PRINTED: 04/09/2018 FORM APPROVED OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE COMP		
		340047	B. WING			R-	-C 26/2018
NAME OF PI	ROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, 2	ZIP CODE	03/	20/2010
		·		MEDICAL CENTER BOULEVARD)		
NORTH C	AROLINA BAPTIST HOS	PIIAL		WINSTON-SALEM, NC 2715	7		
(X4) ID PREFIX TAG	EFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL		ID PREFI TAG	(EACH CORRECTIVE CROSS-REFERENCED			(X5) COMPLETION DATE
{A 000}	INITIAL COMMENTS		{A 0	00}			
	with members of DHS 2018 through Februar facility's compliance of Conditions of Particip complaint investigation an immediate jeopard patients as evidenced Medical Staff's failure ensure laboratory sperocessed with accurrinterventions. Pursua Body and 482.22 Medical provide oversight of particularly the subsport facility's administrative february 8, 2018 at 1 the immediate jeopard The laboratory failed problems in the subsport laboratory failed manual was completed manual was completed from the laboratory failed of procedures were validated in the subsport of the laboratory failed of the laboratory failed to procedures were validated in the subsport of the laboratory failed to procedure failed to procedure failed to procedure failed to procedure failed to material failed to procedure failed to p	to identify and correct pecialty of histopathology. Ito ensure the procedure error all testing performed. Ito ensure equipment and dated prior to use for patient perform manufacturers' error as required. The conitor water quality, midity as required. The erform and document quality atoxylin and eosin) stains as or discard expired supplies.					
ADODATORY	•	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.

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		(X2) MULT A. BUILDIN	IPLE CONSTRUCTION NG		ATE SURVEY OMPLETED	
		340047	B. WING			R-C
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	•	03/26/2018
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI) TAG	PROVIDER'S PLAN OF COR ((EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
{A 000}	and failed to ensure pestablished and follow personnel competence. The laboratory tests a surgical pathology ca 8, 2018, the laborato which erroneous historeported, resulting in three patients and a condition fourth patient. Case in the laboratory was determined to be a follow-up survey was march 21, 2018 throup March 26, 2018. Bas findings, the Immediate conditions remain unconditions remains and a potenticion patients and a potenticion patients. For the	led to ensure testing and prior to testing patients, solicies and procedures were wed for monitoring testing by. Approximately 25,000 are per year. As of February ry identified four (4) cases in opathology test results were unnecessary treatment for delay in diagnosis for a eviews are ongoing. For of the deficiencies and jeopardy was not abated on-going. As conducted at the facility gh March 23, 2018, and ed on follow-up survey te Jeopardy was abated and corrected. As the laboratory had 291 histopathology cases reviews had been of the cases. During reviews february 5-8, 2018 an survey, the laboratory had al 25 cases in which logy test results were ous histopathology test necessary treatment for 3 al delay in treatment for 3	{A 0			

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NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	
(X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
(A 043) (A 043	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULT A. BUILDIN	IPLE CONSTRUCTION NG	, ,	ATE SURVEY OMPLETED		
		340047	B. WING _			R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CODI MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	•	1 00/20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COI (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
{A 043}	surgical pathology ca 8, 2018, the laborato which erroneous hist reported, resulting in three patients and a fourth patient. Case of B) The laboratory dir responsibilities to an Pathology Director), delegated duties were by the following: Review of procedure (Operating Room) Pa Special Stains laboral laboratory revealed of delegation dated Jan labeled "MEMORAN was signed by the culletter designated the Surgical Pathology directory Agencies specific, detailed list. The procedure manu "MEMORANDUM Of pathologist serving a director which delegation documentation as Agencies and to assifor the laboratory sechistology supervisor	sts approximately 25,000 ases per year. As of February ry had identified 4 cases in opathology test results were unnecessary treatment for delay in diagnosis for a reviews are ongoing. ector delegated other pathologist (Surgical but failed to ensure the re performed as evidenced manuals in the OR athology laboratory, the atory, and the Main Histology copies of a letter of uary 1, 2014. The letter, DUM OF INFORMATION", arrent laboratory director. The pathologist serving as the irector "To sign off on and cion as required by our ." The letter did not include a of duties and responsibilities. als also contained a F INFORMATION" from the s the Surgical Pathology ated "the authority to sign off or required by our Regulatory ess employee competency ction(s) noted above" to the (assistant manager). This F INFORMATION" was also	{A O	43}			

AND DI AN OF CORRECTION IDENTIFICATION NUMBER		I ' '	X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		340047	B. WING				-C 26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	l		MED	ICAL CENTER BOULEVARD STON-SALEM, NC 27157	1 03/	20/2010
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFI TAG	x	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)		(X5) COMPLETION DATE
{A 043}	Continued From page		{A 0	43}			
	meet the education re technical supervisor of high complexity histo responsibilities for re- personnel competence	records revealed the (assistant manager) does not equirements to serve as a or general supervisor in a pathology laboratory. The view of records and testing by assessment could not be ology supervisor (assistant					
	director at the time of laboratory employme	nt in September 2017, but locumentation had not been ecific responsibilities					
		ector failed to provide overall ection for the laboratory.					
	procedures were vali	ed to ensure equipment and dated prior to use for patient perform manufacturers' se as required.					
	the absence of 2017 interview with the his manager) 2/5/18 - 2/8						
	the two Leica Auto St Histology laboratory s exhausted through th	tructions (user manual) for tainers located in the Main stated "Fumes are le activated carbon filter led every three months"					

The state of the s		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` '	IPLE CONSTRUCTION	· ,	TE SURVEY MPLETED	
		340047	B. WING			R-C	
	ROVIDER OR SUPPLIER AROLINA BAPTIST H		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157			03/26/2018 E	
(X4) ID PREFIX TAG	(EACH DEFICI	Y STATEMENT OF DEFICIENCIES ENCY MUST BE PRECEDED BY FULL OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF ((EACH CORRECTIVE ACTI CROSS-REFERENCED TO TI DEFICIENC'	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
{A 043}	was changed eventhe manufacturer. 2. Manufacturer's the two Artisian St Neuro IHC (Immuincluded a list of nperformed on a da 11.1 - Daily and M Procedures". The daily maintenance bottles, perform with platform, clean respill tray. The tablemonthly maintenal liquid bottles and ethanol. There was required daily and procedures were manufacturer. 3. Manufacturer's the two Leica CM OR Pathology lab "Instructions for cheat the specified by the months." There wis filter was changed specified by the months." There wis filter was changed specified by the months. There wis filter was changed specified by the month of the equipment in the equipment in the control of the laboratory.	instructions (user manual) for taining Systems located in the nohistochemistry) laboratory maintenance procedures to be ally and weekly basis: "Table lonthly Maintenance table included the following procedures: prime bulk liquid taste valve rinse, clean slide agent drip ring, check and clean e also included the following nice procedures: clean bulk flush bulk liquid lines with as no documentation that the monthly maintenance performed as specified by the instructions (user manual) for 1950 Cryostats located in the oratory stated in the section manging the bacteria filter", that e changed approx. every 3 as no documentation that the levery three months as	{A 0-4	43}			

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPL A. BUILDING	E CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		340047	B. WING		R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HO	1.11		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	03/20/2016
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPRIDEFICIENCY)	JLD BE COMPLETION
{A 043}	humidity ranges that manufacturers' requifollowing: Review of laboratory deionized water test histology laboratory records, review of mand interview with the (assistant manager) laboratory failed to monitor and docume and failed to define requirements which manufacturers' requ	to establish temperature and to were consistent with irements as evidenced by the procedures, review of 2017 temperature and humidity fanufacturers' instructions the histology supervisor 2/5/18 - 2/8/18, the monitor water quality, failed to ent temperature and humidity, temperature and humidity were consistent with irements. Safory's "Deionized Water 6SGP-3" procedure revealed rocedure: Deionized Water ple of the water from the ks in the Histology Special ke each month. The to covering that lab shall be forming the following monthly, unless > 2000 ted three months in a row. Ger should be notified of this vice on the unit ordered. The month span with no growth."	{A 043		
	to the laboratory mid month for testing. T	ation that a sample was sent crobiology department each here were no records to s were obtained from the			

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		, ,	1 ' '	PLE CONSTRUCTION	CON	E SURVEY IPLETED	
		340047	B. WING			R-C 8/ 26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HO	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		1 03/20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
{A 043}	results were reviewed testing was needed. During interview 2/6, a.m., the histology s manager) confirmed receive reports or refrom the deionized was 2. Temperature and a. There were no ter records available for (Operating Room) Plaboratory operates Shandon Varistain in During interview 2/8, a.m., the histology s manager) confirmed documenting the tenthe OR Pathology lab. The Artisan staining specifies operation in temperature of 15-33 degrees Fahrenheit) Review of temperature Neuro IHC (Immuno where two Artisan staining were operated by the laboratory defined arrange of 64-104 deglaboratory defined arrange of 60%.	e deionized water or if the ed to determine if weekly /18 at approximately 11:00 upervisor (assistant the laboratory did not view the results obtained vater testing. Humidity Imperature and humidity Imperature and humid	{A 04:	3}			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTI A. BUILDIN	PLE CONSTRUCTION G	, ,	TE SURVEY MPLETED	
		340047	B. WING			R-C 3/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		3/20/2010
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
{A 043}	degrees Celsius (59-Under "Environmenta" "Operating temperature temperature): 18 deg specifications related only up to an ambien C and an air humidity. Review of temperature Special Stains laboratory defined a laboratory defined a temperature range of and a laboratory defined as "Relative humidity: Review of temperature a "Relative humidity: Review of temperature humidity: Review of the Leice humidity: Review of temperature humidity: Review of temperature humidity: Review of the Leice humidity: Review of	temperature range of 15-30 86 degrees Fahrenheit). al requirements", it states are range (ambient rees C to 40 degrees C. All to temperature are valid at temperature of 22 degrees a lower than 60%!" The and humidity logs for the tory, where a ClearVue d by the laboratory, revealed acceptable room and 64-104 degrees Fahrenheit and humidity range of The and humidity logs for the atory, where the laboratory utostainers, revealed a ceptable room temperature	{A 04	3)		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ' '		E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		340047	B. WING			R- 03/2	-C 26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		ľ	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRIA DEFICIENCY)		(X5) COMPLETION DATE
{A 043}	p.m., the following ex on the shelves behind use: a. Diff-Quik Solution I Expiration Date 2017- b. Diff-Quik Solution I Expiration Date 2017- 2. During a tour of the (Immunohistochemist approximately 1:00 p. items were observed laboratory, available fa. Sigma Chemical Ta Expiration Date 11-07- b. Sodium Arsenate of A6756-50C, Expiration C. Arsenic Acid, Lot # 03-06. 3. During a tour of the 2/7/18 at approximate expired item was obsthe laboratory, availal a. Thiosemicarbazide Observation revealed in 1998 and opened in expiration date. Review of 2016 and 2 the laboratory complied of the OR Pathology I laboratory, and the Si 7/5/16, 1/12/17, 4/18/	DR (Operating Room) 2/5/17 at approximately 1:30 pired items were observed d the cryostats, available for , Lot # 661616031A, -09-30; I, Lot # 661716031A, -09-30. e Neuro IHC try) laboratory 2/7/18 at t.m., the following expired on the shelves lining the for use: artaric Acid, Lot # T0375,	{A C)43)			

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIP	LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		340047	B. WING		R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	03/20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE COMPLETION	
{A 043}	p.m., the Laboratory Quality Manager consupplies were identificated on the Departr Safety Inspection replatoratory was award. F) The laboratory fail manual was completed. G) The laboratory dispersonnel were trainand failed to ensure established and follopersonnel competen following: Review of personnel training records, and personnel) 2/5/18 - 2 failed to ensure that specimens, 20 of 21 appropriate training accould perform all test provide accurate pate 1. Review of personnel 12/29/17) who perfor specimens in the OR Pathology laboratory documentation of training document labeled "S Room Direct Supervincluded with the per the document did no testing personnel, the name of the reviewer.	Compliance, Safety and firmed that the expired ied during routine audits and ment of Pathology General ports. She verified that the expired ied to ensure the procedure for all testing performed. The external findings and procedure in testing performed are policies and procedures were seed for monitoring testing interviews with TP (testing larger) as evidenced by the records, the absence of interviews with TP (testing larger) and had demonstrated they ting operations reliably to ient test results.	{A 043			

` '		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` '	PLE CONSTRUCTION 3		DATE SURVEY COMPLETED	
		340047	B. WING			R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HO			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		03/26/2018	
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPI DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
{A 043}	complete and she was testing independent. During interview 2/7 p.m. to 12:55 p.m., labeled "Surgical Pasupervision and Codocumentation for TTP #1 also provided grossed during train the interview that the available to indicate complete and she was director to perform to 2. There were no trareview for 19 of 19 in 9, 10, 11, 12, 13, 14 who perform grossis the OR Pathology labeled to 19:00 a. that an upper level in level resident during how to gross each to They stated that after typically gross specifiers is a grossing intranet for reference assistant) is also averaged the properties of the perform and the training was document. During interview 2/7 p.m. to 12:55 p.m.,	ras approved to perform ally. 7/18 from approximately 12:40 TP #1 stated the document athology Gross Room Direct impetency." is the training TP #2. During the interview, if a log of cases that TP #2 aling. TP #1 confirmed during it hat TP #2's training was approved by the laboratory in esting independently. alining records available for residents (TP #3, 4, 5, 6, 7, 8, 4, 15, 16, 17, 18, 19, 20, 21) and of pathology specimens in aboratory. 2/6/18 from approximately in mensioned the first week to go over yee of pathology specimen. For the first week, the residents imens independently, but manual available on the e and the PA (pathologists' allable if needed to answer ted they were not aware of a ey were unsure whether the ented anywhere.	{A 04	3}			

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		PLE CONSTRUCTION IG	(X3	B) DATE SURVEY COMPLETED
		340047	B. WING			R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	I	03/26/2016
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
{A 043}	documented. TP #1 a document training for longer responsible fo not done it in several H) The laboratory faispecifications for the Analyzer prior to use I) The laboratory fails specifications for the performed on the Artiuse in patient testing In summary the Gove oversight and ensure provided overall man the delivery of quality result, laboratory speerroneous results. As of March 26, 2018 identified a total of 9, requiring review, and performed for 1,422 conducted since the complaint investigatic identified an additional erroneous histopathor reported. The erroneresults resulted in un patients and a potent other patients. For the treatment was not imongoing. PATIENT RIGHTS	also stated she used to the residents, but she is no rethat. She stated she has years. led to verify performance faxitron PathVision X-Ray in patient testing. ed to establish performance modified stain procedures san Staining System prior to erning Body failed to provide the Laboratory Director agement and direction for laboratory services. As a cimens were processed with 6, the laboratory had 291 histopathology cases reviews had been of the cases. During reviews February 5-8, 2018 on survey, the laboratory had al 25 cases in which logy test results were ous histopathology test necessary treatment for 3 ial delay in treatment for 3	{A 04			
{A 115}	PATIENT RIGHTS CFR(s): 482.13		{A 1 ²	15}		

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULT A. BUILDIN	PLE CONSTRUCTION IG	` '	E SURVEY PLETED
		340047	B. WING			R-C 8/ 26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	•	126/2016
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COF (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
{A 115}	patient's rights. This CONDITION is Based on review of and procedures, test testing personnel into through February 8, to provide oversight ensure laboratory sp processed with accu interventions, in part histopathology. The provide patients with and services. Findin A. Based on review and procedures, test testing personnel into through February 8, to provide oversight ensure laboratory sp processed with accu interventions, in part histopathology. Methospital's Laboratory	not met as evidenced by: hospital laboratory policies ing personnel files, and erviews February 5, 2018 2018, the hospital staff failed of Laboratory Services and ecimens were appropriately rate results for medical ticularly the subspecialty of ereby, the hospital failed to appropriate care, treatment	{A 1	,		
	Director), were performance. Cross Reference, A-338 B. Based on review review of 2017 labora with staff February 5	§482.22 Medical Staff: of policies and procedures, atory records, and interview, 2018 through February 8, director failed to provide and direction for the				

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULT A. BUILDIN		CONSTRUCTION	(X3) DATE COMP	SURVEY LETED
		340047	B. WING			1	-C
NAME OF PE	ROVIDER OR SUPPLIER	340047	B. WING_	ST	TREET ADDRESS, CITY, STATE, ZIP CODE	03/	26/2018
	AROLINA BAPTIST HOS	PITAL		M	EDICAL CENTER BOULEVARD INSTON-SALEM, NC 27157		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	<	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)		(X5) COMPLETION DATE
{A 115}	Continued From page	: 14	{A 1	15}			
		•					
	~ Cross Reference, § Services: A-576	482.27 Laboratory					
	failed to provide overs Laboratory Director pand direction for the conservices. As a result, processed with errone medical interventions	rovided overall management delivery of quality laboratory laboratory specimens were eous results which impacted					
A 263	QAPI CFR(s): 482.21		A 2	263			
		ongoing, hospital-wide, sessment and performance					
	the program reflects thospital's organization hospital departments those services furnish arrangement); and for	n and services; involves all and services (including and under contract or cuses on indicators related tcomes and the prevention					
		intain and demonstrate program for review by CMS.					
		not met as evidenced by: aboratory procedures,					

	DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	PLE CONSTRUCTION IG	(X3	OMPLETED
		340047	B. WING _			R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	<u> </u>	03/20/2010
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPI DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
A 263	manufacturer's instruct maintenance records (Hematoxylin and Eos lab personnel files, as laboratory failed to de improvements to pror laboratory services w accurate results for m Pursuant to 482.12 G Medical Staff, facility oversight of Laborato the subspecialty of his include: As of March 26, 2018 identified a total of 9,7 requiring review, and performed for 1,422 c conducted since the formplaint investigation investigation in the protect. The erroneous histopatho reported. The erroneous other patients. For the	ctions, laboratory equipment review of 2017 H&E sin) quality control records, distaff interviews, the evelop and implement quality into the delivery of quality into the delivery processed dedical interventions. Overning Body and 482.22 staff failed to provide ry Services, in particularly stopathology. Findings The laboratory had 291 histopathology cases reviews had been of the cases. During reviews rebruary 5-8, 2018 on survey, the laboratory had all 25 cases in which logy test results were out histopathology test necessary treatment for 3 and delay in treatm	A 2			
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	DF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` '	IPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		340047	B. WING _		R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST H	IOSPITAL		STREET ADDRESS, CITY, STATE, ZIP MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	· · · · · · · · · · · · · · · · · · ·
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{A 283}	performance improved (i) Focus on high problem-prone are (ii) Consider the severity of problem (iii) Affect health quality of care. (3) The hospital magnetic performance improved implementing those measure its successive.	nust set priorities for its ovement activities that-gh-risk, high-volume, or	{A 2	83}	
	Based on review manufacturer's ins maintenance reco (Hematoxylin and lab personnel files laboratory failed to improvements to plaboratory service accurate results for Pursuant to 482.1 Medical Staff, faci oversight of Labor the subspecialty of include: A) Based on the adocumentation and director and TP (to 2/8/18, the laborate faxitron PathVision)	is not met as evidenced by: of laboratory procedures, structions, laboratory equipment rds, review of 2017 H&E Eosin) quality control records, and staff interviews, the of develop and implement quality promote the delivery of quality so with appropriately processed or medical interventions. 2 Governing Body and 482.22 lity staff failed to provide ratory Services, in particularly of histopathology. Findings besence of validation d interview with the laboratory resting personnel) 2/5/18 - retory failed to document that the on X-Ray Analyzer installed in the room) Pathology laboratory,			

	DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	' '	PLE CONSTRUCTION IG		DATE SURVEY COMPLETED
		340047	B. WING _			R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HO			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	I	03/20/2016
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES NCY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORR ((EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AF DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE
{A 283}	established by the repatient testing. During interview 2/5 p.m., the laboratory faxitron PathVision recently purchased placed into operation confirmed that the laperformance specific patient testing, and documentation available. During interview 2/5 that the manufacture PathVision X-Ray A Pathology laborator operators were train that immediately after the performance specific began using the deal by Based on review and interview with the days and interview with the confirmed on the trainings: Review of the Artisa revealed special stars.	mance specification standards manufacturer prior to initiating 5/18 at approximately 3:15 director stated that the X-Ray Analyzer had been and had been installed and on in December 2017. He aboratory had not verified the ications prior to initiating there was no validation allable for review. 5/18 at 4:00 p.m., TP #1 stated for installed the faxitron analyzer analyzer in the OR by on 12/22/17 and six need at that time. She stated for patient testing.	{A 28	· ·		
	Libraries CD-ROM Editor. The Procedustaining procedures is loaded when the	or created using the IHC ure Library is the database of that have been imported and system software starts. s listed on the Program				

	DF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ` ′		E CONSTRUCTION	(X3) DATE COMP	
		340047	B. WING			R- 03/2	-C 26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		N	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		-0.2010
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BI CROSS-REFERENCED TO THE APPROPRIA DEFICIENCY)		(X5) COMPLETION DATE
{A 283}	and IHC procedures.' Review of the Artisan Manager" screen reve "user-defined" special designated by the syr special staining procedures and designated by the syr special staining procedures and designatory and designatory and designatory and designatory and designatory and designation and the second s	sist of three classes: user-defined procedures, Staining system "Procedure ealed modified or I staining procedures were mbol NCB. The following edures were modified by the lated by the symbol NCB: last Bacteria) carmine) c acid-schiff) odic acid-schiff diatase) reen aboratory records revealed at performance modified special staining ablished by the laboratory to reliable results. //8/18 at approximately 9:15 pervisor (assistant that the NCB symbol ning procedures that had histology laboratory. She he changes must have been unable to provide of manufacturer's nce of 2017 maintenance	{A 2	283}			

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	PLE CONSTRUCTION G	' '	ATE SURVEY MPLETED
		340047	B. WING _			R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		STREET ADDRESS, CITY, STATE, ZIP CO MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		3372372010
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL .SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTIO CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE
{A 283}	1. Manufacturer's instent two Leica Auto St Histology laboratory sexhausted through the which must be chang There was no docum was changed every the manufacturer. 2. Manufacturer's instent two Artisian Stain Neuro IHC (Immunohincluded a list of mair performed on a daily 11.1 - Daily and Mont Procedures". The table daily maintenance probottles, perform wast platform, clean reage spill tray. The table almonthly maintenance liquid bottles and flus ethanol. There was no required daily and mo procedures were performanufacturer. 3. Manufacturer's instent two Leica CM195 OR Pathology labora "Instructions for chan" "The filter must be children and set of the	e for equipment used in the idenced by the following: tructions (user manual) for ainers located in the Main stated "Fumes are e activated carbon filter ed every three months" entation that the carbon filter nree months as specified by tructions (user manual) for ing Systems located in the istochemistry) laboratory intenance procedures to be and weekly basis: "Table hly Maintenance le included the following ocedures: prime bulk liquid e valve rinse, clean slide int drip ring, check and clean so included the following is procedures: clean bulk h bulk liquid lines with o documentation that the porthly maintenance formed as specified by the structions (user manual) for 0 Cryostats located in the tory stated in the section ging the bacteria filter", that anged approx. every 3 no documentation that the ery three months as	{A 28			

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	PLE CONSTRUCTION	, ,	ATE SURVEY OMPLETED	
		340047	B. WING			R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	ı	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157				
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF ((EACH CORRECTIVE ACTI CROSS-REFERENCED TO TI DEFICIENC'	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
{A 283}	During interview 2/5/p.m., the histology sumanager) stated that maintenance other the equipment in the D) Based on review or review of 2017 H&E quality control record histology supervisor 2/8/18, the laboratory document quality corstaining characteristi and eosin) stains per Room) Pathology lab document quality corperforming H&E stain laboratory. Findings: 1. The histology laboo Checking Criteria His Procedure: Slide Checking Criteria His Pr	at approximately 4:00 apervisor (assistant there is no required nan daily cleaning for any of histology department. of laboratory procedures, (Hematoxylin and Eosin) as and interview with the (assistant manager) 2/5/18 - y failed to perform and nitrol to ensure predictable cs for the H&E (hematoxylin formed in the OR (Operating poratory and failed to nitrol for each instrument ning in the Main Histology aratory procedure, "Slide stology-ML-31", states " 2) ecking Criteria", "H&E esin) QC (Quality Control) - A staining is stained at the The slide is reviewed by the is put at the beginning of the in a form of stain acceptability, along with the form back to e filed." by control records for the H&E in the OR Pathology for review. During interview ely 9:00 a.m., the histology manager) confirmed there not records for the H&E in the CR pathology confirmed there not records for the H&E in the CR p	{A 28	3}			

	DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ' '	RIPLE CONSTRUCTION NG	(X3	ODATE SURVEY COMPLETED
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(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF C X (EACH CORRECTIVE ACTIVE CROSS-REFERENCED TO THE DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE
{A 283}	separate Leica staine laboratory. The Leica and #2. During interv 9:00 a.m., the histolomanager) stated that QUALITY CONTROL EOSIN STAIN" form slides are sent with the Review of the 2017 "HEMATOXYLIN AND to document the daily Histology Room" revused each day that p stained. The form ha acceptability of the stained stained on each lin summary, the labor 25,000 surgical paths	forms H&E staining on two ers in the Main Histology a stainers are designated #1 iew 2/6/18 at approximately gy supervisor (assistant they use one "DAILY AHEMATOXYLIN AND each day of testing and two ne form, labeled #1 and #2. DAILY QUALITY CONTROL DEOSIN STAIN" forms used AH&E controls for the "Main ealed only one form was atient H&E slides were d a space to document ain, but did not include cceptability for the control a instrument (#1 and #2). ratory tests approximately plogy cases per year. As of e laboratory identified four	{A 2	83}		
{A 338}	(4) cases in which er results were reported treatment for three padiagnosis for a fourth ongoing since the init September 2017. MEDICAL STAFF CFR(s): 482.22 The hospital must has staff that operates ungoverning body, and	roneous histopathology test l, resulting in unnecessary atients and a delay in patient. Case reviews are	{A 3	38}		

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` '	PLE CONSTRUCTION		TE SURVEY	
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	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		STREET ADDRESS, CITY, STATE, ZIP CO MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		•	
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTIV CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
{A 338}	Based on review of and procedures, test testing personnel into through February 8, 2 to provide oversight of ensure laboratory specessed with accur interventions, in part histopathology. Mee hospital's Laboratory to ensure the delegat to another pathologis Director), were performed include: A) Review of procedu (Operating Room) Paspecial Stains laborated laboratory revealed of delegation dated Jan labeled "MEMORAN was signed by the culetter designated the Surgical Pathology dimaintain documentating Regulatory Agencies specific, detailed list. The procedure manu "MEMORANDUM Of pathologist serving a director which delegation documentation as Agencies and to assert for the laboratory sechistology supervisor.	not met as evidenced by: nospital laboratory policies ing personnel files, and erviews February 5, 2018 2018, the Medical Staff failed of Laboratory Services and ecimens were appropriately rate results for medical icularly the subspecialty of dical Staff failed ensure to the Director provided oversight ted responsibilities assigned at (Surgical Pathology ormed as required. Findings ure manuals in the OR athology laboratory, the atory, and the Main Histology copies of a letter of uary 1, 2014. The letter, DUM OF INFORMATION", irrent laboratory director. The pathologist serving as the irector "To sign off on and ion as required by our ." The letter did not include a of duties and responsibilities.	{A 33	8}			

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	, ,	ELE CONSTRUCTION	COMPLETE	
		340047	B. WING		R-C 03/26/2	018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HO	SPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157			
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORF (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AI DEFICIENCY)	HOULD BE CO	(X5) DMPLETION DATE
{A 338}	dated January 1, 20 B) Review of persor histology supervisor meet the education technical supervisor high complexity historesponsibilities for repersonnel competer delegated to the historian manager). C) The pathologist director at the time of laboratory employm delegation of duties updated to reflect specification of the delegated to current by Review of person training records, and personnel) 2/5/18 - 2 failed to ensure that specimens, 20 of 21 appropriate training could perform all tesprovide accurate particular evidenced by the following training in the OF Pathology laboratory documentation of training for the date of the person of	anel records revealed the (assistant manager) did not requirements to serve as a or general supervisor in a opathology laboratory. The eview of records and testing ney assessment could not be tology supervisor (assistant) serving as Surgical Pathology of the delegation left ent in September 2017, and documentation had not been pecific responsibilities a designees. Innel records, the absence of dinterviews with TP (testing 2/8/18, the laboratory director prior to testing patient testing personnel received and had demonstrated they sting operations reliably to tient test results. As llowing: Inel records for TP #2 (hired times grossing of pathology)	{A 33	8}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		` ′	LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED R-C			
		340047	B. WING)3/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HO	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		1 33/20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPF DEFICIENCY)	ULD BE	(X5) COMPLETION DATE	
{A 338}	name of the reviewed available to docume complete and she we testing independent. During interview 2/7 p.m. to 12:55 p.m., labeled "Surgical Passupervision and Codocumentation for TTP #1 also provided grossed during train the interview that the available to indicate complete and she we director to perform to 2. There were no train review for 19 of 19 in 9, 10, 11, 12, 13, 14 who perform grossis the OR Pathology labeled During interview on 8:30 a.m. to 9:00 a. that an upper level level resident during how to gross each to They stated that after typically gross specific there is a grossing intranet for reference assistant) is also avequestions. They stated that states are the states and they are they stated that after typically gross specific there is a grossing intranet for reference assistant) is also avequestions. They stated that after typically gross specific them.	er. There were no records and that TP #2's training was as approved to perform by. /18 from approximately 12:40 TP #1 stated the document athology Gross Room Direct impetency." is the training in P #2. During the interview, if a log of cases that TP #2 ing. TP #1 confirmed during in that TP #2's training was was approved by the laboratory esting independently. anining records available for residents (TP #3, 4, 5, 6, 7, 8, 7, 15, 16, 17, 18, 19, 20, 21) and of pathology specimens in aboratory. 2/6/18 from approximately in the first week to go over the first week, the residents independently, but manual available on the e and the PA (pathologists' ailable if needed to answer ted they were not aware of a ey were unsure whether the	{A 338				
		/18 from approximately 12:40 TP #1 stated first year					

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING			(X3) DATE SURVEY COMPLETED			
		340047	B. WING		R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HO	SPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		1 00/20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPF DEFICIENCY)	ULD BE COMPLETION	
{A 338}	she was unsure who documented. TP #1 document training for longer responsible in not done it in several E) Review of the lat procedures 2/5/18 - the laboratory direct policies and procedure monitoring the comparties of the OR (Operating Frase evidenced by the sevidenced several comparts as evidenced several comparts as evidenced several comparts (TP #1) in the OR (Claboratory. 2) Review of person revealed several comparts several comparts sevidenced several comparts in the body descriptive statement performance. Providence is the following in Quality of Work, Quorganization, Job Kommunication, De Attendance, Punctuand Safety, Leaders	aby fourth year residents, but either the training is also stated she used to or the residents, but she is no or that. She stated she has all years. Doratory's policies and 2/8/18 and survey findings, or failed to ensure that ures were established for betency of testing personnel in Room) Pathology laboratory following: . Interpretation of the form and ency evaluation for 1 of 21 TP operating Room) Pathology Interpretating Room) Pathology Interpretating Room Pathology Interpretation of Skills and Abilities for visory & Management ons at the top of the form state of the employee's le additional feedback in the sappropriate. The form terms to be evaluated: antity of Work, Planning and nowledge, Problem Solving,	{A 33{			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		IDENTIFICATION NUMBER		(2) MULTIPLE CONSTRUCTION . BUILDING			(X3) DATE SURVEY COMPLETED	
		340047	B. WING			R- 03/2	-C 26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL	•	N	TREET ADDRESS, CITY, STATE, ZIP CODE IEDICAL CENTER BOULEVARD VINSTON-SALEM, NC 27157			
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{A 338}	instructions, and differ handwritten on the last copies did not included were conducted, and was unclear who commodified was unclear who commodified was unclear who commodified was unclear who commodified was unclear who served director used to evaluate that changed in the last Surgical Pathology her competency during the Chief Medical Off work flow/work force revealed there had be changes in the anator as a result of express reasons that led to a result of feedback the are deep in the midst review to see if we have interview revealed "Wexternally reviewed a meet our standards." review process and we percent of the breast interview revealed the reached a "summative disclosure meetings with the process of the process	illed out according to the rent comments were at page of each copy. The a dates that the "evaluations" they were not signed, so it ducted them. 7/18 from approximately .m., TP #1 stated that the ed as Surgical Pathology that her competency, but the state of the ed as Surgical Pathology at the her competency, but the ed as Surgical Pathology at the her competency, but the ed as Surgical Pathology at the her competency, but the ed as Surgical Pathology at the her competency, but the ed as Surgical Pathology at the her competency, but the ed as Surgical Pathology at the ed as the ed	{A 3	:38}				

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING			(X3) DATE SURVEY COMPLETED				
		340047	B. WING _				-C 26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	SPITAL		M	REET ADDRESS, CITY, STATE, ZIP CODE EDICAL CENTER BOULEVARD VINSTON-SALEM, NC 27157		
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFI TAG	x	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRIA DEFICIENCY)		(X5) COMPLETION DATE
{A 338}	O2/08/2018 at 1415 when the pathology Department his position since Augrevealed he was asked Chair (MD #7) separa Interview revealed the last Monday," hired a Pathology. Interview mandatory second rebiopsies to be docum. The interview revealed breast biopsies, and policy (mandatory sebreast biopsies) was Interview revealed ardiagnosis, whether into be reviewed by two revealed "pink sheets second reading for all cancer specimens. In "ultimate goal" would for all positive malign monitoring the "pink steets two reads, MD #7 the first month and himonths then identify see if we have a pink serves asked to the pathology of the two approximates and the pathology of th	who is now gone." 15/2018 at 1245 and on with MD #10, the Chair of the nt, revealed he had been in gust of 2017. Interview ed to chair after the previous ated from the organization. The hospital had recently "as of a new Director of Surgical revealed they implemented a eview for all new breast nented on the pink sheets. The "the nexus was clearly on the "new breast cancer cond review for all new implemented January first. The new breast cancer in house or external, was now to Pathologists. Interview is "were created to ensure a lift the newly diagnosed breast interview revealed the lift be to add a second reading francies. When asked about sheets" for compliance with 10 replied they were only in its plan was "to wait a few all the breast cancers, then its sheet." MD #10 stated he implementation before	{A 3				
	adequate laboratory	aintain, or have available, services to meet the needs ospital must ensure that all					

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			(X2) MULT A. BUILDII	IPLE CONSTRUCTION NG	, ,	(X3) DATE SURVEY COMPLETED	
		340047	B. WING _			R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	•	00/20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COF (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
{A 576}	performed in a facility Part 493 of this chap This CONDITION is Based on review of review of 2017 labora with staff February 5 2018, the laboratory overall management laboratory. The laboratory. The laboratory implemente appropriately process medical interventions subspecialty of history A) The hospital laboratory compliance with CFF report of survey condimprovement Amend 5, 2018 through February 105028: Histopathology	rovided to its patients are y certified in accordance with ter. not met as evidenced by: policies and procedures, atory records, and interview y 2018 through February 8, director failed to provide and direction for the pratory failed to have do to ensure specimens were used with accurate results for so, in particularly the pathology. Findings include: pratory failed to be in a 493 as referenced in the ducted by Clinical Laboratory ment (CLIA) staff February truary 8, 2018.	{A 5				
	Performance: CFR D5601: Histopatholo D6076: Laboratory ICFR 493.1441 D6079: Laboratory ICFR 493.1445(a)(b) D6102: Laboratory ICFR 493.1445(e)(12 B) The laboratory dir responsibilities to an Pathology director), Idelegated duties wer	493.1253(b)(1) egy: CFR 493.1273(a)(f)) Director Responsibilities: Director Responsibilitie: CFR Director Responsibilities:					

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: (X2) MUL A. BUILDI		LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		340047	B. WING		R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS		STREET ADDRESS, CITY, STATE, ZIP CO MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		•	
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE COMPLETION	
{A 576}	Continued From page		{A 576	5}		
	problems in the subs 6079	pecialty of histopathology.				
1 1 1 3	C) The laboratory director failed to provide overall management and direction for the laboratory.					
	procedures were valid	ed to ensure equipment and dated prior to use for patient perform manufacturers' e as required.				
	E) The laboratory fail temperature, and hur	ed to monitor water quality, nidity as required.				
	failed to monitor and					
	manual was complete Review of the Operat laboratory procedure and current for the terevidenced by the follows: 1. The procedure mastep-by-step procedure faxitron PathVision X a. requirements for system of the selection, and procests b. startup and shutdown c. calibration, includir frequency; d. safety checks, including the selection of the se	owing: nual did not include res for operation of the -Ray Analyzer, including: pecimen collection, using; wn; ng the material used and the uding the documentation uency of performance;				
		course of action to take if				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIP	LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
		340047	B. WING		R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	1 11	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157			
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPI DEFICIENCY)	OULD BE COMPLETION	
{A 576}	Continued From page 30 2. The procedure manual did not include		{A 576	5}		
	instructions for issuir surgical pathology re	ng a corrected or amended port.				
		o.m., TP #1 confirmed that all did not include policies and				
	personnel were train and failed to ensure	ector failed to ensure testing ed prior to testing patients, policies and procedures were wed for monitoring testing cy.				
		ed to verify performance faxitron PathVision X-Ray in patient testing.				
		ures for operation of the i-Ray Analyzer, including: pecimen collection, ssing;				
	c. calibration, including frequency; d. safety checks, including required and the frequency	ng the material used and the uding the documentation uency of performance; e course of action to take if				
	2. The procedure ma	nual did not include ng a corrected or amended				
	p.m., TP #1 confirme	/7/18 at approximately 3:30 and that the procedure manual es and procedures for all				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		340047	B. WING				R-C	
NAME OF P	ROVIDER OR SUPPLIER	340047		STREET ADDRES	SS, CITY, STATE, ZIP CODE	03/	/26/2018	
		000,711		MEDICAL CENTI	ER BOULEVARD			
NORTH	AROLINA BAPTIST H	OSPITAL		WINSTON-SAL	LEM, NC 27157			
(X4) ID PREFIX TAG	(EACH DEFICIE	STATEMENT OF DEFICIENCIES ENCY MUST BE PRECEDED BY FULL OR LSC IDENTIFYING INFORMATION)	ID PREFI TAG	(EAC	PROVIDER'S PLAN OF CORRECT CH CORRECTIVE ACTION SHOUI S-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
{A 576}	specifications for the performed on the puse in patient testion. 1. The Artisan stain specifies operation temperature of 15-degrees Fahrenhe 2. Review of temperature of HC (Implementation of the Neuro IHC (Implementation of temperature range and a laboratory drange of 10% - 60° K) The laboratory surgical pathology 8, 2018, the laboration which erroneous hours and fourth patient. Case 1. The laboratory delegated responses	failed to establish performance he modified stain procedures Artisan Staining System prior to ng' ning system operators manual in an environment with room 35 degrees Celsius (59-95 it) at 15-75% relative humidity. erature and humidity logs for munohistochemistry) two Artisan staining system operated by the laboratory, ory defined acceptable room of 64-104 degrees Fahrenheit efined acceptable humidity	{A 5	76}	DEFICIENCY)			
	personnel were tra	director failed to ensure testing nined and the training was to testing patient specimens.						
	1	director failed to ensure						

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	l ` ′		E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		340047	B. WING			1	-C 26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		ı	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRIA DEFICIENCY)		(X5) COMPLETION DATE
{A 576}	Continued From page and followed.		{A 5	576]	}		
{A 582}	requiring review, and performed for 1,422 conducted since the F complaint investigation identified an additional erroneous histopatho reported. The erroneous results resulted in unpatients and a potenti other patients. For the treatment was not impongoing.	291 histopathology cases reviews had been of the cases. During reviews February 5-8, 2018 on survey, the laboratory had al 25 cases in which logy test results were ous histopathology test necessary treatment for 3 fall delay in treatment for 3	{A 5	(82)			
	available, either direct agreement with a cent the requirements of positive the standard of the requirement of the requirement of the requirements of	ate results for medical cularly the subspecialty of mpled patients (Patient #1, 8, Patient #4). The findings					
	surgical pathology ca	ses per year. As of February					

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING		` ′	(X3) DATE SURVEY COMPLETED			
		340047	B. WING			R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	1		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	1	33/26/2016
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
{A 582}	which erroneous hist reported, resulting in three patients and a fourth patient. Case B) Review of the fact Case Reviews Prior effective 01/02/2018 department provides critical to successful The pathologist's intespecimens are critical treatment for all candare important members and are a significant for [the facility] It is [name of facility] to eand other surgical proutside facility are rethe patient receiving C) Review of the "MI POLICIES, AND RU OF [NAME OF FACI PERFORMANCE IM (1) The Medical Staff measurement, assessat least the following processes to response to response to patient safety grafety risks;(f) oper procedures, including discrepancies between post-operative diagn	ry had identified 4 cases in opathology test results were unnecessary treatment for delay in diagnosis for a reviews are ongoing. lity policy "Breast Cancer to Initiating Therapy," revealed "The pathology diagnostic services that are treatment of cancer patients. Expretations and review of all to determining appropriate exer patients, and thus they exer of the treatment team component of quality care is therefore the policy of insure that all breast biopsies ocedures performed by an viewed by Pathology prior to the first course of treatment." EDICAL STAFF BYLAWS, LES AND REGULATIONS Is actively involved in the exement, and improvement of a (a) patient safety, including to patient safety alerts, incals, and reduce patient ative and other invasive greater than the pre-operative and oses;"	{A 58	32}		
	procedures, including discrepancies betwee post-operative diagn D) Review of Patient revealed a female part of the procedures of the procedures of the procedure of the procedures of the proce	g tissue review and review of en pre-operative and oses;" #3's medical record				

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		(X2) MULT A. BUILDIN	TIPLE CONSTRUCTION	, , ,	(X3) DATE SURVEY COMPLETED	
		340047	B. WING			R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS			STREET ADDRESS, CITY, STATE, ZII MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	P CODE	03/26/2016
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN ((EACH CORRECTIVE A CROSS-REFERENCED T DEFICIE	ACTION SHOULD BE TO THE APPROPRIATE	(X5) COMPLETION DATE
{A 582}	medial central left bredocumented "addition needed with magnific the patient had a diag left digital breast tome and diagnostic breast the early detection of radiology report docu and "recommend a neo6/13/2017, a stereot procedure that uses ridentify and biopsy arbreast), was performed. The pathology result the left breast by MD carcinoma (a cancer grows through the dubreast tissue), and du ([DCIS] cancer contain A surgical consult wa 07/18/2017, the patien node biopsies of four surgical procedure what tissue is removed). The pathology result the pathology result the left breast of the pathology result the left breast tissue), and du ([DCIS] cancer contain A surgical consult wa 07/18/2017, the patien node biopsies of four surgical procedure what tissue is removed). The pathology of the lurcarcinoma in-situ, into left breast. Patient #3 treatments to the left through 09/15/2017. If amended report for the dated 01/04/2018. "The reveiled and also external facility (1/4/201/20/2018, from MD	aled calcifications in the east, middle third and hal imaging evaluation ation views." On 06/05/2017 gnostic mammogram with posynthesis (a new screening timaging process to improve breast cancer). The mented "mildly suspicious," eedle biopsy." On factic left breast biopsy (a mammography to precisely in abnormality within the ed. For the 6/15/2017 biopsy of #7, revealed invasive ductal that is not contained and ct walls into the surrounding factal carcinoma in situ fined in the mammary ducts). It is recommended, and on the interest form of the lymph meetomy, "ductal ermediate grade" of the final pathologic diagnosis	{A 5	82}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: (X2) MULTIPLE CONSTRUCTION A. BUILDING		(.	(X3) DATE SURVEY COMPLETED			
		340047	B. WING			R-C 03/26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS			STREET ADDRESS, CITY, STATE, ZIP O MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	CODE	03/20/2016
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFII TAG	PROVIDER'S PLAN OF (EACH CORRECTIVE ACT CROSS-REFERENCED TO DEFICIENCE	TION SHOULD BE THE APPROPRIAT	(X5) COMPLETION DATE
{A 582}	LEFT, LUMPECTOM hyperplasia within a with usual ductal hyperplasia with usual ductal hyperplasia with usual ductal hyperplasia with usual lumpector did not meet criteria for the sentinel lymph no "unchanged." Interview on 02/05/20 Chief Medical Officer, work flow/work force revealed there had be changes in the anator as a result of express reasons that led to a result of feedback the are deep in the midst review to see if we had interview revealed "Wexternally reviewed a meet our standards." review process and we percent" of the breast interview revealed the reached a "summative disclosure meetings with the had "attempted to individuals into the work and upregulated the percent of the work by MD #7, "Vertical literal work by MD #7," Interview on 02/05/20 02/08/2018 at 1415 were also with the work by MD #7," "Interview on 02/05/20 02/08/2018 at 1415 were also with the work by MD #7," "We with the comment of the work by MD #7," "We with the work by MD #7," "We	is revisedBREAST, Y: Focal atypical ductal a background of sclerosis erplasia, see COMMENT." ed the "focus of atypia in the my was concerning," but it or DCIS. The diagnoses for de biopsies was 18 at 1200 with MD #11, the revealed "We've had a imbalance." Interview een corrective actions and mical pathology laboratory ed concerns. "There were change in leadership as a rorganization received. We of a complex and deep live a quality issue." The le've internally and and found our care did not The hospital was now in a livere re-reviewing "100 a cancer cases. The e organization had not be conclusion" and they had with all patients involved, o put more qualified orkflow," new leadership, orocess of dual reads ds on all outside cases). ere was no evidence to date had a problem other than who is now gone." 18 at 1245 and on with MD #10, the Chair of the	{A 5	82}		
	Pathology Departmen	it, revealed he had been in				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	l ' '	PLE CONSTRUCTION G		(X3) DATE SURVEY COMPLETED		
		340047	B. WING		I	R-C 3/26/2018		
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CO MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		0/20/2010		
(X4) ID PREFIX TAG			ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE		
{A 582}	revealed he was ask Chair (MD #7) separ Interview revealed the last Monday," hired a Pathology. Interview mandatory second rebiopsies to be docur. The interview reveal breast biopsies, and policy (mandatory sebreast biopsies) was Interview revealed a diagnosis, whether into be reviewed by two revealed "pink sheet second reading for a cancer specimens. In "ultimate goal" would for all positive malign monitoring the "pink the two reads, MD # the first month and homonths then identify see if we have a pink wanted to "allow for collecting data." Review of an email sepathology (breast bid reviewed here prior for recognize that this is oncologists (medical but you may come a	gust of 2017. Interview and to chair after the previous ated from the organization. The hospital had recently "as of a new Director of Surgical revealed they implemented a review for all new breast mented on the pink sheets. The "new breast cancer recond review for all new the "new breast cancer recond review for all new the implemented January first. The nouse or external, was now to Pathologists. Interview to Pathologist	{A 58	2}				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ` '	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		340047	B. WING			R-C 3/26/2018	
	ROVIDER OR SUPPLIER	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CO MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		3/23/2010	
(X4) ID PREFIX TAG			ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTIC CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
{A 582}	Interview on 02/07/2 Manager of Laborato Assurance, Point of was mentioned to m that there were some reports and they wer Management to be h she was the one who Case Reviews Prior effective 01/02/2018 policy stated any cas outside consult had source before we tre revealed "The policy cases." The Manage was unaware of a ne #10, requiring a secc external biopsies ind Interview revealed th been compiled yet si enough time to proce revealed the tracking been added to QA (C Interview revealed th the policy a "step for process." When eve about the problem, to and they can write a revealed the incorrect	sheet], for all newly ncers. This includes both	{A 58				
	shared with anyone MD #10 met with the Pathology Departme 2018 at 1200 and pr	in the lab." Interview revealed Pathology staff during the ent meeting on January 2, esented the pink form					

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULT A. BUILDIN	IPLE CONSTRUCTION NG	, ,	(X3) DATE SURVEY COMPLETED		
		340047	B. WING _			R-C 03/26/2018		
	ROVIDER OR SUPPLIER	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CO MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	•	03/20/2010		
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{A 582}	revealed she could remonthly QA meeting each month. Interview meetings occurred the month. As the new pall new breast cancer. January, the data have, but would be pareting. Interview recome directly to her she will review, track. Interview on 02/05/2 Physics for Radiation Safety Officer, reveau December of 2017, received a full cours diagnosis was incorrectly they had breast cancer. Interview on they had breast cancer they had breast cancer. Interview of Radiation Oncologiand the North Carolia Regulation were not immediately investig treatments were dorno errors or deviation section from the State cases in detail and the non-compliance were department. Interview Oncologist conducted hundreds of cases."	2018 at 1020 with Staff #2, not begin compiling data for is until after the seventh of ew revealed the monthly QA he last Wednesday of each process of a second read for ers was initiated the first of as not been added to the QA int of the February QA evealed all "pink sheets" mailbox. Interview revealed and monitor for compliance. 2018 at 1400 with the Chief of in Oncology and the Radiation aled they discovered in after the Patient #3 had the of radiation therapy, the rect. "The Pathologist said cer, we went through our terview revealed, after int, it was discovered she did erview revealed the Director gy, the facility Safety Officer, na Division of Health Service iffed, and the situation was lated. Interview revealed the me properly, and there were ins. The Radiation compliance the came on site, reviewed the look a full report. No issues of the identified in the radiology we revealed the Radiation and a "thorough review of Interview revealed "Moving"	{A 5	82}				
	Oncologist conducte hundreds of cases." forward, we are look	ed a "thorough review of						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:				(X3) DATE SURVEY COMPLETED	
			A. BOILDI			R-C	
		340047	B. WING				26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HO	DSPITAL		STREET ADDRESS, MEDICAL CENTER WINSTON-SALE			
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{A 582}	1050 with the Direct revealed in Septem Management was regarding 10 patier revealed the conce Director's attention complaints by emplementary revealed reviewing cases an externally reviewed re-reviewed and se Risk Management's case files revealed care would be affect diagnosis, which in re-reviewing the brown confirming reports received on Decement Hammediately set in involved. The interviewing the involved. The interviewent for the revealed the invest updated results we Committee. E. Review of Patier revealed a female parammogram screen.	6/2018 at 1505, 02/06/2018 at stor of Risk Management, aber of 2017, Risk made aware of concerns at sof MD #7. Interview rns were brought to the as a result of several doyees from the laboratory. Risk Management started d getting ready to have them 1. The cases were internally and for external review as well. It is review of the 10 patients' 4 of the 10 patients' plans of exted with an incorrect cluded Patient #3. After least cancer cases, and the room external reviews, aber 15, 2017, it was found that least cancer was incorrect for we revealed Risk Management to action and got physicians view revealed Patient #3 had misdiagnoses. The interview igation is still ongoing and all regoing to the Medical Review bort to the Medical Executive at #4's medical record, catient who underwent a rening on 02/10/2016. The	{A 5	82}	DEFICIENCY)		
	"Incomplete" and n "The patient should left mammogram a ultrasound." Review	evealed the results were eeded additional imaging. I be recalled for a diagnostic nd possible left breast v revealed on 05/24/2016, a gram and ultrasound of the left					

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ' '	FIPLE CONSTRUCTION NG	(X3) DATE SURVEY COMPLETED
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		340047	B. WING _		03/26/2018
NAME OF F	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP	CODE
NODTH (AROLINA BAPTIST H	IOSDITAL		MEDICAL CENTER BOULEVARD	
NOKIH	AROLINA BAPTIST H	IOSPITAL		WINSTON-SALEM, NC 27157	
(X4) ID PREFIX TAG	(EACH DEFICIE	Y STATEMENT OF DEFICIENCIES ENCY MUST BE PRECEDED BY FULL OR LSC IDENTIFYING INFORMATION)	ID PREFI TAG	PROVIDER'S PLAN C X (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIE	CTION SHOULD BE COMPLETION DATE
{A 582}	breast were perford documented "CON the left breast, bet mammographically biopsy is recomme abnormality. Biopsy 06/15/2016, the pation biopsy of the left breported by MD #7 carcinoma and DC complex sclerosing Patient #4 underw breast with left ser pathology report by nodes were negat malignancy was in lumpectomy. Patient treatments to the last through 09/23/201 09/30/2016. Revied on 08/11/2017, for with tomo. The individual was breast cancer central portion of last Radiologist conclus mammographic expression of the commended routed in the middle of the pation of the pat	med. The Radiologist NCLUSION: Focal asymmetry in ter delineated y, for which stereotactic guided ended Suspicious sy should be considered." On atient underwent a core needle creast. The pathology findings revealed invasive ductal CIS in a background of a g lesion. On 07/21/2016, rent a lumpectomy of the left nitinel node biopsies X2. The y MD #9, revealed the lymph live for tumor and no dentified in the breast tissue ent #4 received daily radiation eft breast from 09/26/2016 through the revealed the patient returned a diagnostic left mammogram effication for the mammogram of eff female breast" The ided there was no yidence of malignancy, and	{A 5	82}	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	l ` ′	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED		
		340047	B. WING				R-C		
NAME OF P	ROVIDER OR SUPPLIER	340047		STRE	ET ADDRESS, CITY, STATE, ZIP CODE	03	/26/2018		
IVAIVIL OF T	TOVIDEIT OIL OOI 1 EIEIT				CAL CENTER BOULEVARD				
NORTH C	AROLINA BAPTIST H	OSPITAL			STON-SALEM, NC 27157				
	OLIMANA DV	OTATEMENT OF REFIGIENCIES			·	N.			
(X4) ID PREFIX TAG	(EACH DEFICIE	STATEMENT OF DEFICIENCIES NCY MUST BE PRECEDED BY FULL DR LSC IDENTIFYING INFORMATION)	ID PREFI TAG	×	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULE CROSS-REFERENCED TO THE APPROP DEFICIENCY)	BE	(X5) COMPLETION DATE		
{A 582}	Continued From pa	age 41	{A 5	82}					
	· ·	d and found our care did not		1					
		s." The hospital was now in a							
		d were re-reviewing "100							
	•	ast cancer cases. The							
	·	the organization had not							
		tive conclusion" and they had							
		s with all patients involved,							
	_	ed to put more qualified							
		workflow," new leadership,							
		e process of dual reads							
		reads on all outside cases).							
	Interview revealed there was no evidence to date								
	that the organization	on had a problem other than							
	the work by MD #7	, "who is now gone."							
		/2018 at 1245 and on							
		5 with MD #10, the Chair of the							
		nent, revealed he had been in							
		August of 2017. Interview							
		sked to chair after the previous							
	·	arated from the organization.							
		the hospital had recently "as of							
	· ·	d a new Director of Surgical							
		w revealed they implemented a							
		review for all new breast							
		umented on the pink sheets. aled "the nexus was clearly on							
		id the "new breast cancer							
		second review for all new							
		as implemented January first.							
		any new breast cancer							
		in house or external, was now							
	_	two Pathologists. Interview							
		ets" were created to ensure a							
		all the newly diagnosed breast							
		Interview revealed the							
		ald be to add a second reading							
	_	gnancies. When asked about							
		k sheets" for compliance with							

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		IDENTIFICATION NI IMBED		TIPLE CONSTRUCTION NG	' '	(X3) DATE SURVEY COMPLETED	
		340047	B. WING _			R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CO MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	I DDE	00/20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFII TAG	PROVIDER'S PLAN OF ((EACH CORRECTIVE ACTI CROSS-REFERENCED TO TI DEFICIENC	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
{A 582}	the first month and h months then identify see if we have a pink wanted to "allow for icollecting data." Review of an email see Pathologists] and Cyse See Cyto Fellows, a 28, 2017 at 0853, reviewed here prior to recognize that this is oncologists (medical but you may come an addition, we need into attached form [pink seed internal and external linterview on 02/07/20. Manager of Laborator Assurance, Point of was mentioned to me that there were some reports and they were Management to be his she was the one who Case Reviews Prior effective 01/02/2018 policy stated any case outside consult has to source before we tre revealed "The policy cases." The Manage	all the breast cancers, then a sheet." MD #10 stated he implementation before ent "To all SP [Surgical to [cytopathology] Faculty, and Residents, on December wealed "Starting January 2, Briefly, all outside epsies, etc.) must be initiating therapy. I largely in the purview of & radiation) and surgeons cross such patients. * In ernal confirmation, using the cheet], for all newly incers. This includes both	{A 5	82}			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(>	(X3) DATE SURVEY COMPLETED	
		340047	B. WING _			R-C 03/26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		STREET ADDRESS, CITY, STATE, ZIP MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	CODE	03/20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	(EACH CORRECTIVE AC CROSS-REFERENCED TO	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		
{A 582}	Interview revealed the been compiled yet sire enough time to proce revealed the tracking been added to QA (Q Interview revealed the the policy a "step for process." When ever about the problem, the and they can write a revealed the incorrect guarded and so highly shared with anyone in MD #10 met with the Pathology Departmer 2018 at 1200 and prerequiring a second rebiopsies.	cating new breast cancer. e January 2018 data had not not the there had not been so the information. Interview of the "pink sheets" had not the suality Assurance) yet. e "pink sheets" were taking ward" to start collection yone else is allowed to know the everyone else can know the neveryone else can know the neveryone was "so highly your confidential it was not not the lab." Interview revealed Pathology staff during the not meeting on January 2, the sented the pink form adding on all new breast	{A 5	82}			
	revealed she could no monthly QA meetings each month. Intervie meetings occurred the month. As the new properties all new breast cancer January, the data has yet, but would be parameeting. Interview recome directly to her reshe will review, track. Interview on 02/05/20 Physics for Radiation Safety Officer, reveal December of 2017, a received a full course.	ot begin compiling data for a until after the seventh of we revealed the monthly QA e last Wednesday of each cocess of a second read for se was initiated the first of so not been added to the QA to of the February QA vealed all "pink sheets" mailbox. Interview revealed and monitor for compliance. One of the Patient #3 had to of radiation therapy, the sect. "The Pathologist said					

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA (X2) MI IDENTIFICATION NUMBER: A. BUIL		PLE CONSTRUCTION 3	(X3) DATE SURVEY COMPLETED	(X3) DATE SURVEY COMPLETED		
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NAME OF PI	ROVIDER OR SUPPLIER	040047		STREET ADDRESS, CITY, STATE, ZIP CODE	03/26/201	8		
				MEDICAL CENTER BOULEVARD				
NORTH C	AROLINA BAPTIST HOS	SPITAL		WINSTON-SALEM, NC 27157				
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE COMPL	LETION		
{A 582}	Continued From pag	e 44	{A 58	2}				
	they had breast cand	er, we went through our	,					
	1	terview revealed, after						
		nt, it was discovered she did						
	not have cancer. Inte	erview revealed the Director						
	of Radiation Oncolog	yy, the facility Safety Officer,						
		na Division of Health Service						
	_	fied, and the situation was						
	, ,	ated. Interview revealed the						
	I .	e properly, and there were						
		ns. The Radiation compliance						
		e came on site, reviewed the						
	I .	ook a full report. No issues of e identified in the radiology						
	-	w revealed the Radiation						
	·	d a "thorough review of						
	_	Interview revealed "Moving						
	I .	ng into possibly doing a step						
		o sign offs in pathology."						
	Interviews on 02/05/2	2018 at 1505, 02/06/2018 at						
	1050 with the Directo	or of Risk Management,						
	revealed in Septemb	er of 2017, Risk						
	Management was ma	ade aware of concerns						
	regarding 10 patients							
	revealed the concern	s were brought to the						
	Director's attention a							
		yees from the laboratory.						
		isk Management started						
	_	getting ready to have them						
		The cases were internally						
		t for external review as well. review of the 10 patients'						
	_	of the 10 patients' plans of						
	I .	ed if the results came back						
		gnosis, which included						
	1	eviewing the breast cancer						
		irming reports" from external						
	I .	December 15, 2017, it was						
		osis of breast cancer was						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	PLE CONSTRUCTION 3		(X3) DATE SURVEY COMPLETED		
		340047	B. WING			R-C		
NAME OF PE	ROVIDER OR SUPPLIER	340047	B: Willo _	STREET ADDRESS, CITY, STATE, ZIP COI		3/26/2018		
TO UNIC OF TH	TO VIDER OR OUT FEEL			MEDICAL CENTER BOULEVARD				
NORTH C	AROLINA BAPTIST HOS	SPITAL						
				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 CO (EACH CORRECTIVE ACTIO CROSS-REFERENCED TO THI DEFICIENCY)	N SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE		
{A 582}	Continued From pag	e 45	{A 58	2}				
	Management "immed got physicians involved Patient #4 had been The interview revealed ongoing and all updated Medical Review Communical Executive Communication F. Investigative finding revealed Patient #1, cancer by MD #7 in 2 a lumpectomy and changeressive route of a	#4. Interview revealed Risk diately set into action" and ed. The interview revealed notified of the misdiagnoses. ed the investigation is still ted results were going to the mittee who report to the ommittee. Ings on February 6, 2018, was diagnosed with breast 2017. The patient underwent mose to undergo the more in bilateral mastectomy.						
	Chief Medical Officer work flow/work force revealed there had be changes in the anator as a result of express reasons that led to a result of feedback the are deep in the midstreview to see if we had interview revealed "Vexternally reviewed a meet our standards." review process and vereit of the breast interview revealed the reached a "summative disclosure meetings they had "attempted individuals into the wand upregulated the	and found our care did not The hospital was now in a were re-reviewing "100 t cancer cases. The e organization had not we conclusion" and they had with all patients involved,						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		340047	B. WING				R-C /26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS			MEDIC	TADDRESS, CITY, STATE, ZIP CODE CAL CENTER BOULEVARD TON-SALEM, NC 27157	1 03/	20/2010
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFII TAG	(PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE
{A 582}	that the organization the work by MD #7, " Interview on 02/05/20 02/08/2018 at 1415 v Pathology Department his position since Augrevealed he was asked Chair (MD #7) separated Interview revealed the last Monday," hired a Pathology. Interview mandatory second rebiopsies to be document to be review revealed breast biopsies, and policy (mandatory sebreast biopsies) was Interview revealed are diagnosis, whether into be reviewed by two revealed "pink sheets second reading for all cancer specimens. In "ultimate goal" would for all positive malign monitoring the "pink step the two reads, MD #1 the first month and himonths then identify see if we have a pink	ere was no evidence to date had a problem other than who is now gone." 218 at 1245 and on with MD #10, the Chair of the nt, revealed he had been in gust of 2017. Interview ed to chair after the previous ated from the organization. The hospital had recently "as of new Director of Surgical revealed they implemented a review for all new breast tented on the pink sheets. The ded "the nexus was clearly on the "new breast cancer cond review for all new implemented January first. The previous or external, was now to Pathologists. Interview so were created to ensure a I the newly diagnosed breast	{A 5	82}			
	Pathologists] and Cylor SP & Cyto Fellows, a	ent "To all SP [Surgical to [cytopathology] Faculty, nd Residents, on December realed "Starting January 2,					

	DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		TIPLE CONS	STRUCTION		LETED
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NAME OF P	ROVIDER OR SUPPLIER	340047	B. WING		T ADDRESS, CITY, STATE, ZIP CODE	03/	26/2018
					AL CENTER BOULEVARD		
NORTH C	AROLINA BAPTIST HOS	PITAL		WINST	FON-SALEM, NC 27157		
(X4) ID PREFIX TAG	(EACH DEFICIENC	(EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOU		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)		(X5) COMPLETION DATE	
{A 582}	oncologists (medical but you may come ad addition, we need into attached form [pink s diagnosed breast car internal and external Interview on 02/07/20 Manager of Laborato Assurance, Point of C was mentioned to me that there were some reports and they were Management to be has he was the one who Case Reviews Prior t effective 01/02/2018. policy stated any casoutside consult has to source before we trear revealed "The policy cases." The Manager was unaware of a new #10, requiring a seco external biopsies indi Interview revealed the been compiled yet sire enough time to proce revealed the tracking been added to QA (Conterview revealed the tracking been added to Top process. "When every process."	Briefly, all outside psies, etc.) must be pries, etc.) must be pries, etc.) must be pries, etc.) must be pries, etc.) must be priested initiating therapy. I plargely in the purview of & radiation) and surgeons pross such patients. * Internal confirmation, using the priested in the prie	{A 5	82}			
		en everyone else can know new policy." Interview					

AND PLAN OF CORRECTION IDENTIFICATION NU		IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		340047	B. WING			R-C 03/26/2018		
NAME OF PROVIDER OR SUPPLIER NORTH CAROLINA BAPTIST HOSPITAL				STREET ADDRESS, CITY, STATE, ZIP COI MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	DE	,		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	FIX (EACH CORRECTIVE ACTION SHOULD BE			(X5) COMPLETION DATE	
{A 582}	Continued From page 48 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.		{A 58	32}				
	revealed she could no monthly QA meetings each month. Intervie meetings occurred the month. As the new properties all new breast cancer January, the data has yet, but would be par meeting. Interview recome directly to her recome monthly QA meeting.	ot begin compiling data for until after the seventh of w revealed the monthly QA e last Wednesday of each ocess of a second read for s was initiated the first of a not been added to the QA						
	1050 with the Directorevealed in September Management was maregarding 10 patients revealed the concern Director's attention as complaints by employ Interview revealed Rireviewing cases and externally reviewed. The reviewed and sent Risk Management's recase files revealed 4 care would be affected with an incorrect diagonal revealed in the property of the province o	nde aware of concerns of MD #7. Interview s were brought to the						

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			COMPLETED		
		340047	B. WING			R-C 03/26/2018		
	NAME OF PROVIDER OR SUPPLIER NORTH CAROLINA BAPTIST HOSPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		l	03/26/2018		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORE (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AF DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE		
{A 582}	reviews, received on found that the diagnoric incorrect for Patient of Management "immed got physicians involved Patient #1 had been. The interview revealed ongoing and all updated Medical Review Commedical Executive Co	December 15, 2017, it was usis of breast cancer was the interview revealed Risk diately set into action" and ed. The interview revealed notified of the misdiagnoses. The investigation is still ted results were going to the imittee who report to the imittee. It 1050 with Risk ed, Patient #2, was the a pathology report from a 20/2016, from MD #7, did not have breast cancer. In another breast biopsy screening mammogram) on as positive for breast cancer. The patient was currently under ast cancer. In an at 1200 with MD #11, the revealed "We've had a imbalance." Interview een corrective actions and mical pathology laboratory sed concerns. "There were change in leadership as a reorganization received. We are a quality issue. The We've internally and and found our care did not The hospital was now in a were re-reviewing "100"	{A 58	32}				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		IDENTIFICATION NUMBER:		IPLE CONSTRUCTION NG	(X3) DATE SURVEY COMPLETED		
		340047	B. WING			R-C	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		ARD	03/26/2018	
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFI TAG	((EACH CORRECTI CROSS-REFERENC	LAN OF CORRECTION IVE ACTION SHOULD B ED TO THE APPROPRIA FICIENCY)	DATE	
{A 582}	disclosure meetings of they had "attempted to individuals into the work and upregulated they (already had dual real Interview revealed they that the organization the work by MD #7, "Interview on 02/05/20 02/08/2018 at 1415 or Pathology Department his position since Augrevealed he was asked Chair (MD #7) separa Interview revealed the last Monday," hired a Pathology. Interview mandatory second rebiopsies to be docum. The interview revealed breast biopsies, and spolicy (mandatory second rebiopsies) was Interview revealed and diagnosis, whether in to be reviewed by two revealed "pink sheets second reading for all cancer specimens. In "ultimate goal" would for all positive malign monitoring the "pink steets two reads, MD #1 the first month and hi months then identify see if we have a pink	e conclusion" and they had with all patients involved, to put more qualified orkflow," new leadership, process of dual reads ds on all outside cases). The ere was no evidence to date had a problem other than who is now gone." 118 at 1245 and on with MD #10, the Chair of the nt, revealed he had been in gust of 2017. Interview and to chair after the previous attend from the organization. The hospital had recently "as of new Director of Surgical revealed they implemented a view for all new breast ented on the pink sheets. The "new breast cancer cond review for all new implemented January first. By new breast cancer house or external, was now of Pathologists. Interview "were created to ensure a the newly diagnosed breast	{A 5	82}			

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		` '	PLE CONSTRUCTION G	, ,	(X3) DATE SURVEY COMPLETED		
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	ROVIDER OR SUPPLIER		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		I	03/26/2018	
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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		{A 58	32}			
	was mentioned to me that there were some reports and they were Management to be highly she was the one who Case Reviews Prior effective 01/02/2018 policy stated any case outside consult has source before we transport to be with the mean of a new transport of the mean of	Care and Safety, revealed "It e on a need to know basis e issues with some pathology re in the hands of Risk handled." Interview revealed to wrote the "Breast Cancer to Initiating Therapy," policy and Interview revealed the see that comes in as an to be reviewed by an internal eat patients Interview references only outside er of Laboratory Compliance ew policy put in place by MD and read on both internal and dicating new breast cancer. The January 2018 data had not ince there had not been ess the information. Interview g of the "pink sheets" had not					

` '		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING			ATE SURVEY DMPLETED		
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	ROVIDER OR SUPPLIER	l	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		I	03/26/2018		
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SI CROSS-REFERENCED TO THE AF DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE		
{A 582}	Interview revealed the policy a "step for process." When ever about the problem, the and they can write a revealed the incorreguarded and so high shared with anyone MD #10 met with the Pathology Departme 2018 at 1200 and proceeding a second of the process. Interview on 02/07/2 revealed she could of monthly QA meeting each month. Interview meetings occurred the month. As the new pall new breast cancer January, the data has yet, but would be part meeting. Interview on 02/05/1050 with the Direct revealed in Septemb Management was more revealed the concern Director's attention a complaints by emplointerview revealed Freviewing cases and reviewing cases and review revealed from the process reviewing cases and review revealed from the process reviewing cases and review revealed from the process review revealed f	Quality Assurance) yet. The "pink sheets" were taking ward" to start collection ryone else is allowed to know hen everyone else can know new policy." Interview of lab reporting was "so highly ally confidential it was not in the lab." Interview revealed to Pathology staff during the ent meeting on January 2nd, resented the pink form reading on all new breast and the last Wednesday of each process of a second read for ears was initiated the first of as not been added to the QA rt of the February QA revealed all "pink sheets" mailbox. Interview revealed and monitor for compliance. 2018 at 1505, 02/06/2018 at or of Risk Management, per of 2017, Risk reade aware of concerns so f MD #7. Interview ns were brought to the	{A 58	2}				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
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NAME OF P	ROVIDER OR SUPPLIER				STREET ADDRESS, CITY, STATE, ZIP CODE			
NORTH C	AROLINA BAPTIST HO	SPITAL			MEDICAL CENTER BOULEVARD			
	I				WINSTON-SALEM, NC 27157			
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{A 582}	Risk Management's case files revealed a care would be affect with an incorrect dia Patient #2. After recases, and the "con reviews, received or found that the diagn incorrect for Patient Management "immegot physicians involvatient #1 had been The interview revea ongoing and all upd Medical Review Cor Medical Executive Cornections in the summary, laborated oversight of Laborated laboratory specimer processed with accurate would be affected as a summary of the summary of the summary oversight of Laborated laboratory specimer processed with accurate would be affected as a summary of the summary of the summary oversight of Laborated laboratory specimer processed with accurate would be affected as a summary of the summary	nt for external review as well. review of the 10 patients' 4 of the 10 patients' plans of ted if the results came back ignosis, which included reviewing the breast cancer firming reports" from external in December 15, 2017, it was osis of breast cancer was #2. Interview revealed Risk rediately set into action" and wed. The interview revealed in notified of the misdiagnoses. Ided the investigation is still ated results were going to the mmittee who report to the	{A 5	582}				