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

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULT A. BUILDII		NSTRUCTION	(X3) DATE COMF	SURVEY
			B WING	R WING		R-C	
		340047	B. WING _			03/	26/2018
NAME OF PI	ROVIDER OR SUPPLIER				ET ADDRESS, CITY, STATE, ZIP CODE		
NORTH C	AROLINA BAPTIST HOS	SPITAL		MEDIC	CAL CENTER BOULEVARD		
				WINS	TON-SALEM, NC 27157		
(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 CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRIA DEFICIENCY)		(X5) COMPLETION DATE
{A 000}	INITIAL COMMENTS	3	(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 speprocessed with accurate interventions. Pursua Body and 482.22 Meto provide oversight of particularly the subspandicularly the subspandicularly the subspandicularly facility's administrebruary 8, 2018 at a the immediate jeopar. The laboratory failed problems in the subspandicular the subspandicular facility failed procedures were valided to specified maintenance laboratory failed to maintenance laboratory failed to procedure and failed to procedure a	to identify and correct pecialty of histopathology. to ensure the procedure e for all testing performed. to ensure equipment and dated prior to use for patient perform manufacturers' as as required. The nonitor water quality, midity as required. The erform and document quality natoxylin and eosin) stains as o discard expired supplies.					
	management and dir	or failed to provide overall ection for the laboratory. The iled to ensure delegated ed as required. The					
ADODATORY	DIDECTORIO OR PROVINCES	COURDINED DEDDECENTATIVE COLORVATOR) DE		TITLE		(VC) DATE
LABURATURY	DIRECTOR'S OR PROVIDER/	SUPPLIER REPRESENTATIVE'S SIGNATUR	ベヒ		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

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 AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ' '	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		340047	B. WING _			I	-C 26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		STREET ADDRESS, CITY, STATI MEDICAL CENTER BOULEVA WINSTON-SALEM, NC 27	ARD			
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{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 results and the severity action the immediate and 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 potention other patients. For the	led to ensure testing ad prior to testing patients, policies and procedures were wed for monitoring testing by. approximately 25,000 ases 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. To of the deficiencies and jeopardy was not abated on-going. as conducted at the facility gh March 23, 2018, and and ded on follow-up survey the Jeopardy was abated and corrected. To 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 out histopathology test necessary treatment for 3 ial delay in treatment for 3	{A 00	00}				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIF	PLE CONSTRUCTION G	COMF	(X3) DATE SURVEY COMPLETED	
		340047	B. WING		ı	R-C /26/2018	
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	SPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 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 CORRE (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
{A 043} {A 043}	legally responsible for If a hospital does not governing body, the for the conduct of the functions specified in governing body This CONDITION is Based on review of and procedures, test testing personnel into through February 8, failed to provide over and ensure laborator appropriately process medical interventions subspecialty of history of the hospital laboratory with CFR 493 as resurvey conducted by Improvement Amend 5, 2018 through February 8, failed to provide over any propriately process medical interventions subspecialty of history of the hospital laboratory of the	fective governing body that is or the conduct of the hospital. I have an organized persons legally responsible to hospital must carry out the lithis part that pertain to the lithis pertain that pertain the lithis part that pertain to the lithis part that pertain the lithis part that pertain to the lithis part that pertain to the lithis p	{A 04:	- 1			
	CFR 493.1445(a)(b)	Director Responsibilities: Director Responsibilities:					

Facility ID: 943495

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` '	PLE CONSTRUCTION G	' '	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 03/20/2010	
(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 CORRI (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE API DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
{A 043}	CFR 493.1445(e)(1.2. A) The laboratory to surgical pathology of 8, 2018, the laboratory which erroneous his reported, resulting in three patients and a fourth patient. Case B) The laboratory diresponsibilities to an Pathology Directory delegated duties we by the following: Review of procedur (Operating Room) F Special Stains labor laboratory revealed delegation dated Jalabeled "MEMORAN was signed by the oletter designated the Surgical Pathology maintain documenta Regulatory Agencies specific, detailed liss. The procedure man "MEMORANDUM Copathologist serving director which delegation documentation and Agencies and to assifor the laboratory sehistology supervisor	ests approximately 25,000 cases per year. As of February ory had identified 4 cases in stopathology test results were in unnecessary treatment for idelay in diagnosis for a reviews are ongoing. Frector delegated inother pathologist (Surgical ibut failed to ensure the ere performed as evidenced e manuals in the OR Pathology laboratory, the reatory, and the Main Histology	{A 04	13)		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			(X2) MULT A. BUILDIN	PLE CONSTRUCTION IG	COMF	(X3) DATE SURVEY COMPLETED		
		340047	B. WING _		l	R-C / 26/2018		
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	, <u>33</u> ,	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 CORI (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE		
{A 043}	Continued From pag	e 4	{A 04	13}				
	meet the education rechnical supervisor high complexity historesponsibilities for repersonnel competendelegated to the histomanager). The pathologist servidirector at the time of laboratory employments.	(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 blogy supervisor (assistant as Surgical Pathology of the delegation left ent in September 2017, but documentation had not been						
	management and dir D) The laboratory fai procedures were vali	ector failed to provide overall ection for the laboratory. led to ensure equipment and dated prior to use for patient perform manufacturers'						
	the absence of 2017 interview with the his manager) 2/5/18 - 2/5	- -						
	the two Leica Auto S Histology laboratory exhausted through th	tructions (user manual) for tainers located in the Main stated "Fumes are ne activated carbon filter ged every three months"						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	I ' '	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
			7. 50.25.			R	-C	
		340047	B. WING			03/	26/2018	
NAME OF P	ROVIDER OR SUPPLIER	•		S	TREET ADDRESS, CITY, STATE, ZIP CODE			
NODTH C	ADOLINA DADTICT HO	CDITAL		М	EDICAL CENTER BOULEVARD			
NORTH C	AROLINA BAPTIST HO	SPIIAL		W	/INSTON-SALEM, NC 27157			
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R 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}	was changed every the manufacturer. 2. Manufacturer's inthe two Artisian Stain Neuro IHC (Immuno included a list of maperformed on a daily 11.1 - Daily and Mor Procedures". The tadaily maintenance phottles, perform was platform, clean reaging spill tray. The table amonthly maintenance liquid bottles and fluethanol. There was required daily and more procedures were permanufacturer. 3. Manufacturer's inthe two Leica CM19 OR Pathology laboral "The filter must be comonths." There was filter was changed especified by the manufacturer was changed especified by the manufacturer was filter was changed especified by the manufacturer was filter was changed especified by the manufacturer was changed especified by	structions (user manual) for ning Systems located in the shistochemistry) laboratory intenance procedures to be and weekly basis: "Table of the included the following rocedures: prime bulk liquid ste valve rinse, clean slide ent drip ring, check and clean also included the following reprocedures: clean bulk she bulk liquid lines with no documentation that the nonthly maintenance of the following steprocedures: clean bulk she bulk liquid lines with no documentation that the nonthly maintenance of the following steprocedures: clean bulk she bulk liquid lines with no documentation that the nonthly maintenance of the following steprocedures: clean bulk she bulk liquid lines with no documentation that the nonthly maintenance of the following steprocedures (user manual) for 50 Cryostats located in the latory stated in the section niging the bacteria filter", that hanged approx. every 3 no documentation that the very three months as nufacturer. 18 at approximately 4:00 upervisor (assistant at there is no required than daily cleaning for any of thistology department.	{A 0	43}				
	p.m., the histology s manager) stated tha maintenance other t the equipment in the E) The laboratory fa	upervisor (assistant t there is no required han daily cleaning for any of						

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIP	LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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	ROVIDER OR SUPPLIER AROLINA BAPTIST HO	1.11		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	1 03/20/2010
(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 SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	ULD 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' requirements and sent the satisfacturers and sent the assistant manufacturers and sent the water test there is a full three-in the water test the test the test three in the water test th	to establish temperature and to were consistent with hirements as evidenced by the sy procedures, review of 2017 ting records, review of 2017 temperature and humidity hanufacturers' instructions he histology supervisor of 2/5/18 - 2/8/18, the monitor water quality, failed to ent temperature and humidity, temperature and humidity were consistent with hirements. SGP-3" procedure revealed rocedure: Deionized Water ple of the water from the ks in the Histology Special ike each month. The to covering that lab shall be	{A 043		
	to the laboratory mid month for testing. T	crobiology department each There were no records to s were obtained from the			

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPI A. BUILDING	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		
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{A 043}	monthly testing of the results were reviewed testing was needed. During interview 2/6, a.m., the histology semanager) confirmed receive reports or refrom the deionized was 2. Temperature and a. There were no terrecords available for (Operating Room) Pelaboratory operates and Shandon Varistain in During interview 2/8, a.m., the histology semanager) confirmed documenting the tenthe OR Pathology laboratory defined in temperature of 15-38 degrees Fahrenheit) Review of temperature of 15-38 degrees Fahrenheit) Review of temperature of 16-40 degrees fellowers of 64-104 degrees fellowers defined and range of 64-104 degrees fellowers defined and 10% - 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 mperature and humidity review from the OR athology laboratory. The two Leica cryostats and one astrument in this area. /18 at approximately 9:15 upervisor (assistant they were not monitoring or apperature and humidity for	{A 043	}			

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ' '	IPLE CONSTRUCTION IG		(X3) DATE COMP	SURVEY LETED
		340047	B. WING			1	-C 26/2018
	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL		STREET ADDRESS MEDICAL CENTE WINSTON-SALI		1 03/	20/2010
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL .SC IDENTIFYING INFORMATION)	ID PREFI TAG	(EAC	ROVIDER'S PLAN OF CORRECTION IH CORRECTIVE ACTION SHOULD B S-REFERENCED TO THE APPROPRIA DEFICIENCY)		(X5) COMPLETION DATE
{A 043}	degrees Celsius (59-4 Under "Environmenta "Operating temperature temperature): 18 deg specifications related only up to an ambient C and an air humidity Review of temperatur Special Stains labora cryostat was operated a laboratory defined a temperature range of and a laboratory defined and a laboratory defined at temperature range of and a laboratory defined at temperature range of and a laboratory defined ac "Relative humidity: Review of temperatur Main Histology labora operated two Leica A laboratory defined ac range of 50-86 degre laboratory defined ac 10%-90%. 3. Observation, review revealed the laboratory defined ac 10%-90%.	temperature range of 15-30 86 degrees Fahrenheit). Il requirements", it states are range (ambient arees C to 40 degrees C. All to temperature are valid at temperature of 22 degrees a lower than 60%!" The eard humidity logs for the attory, where a ClearVue abby the laboratory, revealed acceptable room 64-104 degrees Fahrenheit and humidity range of The analysis of the acceptable room a Autostainer operators are "Technical amperature range: +10 arees C" (50-95 degrees arators manual also specifies aratory, where the laboratory autostainers, revealed a acceptable room temperature	{A 0	43}			

	AN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION A. BUILDING A. BUILDING		, ,	(X3) DATE SURVEY COMPLETED		
		340047	B. WING			R-C 03/26/2018
	ROVIDER OR SUPPLIER	SPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	'	00/20/20/10
(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 SHI CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
{A 043}	1. During tour of the Pathology laboratory p.m., the following e. on the shelves behin use: a. Diff-Quik Solution Expiration Date 2017 b. Diff-Quik Solution Expiration Date 2017 2. During a tour of th (Immunohistochemis approximately 1:00 pitems were observed laboratory, available a. Sigma Chemical Texpiration Date 11-0 b. Sodium Arsenate A6756-50C, Expiratic. Arsenic Acid, Lot 903-06. 3. During a tour of th 2/7/18 at approximatel expired item was obsthe laboratory, available a. Thiosemicarbazida. Thiosemicarbazida. Thiosemicarbazida. Review of 2016 and the laboratory complof the OR Pathology laboratory, and the \$7/5/16, 1/12/17, 4/18	OR (Operating Room) 2/5/17 at approximately 1:30 cpired items were observed d the cryostats, available for I, Lot # 661616031A, 7-09-30; II, Lot # 661716031A, 7-09-30. e Neuro IHC ctry) laboratory 2/7/18 at o.m., the following expired I on the shelves lining the for use: Fartaric Acid, Lot # T0375, 7; dibasic Heptahydrate, Lot # on Date 11-02-09; # 98H0273, Expiration Date e Special Stains laboratory ely 1:00 p.m., the following served on the shelves lining	{A 04	3}		

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ` ′	PLE CONSTRUCTION G	, ,	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 CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE API DEFICIENCY)	IOULD BE	(X5) COMPLETION DATE
{A 043}	p.m., the Laboratory Quality Manager co supplies were ident noted on the Depar Safety Inspection re laboratory was awa F) The laboratory was awa F) The laboratory was awa F) The laboratory of personnel were trai and failed to ensure established and foll personnel compete following: Review of personnel training records, an personnel) 2/5/18 failed to ensure that specimens, 20 of 2 appropriate training could perform all te provide accurate particular provides accurate particular provides accurate particular provides accurate particular provides accurated accumentation of the document labeled. Room Direct Super included with the performent did not testing personnel, to name of the reviews.	7/18 at approximately 2:30 y Compliance, Safety and infirmed that the expired iffed during routine audits and trent of Pathology General exports. She verified that the re of the audit findings. Alled to ensure the procedure ete for all testing performed. Airector failed to ensure testing patients, a policies and procedures were owed for monitoring testing necy as evidenced by the Pel records, the absence of d interviews with TP (testing 2/8/18, the laboratory director to testing patient and had demonstrated they esting operations reliably to	{A 04	3}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULT A. BUILDIN	IPLE 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 COL MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	•	30/23/2010
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFI) TAG	PROVIDER'S PLAN OF CC ((EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	N SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE
{A 043}	During interview 2/7/p.m. to 12:55 p.m., Tlabeled "Surgical Par Supervision and Cordocumentation for TFTP #1 also provided grossed during trainithe interview that the available to indicate complete and she wadirector to perform te 2. There were no traineview for 19 of 19 re 9, 10, 11, 12, 13, 14, who perform grossin the OR Pathology lall During interview on 28:30 a.m. to 9:00 a.m. that an upper level relevel resident during how to gross each ty They stated that after typically gross specific there is a grossing mintranet for reference assistant) is also avaquestions. They stated that training form and the training was docume. During interview 2/7/p.m. to 12:55 p.m., T	as approved to perform (*). 18 from approximately 12:40 P #1 stated the document thology Gross Room Direct appetency." is the training P #2. During the interview, a log of cases that TP #2 ang. TP #1 confirmed during are was no documentation that TP #2's training was as approved by the laboratory esting independently. Ining records available for esidents (TP #3, 4, 5, 6, 7, 8, 15, 16, 17, 18, 19, 20, 21) go f pathology specimens in coratory. Parameter of pathology specimen. The first week to go over pe of pathology specimen. The first week, the residents mens independently, but annual available on the eand the PA (pathologists' sillable if needed to answered they were not aware of a y were unsure whether the inted anywhere. 18 from approximately 12:40 P #1 stated first year by fourth year residents, but	{A O	43}		

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:			PLE CONSTRUCTION IG		(X3) DATE SURVEY COMPLETED	
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	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 .SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOWS CROSS-REFERENCED TO THE API 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 fai specifications for the Analyzer prior to use I) The laboratory fails specifications 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 investigation investigation dentified an additional erroneous histopathor reported. The erroneous results resulted in unipatients and a potent other patients. For the	also stated she used to the residents, but she is no rethat. She stated she has years. Iled to verify performance faxitron PathVision X-Ray in patient testing. In patient testing. In patient testing the description of the cases of the cases. During reviews reviews had been of the cases in which logy test results were pus histopathology test necessary treatment for 3 in lad eday in treatment for 3	{A 04			
	51 11(5). 1 02.10					

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		(X2) MULT A. BUILDII	IPLE CONSTRUCTION NG	, ,	(X3) DATE SURVEY COMPLETED	
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(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 CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE 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 to ensure the delega	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 gs include: of hospital 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 ticularly the subspecialty of dical Staff failed ensure to the Director provided oversight ted responsibilities assigned at (Surgical Pathology	{A 1	,		
		§482.22 Medical Staff :				
	review of 2017 labora with staff February 5					

	DF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
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	ROVIDER OR SUPPLIER AROLINA BAPTIST HOS	PITAL	•	N	STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		
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{A 115}	appropriately process medical interventions subspecialty of histop ~ Cross Reference, Services: A-576 In summary the Gover failed to provide overstaboratory Director pand direction for the conference of the co	d to ensure specimens were sed with accurate results for a, in particularly the pathology. §482.27 Laboratory erning Body, Medical Staff sight and ensure the rovided overall management delivery of quality laboratory, laboratory specimens were eous results which impacted a rendered to patients. Evelop, implement and a ongoing, hospital-wide, seessment and performance in. Evelop implement and seessment and performance in. Evelop implement and	{A 1	263			
	Based on review of la	aboratory procedures,					

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION 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			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		03/26/2016
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A 263	manufacturer's instruct maintenance records (Hematoxylin and Eos lab personnel files, ac laboratory failed to de improvements to pror laboratory services w accurate results for musuant to 482.12 G Medical Staff, facility oversight of Laborato the subspecialty of his include: As of March 26, 2018 identified a total of 9,3 requiring review, and performed for 1,422 conducted since the formplaint investigation identified an additional	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 the laboratory had been of the cases. During reviews reviews had been of the cases. During reviews rebruary 5-8, 2018 on survey, the laboratory had al 25 cases in which	A 2	263		
{A 283}	results resulted in unit patients and a potenti other patients. For the treatment was not impongoing. QUALITY IMPROVENT CFR(s): 482.21(b)(2)(b) Program Data (2) [The hospital musum.]	ous histopathology test necessary treatment for 3 al delay in treatment for 3 e other 19 patients, pacted. Case reviews are MENT ACTIVITIES (ii), (c)(1), (c)(3) St use the data collected to - unities for improvement and to improvement.	{A 2	33}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		I ` ′	PLE CONSTRUCTION	` ´coı	(X3) DATE SURVEY COMPLETED	
		340047	B. WING			R-C 3/26/2018
	ROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP COD MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		3/20/2010
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{A 283}	(i) Focus on high- problem-prone areas (ii) Consider the in severity of problems (iii) Affect health of quality of care. (3) The hospital must performance improve implementing those a	est set priorities for its ement activities that- risk, high-volume, or i; ncidence, prevalence, and in those areas; and outcomes, patient safety, and et take actions aimed at ement and, after actions, the hospital must and track performance to	{A 28	3}		
	Based on review of manufacturer's instrumaintenance records (Hematoxylin and Edlab personnel files, a laboratory failed to dimprovements to prolaboratory services waccurate results for repursuant to 482.12 (Medical Staff, facility oversight of Laborator the subspecialty of hinclude: A) Based on the absidocumentation and indirector and TP (test 2/8/18, the laborator faxitron PathVision X	not met as evidenced by: laboratory procedures, loctions, laboratory equipment loctions, laboratory loctions, laborat				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPL A. BUILDING	E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
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{A 283}	achieved the performestablished by the matient testing. During interview 2/5 p.m., the laboratory faxitron PathVision X recently purchased, placed into operation confirmed that the laperformance specific patient testing, and documentation avail documentation avail During interview 2/5 that the manufacture PathVision X-Ray Al Pathology laboratory operators were train that immediately after began using the deviated interview with the (assistant manager) laboratory failed to echaracteristics for material performed on the two Findings: Review of the Artisa revealed special stand "imported from the Libraries CD-ROM of Editor. The Procedure."	mance specification standards nanufacturer prior to initiating /18 at approximately 3:15 director stated that the K-Ray Analyzer had been and had been installed and in in December 2017. He aboratory had not verified the cations prior to initiating there was no validation able for review. /18 at 4:00 p.m., TP #1 stated er installed the faxitron nalyzer analyzer in the OR y on 12/22/17 and six ed at that time. She stated er training, the laboratory rice for patient testing.	{A 283		

	DF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ` ′		E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
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{A 283}	and IHC procedures.' Review of the Artisan Manager" screen reve "user-defined" special designated by the syr special staining procelaboratory and design 1. NCB-AFB (Acid Fa 2. NCB-Congo Red 3. NCB-Gram 4. NCB-Masson's 5. NCB-Mucin (Mucid 6. NCB-PAS (Periodi 7. NCB-PAS-D (Periodi 7. NCB-PAS-D (Periodi 8. NCB-Trichrome Gine Common Review of histology land documentation that characteristics of the procedures were estatensure accurate and During interview on 2 a.m., the histology sumanager) confirmed the indicated special stain been modified by the stated she was sure the verified, but she was documentation. C) Based on review of instructions, the absert records, and interview supervisor (assistant).	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}			

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		` ′	PLE CONSTRUCTION G	' '	(X3) DATE SURVEY COMPLETED	
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{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 performed to the two Leica CM195 OR Pathology labora "Instructions for chan" The filter must be children and set of the set of t	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 bree 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 occdures: 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	33}		

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	LE CONSTRUCTION	CON	(X3) DATE SURVEY COMPLETED		
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{A 283}	p.m., the histology s manager) stated that maintenance other the equipment in the D) Based on review review of 2017 H&E quality control record histology supervisor 2/8/18, the laborator document quality control staining characteristand eosin) stains performing H&E stallaboratory. Findings 1. The histology laboratory. Findings 1. The histology laboratory. Findings 1. The histology laboratory of a run histo tech. The slide or H&I beginning of a run histo tech. The slide or staining performed laboratory available 2/6/18 at approximations supervisor (assistant of the slide is returned laboratory available 2/6/18 at approximations approximation of the slide is returned laboratory available 2/6/18 at approximations approximation of the slide is returned laboratory available 2/6/18 at approximations approximation of the slide is returned laboratory available 2/6/18 at approximations approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is returned laboratory available 2/6/18 at approximation of the slide is r	supervisor (assistant at there is no required than daily cleaning for any of the histology department. If of laboratory procedures, the (Hematoxylin and Eosin) and interview with the reast (assistant manager) 2/5/18 - try failed to perform and the ontrol to ensure predictable tics for the H&E (hematoxylin the or (Operating aboratory and failed to performed in the OR (Operating aboratory and failed to perform the Main Histology of the operation of the operation of the main the or (Albert of the operation of the	{A 283	3}				
	There were no qual staining performed laboratory available 2/6/18 at approxima supervisor (assistar were no quality con staining performed laboratory. She stat	ity control records for the H&E in the OR Pathology for review. During interview ately 9:00 a.m., the histology						

AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONS IDENTIFICATION NUMBER: A. BUILDING		TIPLE CONSTRUCTION NG		(X3) DATE SURVEY COMPLETED		
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{A 338}	performed. 2. The laboratory per separate Leica stained laboratory. The Leica and #2. During interv 9:00 a.m., the histolog manager) stated that QUALITY CONTROLEOSIN STAIN" formed slides are sent with the Review of the 2017 "HEMATOXYLIN AND to document the daily Histology Room" reveused each day that pustained. The form had acceptability of the st space to document a slide stained on each In summary, the laborous 25,000 surgical pathor February 8, 2018, the (4) cases in which erresults 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 un governing body, and	forms H&E staining on two rs in the Main Histology stainers are designated #1 ew 2/6/18 at approximately gy supervisor (assistant they use one "DAILY HEMATOXYLIN AND each day of testing and two he form, labeled #1 and #2. DAILY QUALITY CONTROL EOSIN STAIN" forms used H&E controls for the "Main healed only one form was hatient H&E slides were d a space to document hain, but did not include hoceptability for the control hinstrument (#1 and #2). Fratory tests approximately hology cases per year. As of he laboratory identified four honeous histopathology test horselve in the control hinstrument in the control hinstrument (#1 and #2). Fratory tests approximately hology cases per year. As of he laboratory identified four honeous histopathology test horselve in unnecessary hatients and a delay in horselve in the main in the control hinstrument (#1 and #2).	{A 2			

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		` '	LE CONSTRUCTION	· ,	(X3) DATE SURVEY COMPLETED		
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{A 338}	hospital. 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 parhistopathology. Me hospital's Laboratory to ensure the delegat to another pathologis Director), were performed include: A) Review of proced (Operating Room) Pospecial Stains laboral laboratory revealed delegation dated Jar labeled "MEMORAN was signed by the culetter designated the Surgical Pathology of maintain documenta Regulatory Agencies specific, detailed list. The procedure manu "MEMORANDUM Opathologist serving a director which delegation documentation as Agencies and to ass for the laboratory see histology supervisor.	not met as evidenced by: hospital 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 ticularly the subspecialty of dical Staff failed ensure to the policetor provided oversight ted responsibilities assigned st (Surgical Pathology formed as required. Findings ure manuals in the OR athology laboratory, the atory, and the Main Histology copies of a letter of fluary 1, 2014. The letter, DUM OF INFORMATION", furrent laboratory director. The pathologist serving as the lirector "To sign off on and tion as required by our s." The letter did not include a of duties and responsibilities.	{A 338				

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		` ′		COMPLETED	
	340047	B. WING		R-C 03/26/2018	
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B) Review of persor histology supervisor meet the education technical supervisor high complexity hist responsibilities for repersonnel competer delegated to the his manager). C) The pathologist director at the time of laboratory employmed delegation of duties updated to reflect specified to current D) Review of person training records, and personnel) 2/5/18 - failed to ensure that specimens, 20 of 21 appropriate training could perform all tesprovide accurate paevidenced by the form 1. Review of person 12/29/17) who performs in the Ol Pathology laborator documentation of training laborator documentation of training laborator in the Ol Pathology laborator documentation of training laborator in the Ol Pathology laborator documentation of training laborator in the Ol Pathology laborator documentation of training laborator in the Ol Pathology laborator documentation of training laborator in the Ol Pathology laborator documentation of training laborator documentation of training laborator in the Ol Pathology laborator documentation of training laborator in the Ol Pathology laborator documentation of training laborator documentation documentation of training laborator documentation	annel records revealed the cassistant manager) did not requirements to serve as a cor general supervisor in a copathology laboratory. The eview of records and testing and assessment could not be tology supervisor (assistant serving as Surgical Pathology of the delegation left cent in September 2017, and documentation had not been decific responsibilities to designees. Innel records, the absence of dinterviews with TP (testing 2/8/18, the laboratory director aprior to testing patient testing personnel received and had demonstrated they sting operations reliably to tient test results. As allowing: Innel records for TP #2 (hired forms grossing of pathology R (Operating Room) y revealed there was no canning available for review. A	{A 338			
	OVIDER OR SUPPLIER ROLINA BAPTIST HO SUMMARY S (EACH DEFICIEN REGULATORY OF SUPPLIER REGU	OVIDER OR SUPPLIER SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) Continued From page 23 dated January 1, 2014. B) Review of personnel records revealed the histology supervisor (assistant manager) did not meet the education requirements to serve as a technical supervisor or general supervisor in a high complexity histopathology laboratory. The responsibilities for review of records and testing personnel competency assessment could not be delegated to the histology supervisor (assistant manager). C) The pathologist serving as Surgical Pathology director at the time of the delegation left laboratory employment in September 2017, and delegation of duties documentation had not been updated to reflect specific responsibilities delegated to current designees. D) Review of personnel records, the absence of training records, and interviews with TP (testing personnel) 2/5/18 - 2/8/18, the laboratory director failed to ensure that prior to testing patient specimens, 20 of 21 testing personnel received appropriate training and had demonstrated they could perform all testing operations reliably to provide accurate patient test results. As evidenced by the following: 1. Review of personnel records for TP #2 (hired 12/29/17) who performs grossing of pathology specimens in the OR (Operating Room) Pathology laboratory revealed there was no documentation of training available for review. A	OVIDER OR SUPPLIER ROLINA BAPTIST HOSPITAL SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) Continued From page 23 dated January 1, 2014. B) Review of personnel records revealed the histology supervisor (assistant manager) did not meet the education requirements to serve as a technical supervisor or general supervisor in a high complexity histopathology laboratory. The responsibilities for review of records and testing personnel competency assessment could not be delegated to the histology supervisor (assistant manager). C) The pathologist serving as Surgical Pathology director at the time of the delegation left laboratory employment in September 2017, and delegation of duties documentation had not been updated to reflect specific responsibilities delegated to current designees. D) Review of personnel records, the absence of training records, and interviews with TP (testing personnel) 2/5/18 - 2/8/18, the laboratory director failed to ensure that prior to testing patient specimens, 20 of 21 testing personnel received appropriate training and had demonstrated they could perform all testing operations reliably to provide accurate patient test results. As evidenced by the following: 1. Review of personnel records for TP #2 (hired 12/29/17) who performs grossing of pathology specimens in the OR (Operating Room) Pathology laboratory revealed there was no documentation of training available for review. A	OVIDER OR SUPPLIER ROLINA BAPTIST HOSPITAL SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) Continued From page 23 dated January 1, 2014. B) Review of personnel records revealed the histology supervisor (assistant manager). C) The pathologist serving as Surgical Pathology director at the time of the delegation left laboratory employment in September 2017, and delegated to the histology supervisor (assistant manager). C) The pathologist serving as Surgical Pathology director at the time of the delegation left laboratory employment in September 2017, and delegated to current designees. D) Review of personnel records, the absence of training records, and interviews with TP (testing personnel) 2/5/18 - 2/8/18, the laboratory director failed to ensure that prior to testing patient specimens, 20 of 21 testing personnel received appropriate training and had demonstrated they could perform all testing operations reliably to provide accurate patient test results. As evidenced by the following: 1. Review of personnel records for TP #2 (hired 12/29/17) who performs grossing of pathology specimens in the OR (Operating Room) Pathology laboratory revealed there was no	

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{A 338}	available to document complete and she was testing independently. During interview 2/7/7 p.m. to 12:55 p.m., Tillabeled "Surgical Path Supervision and Composition of TP TP #1 also provided a grossed during training the interview that their available to indicate the complete and she was director to perform testing the OR Pathology lab to the OR Pathology lab During interview on 2 8:30 a.m. to 9:00 a.m. that an upper level relevel resident during I how to gross each typ. They stated that after typically gross specing there is a grossing maintranet for reference assistant) is also avail questions. They stated training form and they training was document.	that TP #2's training was approved to perform 18 from approximately 12:40 P #1 stated the document hology Gross Room Direct apetency." is the training P #2. During the interview, a log of cases that TP #2 ag. TP #1 confirmed during re was no documentation that TP #2's training was approved by the laboratory sting independently. Ining records available for sidents (TP #3, 4, 5, 6, 7, 8, 15, 16, 17, 18, 19, 20, 21) g of pathology specimens in foratory. In #6 and TP #7 stated sident works with each lower his/her first week to go over the of pathology specimen. If the first week, the residents mens independently, but anual available on the and the PA (pathologists' illable if needed to answer and they were not aware of a y were unsure whether the inted anywhere.	{A 3	38}			
	p.m. to 12:55 p.m., Tl						

	DF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ' '		E CONSTRUCTION	(X3) DATE COMP	SURVEY LETED
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{A 338}	she was unsure whet documented. TP #1 a document training for longer responsible for not done it in several E) Review of the labe procedures 2/5/18 - 2 the laboratory director policies and procedure monitoring the compete the OR (Operating Reas evidenced by the form of the OR (Operating Reas evidenced by the form of the OR (Operating Reas evidenced by the form of the OR (Operating Reas evidenced by the form of the OR (Operating Reas evidenced by the form of the OR (Operating Reas evidenced by the form of the OR (Operating Reas evidenced by the form of the OR (Operating Personner technical supervisor form form of the OR (Operating Personner technical supervisor form of the OR (Operating Personner technical supervisor form of the Operation of th	by fourth year residents, but her the training is also stated she used to the residents, but she is no rethat. She stated she has years. bratory's policies and /8/18 and survey findings, refailed to ensure that resewere established for etency of testing personnel in form) Pathology laboratory following: . el records and interview with (a) 2/5/18 - 2/8/18, the ailed to perform and fincy evaluation for 1 of 21 TP for eating Room) Pathology el records for TP #1 es of the same document on of Skills and Abilities for sory & Management as at the top of the form state beside the most appropriate of the employee's eadditional feedback in the appropriate." The form ms to be evaluated: Intity of Work, Planning and owledge, Problem Solving,	{A 3	338)			

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	ROVIDER OR SUPPLIER AROLINA BAPTIST HO			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	·	03/26/2018
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{A 338}	document had beer instructions, and dif handwritten on the loopies did not includ were conducted, and was unclear who could be a substitute of the last of the last Surgical Pathologist who ser director used to evaluate changed in the last Surgical Pathologist who ser director used to evaluate changed in the last Surgical Pathologist who ser director used to evaluate changed in the last Surgical Pathologist who ser director used to evaluate the chief Medical Cowork flow/work force revealed there had changes in the analuas a result of exprese reasons that led to a result of feedback that are deep in the midireview to see if we interview revealed the externally reviewed meet our standards review process and percent" of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the breat interview revealed to the last of the last our standards review process and percent of the breat interview revealed to the last our standards review process and percent of the last our standards review process and percent of the last our standards review process and percent of the last our standards review process and percent of the last our standards review process and pe	filled out according to the ferent comments were ast page of each copy. The de dates that the "evaluations" d they were not signed, so it	(A 33	8}		

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` '	PLE CONSTRUCTION G	(X	(3) DATE SURVEY COMPLETED
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{A 576}	O2/08/2018 at 1415 Pathology Departments position since Aurevealed he was ask Chair (MD #7) separ Interview revealed the last Monday," hired a Pathology. Interview mandatory second rebiopsies to be documented the interview revealed breast biopsies, and policy (mandatory second rest 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 maligromonitoring the "pink the two reads, MD # the first month and honoths then identify see if we have a pinl	"who is now gone." 25/2018 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. He hospital had recently "as of a new Director of Surgical revealed they implemented a eview for all new breast mented on the pink sheets. He "the nexus was clearly on the "new breast cancer accond 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 ll the newly diagnosed breast interview revealed the labe to add a second reading financies. When asked about sheets" for compliance with 10 replied they were only in is plan was "to wait a few all the breast cancers, then is sheet." MD #10 stated he implementation before	{A 33			
	The hospital must m adequate laboratory	aintain, or have available, services to meet the needs nospital must ensure that all				

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULT A. BUILDII	TIPLE CONSTRUCTION NG	(X3) DATE SURVEY COMPLETED
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{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 overall management appropriately process medical interventions subspecialty of history A) The hospital laboratory of survey conclumprovement Amend 5, 2018 through February Constant of Survey Conclumprovement Amend 5, 2018 through February Amend 5, 2018 through 5, 2	rovided to its patients are y certified in accordance with ter. not met as evidenced by: policies and procedures, atory records, and interview, 2018 through February 8, director failed to provide and direction for the pratory failed to have do to ensure specimens were sed with accurate results for s, in particularly the pathology. Findings include: ratory failed to be in R 493 as referenced in the ducted by Clinical Laboratory ment (CLIA) staff February ruary 8, 2018.	{A 5	,		
	D6076: Laboratory II CFR 493.1441 D6079: Laboratory II 493.1445(a)(b) D6102: Laboratory II CFR 493.1445(e)(12 B) The laboratory dir responsibilities to an Pathology director), I delegated duties wer	ogy: CFR 493.1273(a)(f)) Director Responsibilities: Director Responsibilitie: CFR Director Responsibilities:				

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{A 576}	C) The laboratory dimanagement and failed to specified maintenant. E) The laboratory fait temperature, and humidity, and failed humidity, and failed humidity ranges that manufacturers' required. G) The laboratory fait manual was completed to monitor and humidity ranges that manufacturers' required. G) The laboratory fait manual was completed to the Operate laboratory procedure and current for the tevidenced by the fold. The procedure mastep-by-step procedifaxitron PathVision 2 a. requirements for selection, and procedure and startup and shutder.	rector failed to provide overall rection for the laboratory. illed to ensure equipment and lidated prior to use for patient perform manufacturers' ce as required. illed to monitor water quality, midity as required. illed to monitor water quality, I document temperature and to establish temperature and	{A 57	76}		
	required and the free	cluding the documentation quency of performance; se course of action to take if sinoperable.				

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:	` ′	PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED			
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{A 576}	instructions for issus surgical pathology is surgical pathology in the procedure many procedures for all to the personnel were trained failed to ensure established and followers personnel compete. I) The laboratory for specifications for the Analyzer prior to use the procedure most procedure most procedure most procedure most procedure. The procedure most proc	bruary 7, 2018 at p.m., TP #1 confirmed that ual did not include policies and esting performed. irector failed to ensure testing ned prior to testing patients, expolicies and procedures were owed for monitoring testing ney. silled to verify performance explain failed to verify performance explain failed to testing. In patient testing. In patient testing. In patient testing. In patient testing include dures for operation of the X-Ray Analyzer, including: specimen collection, essing; down; ding the material used and the coluding the documentation equency of performance; the course of action to take if its inoperable.	{A 57	6}		
	instructions for issu surgical pathology i 3. During interview p.m., TP #1 confirm	nanual did not include ing a corrected or amended report. 2/7/18 at approximately 3:30 led that the procedure manual cies and procedures for all				

PRÉFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE COMPLE		OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ` ′	PLE CONSTRUCTION G		ATE SURVEY DMPLETED
NORTH CAROLINA BAPTIST HOSPITAL (X4) ID PREFIX TAG (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) (A 576) Continued From page 31 testing performed. J) The laboratory failed to establish performance specifications for the modified stain procedures performed on the Artisan Staining System prior to use in patient testing' 1. The Artisan staining system operators manual specifies operation in an environment with room temperature of 15-35 degrees Celsius (59-95 degrees Fahrenheit) at 15-75% relative humidity. 2. Review of temperature and humidity logs for the Neuro IHC (Immunohistochemistry) laboratory, where two Artisan staining system instruments were operated by the laboratory, revealed a laboratory defined acceptable room temperature range of 64-104 degrees Fahrenheit and a laboratory defined acceptable humidity range of 10% - 60%. K) The laboratory tests approximately 25,000			340047	B. WING			
REFIX TAG REGULATORY OR LSC IDENTIFYING INFORMATION) (A 576) Continued From page 31 testing performed. J) The laboratory failed to establish performance specifications for the modified stain procedures performed on the Artisan Staining System prior to use in patient testing' 1. The Artisan staining system operators manual specifies operation in an environment with room temperature of 15-35 degrees Celsius (59-95 degrees Fahrenheit) at 15-75% relative humidity. 2. Review of temperature and humidity logs for the Neuro IHC (Immunohistochemistry) laboratory, where two Artisan staining system instruments were operated by the laboratory, revealed a laboratory defined acceptable room temperature range of 64-104 degrees Fahrenheit and a laboratory defined acceptable humidity range of 10% - 60%. K) The laboratory tests approximately 25,000			1		MEDICAL CENTER BOULEVARD		03/20/2010
testing performed. J) The laboratory failed to establish performance specifications for the modified stain procedures performed on the Artisan Staining System prior to use in patient testing' 1. The Artisan staining system operators manual specifies operation in an environment with room temperature of 15-35 degrees Celsius (59-95 degrees Fahrenheit) at 15-75% relative humidity. 2. Review of temperature and humidity logs for the Neuro IHC (Immunohistochemistry) laboratory, where two Artisan staining system instruments were operated by the laboratory, revealed a laboratory defined acceptable room temperature range of 64-104 degrees Fahrenheit and a laboratory defined acceptable humidity range of 10% - 60%. K) The laboratory tests approximately 25,000	PREFIX	(EACH DEFICIENC	CY MUST BE PRECEDED BY FULL	PREFIX	(EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE
8, 2018, the laboratory had identified 4 cases in which erroneous histopathology test results were reported, resulting in unnecessary treatment for three patients and a delay in diagnosis for a fourth patient. Case reviews are ongoing. 1. The laboratory director failed to ensure delegated responsibilities were detailed, specific, and were performed as required by the designee. 2. The laboratory director failed to ensure testing personnel were trained and the training was documented prior to testing patient specimens.	{A 576}	testing performed. J) The laboratory fai specifications for the performed on the Art use in patient testing 1. The Artisan stainin specifies operation in temperature of 15-35 degrees Fahrenheit) 2. Review of temperathe Neuro IHC (Immillaboratory, where twinstruments were operevealed a laboratory temperature range of and a laboratory defirange of 10% - 60%. K) The laboratory tessurgical pathology case, 2018, the laboratory which erroneous hist reported, resulting in three patients and a fourth patient. Case 1. The laboratory directly delegated responsibility and were performed 2. The laboratory directly d	iled to establish performance modified stain procedures isan Staining System prior to ' Ing system operators manual in an environment with room of degrees Celsius (59-95 at 15-75% relative humidity. In a staining system erated by the laboratory, of defined acceptable room of 64-104 degrees Fahrenheit in a ceptable humidity. In a staining system erated by the laboratory, of defined acceptable room of 64-104 degrees Fahrenheit in a ceptable humidity. In a staining system erated by the laboratory, of defined acceptable humidity. In a staining system erated by the design of same proximately 25,000 asses per year. As of February or had identified 4 cases in topathology test results were unnecessary treatment for delay in diagnosis for a reviews are ongoing. In a staining was the designee.	{A 57	6}		

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{A 576}	Continued From page and followed. As of March 26, 2018 identified a total of 9.3		{A 5	76}			
{A 582}	requiring review, and performed for 1,422 conducted since the F complaint investigation identified an additional erroneous histopathor reported. The erroneous results resulted in unrepatients and a potentiother patients. For the treatment was not impongoing.	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 5	82}			
	available, either direct agreement with a cert the requirements of p. This STANDARD is r. Based on review of fa. Medical Staff Bylaws, interview, the facility I oversight of Laborator laboratory specimens processed with accurrinterventions, in particular histopathology for sar Patient #2, Patient #3 include:	ve laboratory services citly or through a contractual tified laboratory that meets part 493 of this chapter. not met as evidenced by: facility policies, facility's medical record review, and laboratory failed provide sury Services and ensure sewere appropriately facter results for medical icularly the subspecialty of mpled patients (Patient #1, B, Patient #4). The findings ests approximately 25,000					
		sts approximately 25,000 ses per year. As of February					

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPI A. BUILDING	E CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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{A 582}	8, 2018, the laborato which erroneous hist reported, resulting in three patients and a fourth patient. Case B) Review of the faci Case Reviews Prior effective 01/02/2018 department provides critical to successful The pathologist's interpathologist's interpatho	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. Perpretations and review of alto determining appropriate per patients, and thus they eas 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 LITY]," revealed "5.E. PROVEMENT FUNCTIONS is actively involved in the assment, and improvement of (a) patient safety, including dot to patient safety alerts, goals, and reduce patient ative and other invasive go tissue review and review of en pre-operative and oses;"	{A 582		

	DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	PLE CONSTRUCTION IG	` '	DATE SURVEY COMPLETED
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{A 582}	medial central left brodocumented "addition needed with magnific the patient had a dialeft digital breast torm and diagnostic breast the early detection or radiology report doct and "recommend a mo6/13/2017, a stereo procedure that uses identify and biopsy a breast), was perform. The pathology result the left breast by MD carcinoma (a cancer grows through the dobreast tissue), and dof ([DCIS] cancer contaled A surgical consult was 07/18/2017, the patien ode biopsies of four surgical procedure work tissue and a small art tissue is removed). The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue and a small art tissue is removed. The patient was a small art tissue and a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is removed. The patient was a small art tissue is remov	aled calcifications in the east, middle third and nal imaging evaluation cation views." On 06/05/2017 gnostic mammogram with osynthesis (a new screening it imaging process to improve fibreast cancer). The imented "mildly suspicious," leedle biopsy." On tactic 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 first walls into the surrounding fined in the mammary ducts). It is recommended, and on the entire and suct walls into the surrounding fined in the mammary ducts. It is recommended, and on the entire cancerous breast the east of surrounding healthy the pathology report by MD inoma (cancer) in the lymph mipectomy, "ductal ermediate grade" of the sunderwent radiation breast from 08/24/2017 Review revealed an the final pathologic diagnosis	{A 58	32}		

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NORTH C	AROLINA BAPTIST HOS	PITAL		WINSTON-SALEM, NC 27157			
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{A 582}	LEFT, LUMPECTOM hyperplasia within with usual ductal hyperplasia with usual ductal hyperplasia with usual ductal ductal fither sentinel lymph nor "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 geal (already had dual real Interview revealed the that the organization the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on 02/05/20 chief Myperplasia within the work by MD #7, "Interview on	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 118 at 1200 with MD #11, the my revealed "We've had a imbalance." Interview een corrective actions and mical pathology laboratory eed concerns. "There were change in leadership as a corganization received. We of a complex and deep ave a quality issue." The Me've internally and nd found our care did not The hospital was now in a my rere re-reviewing "100 my tacancer cases. The my organization had not my organization and they had my that all patients involved, my op ut more qualified my organization of the conclusion" and they had my that all patients involved, my op ut more qualified my organization of the conclusion	{A 5	82}			
		nt, revealed he had been in					

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{A 582}	revealed he was a Chair (MD #7) sep Interview revealed last Monday," hired Pathology. Interview mandatory second biopsies to be doc The interview reve breast biopsies, ar policy (mandatory breast biopsies) wo Interview revealed diagnosis, whether to be reviewed by revealed "pink she second reading for cancer specimens "ultimate goal" wor for all positive mali monitoring the "pint the two reads, MD the first month and months then identified in the see if we have a proposition was a possible to "allow for collecting data."	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 two revealed they implemented a review for all new breast tumented on the pink sheets. The all the nexus was clearly on the "new breast cancer second review for all new as implemented January first. The any new breast cancer in house or external, was now two Pathologists. Interview ets" were created to ensure a stall the newly diagnosed breast. Interview revealed the all the to add a second reading gnancies. When asked about the sheets" for compliance with #10 replied they were only in this plan was "to wait a few fy all the breast cancers, then the sheet." MD #10 stated he or implementation before	{A 5	82}		
	Pathologists] and 0 SP & Cyto Fellows 28, 2017 at 0853, 2018 (next week): pathology (breast reviewed here priorecognize that this oncologists (medic but you may come	Cyto [cytopathology] Faculty, a, and Residents, on December revealed "Starting January 2, * Briefly, all outside biopsies, etc.) must be r to initiating therapy. I is largely in the purview of tal & radiation) and surgeons across such patients. * In				

DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCT A. BUILDING			(X3) DATE SURVEY COMPLETED		
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attached form [pink diagnosed breast ca internal and external Interview on 02/07/2 Manager of Laborat Assurance, Point of was mentioned to not that there were some reports and they we Management to be she was the one who Case Reviews Prior effective 01/02/2018 policy stated any ca outside consult had source before we the revealed "The policy cases." The Managemas unaware of a not was unaware of a not provided the policy and they can write a senough time to proceed the tracking been added to QA (Interview revealed to the policy a "step for process." When ever about the problem, and they can write a revealed the incorregular guarded and so high shared with anyone MD #10 met with the senough time to process.	sheet], for all newly ancers. This includes both all cases." 2018 at 1000 with Staff #1, the ory Compliance, Quality Care and Safety, revealed "It he on a need to know basis he issues with some pathology are in the hands of Risk handled." Interview revealed no wrote the "Breast Cancer to Initiating Therapy," policy 3. Interview revealed the see that comes in as an to be reviewed by an internal eated patients Interview y references only outside her of Laboratory Compliance hew policy put in place by MD and read on both internal and dicating new breast cancer. The January 2018 data had not since there had not been here sees the information. Interview ag of the "pink sheets" had not Quality Assurance) yet. The "pink sheets" were taking rward to start collection between else is allowed to know then everyone else can know a new policy." Interview revealed the Pathology staff during the	{A 5	82}			
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Interview revealed MD #10 met with the Pathology staff during the Pathology Department meeting on January 2, 2018 at 1200 and presented the pink form	DOUDER OR SUPPLIER ROLINA BAPTIST HOSPITAL SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) Continued From page 37 attached form [pink sheet], for all newly diagnosed breast cancers. This includes both internal and external cases." Interview on 02/07/2018 at 1000 with Staff #1, the Manager of Laboratory Compliance, Quality Assurance, Point of Care and Safety, revealed "It was mentioned to me on a need to know basis that there were some issues with some pathology reports and they were in the hands of Risk Management to be handled." Interview revealed she was the one who wrote the "Breast Cancer Case Reviews Prior to Initiating Therapy," policy effective 01/02/2018. 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The Manager of Laboratory Compliance was unaware of a new policy but in place by MD #10, requiring a second read on both internal and external biopsies indicating new breast cancer, Interview revealed the Jink pink sheets" had not been added to QA (Quality Assurance) yet, Interview revealed the pink sheets" were taking the policy a "step forward" to start collection process. When everyone else is allowed to know about the problem, then everyone else can know and they can write a new policy." Interview revealed the pink form "Interview revealed MD #10 met with the Pathology staff during the Pathology Department meeting on January 2, 2018 at 1200 and presented the pink form

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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 havet, but would be pareting. Interview recome directly to her she will review, track of the month of the mo	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 in the February QA evealed all "pink sheets" mailbox. Interview revealed is 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	32}		
	Oncologist conducte hundreds of cases." forward, we are look	ed a "thorough review of				

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{A 582}	the left breast, better mammographically, for biopsy is recommend abnormality. Biopsy 906/15/2016, the patie biopsy of the left breat reported by MD #7 recarcinoma and DCIS complex sclerosing left Patient #4 underwen breast with left senting pathology report by Modes were negative malignancy was iden lumpectomy. Patient treatments to the left through 09/23/2016 a 09/30/2016. Review on 08/11/2017, for a with tomo. The indication was breast cancer "Modes are a portion of left Radiologist conclude mammographic evider recommended routing linterview on 02/05/20 Chief Medical Officer work flow/work force revealed there had be changes in the anatog as a result of express reasons that led to a result of feedback the are deep in the mids.	ed. The Radiologist LUSION: Focal asymmetry in delineated for which stereotactic guided ded Suspicious should be considered." On ent underwent a core needle ast. The pathology findings evealed invasive ductal in a background of a esion. On 07/21/2016, t a lumpectomy of the left nel node biopsies X2. The MD #9, revealed the lymph for tumor and no atified in the breast tissue #4 received daily radiation breast from 09/26/2016 through revealed the patient returned diagnostic left mammogram Malignant neoplasm of female breast" The d there was no ence of malignancy, and e follow-up. 018 at 1200 with MD #11, the r, revealed "We've had a imbalance." Interview een corrective actions and mical pathology laboratory sed concerns. "There were change in leadership as a e organization received. We t of a complex and deep ave a quality issue. The	3 A}	582}				

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{A 582}	meet our standards." review process and opercent" of the breast interview revealed the reached a "summative disclosure meetings they had "attempted individuals into the wand upregulated the (already had dual real Interview revealed the that the organization the work by MD #7," Interview on 02/05/20 02/08/2018 at 1415 over Pathology Department his position since Augrevealed he was ask Chair (MD #7) separatively revealed the last Monday," hired a Pathology. Interview mandatory second rebiopsies to be docum. The interview revealed the interview revealed breast biopsies, and policy (mandatory sebreast biopsies) was Interview revealed and diagnosis, whether in to be reviewed by two revealed "pink sheets second reading for a cancer specimens. In "ultimate goal" would for all positive malign."	and found our care did not The hospital was now in a were re-reviewing "100 It cancer cases. The e organization had not we conclusion" and they had with all patients involved, to put more qualified orkflow," new leadership, process of dual reads ads on all outside cases). ere was no evidence to date had a problem other than who is now gone." 1018 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. e hospital had recently "as of a new Director of Surgical revealed they implemented a eview for all new breast hented on the pink sheets. ed "the nexus was clearly on the "new breast cancer cond review for all new implemented January first. hy new breast cancer n house or external, was now to Pathologists. Interview se" were created to ensure a ll the newly diagnosed breast	{A 5	32}				

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{A 582}	Continued From page	e 42	{A 58	32}			
	the two reads, MD #1 the first month and hi months then identify a see if we have a pink	0 replied they were only in s plan was "to wait a few all the breast cancers, then sheet." MD #10 stated he applementation before					
	Pathologists] and Cyt SP & Cyto Fellows, a 28, 2017 at 0853, rev 2018 (next week): * pathology (breast bio reviewed here prior to recognize that this is oncologists (medical but you may come ac addition, we need into attached form [pink s	psies, etc.) must be initiating therapy. I largely in the purview of a radiation) and surgeons cross such patients. * In ernal confirmation, using the heet], for all newly acers. This includes both					
	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 cas outside consult has to source before we treat revealed "The policy cases." The Manager was unaware of a new	on a need to know basis issues with some pathology in the hands of Risk andled." Interview revealed wrote the "Breast Cancer to Initiating Therapy," policy Interview revealed the ethat comes in as an obe reviewed by an internal at patients Interview references only outside of Laboratory Compliance of policy put in place by MD and read on both internal and					

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{A 582}	Interview revealed been compiled yet enough time to pro revealed the trackin been added to QA Interview revealed the policy a "step for process." When evabout the problem, and they can write revealed the incorriguarded and so high shared with anyone MD #10 met with the Pathology Departm 2018 at 1200 and prequiring a second biopsies. Interview on 02/07/revealed she could monthly QA meeting each month. Interview all new breast cand January, the data hyet, but would be preeting. Interview come directly to he she will review, tracking for Radiation Safety Officer, rever December of 2017, received a full cour	age 43 Indicating new breast cancer. Ithe January 2018 data had not since there had not been cess the information. Interviewing of the "pink sheets" had not (Quality Assurance) yet. Ithe "pink sheets" were taking proward to start collection eryone else is allowed to know then everyone else can know a new policy." Interview ect lab reporting was "so highly ghly confidential it was not entered in the lab." Interview revealed the Pathology staff during the nent meeting on January 2, presented the pink form reading on all new breast Interview revealed the monthly QA the last Wednesday of each process of a second read for the last Wednesday of each process of a second read for the series was initiated the first of the second read for the se	{A 5	82}		

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{A 582}	Continued From page	e 44	{A 58	2}			
	they had breast cano	er, we went through our	,				
	1	terview revealed, after					
	I .	nt, it was discovered she did					
	I .	erview revealed the Director					
	of Radiation Oncolog	y, the facility Safety Officer,					
	and the North Carolin	na Division of Health Service					
	Regulation were noti	fied, and the situation was					
	immediately investiga	ated. Interview revealed the					
		e properly, and there were					
		ns. The Radiation compliance					
		e came on site, reviewed the					
		ook a full report. No issues of					
		e identified in the radiology					
	1 -	w revealed the Radiation					
	_	d a "thorough review of Interview revealed "Moving					
	I .	ing into possibly doing a step					
	I .	o sign offs in pathology."					
	lo verny there are two	o digit one in patriology.					
	Interviews on 02/05/2	2018 at 1505, 02/06/2018 at					
		or of Risk Management,					
	revealed in Septemb						
	· ·	ade aware of concerns					
	regarding 10 patients	s of MD #7. Interview					
	revealed the concern	ns were brought to the					
	Director's attention a	s a result of several					
		yees from the laboratory.					
		isk Management started					
		getting ready to have them					
		The cases were internally					
	I .	t for external review as well.					
	_	review of the 10 patients'					
		of the 10 patients' plans of					
		ed if the results came back					
	1	gnosis, which included					
		eviewing the breast cancer					
		irming reports" from external					
	· ·	December 15, 2017, it was osis of breast cancer was					
	FIGURIO MALTRE GIACINO	JSIS ULDIEASI CALICEL WAS	1	The state of the s		1	

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{A 582}	Management "immed got physicians involve Patient #4 had been The interview revealed ongoing and all upda Medical Review Com Medical Executive Company and chargessive route of a Findings revealed the radiation treatment. Interview on 02/05/20 Chief Medical Officer work flow/work force revealed there had be changes in the anato 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 "Vexternally reviewed a meet our standards." review process and verification of the breas interview revealed the reached a "summative disclosure meetings of the had "attempted individuals into the wand upregulated the got Patients and Patient	t4. Interview revealed Risk liately 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. Interview going to the mittee who report to the ommittee. Interview going to the ommittee. Interview going to the ommittee. Interview going to the more bilateral mastectomy. The patient underwent mose to undergo the more bilateral mastectomy. The patient did not receive going to the more bilateral mastectomy. There were change in leadership as a goorganization received. We go for a complex and deep gove a quality issue. The gove internally and found our care did not the hospital was now in a govern the goorganization had not the conclusion and they had with all patients involved,	{A 5	82}		

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{A 582}	Interview revealed the that the organization the work by MD #7, "Interview on 02/05/20 02/08/2018 at 1415 w Pathology Departmenhis 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 to policy (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 malignmonitoring the "pink set the two reads, MD #1 the first month and himonths then identify a	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 hat, revealed he had been in gust of 2017. Interview ed to chair after the previous sted 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. In the nexus was clearly on the "new breast cancer cond review for all new implemented January first. In y new breast cancer house or external, was now of Pathologists. Interview "were created to ensure a lithe newly diagnosed breast"	{A 5				
	collecting data." Review of an email so Pathologists] and Cyt SP & Cyto Fellows, a	ent "To all SP [Surgical of [cytopathology] Faculty, and Residents, on December ealed "Starting January 2,					

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{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 his she was the one who Case Reviews Prior teffective 01/02/2018. policy stated any cas outside consult has to source before we trear revealed "The policy cases." The Manager was unaware of a ne #10, requiring a secon external biopsies indicented interview revealed the been compiled yet sing enough time to proce revealed the tracking been added to QA (Conterview revealed the policy a "step for process." When ever about the problem, the	Briefly, all outside psies, etc.) must be or initiating therapy. I largely in the purview of & radiation) and surgeons cross such patients. * In ternal confirmation, using the heet], for all newly neers. This includes both cases." 118 at 1000 with Staff #1, the ry Compliance, Quality Care and Safety, revealed "It e on a need to know basis issues with some pathology	{A 5	82}			

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{A 582}	guarded and so high shared with anyone MD #10 met with the Pathology Departme 2018 at 1200 and pr requiring a second re biopsies.	te 48 ct lab reporting was "so highly ally confidential it was not in the lab." Interview revealed a Pathology staff during the ent meeting on January 2nd, essented the pink form leading on all new breast	{A 58.	2}			
	revealed she could r monthly QA meeting each month. Intervie meetings occurred th month. As the new p all new breast cance January, the data ha yet, but would be pa meeting. Interview re come directly to her	not begin compiling data for suntil after the seventh of ew revealed the monthly QA ne last Wednesday of each process of a second read for ers was initiated the first of es not been added to the QA rt of the February QA evealed all "pink sheets" mailbox. Interview revealed and monitor for compliance.					
	1050 with the Director revealed in Septemb Management was m regarding 10 patients revealed the concern Director's attention a complaints by emplointerview revealed R reviewing cases and externally reviewed. re-reviewed and sen Risk Management's case files revealed 4 care would be affect with an incorrect diag	ade aware of concerns s of MD #7. Interview ns were brought to the					

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 PROVIDER OR SUPPLIER NORTH CAROLINA BAPTIST HOSPITAL			STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		I	03/26/2018	
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFI) TAG	PROVIDER'S PLAN OF CORI (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
{A 582}	reviews, received of found that the diagrincorrect for Patient Management "immer got physicians invol Patient #1 had been The interview revea ongoing and all upon Medical Review Comedical Executive Comedica	in December 15, 2017, it was nosis of breast cancer was #1. Interview revealed Risk ediately set into action" and ved. The interview revealed in notified of the misdiagnoses. Iteld the investigation is still lated results were going to the mmittee who report to the Committee. at 1050 with Risk led, Patient #2, was with a pathology report from a #2/20/2016, from MD #7, and did not have breast cancer. The ent another breast biopsy the screening mammogram) on was positive for breast cancer. The patient was currently under	{A 5	32}			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING			COMPLETED	
		340047	B. WING_			R-C	
NAME OF PROVIDER OR SUPPLIER NORTH CAROLINA BAPTIST HOSPITAL			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 CORR (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AP DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE	
{A 582}	disclosure meetings they had "attempted individuals into the and upregulated the (already had dual re Interview revealed to that the organization the work by MD #7, Interview on 02/05/202/08/2018 at 1415 Pathology Departm his position since Arrevealed he was as Chair (MD #7) sepa Interview revealed to last Monday," hired Pathology. Interview mandatory second biopsies to be docu The interview revealed biopsies, and policy (mandatory second biopsies) was Interview revealed adiagnosis, whether to be reviewed by to revealed "pink sheet second reading for cancer specimens." "ultimate goal" woul for all positive maligmonitoring the "pink the two reads, MD at the first month and months then identificate if we have a pin second reading for the two reads, MD at the first month and months then identificate if we have a pin second reading for the two reads, MD at the first month and months then identificate if we have a pin second reading for the two reads, MD at the first month and months then identificate if we have a pin second reading for the first month and months then identificate if we have a pin second reading for the first month and months then identificate if we have a pin second reading for the first month and months then identificate if we have a pin second reading for the first month and months then identificate in the first month and months then ide	ive conclusion" and they had swith all patients involved, do to put more qualified workflow," new leadership, exprocess of dual reads eads on all outside cases). There was no evidence to date in had a problem other than	{A 58	32}			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA (X2) MUI IDENTIFICATION NUMBER: A. BUILD		FIPLE CONSTRUCTION NG	' '	(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 MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157	CODE	03/20/2016	
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFII TAG	,	TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE	
{A 582}	Pathologists] and Cy SP & Cyto Fellows, a 28, 2017 at 0853, rev 2018 (next week): * pathology (breast bid reviewed here prior to recognize that this is oncologists (medical but you may come an addition, we need into attached form [pink is diagnosed breast cal internal and external linterview on 02/07/20 Manager of Laborated Assurance, Point of was mentioned to me that there were some reports and they were Management to be his he 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 was unaware of a new #10, requiring a second external biopsies ind linterview revealed the	ent "To all SP [Surgical to [cytopathology] Faculty, and Residents, on December vealed "Starting January 2, Briefly, all outside opsies, etc.) must be o initiating therapy. I largely in the purview of & radiation) and surgeons cross such patients. * In ernal confirmation, using the sheet], for all newly neers. This includes both	{A 5	82}			
	#10, requiring a second external biopsies ind Interview revealed the been compiled yet side enough time to process.	ond read on both internal and icating new breast cancer. e January 2018 data had not					

		IDENTIFICATION NUMBER.		MULTIPLE CONSTRUCTION JILDING		COMPLETED	
		340047	B. WING			R-C	
NAME OF PROVIDER OR SUPPLIER NORTH CAROLINA BAPTIST HOSPITAL				STREET ADDRESS, CITY, STATE, ZIP CODE MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		03/26/2018	
(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 CORI (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
{A 582}	Interview revealed to the policy a "step for process." When ever about the problem, it and they can write a revealed the incorrer guarded and so high shared with anyone MD #10 met with the Pathology Departme 2018 at 1200 and prequiring a second or biopsies. Interview on 02/07/2 revealed she could monthly QA meeting each month. Interview all new breast cancer January, the data hayet, but would be part meeting. Interview on 02/05/1050 with the Direct revealed in Septem Management was more garding 10 patient revealed the concert Director's attention a complaints by emplointerview revealed Freviewing cases and	Quality Assurance) yet. The "pink sheets" were taking rward" to start collection ryone else is allowed to know then everyone else can know a new policy." Interview ct lab reporting was "so highly ally confidential it was not in the lab." Interview revealed as Pathology staff during the ent meeting on January 2nd, resented the pink form eading on all new breast and begin compiling data for us until after the seventh of the last Wednesday of each process of a second read for the sent was initiated the first of the sent added to the QA and of the February QA evealed all "pink sheets" mailbox. Interview revealed at and monitor for compliance.	{A 58	2}			

AND PLAN OF CORRECTION IDENTIFICATION		(X1) PROVIDER/SUPPLIER/CLIA 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 CO MEDICAL CENTER BOULEVARD WINSTON-SALEM, NC 27157		0/20/2010	
(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 ((EACH CORRECTIVE ACTI CROSS-REFERENCED TO TI DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
{A 582}	Risk Management's recase files revealed 4 care would be affected with an incorrect diagonal patient #2. After recases, and the "confireviews, received on found that the diagnorincorrect for Patient # Management "immediated got physicians involved Patient #1 had been The interview revealed ongoing and all updated Medical Review Communical Executive Communication oversight of Laborated laboratory speciments processed with accurrent would be affected as the case of the cas	refor external review as well. review of the 10 patients' of the 10 patients' plans of ed if the results came back phosis, which included reviewing the breast cancer rming reports" from external December 15, 2017, it was easied by the second of the misdiagnoses. The interview revealed notified of the misdiagnoses. The investigation is still ted results were going to the imittee who report to the ommittee.	{A 58	32}			