediately set into action" and got physicians involved. The interview revealed Patient #3 had been notified of the misdiagnoses. The interview revealed the investigation is still ongoing and all updated results were going to the Medical Review Committee who report to the Medical Executive Committee. E. Review of Patient #4's medical record, revealed a female patient who underwent a mammogram screening on 02/10/2016. The Radiologist report revealed the results were "Incomplete" and needed additional imaging. "The patient should be recalled for a diagnostic left mammogram and possible left breast ultrasound." Review revealed on 05/24/2016, a diagnostic mammogram and ultrasound of the left	{A 582}		

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

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{A 582}	Continued From page 40 breast were performed. The Radiologist documented "CONCLUSION: Focal asymmetry in the left breast, better delineated mammographically, for which stereotactic guided biopsy is recommended ... Suspicious abnormality. Biopsy should be considered." On 06/15/2016, the patient underwent a core needle biopsy of the left breast. The pathology findings reported by MD #7 revealed invasive ductal carcinoma and DCIS in a background of a complex sclerosing lesion. On 07/21/2016, Patient #4 underwent a lumpectomy of the left breast with left sentinel node biopsies X2. The pathology report by MD #9, revealed the lymph nodes were negative for tumor and no malignancy was identified in the breast tissue lumpectomy. Patient #4 received daily radiation treatments to the left breast from 09/01/2016 through 09/23/2016 and from 09/26/2016 through 09/30/2016. Review revealed the patient returned on 08/11/2017, for a diagnostic left mammogram with tomo. The indication for the mammogram was breast cancer "Malignant neoplasm of central portion of left female breast ..." The Radiologist concluded there was no mammographic evidence of malignancy, and recommended routine follow-up. Interview on 02/05/2018 at 1200 with MD #11, the Chief Medical Officer, revealed "We've had a work flow/work force imbalance." Interview revealed there had been corrective actions and changes in the anatomical pathology laboratory as a result of expressed concerns. "There were reasons that led to a change in leadership as a result of feedback the organization received. We are deep in the midst of a complex and deep review to see if we have a quality issue. The interview revealed "We've internally and	{A 582}		

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{A 582}	Continued From page 41	{A 582}		

externally reviewed and found our care did not meet our standards." The hospital was now in a review process and were re-reviewing "100 percent" of the breast cancer cases. The interview revealed the organization had not reached a "summative conclusion" and they had disclosure meetings with all patients involved, they had "attempted to put more qualified individuals into the workflow," new leadership, and upregulated the process of dual reads (already had dual reads on all outside cases). Interview revealed there was no evidence to date that the organization had a problem other than the work by MD #7, "who is now gone."

Interview on 02/05/2018 at 1245 and on 02/08/2018 at 1415 with MD #10, the Chair of the Pathology Department, revealed he had been in his position since August of 2017. Interview revealed he was asked to chair after the previous Chair (MD #7) separated from the organization. Interview revealed the hospital had recently "as of last Monday," hired a new Director of Surgical Pathology. Interview revealed they implemented a mandatory second review for all new breast biopsies to be documented on the pink sheets. The interview revealed "the nexus was clearly on breast biopsies, and the "new breast cancer policy (mandatory second review for all new breast biopsies) was implemented January first. Interview revealed any new breast cancer diagnosis, whether in house or external, was now to be reviewed by two Pathologists. Interview revealed "pink sheets" were created to ensure a second reading for all the newly diagnosed breast cancer specimens. Interview revealed the "ultimate goal" would be to add a second reading for all positive malignancies. When asked about monitoring the "pink sheets" for compliance with

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{A 582}	Continued From page 42	{A 582}		

the two reads, MD #10 replied they were only in the first month and his plan was "to wait a few months then identify all the breast cancers, then see if we have a pink sheet." MD #10 stated he wanted to "allow for implementation before collecting data."

Review of an email sent "To all SP [Surgical Pathologists] and Cyto [cytopathology] Faculty, SP & Cyto Fellows, and Residents, on December 28, 2017 at 0853, revealed "Starting January 2, 2018 (next week): * ... Briefly, all outside pathology (breast biopsies, etc.) must be reviewed here prior to initiating therapy. I recognize that this is largely in the purview of oncologists (medical & radiation) and surgeons but you may come across such patients. * In addition, we need internal confirmation, using the attached form [pink sheet], for all newly diagnosed breast cancers. This includes both internal and external cases."

Interview on 02/07/2018 at 1000 with Staff #1, the Manager of Laboratory Compliance , Quality Assurance, Point of Care and Safety, revealed "It was mentioned to me on a need to know basis that there were some issues with some pathology reports and they were in the hands of Risk Management to be handled." Interview revealed she was the one who wrote the "Breast Cancer Case Reviews Prior to Initiating Therapy," policy effective 01/02/2018. Interview revealed the policy stated any case that comes in as an outside consult has to be reviewed by an internal source before we treat patients ... Interview revealed "The policy references only outside cases." The Manager of Laboratory Compliance was unaware of a new policy put in place by MD #10, requiring a second read on both internal and

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{A 582}	Continued From page 43	{A 582}		

external biopsies indicating new breast cancer. Interview revealed the January 2018 data had not been compiled yet since there had not been enough time to process the information. Interview revealed the tracking of the "pink sheets" had not been added to QA (Quality Assurance) yet. Interview revealed the "pink sheets" were taking the policy a "step forward" to start collection process. "When everyone else is allowed to know about the problem, then everyone else can know and they can write a new policy." Interview revealed the incorrect lab reporting was "so highly guarded and so highly confidential it was not shared with anyone in the lab." Interview revealed MD #10 met with the Pathology staff during the Pathology Department meeting on January 2, 2018 at 1200 and presented the pink form requiring a second reading on all new breast biopsies.

Interview on 02/07/2018 at 1020 with Staff #2, revealed she could not begin compiling data for monthly QA meetings until after the seventh of each month. Interview revealed the monthly QA meetings occurred the last Wednesday of each month. As the new process of a second read for all new breast cancers was initiated the first of January, the data has not been added to the QA yet, but would be part of the February QA meeting. Interview revealed all "pink sheets" come directly to her mailbox. Interview revealed she will review, track and monitor for compliance.

Interview on 02/05/2018 at 1400 with the Chief of Physics for Radiation Oncology and the Radiation Safety Officer, revealed they discovered in December of 2017, after the Patient #3 had received a full course of radiation therapy, the diagnosis was incorrect. "The Pathologist said

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{A 582}	Continued From page 44 they had breast cancer, we went through our standard of care." Interview revealed, after Patient #4's treatment, it was discovered she did not have cancer. Interview revealed the Director of Radiation Oncology, the facility Safety Officer, and the North Carolina Division of Health Service Regulation were notified, and the situation was immediately investigated. Interview revealed the treatments were done properly, and there were no errors or deviations. The Radiation compliance section from the State came on site, reviewed the cases in detail and took a full report. No issues of non-compliance were identified in the radiology department. Interview revealed the Radiation Oncologist conducted a "thorough review of hundreds of cases." Interview revealed "Moving forward, we are looking into possibly doing a step to verify there are two sign offs in pathology." Interviews on 02/05/2018 at 1505, 02/06/2018 at 1050 with the Director of Risk Management, revealed in September of 2017, Risk Management was made aware of concerns regarding 10 patients of MD #7. Interview revealed the concerns were brought to the Director's attention as a result of several complaints by employees from the laboratory. Interview revealed Risk Management started reviewing cases and getting ready to have them externally reviewed. The cases were internally re-reviewed and sent for external review as well. Risk Management's review of the 10 patients' case files revealed 4 of the 10 patients' plans of care would be affected if the results came back with an incorrect diagnosis, which included Patient #4. After re-reviewing the breast cancer cases, and the "confirming reports" from external reviews, received on December 15, 2017, it was found that the diagnosis of breast cancer was	{A 582}		

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{A 582}	Continued From page 45	{A 582}		

incorrect for Patient #4. Interview revealed Risk Management "immediately set into action" and got physicians involved. The interview revealed Patient #4 had been notified of the misdiagnoses. The interview revealed the investigation is still ongoing and all updated results were going to the Medical Review Committee who report to the Medical Executive Committee.

F. Investigative findings on February 6, 2018, revealed Patient #1, was diagnosed with breast cancer by MD #7 in 2017. The patient underwent a lumpectomy and chose to undergo the more aggressive route of a bilateral mastectomy. Findings revealed the patient did not receive radiation treatment.

Interview on 02/05/2018 at 1200 with MD #11, the Chief Medical Officer, revealed "We've had a work flow/work force imbalance." Interview revealed there had been corrective actions and changes in the anatomical pathology laboratory as a result of expressed concerns. "There were reasons that led to a change in leadership as a result of feedback the organization received. We are deep in the midst of a complex and deep review to see if we have a quality issue. The interview revealed "We've internally and externally reviewed and found our care did not meet our standards." The hospital was now in a review process and were re-reviewing "100 percent" of the breast cancer cases. The interview revealed the organization had not reached a "summative conclusion" and they had disclosure meetings with all patients involved, they had "attempted to put more qualified individuals into the workflow," new leadership, and upregulated the process of dual reads (already had dual reads on all outside cases).

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{A 582}	Continued From page 46 Interview revealed there was no evidence to date that the organization had a problem other than the work by MD #7, "who is now gone." Interview on 02/05/2018 at 1245 and on 02/08/2018 at 1415 with MD #10, the Chair of the Pathology Department, revealed he had been in his position since August of 2017. Interview revealed he was asked to chair after the previous Chair (MD #7) separated from the organization. Interview revealed the hospital had recently "as of last Monday," hired a new Director of Surgical Pathology. Interview revealed they implemented a mandatory second review for all new breast biopsies to be documented on the pink sheets. The interview revealed "the nexus was clearly on breast biopsies, and the "new breast cancer policy (mandatory second review for all new breast biopsies) was implemented January first. Interview revealed any new breast cancer diagnosis, whether in house or external, was now to be reviewed by two Pathologists. Interview revealed "pink sheets" were created to ensure a second reading for all the newly diagnosed breast cancer specimens. Interview revealed the "ultimate goal" would be to add a second reading for all positive malignancies. When asked about monitoring the "pink sheets" for compliance with the two reads, MD #10 replied they were only in the first month and his plan was "to wait a few months then identify all the breast cancers, then see if we have a pink sheet." MD #10 stated he wanted to "allow for implementation before collecting data." Review of an email sent "To all SP [Surgical Pathologists] and Cyto [cytopathology] Faculty, SP & Cyto Fellows, and Residents, on December 28, 2017 at 0853, revealed "Starting January 2,	{A 582}		

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{A 582}	Continued From page 47 2018 (next week): * ... Briefly, all outside pathology (breast biopsies, etc.) must be reviewed here prior to initiating therapy. I recognize that this is largely in the purview of oncologists (medical & radiation) and surgeons but you may come across such patients. * In addition, we need internal confirmation, using the attached form [pink sheet], for all newly diagnosed breast cancers. This includes both internal and external cases." Interview on 02/07/2018 at 1000 with Staff #1, the Manager of Laboratory Compliance , Quality Assurance, Point of Care and Safety, revealed "It was mentioned to me on a need to know basis that there were some issues with some pathology reports and they were in the hands of Risk Management to be handled." Interview revealed she was the one who wrote the "Breast Cancer Case Reviews Prior to Initiating Therapy," policy effective 01/02/2018. Interview revealed the policy stated any case that comes in as an outside consult has to be reviewed by an internal source before we treat patients ... Interview revealed "The policy references only outside cases." The Manager of Laboratory Compliance was unaware of a new policy put in place by MD #10, requiring a second read on both internal and external biopsies indicating new breast cancer. Interview revealed the January 2018 data had not been compiled yet since there had not been enough time to process the information. Interview revealed the tracking of the "pink sheets" had not been added to QA (Quality Assurance) yet. Interview revealed the "pink sheets" were taking the policy a "step forward" to start collection process. "When everyone else is allowed to know about the problem, then everyone else can know and they can write a new policy." Interview	{A 582}		

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{A 582}	Continued From page 48	{A 582}		

revealed the incorrect lab reporting was "so highly guarded and so highly confidential it was not shared with anyone in the lab." Interview revealed MD #10 met with the Pathology staff during the Pathology Department meeting on January 2nd, 2018 at 1200 and presented the pink form requiring a second reading on all new breast biopsies.

Interview on 02/07/2018 at 1020 with Staff #2, revealed she could not begin compiling data for monthly QA meetings until after the seventh of each month. Interview revealed the monthly QA meetings occurred the last Wednesday of each month. As the new process of a second read for all new breast cancers was initiated the first of January, the data has not been added to the QA yet, but would be part of the February QA meeting. Interview revealed all "pink sheets" come directly to her mailbox. Interview revealed she will review, track and monitor for compliance.

Interviews on 02/05/2018 at 1505, 02/06/2018 at 1050 with the Director of Risk Management, revealed in September of 2017, Risk Management was made aware of concerns regarding 10 patients of MD #7. Interview revealed the concerns were brought to the Director's attention as a result of several complaints by employees from the laboratory. Interview revealed Risk Management started reviewing cases and getting ready to have them externally reviewed. The cases were internally re-reviewed and sent for external review as well. Risk Management's review of the 10 patients' case files revealed 4 of the 10 patients' plans of care would be affected if the results came back with an incorrect diagnosis, which included Patient #1. After re-reviewing the breast cancer

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{A 582}	Continued From page 49	{A 582}		

cases, and the "confirming reports" from external reviews, received on December 15, 2017, it was found that the diagnosis of breast cancer was incorrect for Patient #1. Interview revealed Risk Management "immediately set into action" and got physicians involved. The interview revealed Patient #1 had been notified of the misdiagnoses. The interview revealed the investigation is still ongoing and all updated results were going to the Medical Review Committee who report to the Medical Executive Committee.

Interview on 2/6/18 at 1050 with Risk Management revealed, Patient #2, was "underdiagnosed" with a pathology report from a breast biopsy on 07/20/2016, from MD #7, indicating the patient did not have breast cancer. The patient underwent another breast biopsy (after a questionable screening mammogram) on 08/31/2017, which was positive for breast cancer. Interview revealed the patient was currently under treatment for her breast cancer.

Interview on 02/05/2018 at 1200 with MD #11, the Chief Medical Officer, revealed "We've had a work flow/work force imbalance." Interview revealed there had been corrective actions and changes in the anatomical pathology laboratory as a result of expressed concerns. "There were reasons that led to a change in leadership as a result of feedback the organization received. We are deep in the midst of a complex and deep review to see if we have a quality issue. The interview revealed "We've internally and externally reviewed and found our care did not meet our standards." The hospital was now in a review process and were re-reviewing "100 percent" of the breast cancer cases. The interview revealed the organization had not

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{A 582}	Continued From page 50	{A 582}		

reached a "summative conclusion" and they had disclosure meetings with all patients involved, they had "attempted to put more qualified individuals into the workflow," new leadership, and upregulated the process of dual reads (already had dual reads on all outside cases). Interview revealed there was no evidence to date that the organization had a problem other than the work by MD #7, "who is now gone."

Interview on 02/05/2018 at 1245 and on 02/08/2018 at 1415 with MD #10, the Chair of the Pathology Department, revealed he had been in his position since August of 2017. Interview revealed he was asked to chair after the previous Chair (MD #7) separated from the organization. Interview revealed the hospital had recently "as of last Monday," hired a new Director of Surgical Pathology. Interview revealed they implemented a mandatory second review for all new breast biopsies to be documented on the pink sheets. The interview revealed "the nexus was clearly on breast biopsies, and the "new breast cancer policy (mandatory second review for all new breast biopsies) was implemented January first. Interview revealed any new breast cancer diagnosis, whether in house or external, was now to be reviewed by two Pathologists. Interview revealed "pink sheets" were created to ensure a second reading for all the newly diagnosed breast cancer specimens. Interview revealed the "ultimate goal" would be to add a second reading for all positive malignancies. When asked about monitoring the "pink sheets" for compliance with the two reads, MD #10 replied they were only in the first month and his plan was "to wait a few months then identify all the breast cancers, then see if we have a pink sheet." MD #10 stated he wanted to "allow for implementation before

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{A 582}	Continued From page 51 collecting data." Review of an email sent "To all SP [Surgical Pathologists] and Cyto [cytopathology] Faculty, SP & Cyto Fellows, and Residents, on December 28, 2017 at 0853, revealed "Starting January 2, 2018 (next week): * ... Briefly, all outside pathology (breast biopsies, etc.) must be reviewed here prior to initiating therapy. I recognize that this is largely in the purview of oncologists (medical & radiation) and surgeons but you may come across such patients. * In addition, we need internal confirmation, using the attached form [pink sheet], for all newly diagnosed breast cancers. This includes both internal and external cases." Interview on 02/07/2018 at 1000 with Staff #1, the Manager of Laboratory Compliance , Quality Assurance, Point of Care and Safety, revealed "It was mentioned to me on a need to know basis that there were some issues with some pathology reports and they were in the hands of Risk Management to be handled." Interview revealed she was the one who wrote the "Breast Cancer Case Reviews Prior to Initiating Therapy," policy effective 01/02/2018. Interview revealed the policy stated any case that comes in as an outside consult has to be reviewed by an internal source before we treat patients ... Interview revealed "The policy references only outside cases." The Manager of Laboratory Compliance was unaware of a new policy put in place by MD #10, requiring a second read on both internal and external biopsies indicating new breast cancer. Interview revealed the January 2018 data had not been compiled yet since there had not been enough time to process the information. Interview revealed the tracking of the "pink sheets" had not	{A 582}		

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been added to QA (Quality Assurance) yet. Interview revealed the "pink sheets" were taking the policy a "step forward" to start collection process. "When everyone else is allowed to know about the problem, then everyone else can know and they can write a new policy." Interview revealed the incorrect lab reporting was "so highly guarded and so highly confidential it was not shared with anyone in the lab." Interview revealed MD #10 met with the Pathology staff during the Pathology Department meeting on January 2nd, 2018 at 1200 and presented the pink form requiring a second reading on all new breast biopsies.

Interview on 02/07/2018 at 1020 with Staff #2, revealed she could not begin compiling data for monthly QA meetings until after the seventh of each month. Interview revealed the monthly QA meetings occurred the last Wednesday of each month. As the new process of a second read for all new breast cancers was initiated the first of January, the data has not been added to the QA yet, but would be part of the February QA meeting. Interview revealed all "pink sheets" come directly to her mailbox. Interview revealed she will review, track and monitor for compliance.

Interviews on 02/05/2018 at 1505, 02/06/2018 at 1050 with the Director of Risk Management, revealed in September of 2017, Risk Management was made aware of concerns regarding 10 patients of MD #7. Interview revealed the concerns were brought to the Director's attention as a result of several complaints by employees from the laboratory. Interview revealed Risk Management started reviewing cases and getting ready to have them externally reviewed. The cases were internally

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340047	A. BUILDING _____ B. WING _____	R-C 03/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTH CAROLINA BAPTIST HOSPITAL	MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
{A 582}	Continued From page 53	{A 582}		

re-reviewed and sent for external review as well. Risk Management's review of the 10 patients' case files revealed 4 of the 10 patients' plans of care would be affected if the results came back with an incorrect diagnosis, which included Patient #2. After re-reviewing the breast cancer cases, and the "confirming reports" from external reviews, received on December 15, 2017, it was found that the diagnosis of breast cancer was incorrect for Patient #2. Interview revealed Risk Management "immediately set into action" and got physicians involved. The interview revealed Patient #1 had been notified of the misdiagnoses. The interview revealed the investigation is still ongoing and all updated results were going to the Medical Review Committee who report to the Medical Executive Committee.

In summary, laboratory staff failed to provide oversight of Laboratory Services and ensure laboratory specimens were appropriately processed with accurate results for medical interventions, in particularly the subspecialty of histopathology.