	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CIDENTIFICATION NUMBER:	LIA	(X2) A. Bl		X3) DATE : COMPLETE	
				B. W	ING	01/18	8/2022
NAME OF PRO	OVIDER OR SUPPLIER			STR	EET ADDRESS, CITY, STATE, ZIP CODE		
NORTHSHOR	E CLINICAL LABORATO	RIES INC		9655	LAS VEGAS BLVD S OFFICE, LAS VEGAS, NEV	/ADA ,891	23
(X4)		MENT OF DEFICIENCIES	ID		PROVIDER'S PLAN OF CORRECTION		(X5)
ID PREFIX TAG	` REG	UST BE PRECEDED BY FULL GULATORY FYING INFORMATION)	PREF TAC		(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIA DEFICIENCY)		DATE
0000	Initial Comments - Laboratories	Chapter 652 Medical	0	000			
	Deficiencies was gethe on-site complated at your 2022, for State lice investigation was in of Northshore Clinic COVID-19 PCR test Nevada which was unsubstantiated, Nerforming COVID Nevada without all to be substantiated results which was substantiated. Pleasubstantiated Pleasubstantiated Pleasubstantiated within 14 Statement of Deficienclusions of any Division of Public as shall not be constructional or civil invother claims for relational to any party under	facility on January 18, nse #11547 EXL. The n response to allegations cal Labs performing sting in Las Vegas, found to be orthshore Clinical Labs -19 testing in Northern icense which was found I and providing erroneous					
0002	The director, a des licensed physician the test is performe person is compete.  Inspector Commer laboratory records consultant, Admini. Nevada Represent director failed to er competency asses personnel was conthe accuracy of lab Findings include: A there was no docu competency asses testing personnel is waived COVID-19	(1) - Applicability - (b) ignee of the director or a at the laboratory at which ed: (1) Verifies that the int to perform the test; ats: Based on a review of and an interview with the strative Assistant and ative, the laboratory issure that training and sments of all testing inpleted in order to ensure ioratory test results. It the time of the survey, mentation of training and sment for 47 out of 48 in the performance of Antigen specimen		002	1. We have found that no patie were affected by the deficier practice. Although the labora ("Laboratory" or "Northshore did not have proper written documentation for proof of training and competency assessments of all testing personnel at the time of the inspection, all personnel wer properly trained on proper w to perform waived COVID-19. Antigen specimen collection PCR specimen collection in	ents nt atory e") ere vays 9 n and	03/01/202 2
	IVE'S SIGNATURE	LIVOUT LIEN NAME JUSEFI	LEDRID	JL I	Fitle: Laboratory Director	Da	nc. 02/14/2022

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 protec ion to he patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participa ion.

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	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		LIA		IULTIPLE CONSTRUCTION ILDING	(X3) DATE SURVEY COMPLETED	
				B. WIN	NG	01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STRE	ET ADDRESS, CITY, STATE, ZIP CODE		
NORTHSHORI	E CLINICAL LABORATOR	RIES INC		9655 I	LAS VEGAS BLVD S OFFICE, LAS VEGAS, N	S8, IEVADA	9123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	ID PREF TAC	IX	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	) BE	(X5) COMPLETION DATE
	OR LSC IDENTII  collection and testii collection. This was interview with the collection. Assistant and Neva	FYING INFORMATION) ng and PCR specimen				dance ory s to d in and (3)  and r, the s have mented ument cy y nnel d s prior en g. tored ess. e- ares for ection ests.	
					to ensure the deficient pra do not recur:	ectices	
					<ul> <li>Laboratory has implement document control and revi ensure proper documenta</li> </ul>	iew to	

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			IULTIPLE CONSTRUCTION LDING	(X3) DATE SURVEY COMPLETED			
				B. WIN	NG	01/18/2022			
NAME OF PRO	OVIDER OR SUPPLIER			STREE	ET ADDRESS, CITY, STATE, ZIP CODE				
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655 LAS VEGAS BLVD S OFFICE, LAS VEGAS, NEVADA ,89123					
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL BULATORY FYING INFORMATION)	ID PREF TAG	IX	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULI CROSS-REFERENCED TO THE APPROP DEFICIENCY)	D BE COMPLÉTION			
					kept on personnel training competency assessments hires are given completed and given competency assessment. Once trainin completed, documentation stored electronically for eaccess.  b. Laboratory will continue to monitor and audit compliated with proper testing proced and will require re-training periodic basis and as appropriate.  4. The Laboratory Director and Director of Operations share responsible for ensuring the plan of correction is implemented.  5. This corrective action has initiated as of the submission date, and shall be complemented.  6. Attached are the following standard operating proced (SOPs) related to rapid an administration and PCR specimen collection:	g and s. New training g is n is asy once lures, g on a and all be he been sion ted by ry will dures ntigen			
					<ul><li>a. Attachment 1: Celltrion S0</li><li>b. Attachment 2: Sienna S0</li></ul>				
					c. Attachment 3: Indicaid SC				

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	MENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER:		IA (X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
				B. WING		01/	18/2022	
NAME OF PRO	AME OF PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE				
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655	LAS VEGAS BLVD S OFFICE, LAS VEGAS, I	NEVADA ,89	9123	
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL GULATORY FYING INFORMATION)	ID PREF TAC	IX	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOUL) CROSS-REFERENCED TO THE APPROF DEFICIENCY)	D BE	(X5) COMPLETION DATE	
					d. Attachment 4: GenBody S	SOP		
					e. Attachment 5: Abbot SOF	•		
					f. Attachment 6: Signed Ant SOP	igen		
					g. Attachment 7: Completed competency for antigen to			
					h. Attachment 8: PCR SOP			
0003	The director, a des licensed physician	(2) - Applicability - (b) ignee of the director or a at the laboratory at which	0	003	<u>Item 1: Temperature L</u>	_ogs	03/01/202	
	the test is performed test is performed in instructions of the instructions and an interest instruction of test kits, and an interest consultant and addirector failed to enwere performed in manufacturer's instinctude: 1. The label document the room with the manufacture requirements in an four Indicaid COVII were found sitting instructions for use provided in the kit is specimen collection for use state "The Instruction of the instruction used to collect pations of the instruction used to collect pations of the instruction used to collect pations of the instruction of the instruction used to collect pations of the instruction of the instruction used to collect pations of the instruction used to collect pations of the instruction used to collect pations of the instruction of the instruction used to collect pations of the instruc	ed: (2) Ensures that the accordance with manufacturer of the test; ats: Based on a review of a review of tructions for test bservation of laboratory erview with the ministrative assistant, the accordance with the tructions. Findings or tenter that laboratory tests accordance with the tructions. Findings or temperature consistent against acceptable storage adjacent office where D-19 antigen test kits on the floor. 2. GenBody a state "Only the swab as to be used for swab on". Indicaid instructions indicaid Covid-19 Rapid donly be used with the the kit to collect direct ording to the procedures as for use". Nasal swabs ent samples were gled in a carrier outside of			1. We have found that no pay were affected by the deficipractice. At the time of the survey, the temperature learned in the adjacent to the main Laboratory rowhich is run on the same condition system. Laboratory did keep temperature log for the acroom. The Laboratory has systemic changes/correct actions to this deficiency identified in response to sections (2) and (3) below each of the items identified.  2. To address the deficiency ensure it does not recur, the following systematic changes/corrective actions been implemented:  2. For antigen tests being use the standard part of the interest actions to the section of the items.	cient e og was at room om, e air djacent s made tive as of for ed. of and to the as have		
	the individual test k				<ul> <li>For antigen tests being us written SOPs have been</li> </ul>	sed,		

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CL IDENTIFICATION NUMBER:	.IA		TIPLE CONSTRUCTION NG	(X3) DAT COMPLE	E SURVEY TED
				B. WING		01	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STREET A	DDRESS, CITY, STATE, ZIP CODE		
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655 LAS	VEGAS BLVD S OFFICE, LAS VEGAS,	NEVADA ,8	9123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
IAG	policies in place for only use the specific manufacturer for the available on-site. 3 survey, there was to the collection and to specimens for PCF in Illinois. This was interview with the coadministrative assistance.	r laboratory personnel to ic swabs provided by the le different antigen tests. At the time of the no policy or procedure for ransport of COVID-19 R testing to the main lab confirmed in an		b.	developed and list all manufacturer's instruction use. The corresponding identified in response to (6) have been reviewed approved by the Laborat Director/Designee. SOPs shared with personnel performing antigen testing review and sign-off, and appropriate competencies be completed as outlined SOP. The Temperature It also been included in restorequest (6).  Storage of Kits: Temperature It also been included in restorequest (6).  Storage of Kits: Temperature It include instruction for temperature monitoring of storage conditions and retemperature to ensure the reagent kits are stored pland testing is performed optimal temperature. Temperature logs at each testing facility will be contended and it included in testing testing facility will be contended and it included in the store that will now be provided each site where COVID to are placed.	soPs request and ory s will be ag for s will d by the log has sponse ature ad to of com e roperly at the h h pleted ng. The ed meters at	
				3.	The corrective actions ar monitored in the followin to ensure the deficient produced do not recur:	g ways	

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	TEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		LIA	(X2) MU A. BUIL			E SURVEY TED		
				B. WINC	3	01/	18/2022		
NAME OF PRO	OVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE					
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655 LAS VEGAS BLVD S OFFICE, LAS VEGAS, NEVADA ,89123					
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL ULATORY FYING INFORMATION)	ID PREF TAG	IX	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE		
				ć	a. Laboratory has reviewed updated all SOPs to incl proper storage and hand test kits.	ude			
					i. The Laboral now has a policy in puthat requisithermostal located at site where antigen temperformed Manager daily check thermostal at the site ii. The laborate review procedure annual bareview pedocument appropriation.	a written place res ats be revery eresting is d. will do eks that ats are eres. For will eres on an eres and resonnel is for			
				4	<ol> <li>The Laboratory Director Director of Operations sl responsible for ensuring plan of correction is implemented.</li> </ol>	nall be			
				į	<ol> <li>This corrective action had initiated as of the submistrated, and shall be completed March 1, 2022. Laborate continue to monitor for</li> </ol>	ssion eted by			

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	OF DEFICIENCIES CORRECTION	F DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (CORRECTION IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING (X3) DATI			E SURVEY TED		
					_				
					<u> </u>	01/	18/2022		
NAME OF PRO	OVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE					
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655 LAS VEGAS BLVD S OFFICE, LAS VEGAS, NEVADA ,89123					
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROFIDENCY)	D BE	(X5) COMPLETION DATE		
					compliance.				
				6	6. Attached are the following standard operating proce (SOPs) related to rapid a tests, including the refere temperature log:	dures ntigen			
				í	a. Antigen tests:				
				1	1. Attachment 1: Celltrion S	OP			
				2	2. Attachment 2: Sienna SO	Р			
				3	3. Attachment 3: Indicaid SC	OP			
				4	4. Attachment 4: GenBody S	SOP			
					5. Attachment 5: Abbot SOF	)			
				6	<ol> <li>Attachment 6: Signed SO examples</li> </ol>	Р			
				7	<ol> <li>Attachment 7: Completed competency for antigen to</li> </ol>				
				8	<ol> <li>Attachment 10: Communi Daily Standard Operating Procedures</li> </ol>				
				ŀ	o. Storage of Kits:				
					1. Attachment 1-5: Antigen	SOPs			
				2	2. Attachment 9: Temperatu	re Log			
				3	<ol> <li>Attachment 10: Communi Daily Standard Operating Procedures</li> </ol>				
				<u> </u>	tem 2: Sample Collection				

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA		ULTIPLE CONSTRUCTION LDING	(X3) DATE	SURVEY ED	
				B. WIN	G	01/1	18/2022	
NAME OF PRO	OVIDER OR SUPPLIER			STREE	ET ADDRESS, CITY, STATE, ZIP CODE	<u> </u>		
NORTHSHOR	E CLINICAL LABORATOI	RIES INC		9655 LAS VEGAS BLVD S OFFICE, LAS VEGAS, NEVADA ,89123				
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPRODEFICIENCY)	D BE	(X5) COMPLETION DATE	
					1. We have found that no pay were affected by the deficiency practice. All instructions of for antigen testing current being performed by the Laboratory has been revisively. Written SOPs have been updated to include that so from other test kits shall used. The only swab that used for sample collection be the swab provided in the kit and followed according manufacturer's instruction. Laboratory conducted a rand confirmed that no incompatients.	ewed.  wabs not be will be n will he test g to the n. eview correct		
					<ol><li>To address the deficiency following systemic changes/corrective action been implemented:</li></ol>			
					a. The Laboratory does not intermingle swabs and in all personnel to use the s and parts that come with corresponding kits. All personnel must review S and be trained prior to performing testing on pat	wabs the OPs		
					<ul> <li>Additionally, when empty antigen kit, the contents a stored into a container resembling a pencil holde container is labeled with brand name of the antige</li> </ul>	ere er. The the		

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CL IDENTIFICATION NUMBER:	IA	(X2) MULTIPLE CONSTRUCTION (X3) I COMI			E SURVEY TED
				B. WING		01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER		+	STREET	ADDRESS, CITY, STATE, ZIP CODE	l	
	E CLINICAL LABORATOR	RIES INC			VEGAS BLVD S OFFICE, LAS VEGAS, I	NEVADA ,89	0123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL GULATORY FYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROF DEFICIENCY)	D BE	(X5) COMPLETION DATE
					the date the kit was open the expiration date of the		
				c.	There are three container each kit: (1) one holder st the swabs, (2) another ho stores the agent and (3) t third stores the cartridges	ores Ider he	
				3.	The corrective actions are monitored in the following to ensure the deficient prado not recur:	ways	
				a.	The Laboratory has reviet and updated the antigen is and will have an annual re of SOPs to ensure quality make necessary changes on laboratory testing practand CLIA requirements. Vinitial implementation of a antigen test, an SOP will created. The Lab Director/Designee will revisions for all new antigen prior to use.	SOPs eview and based tices Vith new be	
				b.	All personnel performing a testing will be required to the new SOP(s) as part of initial training. Follow up competency will be performed.	review f the	
				c.	Laboratory now has a QA in place to monitor pre- analytical, analytical, and analytical phase of testing includes proper storage of reagents, temperature	post- g. This	

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA	(X2) MUI A. BUILE	(X3) DAT COMPLE	E SURVEY TED	
				B. WING		01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STREET	ADDRESS, CITY, STATE, ZIP CODE		
NORTHSHOR	E CLINICAL LABORATOI	RIES INC		9655 LA	S VEGAS BLVD S OFFICE, LAS VEGAS,	NEVADA ,89	9123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROPRIED DEFICIENCY)	D BE	(X5) COMPLETION DATE
					monitoring, and review of personnel documents for appropriate training.		
				4	<ul> <li>The Laboratory Director a Director of Operations sh responsible for ensuring t plan of correction is implemented.</li> </ul>	all be	
				5	This corrective action has initiated as of the submiss date, and shall be comple March 1, 2022. Laborato continue to monitor for compliance.	sion eted by	
				6	<ul> <li>Attached are the following standard operating proce (SOPs) related to sample collection:</li> </ul>	dures	
				а	. Attachments 1-5: Antigen	SOP	
				b	. Attachment 11: QA Policy Forms	and	
				<u>lt</u>	em 3: Transport		
				1	. We have found that no paymere affected by the deficience. Although the Laboratory did not have a written policy in place at the of the inspection, the Laborate in Nevada was following a CDC guidance and protocomonitored by the Laborate Director prior to sending a specimens to the Illinois I	he time oratory proper cols as ory	

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CL IDENTIFICATION NUMBER:	.IA		IPLE CONSTRUCTION NG	(X3) DATI	E SURVEY TED
				B. WING _		01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STREET A	DDRESS, CITY, STATE, ZIP CODE		
	E CLINICAL LABORATOR	RIES INC			VEGAS BLVD S OFFICE, LAS VEGAS, I	NEVADA ,89	123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL GULATORY FYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROP DEFICIENCY)	D BE	(X5) COMPLETION DATE
					no patients were found to impacted.	be	
				2.	To address the deficiency following systemic changes/corrective action been implemented:		
				a.	The Laboratory has implemented a SARS Co Specimen Collection and Handling policy and proce to follow. The policy inclu proper transporting method be followed by the Laboratory in Illinois.	edure des the od to atory in	
				b.	Specifically, the laborator Nevada will ship samples clinical shipping containe an ice pack to ensure prohandling of the specimen laboratory in Illinois will provernight shipping labels Laboratory in Nevada so specimen handling is not compromised.	in a r with per . The rovide	
				3.	The corrective actions are monitored in the following to ensure the deficient produced not recur:	ways	
				a.	Training and competency assessed and provided in training process.		
				b.	The Laboratory Director has reviewed and revised all s		

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA		MULTIPLE CONSTRUCTION ULDING	(X3) DAT	TE SURVEY ETED
				B. WIN	NG	01	/18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STRE	ET ADDRESS, CITY, STATE, ZIP CODE		
NORTHEHOR	E CLINICAL LABORATOR	DIES INC				AS NEVADA 9	9122
NORTHSHOR	E CLINICAL LABORATOR	KIES INC		3633 L	LAS VEGAS BLVD S OFFICE, LAS VEG	AS, NEVADA ,	3123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	ID PREF TAG	IX	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE API DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
			IAG			g SOPs to practices acturers. We been detraining annual ll be SOPs at hanges training. The end of an actual libe a	DATE
0004	NAC652.155(2)(b)(	(3) - Applicability - (b)	00	004			03/01/202

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NAME OF PROVIDER OR SUPPLIER   STREET ADDRESS, CITY, STATE, ZIP CODE		OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA	(X2) I A. BL	MULTIPLE CONSTRUCTION JILDING	(X3) DAT COMPLE	E SURVEY TED		
XXI   CACH LABORATORIES INC   SUMMARY STATEMENT OF DEFICIENCIES ID DEFICE COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL ROPE (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY AND THE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORS-CIVE ACTION TAGE (TAGE TO THE APPROPRIATE DEFICIENCY BATTERY TAGE (CACH CORS-CIVE ACTION TAGE (TAGE TO THE APPROPRIATE DEFICION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY BATTE					B. W	NG	01/	18/2022		
CAMPARTY STATEMENT OF DEFICIENCIES (DEACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LS DESTIFYING INFORMATION)    The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (3) Validates and verifies the manner in which the test is performed verifies the manner in which the test is performed verifies the manner in which the securate and reliable.   Inspector Comments: Based on a review of laboratory records, manufacturer's requirements, and interviews with the consultant and Administrative Assistant, the laboratory director failed to ensure that external quality controls were performed according to the manufacturer's requirement for External Quality Control used to determine if patient testing may be performed. Findings include: 1. There was no evidence that external controls for the COVID-19 antigen test kits: GenBody, Indicaid or Abbott BinaxNOW cards, were performed and documented to validate the accuracy of the tests. 2. Indicaid instructions state "Positive and negative controls should be run once with every new lot, shipment and each new user. If either or both external control results are unexpected or invalid, repeat the external controls with a new swab, buffer solution vial and test device and if results continue to be unexpected or invalid contact PHASE Scientific Technical Support before testing	NAME OF PRO	AME OF PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE					
CAMPARTY STATEMENT OF DEFICIENCIES (DEACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LS DESTIFYING INFORMATION)    The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (3) Validates and verifies the manner in which the test is performed verifies the manner in which the test is performed verifies the manner in which the securate and reliable.   Inspector Comments: Based on a review of laboratory records, manufacturer's requirements, and interviews with the consultant and Administrative Assistant, the laboratory director failed to ensure that external quality controls were performed according to the manufacturer's requirement for External Quality Control used to determine if patient testing may be performed. Findings include: 1. There was no evidence that external controls for the COVID-19 antigen test kits: GenBody, Indicaid or Abbott BinaxNOW cards, were performed and documented to validate the accuracy of the tests. 2. Indicaid instructions state "Positive and negative controls should be run once with every new lot, shipment and each new user. If either or both external control results are unexpected or invalid, repeat the external controls with a new swab, buffer solution vial and test device and if results continue to be unexpected or invalid contact PHASE Scientific Technical Support before testing	NORTHEHOR	E CLINICAL LABORATOR	DIES INC		OCEE	LAS VECAS DI VID S OFFICE LAS VECAS A	JEWADA 00	1102		
CEACH DEFICIENCY MUST BE PRECEDED BY FULL REQUIZATORY OR LSC IDENTIFYING INFORMATION)   The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (3) Validates and verifies the manner in which the test is performed by using controls which ensure that the results of the test will be accurate and reliable.  Inspector Comments: Based on a review of laboratory records, manufacturer's requirements, and interviews with the consultant and Administrative Assistant, the laboratory director falled to ensure that external quality control used to determine if patient testing may be performed. Findings include: 1. There was no evidence that external controls for the COVID-19 antigen test kits: GenBody, Indicaid or Abbott BinaxNOW cards, were performed and documented to validate the accuracy of the tests. 2. Indicaid instructions state "Positive and negative controls should be run once with every new lot, shipment and each new user. If either or both external control results are unexpected or invalid, repeat the external controls with a new swab, buffer solution vial and test device and if results continue to be unexpected or invalid, crepeat the external controls with a new swab, buffer solution vial and test device and if results continue to be unexpected or invalid, crepeat the external controls with a new swab, buffer solution vial and test device and if results continue to be unexpected or invalid, repeat the external controls with a new swab, buffer solution vial and test device and if results continue to be unexpected or invalid contact PHASE Scientific Technical Support before testing	NORTHSHOR	E CLINICAL LABORATOR	(IES INC		3033	LAS VEGAS BLVD S OFFICE, LAS VEGAS, I	VEVADA ,00	7120		
licensed physician at the laboratory at which the test is performed: (3) Validates and verifies the manner in which the test is performed by using controls which ensure that the results of the test will be accurate and reliable.  Inspector Comments: Based on a review of laboratory records, manufacturer's requirements, and interviews with the consultant and Administrative Assistant, the laboratory director failed to ensure that external quality controls were performed according to the manufacturer's requirement for External Quality Control used to determine if patient testing may be performed. Findings include: 1. There was no evidence that external controls for the COVID-19 antigen test kits: GenBody, Indicaid or Abbott BinaxNOW cards, were performed and documented to validate the accuracy of the tests. 2. Indicaid instructions state "Positive and negative controls should be run once with every new lot, shipment and each new user. If either or both external control results are unexpected or invalid, repeat the external controls with a new swab, buffer solution vial and test device and if results continue to be unexpected or invalid contact PHASE Scientific Technical Support before testing	`ID´ PREFIX	(EACH DEFICIENCY M REG OR LSC IDENTI	UST BE PRECEDED BY FULL GULATORY FYING INFORMATION)	PREFI)		(EACH CORRECTIVE ACTION SHOULI CROSS-REFERENCED TO THE APPROF DEFICIENCY)	D BE PRIATE	COMPLÉTION DATE		
state "it is recommended that external control testing be performed with each new operator and before using a new lot or shipment of GenBody COVID-19 Ag kits to confirm the expected quality control results. If external controls do not perform as expected, do not use the test results and contact Technical Support". This was confirmed in an interview with the consultant and Administrative Assistant on 1/18/2022 at approximately 11:00 AM. Severity level = 2  developed for all antigen tests that are being used (Sienna, Celltrion, Abbott, Indicaid, and GenBody). SOPs have been developed and list all manufacturer's instructions for use. The corresponding SOPs will be reviewed and approved by the Lab Director/Designee. SOPs will be shared with personnel performing antigen testing for review and sign-off,		licensed physician the test is performed verifies the manner performed by using that the results of the and reliable.  Inspector Commentation and reliable.  Inspector Commentation and Adriaboratory records, requirements, and consultant and Adriaboratory director external quality correctoring to the marequirement for Extrused to determine performed. Finding no evidence that external controls and documentation accuracy of the test instructions state "It controls should be lot, shipment and external control invalid, repeat the anew swab, buffer device and if result unexpected or invalid, repeat the anew swab, buffer device and if result unexpected or invalid, repeat the anew swab, buffer device and before state "it is recomment on the strength of GenBot confirm the expected, do not use contact Technical Sconfirmed in an interconsultant and Adriable 222 at approximation."	at the laboratory at which ed: (3) Validates and r in which the test is goontrols which ensure he test will be accurate he failed to ensure that he failed to ensure that he failed to ensure that he test will control if patient testing may be so include: 1. There was kernal controls for the test kits: GenBody, BinaxNOW cards, were numented to validate the test. 2. Indicaid Positive and negative run once with every new each new user. If either or old results are unexpected he external controls with a solution vial and test is continue to be alid contact PHASE. I Support before testing herformed with each new he using a new lot or old y COVID-19 Ag kits to be deducity control results. In do not perform as see the test results and support". This was herview with the ministrative Assistant on			were affected by the deficience. Each antigen test includes internal quality of to determine if result is variouslid. An invalid result we be indicative of (1) impropressample collection (2) impropressample collection (3) test improperly perform the laboratory in the laboratory in the laboratory in the laboratory in the laboratory made systemic changes/corrections to this deficiency as identified in response to section (3) below.  2. To address this deficiency as identified in response to section deen implemented:  a. Written SOPs have been developed for all antigenthat are being used (Siena Celltrion, Abbott, Indicaid GenBody). SOPs have been developed and list all manufacturer's instruction use. The corresponding Siena will be reviewed and appropressional performing antipersonnel performing antipersonne	cient st kit control c	2		

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA	(X2) MUL A. BUILD	TIPLE CONSTRUCTION ING	(X3) DATI	E SURVEY TED
						01/	18/2022
NAME OF PROVIDER OR SUPPLIER			STREET	ADDRESS, CITY, STATE, ZIP CODE			
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655 LA	S VEGAS BLVD S OFFICE, LAS VEGAS,	NEVADA ,89	123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL GULATORY FYING INFORMATION)	ID PREF TAG	IX	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPRIED TO THE	D BE	(X5) COMPLETION DATE
		·			and appropriate compete be completed as outlines SOP.		
				b	Testing personnel trained did not have documentati SOPs will be shared with personnel performing ant testing for review and sig and appropriate compete be completed as outlines SOP.	on: igen n-off ncy will	
				С	Competency documentate be maintained by the Lab for a minimum of two year	oratory	
				3	<ul> <li>The corrective actions are monitored in the following to ensure the deficient pro do not recur:</li> </ul>	ways	
					g o ong bas doo atio rela ant	enitorin on an going sis of cument on ated to tigen ting	
				4	<ul> <li>The Laboratory Director a Director of Operations sh responsible for ensuring t plan of correction is implemented.</li> </ul>	all be	

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA		MULTIPLE CONSTRUCTION JILDING	(X3) DAT COMPLE	E SURVEY TED	
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NAME OF PRO	OVIDER OR SUPPLIER			STRE	STREET ADDRESS, CITY, STATE, ZIP CODE			
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655	LAS VEGAS BLVD S OFFICE, LAS VEGAS, I	NEVADA ,89	9123	
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					<ol> <li>This corrective action has initiated as of the submiss date, and shall be comple March 1, 2022. Laborator continue to monitor for compliance.</li> <li>Attachments         <ul> <li>Attachments 1-5: Antiger SOPs</li> </ul> </li> <li>Attachment 6: Signed Ant SOP</li> <li>Attachment 7: Completed competency for antigen to the submission of the</li></ol>	sion eted by ry will		
0011	Health & Safety - A that: 1. Policies and established and en health, welfare, and of the laboratory ar Inspector Commen and discussion with Administrative Assito ensure the healt the personnel of th providing a safe en employees are prochemical, and physinclude: At the time laboratory was equipled and face ship owns or N95 mas laboratory as listed Clinical Labs Person Equipment (PPE) Fronfirmed by observith the consultant	forced to ensure the disafety of the personnel of visitors.  Its: Based on observation in the consultant and istant, the director failed in welfare, and safety of elaboratory by not vironment in which tected from biological, sical hazards. Findings of the survey, the ipped with face masks, ields. No disposable ks were found in the in the Northshore onal Protective Policy. This was evation and discussion and Administrative 12 at approximately 11:00	0	011	1. We have found that no parameter affected by deficient practice. At the time of the survey, the Laboratory did have a written procedure PPE, but did have sufficient PPE on-site and does require at the time inspection, proper PPE. The Laboratory holds an invert N-95 masks/respirators, of face shields, and disposate gowns at all times. Properism worn during testing of pand specimen collection, accordance with CDC guit PPE is provided to all static including N-95 masks, glotace shields, and disposate gowns. The Laboratory has	d not for ent juire e of The ntory of gloves, ble r PPE patients in dance. ff oves, ble	03/01/202	

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA		TIPLE CONSTRUCTION NG	(X3) DATI COMPLE	E SURVEY TED
				B. WING		01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STREET	ADDRESS, CITY, STATE, ZIP CODE		
NORTHSHORE CLINICAL LABORATORIES INC				9655 LAS	VEGAS BLVD S OFFICE, LAS VEGAS,	NEVADA ,89	9123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL GULATORY FYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROF DEFICIENCY)	D BE	(X5) COMPLETION DATE
					made systemic changes/corrective action this deficiency as identified response to sections (2) a below.	ed in	
				2.	To address the deficiency following systematic changes/corrective action been implemented:		
				a.	The Laboratory has creat written SOPs that have be reviewed and signed by the Laboratory Director. All personnel of the Laborator review and sign off on SO and must do so prior to te of patients.	een he ory will )Ps	
				b.	The Laboratory will assigned individual to be responsible ordering of supplies where supplies are running lower ensure a sufficient amount consistently on site. The Laboratory has implement inventory tracker sheet the updated daily.	ole for n to nt is nted an	
				c.	The Laboratory Director/Designee will pe daily inventory checks to the health, welfare, and s the personnel of the labor	ensure afety of	
				3.	The corrective action is b monitored by having the inventory track sheet that supply manager reviews	the	

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA			PLE CONSTRUCTION  G	(X3) DAT COMPLE	E SURVEY TED
				B. WIN	NG _		01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STREE	ET A	DRESS, CITY, STATE, ZIP CODE		
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655 L	LAS V	EGAS BLVD S OFFICE, LAS VEGAS, I	NEVADA ,89	9123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL ULATORY FYING INFORMATION)	ID PREF TAG	IX	C	PROVIDER'S PLAN OF CORRECTIC (EACH CORRECTIVE ACTION SHOUL ROSS-REFERENCED TO THE APPROF DEFICIENCY)	D BE	(X5) COMPLETION DATE
					4	daily basis to ensure that masks, gloves, face shield disposable gowns are alwavailable in sufficient quatonsite. There will be a not sent to Director of Operat for approval of all invento purchases.  The Laboratory Director as	ds, and yays ntities tice ions ry	
					7.	Director of Operations sharesponsible for ensuring to plan of correction is implemented.	all be	
					5.	This corrective action has initiated as of the submiss date, and shall be comple March 1, 2022. Laborato continue to monitor for compliance.	sion eted by	
					6.	The following SOPs have created in response to thi deficiency.		
					a.	Attachment 14: Inventory Tracker Sheet		
					b.	Attachment 13: PPE Procedures		
0049	personnel - 1. Befor laboratory at any to application for certion on a form provided information on the background; (d) Th	d) - Certification of ore working in a echnical level: (a) An fication must be made by the Division giving applicant's educational e fee prescribed in NAC impany the application.	O	049	1.	We have found that no pa were affected by the defic practice. At the time of the survey, all relevant Labor staff held appropriate certification or had filed for appropriate certification v	cient e atory or	03/01/202 2

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIDENTIFICATION NUMBER:			PLE CONSTRUCTION G	(X3) DAT COMPLE	E SURVEY TED	
				B. WING _		01/	18/2022	
NAME OF PRO	DF PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE				
NORTHSHOR	E CLINICAL LABORATOR	RIES INC			/EGAS BLVD S OFFICE, LAS VEGAS, I	NEVADA ,89	9123	
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	Inspector Commen Division of Public a records and an interconsultant, Administ Laboratory Director ensure that certifica 652.470 was obtain Assistants and Lab pay the applicable 652.488. Findings survey on January the laboratory assist Laboratory Assistant Saistant licenses. Interview with the consultance of Public	atts: Based on a review of and Behavioral Health erview with the estrative Assistant and r, the director failed to ation pursuant to NAC med for the Medical poratory Assistants and fees as set forth in NAC include: At the time of the 18, 2022, 35 out of 48 of stants did not have Office in the licenses or Laboratory This was confirmed in an anonsultant, Administrative oratory Director, on at approximately 11:30		a. b.	payment of applicable feeset forth in NAC 652.488. Laboratory has made syschanges/corrective action this deficiency as identified response to sections (2) a below.  To address the deficiency following systematic changes/corrective action been implemented, included creation of certain SOPs identified in Section (6) be Part of the staff training in applying for the application certification using the form provided by the Division.  Upon hiring, new personned by the certification of the staff training in applying for the application certification using the form provided by the Division.  Upon hiring, new personned by the certification, the personnot acquired or attempted acquire the certification, the terminated.  The corrective action is becontinuously monitored by Laboratory Director/Design ensuring the application has been sent and/or approve to lab assistants working at the Laboratory. Proper documentation is held electronically to confirm we have action application of the continuously to confirm we have a provided to confirm we have action approved to lab assistants and/or massistants working at the Laboratory. Proper documentation is held electronically to confirm we have action application of the confirm we have action in the laboratory of the confirm we have action in the laboratory of the confirm we have action in the laboratory of the confirm we have action in the laboratory of the labo	The temic is to ed in and (3)  /, the ling the elow: acludes on for an two-nel has I to hey will eing y gnee has ed prior hedical		

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA			PLE CONSTRUCTION G	(X3) DAT	E SURVEY TED
				B. WII	NG _		01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STRE	ET A	DDRESS, CITY, STATE, ZIP CODE		
NORTHSHORE CLINICAL LABORATORIES INC				9655	LAS V	/EGAS BLVD S OFFICE, LAS VEGAS, N	IEVADA ,89	123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	ID PREF TAC	IX	С	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD ROSS-REFERENCED TO THE APPROP DEFICIENCY)	) BE	(X5) COMPLETION DATE
					4.	personnel acquired certifications, which have pending certifications, and that have not yet applied.  The Laboratory Director a Director of Operations sharesponsible for ensuring the plan of correction is implemented.	nd all be	
					5.	This corrective action has initiated as of the submiss date, and shall be comple March 1, 2022. Laborator continue to monitor for compliance.	ion ted by	
					6.	The following SOPs have created in response to this deficiency.		
					a.	Attachment 15: Proof of Laboratory licenses/applications		
					b.	Attachment 16: Hiring and Training SOP	I	
0140	renewal; inactive - provided in NRS 65 person may operat report from or main without first obtaini issued by the Divis provisions of this cl issued pursuant to subsection 1 is vali	ntain a medical laboratory ng a license to do so ion pursuant to the hapter. 2. A license the provisions of d for 24 months and is ly on or before the date	0	140	1.	We have found that no pa were affected by the defic practice. The Laboratory received the proper licens perform testing across the of Nevada from the Depar of Health and Human Ser Division of Public and Behavioral Health but is	ient ing to state tment	03/01/202

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NAME OF DDO	OF PROVIDER OR SUPPLIER							
NAME OF FRO	WIDER OR SUFFLIER			STREET ADDRESS, CITY, STATE, ZIP CODE				
NORTHSHOR	E CLINICAL LABORATOR	RIES INC		9655	LAS VEGAS BLVD S OFFICE, LAS VEGAS, I	8, NEVADA	9123	
	SUMMARY STATE (EACH DEFICIENCY M REG OR LSC IDENTII  issued to a laborator a laboratory director placed in an inactival approval of the Divicurrent fees. 5. The laboratory that is lostate to be licensed provisions of this collaboratory may exacollected within this determines that the to protect the publical welfare of the residence of the resid	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL JULATORY FYING INFORMATION)  OR Which does not have or. 4. A license may be re status upon the ision and the payment of the Division may require a reated outside of this of in accordance with the mapter before the lumine any specimens to state if the Division the licensure is necessary to health, safety and the licensure is necessary to health the licensure is necessary to health the health the health the health the health health the he	ID PREF TAG	9655	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPRIED TO THE	m evada th and Public ic o this ponse  /, the ective nented: ed for an etewide	(X5) COMPLETION DATE	
					<ul> <li>Pending the approval of the Corrective Plan of Action the Division, operations we commence upon the sign the Compliance Agreement</li> </ul>	with vill ing of		
					<ul> <li>c. Compliance Agreement repending until Plan of Correction is submitted and accepted.</li> </ul>			
					<ol> <li>The corrective action is be monitored in the following to ensure the deficient pre do not recur:</li> </ol>	ways		

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA		IULTIPLE CONSTRUCTIOI LDING	N 	(X3) DATI	E SURVEY TED
				B. WIN	NG		01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STREE	ET ADDRESS, CITY, STAT	TE, ZIP CODE		
NORTHSHOR	NORTHSHORE CLINICAL LABORATORIES INC			9655 L	AS VEGAS BLVD S OFFI	CE, LAS VEGAS, N	NEVADA ,89	9123
(X4) ID PREFIX TAG	(EACH DEFICIENCY MI REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	ID PREF TAG		(EACH CORRECTIVE CROSS-REFERENCEL		) BE	(X5) COMPLETION DATE
					<ul> <li>a. The Laborato Director/Desi further sites of approval of pagreement</li> <li>b. Laboratory do open any furt Nevada at this Director/Desi licensing requopening of ar in the state of</li> <li>4. The Laborator</li> </ul>	gnee will ensopen without roper licensing ses not intended ther testing ses time. Labor agnee will revuirements pring new testing f Nevada.	d to ites in oratory iew ior to g sites	
					Director of Operesponsible for plan of correcting implemented	perations sha or ensuring t ction is	all be	
					<ol> <li>This corrective initiated as of date, and sha March 1, 202 continue to make compliance.</li> </ol>	f the submiss all be comple 2. Laborato	sion ted by	
					<ol><li>The following created in res deficiency:</li></ol>			
					a. Attachment 1 - Exempt Lab Tests			
145	laboratory records	ry Director ts: Based on a review of and an interview with the strative Assistant and		145	We have four were affected practice. At the	d by the defic	ient	03/01/202 2

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA		IULTIPLE CONSTRUCTION ILDING	(X3) DAT COMPLE	E SURVEY TED	
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NAME OF PRO	ME OF PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE				
	IORTHSHORE CLINICAL LABORATORIES INC							
NORTHSHORI	E CLINICAL LABORATOR	RIES INC		9655 L	LAS VEGAS BLVD S OFFICE, LAS VEGA	s, NEVADA ,8	9123	
(X4)	SLIMMADY STATE	MENT OF DEFICIENCIES	ID		PROVIDER'S PLAN OF CORREC	ION	(X5)	
ID PREFIX TAG	(EACH DEFICIENCY M REG	UST BE PRECEDED BY FULL SULATORY FYING INFORMATION)	PREF TAG		(EACH CORRECTIVE ACTION SHOI CROSS-REFERENCED TO THE APPR DEFICIENCY)	JLD BE	COMPLETION DATE	
		CC10757, the laboratory			inspection, the Laborato	ry did		
	director failed to re results of laborator				not have a written proce			
		peration of the laboratory			place for record keeping			
	to the extent neces				results that were perform			
	compliance with the chapter, be respon				site, nor did it keep a Fe			
	performance of all	work in the laboratory			tracking number with sp included in the clinical o			
		ates and retain the health ularly maintained records			However, by its operatir			
	of the laboratory in				procedures, patients pro			
	regulations adopte	d by the Board pursuant			received a phone call up			
		indings include: 1. At the there were no records of			positive rapid results. La			
		performed on-site and			keeps a tracking log of patier			
		nt specimens that had			results at the location that are two (2) years. The Laborator			
	testing. 2. Results	ain lab in Illinois for PCR of antigen testing			made systemic changes/corr			
	reported verbally a	s positive to patient			actions to this deficiency as i			
		7 on 1/5/2022 could not aboratory not having			response to sections (2) and below.	(3)		
		antigen testing. The						
		aboratory report from			2. To address the deficien			
	Northshore Clinical	orted both the antigen			following systematic cor			
		as negative. This was			actions have been imple	ementea:		
		rvation and discussion			a. Laboratory has impleme	nted		
		and Administrative 22 at approximately 11:00			written SOPs to train an			
	AM. Patient NSCL	-WACC10757 was			staff with for Rapid and	PCR		
	interviewed on 1/26 3:30 PM. Severity I	6/2022 at approximately			testing and proper proce	edures		
	5.50 Fivi. Severity i	Level - 2			that must be followed.			
					Personnel will update tr	_		
					log on a daily basis with	patient		
					information and results.			
					b. Written SOPs have bee	า		
					created and reviewed b			
					Laboratory Director.	•		
					•			
					c. All new and existing sta	t are to		
					be trained on proper implementation of patie	.+		
					tracking log.	ıı		
					additing log.			

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA		JLTIPLE CONSTRUCTION DING	(X3) DATE SURVEY COMPLETED
				B. WIN	G	01/18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STREE	T ADDRESS, CITY, STATE, ZIP CODE	
NORTHSHORE CLINICAL LABORATORIES INC				9655 L	AS VEGAS BLVD S OFFICE, LAS VEGAS, I	NEVADA ,89123
(X4) ID PREFIX TAG	(EACH DEFICIENCY M REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL ULATORY FYING INFORMATION)	ID PREF TAC	IX	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULL CROSS-REFERENCED TO THE APPROPERTIES OF THE PROPERTIES OF THE APPROPERTIES OF T	D BE COMPLÉTION
					<ul> <li>d. FedEx tracking log will be to include tracking number patient's specimens sent clinical container.</li> <li>e. Patients will be given a raresult stating that it was gone the state of Nevada, not Illinois. Results will be sessecure HIPAA-compliant</li> </ul>	er with in each pid iven in ent in a
				:	<ol> <li>The corrective action is be monitored in the following to ensure the deficient pra do not recur:</li> </ol>	ways
				1	<ul> <li>Laboratory has implement written SOPs to train and staff with for Rapid and Potential testing and proper proceed that must be followed.</li> </ul>	retrain CR
					<ul> <li>Laboratory Director or De will monitor the patient log daily basis to ensure log i updated daily with proper information</li> </ul>	g on a s being
				,	<ol> <li>The Laboratory Director a Director of Operations sharesponsible for ensuring t plan of correction is implemented.</li> </ol>	all be
				!	<ol> <li>This corrective action has initiated as of the submiss date, and shall be comple March 1, 2022. Laborato</li> </ol>	sion eted by

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	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER:	LIA		MULTIPLE CONSTRUCTION (X3) DATI COMPLE	E SURVEY TED
				B. W	/ING 01/	18/2022
NAME OF PRO	OVIDER OR SUPPLIER			STRE		
NORTHSHORE	E CLINICAL LABORATOR	RIES INC	9655 LAS VEGAS BLVD S OFFICE, LAS VEGAS, NEVADA ,8912			9123
(X4) ID PREFIX TAG	(EACH DEFICIENCY MI REG	MENT OF DEFICIENCIES UST BE PRECEDED BY FULL ULATORY FYING INFORMATION)	ID PREF TAC	IX	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
					continue to monitor for compliance.	
					The following SOPs have been created in response to this deficiency:	
					a. Attachments 1-5: Antigen SOPs	
					b. Attachment 8: PCR SOP	
					c. Attachment 10: Community Sites Daily Standard Operating Procedures	
					d. Attachment 18: Tracking Log for Patient Results	
					e. Attachment 19: SOP for FedEx tracking of PCR specimens being sent to Illinois Lab	