DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		A. BUILDING _____ B. WING _____	01/18/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES INC	9655 LAS VEGAS BLVD S OFFICE, LAS VEGAS, NEVADA ,89123

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0000	Initial Comments - Chapter 652 Medical Laboratories Inspector Comments: This Statement of Deficiencies was generated as a result of the on-site complaint investigation conducted at your facility on January 18, 2022, for State license #11547 EXL. The investigation was in response to allegations of Northshore Clinical Labs performing COVID-19 PCR testing in Las Vegas, Nevada which was found to be unsubstantiated, Northshore Clinical Labs performing COVID-19 testing in Northern Nevada without a license which was found to be substantiated and providing erroneous results which was found to be substantiated. Please log into the Online Licensing System and complete the Plan of Correction. The Plan of Correction must be submitted within 14 days after receipt of this Statement of Deficiencies. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.	0000		
0002	NAC652.155(2)(b)(1) - Applicability - (b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (1) Verifies that the person is competent to perform the test; Inspector Comments: Based on a review of laboratory records and an interview with the consultant, Administrative Assistant and Nevada Representative, the laboratory director failed to ensure that training and competency assessments of all testing personnel was completed in order to ensure the accuracy of laboratory test results. Findings include: At the time of the survey, there was no documentation of training and competency assessment for 47 out of 48 testing personnel in the performance of waived COVID-19 Antigen specimen	0002	1. We have found that no patients were affected by the deficient practice. Although the laboratory ("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 were properly trained on proper ways to perform waived COVID-19 Antigen specimen collection and PCR specimen collection in	03/01/2022

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Name: JOSEPH ELDRIDGE Title: Laboratory Director Date: 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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	collection and testing and PCR specimen collection. This was confirmed in an interview with the consultant, Administrative Assistant and Nevada Representative on 1/18/2022 at approximately 11:00 AM. Severity level = 2		accordance with CDC guidance and manufacturer instructions. The Laboratory has made systemic changes/corrective actions to this deficiency as identified in response to sections (2) and (3) below. 2. To address this deficiency and to ensure it does not recur, the following systematic changes/corrective actions have been implemented: a. The laboratory has implemented a process to properly document all training and competency assessments completed by each personnel. All personnel must complete training and competency assessments prior to performing any specimen collection or waived testing. Training documents are stored in an online forum for access. b. All personnel have been re-trained on proper procedures for both PCR specimen collection and performing waived tests. 3. The corrective actions are being monitored in the following ways to ensure the deficient practices do not recur: a. Laboratory has implemented document control and review to ensure proper documentation is	

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			kept on personnel training and competency assessments. New hires are given complete training and given competency assessment. Once training is completed, documentation is stored electronically for easy access. b. Laboratory will continue to monitor and audit compliance with proper testing procedures, and will require re-training on a periodic basis and as appropriate. 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented. 5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will continue to monitor for compliance. 6. Attached are the following standard operating procedures (SOPs) related to rapid antigen administration and PCR specimen collection: a. Attachment 1: Celltrion SOP b. Attachment 2: Sienna SOP c. Attachment 3: Indicaid SOP	

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			d. Attachment 4: GenBody SOP e. Attachment 5: Abbot SOP f. Attachment 6: Signed Antigen SOP g. Attachment 7: Completed competency for antigen testing h. Attachment 8: PCR SOP	
0003	NAC652.155(2)(b)(2) - Applicability - (b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (2) Ensures that the test is performed in accordance with instructions of the manufacturer of the test; Inspector Comments: Based on a review of laboratory records, a review of manufacturer's instructions for test requirements, an observation of laboratory test kits, and an interview with the consultant and administrative assistant, the director failed to ensure that laboratory tests were performed in accordance with the manufacturer's instructions. Findings include: 1. The laboratory failed to document the room temperature consistent with the manufacturer's acceptable storage requirements in an adjacent office where four Indicaid COVID-19 antigen test kits were found sitting on the floor. 2. GenBody instructions for use state "Only the swab provided in the kit is to be used for swab specimen collection". Indicaid instructions for use state "The Indicaid Covid-19 Rapid Antigen Test should only be used with the swabs provided in the kit to collect direct nasal samples according to the procedures in these instructions for use". Nasal swabs used to collect patient samples were observed intermingled in a carrier outside of the individual test kits. There were no	0003	<u>Item 1: Temperature Logs</u> 1. We have found that no patients were affected by the deficient practice. At the time of the survey, the temperature log was maintained in the adjacent room to the main Laboratory room, which is run on the same air condition system. Laboratory did keep a temperature log for the adjacent room. The Laboratory has made systemic changes/corrective actions to this deficiency as identified in response to sections (2) and (3) below for each of the items identified. 2. To address the deficiency and to ensure it does not recur, the following systematic changes/corrective actions have been implemented: a. For antigen tests being used, written SOPs have been	03/01/2022

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	policies in place for laboratory personnel to only use the specific swabs provided by the manufacturer for the different antigen tests available on-site. 3. At the time of the survey, there was no policy or procedure for the collection and transport of COVID-19 specimens for PCR testing to the main lab in Illinois. 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 and list all manufacturer's instructions for use. The corresponding SOPs identified in response to request (6) have been reviewed and approved by the Laboratory Director/Designee. SOPs will be shared with personnel performing antigen testing for review and sign-off, and appropriate competencies will be completed as outlined by the SOP. The Temperature Log has also been included in response to request (6). b. Storage of Kits: Temperature not monitored: Corresponding SOPs have been updated to include instruction for temperature monitoring of storage conditions and room temperature to ensure the reagent kits are stored properly and testing is performed at the optimal temperature. Temperature logs at each testing facility will be completed each day of patient testing. The Laboratory also purchased additional digital thermometers that will now be provided at each site where COVID test kits are placed. 3. The corrective actions are being monitored in the following ways to ensure the deficient practices do not recur:	

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			a. Laboratory has reviewed and updated all SOPs to include proper storage and handling of test kits. i. The Laboratory now has a written policy in place that requires thermostats be located at every site where antigen testing is performed. Manager will do daily checks that thermostats are at the sites. ii. The laboratory will review procedures on an annual basis and review personnel documents for appropriate training. 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented. 5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will continue to monitor for	

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			compliance. 6. Attached are the following standard operating procedures (SOPs) related to rapid antigen tests, including the referenced temperature log: a. Antigen tests: 1. Attachment 1: Celltrion SOP 2. Attachment 2: Sienna SOP 3. Attachment 3: Indicaid SOP 4. Attachment 4: GenBody SOP 5. Attachment 5: Abbot SOP 6. Attachment 6: Signed SOP examples 7. Attachment 7: Completed competency for antigen testing 8. Attachment 10: Community Site Daily Standard Operating Procedures b. Storage of Kits: 1. Attachment 1-5: Antigen SOPs 2. Attachment 9: Temperature Log 3. Attachment 10: Community Site Daily Standard Operating Procedures <u>Item 2: Sample Collection</u>	

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			1. We have found that no patients were affected by the deficient practice. All instructions for use for antigen testing currently being performed by the Laboratory has been reviewed. Written SOPs have been updated to include that swabs from other test kits shall not be used. The only swab that will be used for sample collection will be the swab provided in the test kit and followed according to the manufacturer's instruction. Laboratory conducted a review and confirmed that no incorrect swabs were used on any patients. 2. To address the deficiency, the following systemic changes/corrective actions have been implemented: a. The Laboratory does not intermingle swabs and instructs all personnel to use the swabs and parts that come with the corresponding kits. All personnel must review SOPs and be trained prior to performing testing on patients. b. Additionally, when emptying an antigen kit, the contents are stored into a container resembling a pencil holder. The container is labeled with the brand name of the antigen test,	

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			the date the kit was opened, and the expiration date of the kit. c. There are three containers for each kit: (1) one holder stores the swabs, (2) another holder stores the agent and (3) the third stores the cartridges. 3. The corrective actions are being monitored in the following ways to ensure the deficient practices do not recur: a. The Laboratory has reviewed and updated the antigen SOPs and will have an annual review of SOPs to ensure quality and make necessary changes based on laboratory testing practices and CLIA requirements. With initial implementation of a new antigen test, an SOP will be created. The Lab Director/Designee will review SOPs for all new antigen tests prior to use. b. All personnel performing antigen testing will be required to review the new SOP(s) as part of the initial training. Follow up competency will be performed. c. Laboratory now has a QA Policy in place to monitor pre-analytical, analytical, and post-analytical phase of testing. This includes proper storage of reagents, temperature	

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			monitoring, and review of personnel documents for appropriate training. 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented. 5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will continue to monitor for compliance. 6. Attached are the following standard operating procedures (SOPs) related to sample collection: a. Attachments 1-5: Antigen SOP b. Attachment 11: QA Policy and Forms <u>Item 3: Transport</u> 1. We have found that no patients were affected by the deficient practice. Although the Laboratory did not have a written policy in place at the time of the inspection, the Laboratory in Nevada was following proper CDC guidance and protocols as monitored by the Laboratory Director prior to sending any specimens to the Illinois lab and	

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			no patients were found to be impacted. 2. To address the deficiency, the following systemic changes/corrective actions have been implemented: a. The Laboratory has implemented a SARS CoV-2 Specimen Collection and Handling policy and procedure to follow. The policy includes the proper transporting method to be followed by the Laboratory in Nevada when shipping to the laboratory in Illinois. b. Specifically, the laboratory in Nevada will ship samples in a clinical shipping container with an ice pack to ensure proper handling of the specimen. The laboratory in Illinois will provide overnight shipping labels to the Laboratory in Nevada so specimen handling is not compromised. 3. The corrective actions are being monitored in the following ways to ensure the deficient practices do not recur: a. Training and competency will be assessed and provided in the training process. b. The Laboratory Director has reviewed and revised all sample	

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			collection and handling SOPs to ensure they follow lab practices and adhere to proper instructions by manufacturers. c. Additionally, SOPs have been provided to all staff and training will be conducted on an annual basis. All personnel will be required to review the SOPs at hire and when major changes are made requiring re-training. d. Laboratory will continue to monitor for compliance on a regular basis. 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented. 5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will continue to monitor for compliance. 6. Attached are the following standard operating procedures (SOPs) related to transport: a. Attachment 12: MOL 110.0 SARS CoV-2 Specimen Collection	
0004	NAC652.155(2)(b)(3) - Applicability - (b)	0004		03/01/202

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	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 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 patient specimens". GenBody instructions 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		1. We have found that no patients were affected by the deficient practice. Each antigen test kit includes internal quality control to determine if result is valid or invalid. An invalid result would be indicative of (1) improper sample collection (2) improperly stored test kit leading to degradation of kit itself and/or (3) test improperly performed. In addition, the laboratory in Illinois confirms that the lot is accurate prior to sending any rapids antigen tests for shipment. The Laboratory has made systemic changes/corrective actions to this deficiency as identified in response to sections (2) and (3) below. 2. To address this deficiency, the following systemic changes/corrective actions have been implemented: a. Written SOPs have been 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,	2

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			and appropriate competency will be completed as outlines by the SOP. b. Testing personnel trained but did not have documentation: SOPs will be shared with personnel performing antigen testing for review and sign-off and appropriate competency will be completed as outlines by the SOP. c. Competency documentation will be maintained by the Laboratory for a minimum of two years. 3. The corrective actions are being monitored in the following ways to ensure the deficient practices do not recur: i. Periodic monitoring on an ongoing basis of documentation related to antigen testing kits. 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented.	

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			5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will continue to monitor for compliance. 6. Attachments a. Attachments 1-5: Antigen SOPs b. Attachment 6: Signed Antigen SOP c. Attachment 7: Completed competency for antigen testing	
0011	NAC652.280(1) - Lab Director Duties: Health & Safety - A director shall ensure that: 1. Policies and procedures are established and enforced to ensure the health, welfare, and safety of the personnel of the laboratory and visitors. Inspector Comments: Based on observation and discussion with the consultant and Administrative Assistant, the director failed to ensure the health, welfare, and safety of the personnel of the laboratory by not providing a safe environment in which employees are protected from biological, chemical, and physical hazards. Findings include: At the time of the survey, the laboratory was equipped with face masks, gloves and face shields. No disposable gowns or N95 masks were found in the laboratory as listed in the Northshore Clinical Labs Personal Protective Equipment (PPE) Policy. This was confirmed by observation and discussion with the consultant and Administrative Assistant on 1/18/22 at approximately 11:00 AM. Severity Level = 2	0011	1. We have found that no patients were affected by deficient practice. At the time of the survey, the Laboratory did not have a written procedure for PPE, but did have sufficient PPE on-site and does require and did require at the time of inspection, proper PPE. The Laboratory holds an inventory of N-95 masks/respirators, gloves, face shields, and disposable gowns at all times. Proper PPE is worn during testing of patients and specimen collection, in accordance with CDC guidance. PPE is provided to all staff including N-95 masks, gloves, face shields, and disposable gowns. The Laboratory has	03/01/2022

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			made systemic changes/corrective actions to this deficiency as identified in response to sections (2) and (3) below. 2. To address the deficiency, the following systematic changes/corrective actions have been implemented: a. The Laboratory has created written SOPs that have been reviewed and signed by the Laboratory Director. All personnel of the Laboratory will review and sign off on SOPs and must do so prior to testing of patients. b. The Laboratory will assign one individual to be responsible for ordering of supplies when supplies are running low to ensure a sufficient amount is consistently on site. The Laboratory has implemented an inventory tracker sheet that is updated daily. c. The Laboratory Director/Designee will perform daily inventory checks to ensure the health, welfare, and safety of the personnel of the laboratory. 3. The corrective action is being monitored by having the inventory track sheet that the supply manager reviews on a	

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			daily basis to ensure that N-95 masks, gloves, face shields, and disposable gowns are always available in sufficient quantities onsite. There will be a notice sent to Director of Operations for approval of all inventory purchases. 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented. 5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will continue to monitor for compliance. 6. The following SOPs have been created in response to this deficiency. a. Attachment 14: Inventory Tracker Sheet b. Attachment 13: PPE Procedures	
0049	NAC 652.470.1(a)(d) - Certification of personnel - 1. Before working in a laboratory at any technical level: (a) An application for certification must be made on a form provided by the Division giving information on the applicant's educational background; (d) The fee prescribed in NAC 652.488 must accompany the application.	0049	1. We have found that no patients were affected by the deficient practice. At the time of the survey, all relevant Laboratory staff held appropriate certification or had filed for appropriate certification with	03/01/2022

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	Inspector Comments: Based on a review of Division of Public and Behavioral Health records and an interview with the consultant, Administrative Assistant and Laboratory Director, the director failed to ensure that certification pursuant to NAC 652.470 was obtained for the Medical Assistants and Laboratory Assistants and pay the applicable fees as set forth in NAC 652.488. Findings include: At the time of the survey on January 18, 2022, 35 out of 48 of the laboratory assistants did not have Office Laboratory Assistant licenses or Laboratory Assistant licenses. This was confirmed in an interview with the consultant, Administrative Assistant and Laboratory Director, on January 18, 2022 at approximately 11:30 AM Severity level = 2		payment of applicable fees as set forth in NAC 652.488. The Laboratory has made systemic changes/corrective actions to this deficiency as identified in response to sections (2) and (3) below. 2. To address the deficiency, the following systematic changes/corrective actions have been implemented, including the creation of certain SOPs identified in Section (6) below: a. Part of the staff training includes applying for the application for certification using the form provided by the Division. b. Upon hiring, new personnel must be certified prior to being scheduled to provide COVID-19 testing to patients. If within two-weeks of hire, the personnel has not acquired or attempted to acquire the certification, they will be terminated. 3. The corrective action is being continuously monitored by Laboratory Director/Designee ensuring the application has been sent and/or approved prior to lab assistants and/or medical assistants working at the Laboratory. Proper documentation is held electronically to confirm which	

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			personnel acquired certifications, which have pending certifications, and those that have not yet applied. 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented. 5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will continue to monitor for compliance. 6. The following SOPs have been created in response to this deficiency. a. Attachment 15: Proof of Laboratory licenses/applications b. Attachment 16: Hiring and Training SOP	
0140	NRS 652.080 - License Required; term; renewal; inactive - 1. Except as otherwise provided in NRS 652.217 and 652.235, no person may operate, conduct, issue a report from or maintain a medical laboratory without first obtaining a license to do so issued by the Division pursuant to the provisions of this chapter. 2. A license issued pursuant to the provisions of subsection 1 is valid for 24 months and is renewable biennially on or before the date of its expiration. 3. No license may be	0140	1. We have found that no patients were affected by the deficient practice. The Laboratory received the proper licensing to perform testing across the state of Nevada from the Department of Health and Human Services - Division of Public and Behavioral Health but is	03/01/2022

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	issued to a laboratory which does not have a laboratory director. 4. A license may be placed in an inactive status upon the approval of the Division and the payment of current fees. 5. The Division may require a laboratory that is located outside of this state to be licensed in accordance with the provisions of this chapter before the laboratory may examine any specimens collected within this state if the Division determines that the licensure is necessary to protect the public health, safety and welfare of the residents of this state. Inspector Comments: Based on a review of Division of Public and Behavioral Health records and an interview with the consultant, Nevada Representative and an Administrative Assistant, the director failed to ensure that patient samples were not tested prior to approval by the Division. Findings include: At the time of the survey on January 18, 2022, the laboratory was found to be performing patient testing at 22 locations prior to approval by the Division. This was confirmed by an interview with the consultant, Nevada Representative and an Administrative Assistant on January 18,2022 at approximately 11:30 AM. Severity level = 2		currently awaiting pending Compliance Agreement. The Laboratory received the licensing exemption to perform testing across the state of Nevada from the Department of Health and Human Services - Division of Public and Behavioral Health. The Laboratory has made systemic changes/corrective actions to this deficiency as identified in response to sections (2) and (3) below. 2. To address the deficiency, the following systematic corrective actions have been implemented: a. The Laboratory had applied for the license and received an exemption that allows the license to be used for statewide testing upon acquiring the Compliance Agreement. b. Pending the approval of the Corrective Plan of Action with the Division, operations will commence upon the signing of the Compliance Agreement. c. Compliance Agreement remains pending until Plan of Corrective Action is submitted and accepted. 3. The corrective action is being monitored in the following ways to ensure the deficient practices do not recur:	

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			a. The Laboratory Director/Designee will ensure no further sites open without approval of proper licensing agreement b. Laboratory does not intend to open any further testing sites in Nevada at this time. Laboratory Director/Designee will review licensing requirements prior to opening of any new testing sites in the state of Nevada. 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented. 5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will continue to monitor for compliance. 6. The following SOPs have been created in response to this deficiency: a. Attachment 17: Nevada License - Exempt Laboratory Waived Tests	
145	Duties of Laboratory Director Inspector Comments: Based on a review of laboratory records and an interview with the consultant, Administrative Assistant and	145	1. We have found that no patients were affected by the deficient practice. At the time of the	03/01/2022

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	patient NSCL-WACC10757, the laboratory director failed to report the findings or results of laboratory tests; actively participate in the operation of the laboratory to the extent necessary to assure compliance with the provisions of this chapter, be responsible for the proper performance of all work in the laboratory and of all subordinates and retain the health care and other regularly maintained records of the laboratory in accordance with regulations adopted by the Board pursuant to NRS 652.135. Findings include: 1. At the time of the survey, there were no records of antigen test results performed on-site and no records of patient specimens that had been sent to the main lab in Illinois for PCR testing. 2. Results of antigen testing reported verbally as positive to patient NSCL-WACC10757 on 1/5/2022 could not be verified due to laboratory not having records for on-site antigen testing. The patient received a laboratory report from Northshore Clinical Labs in Illinois on 1/7/2022 which reported both the antigen and the PCR result as negative. This was confirmed by observation and discussion with the consultant and Administrative Assistant on 1/18/22 at approximately 11:00 AM. Patient NSCL-WACC10757 was interviewed on 1/26/2022 at approximately 3:30 PM. Severity Level = 2		inspection, the Laboratory did not have a written procedure in place for record keeping of test results that were performed on-site, nor did it keep a FedEx tracking number with specimens included in the clinical container. However, by its operating procedures, patients promptly received a phone call upon positive rapid results. Laboratory keeps a tracking log of patient test results at the location that are held for two (2) years. The Laboratory has made systemic changes/corrective actions to this deficiency as identified in response to sections (2) and (3) below. 2. To address the deficiency, the following systematic corrective actions have been implemented: a. Laboratory has implemented written SOPs to train and retrain staff with for Rapid and PCR testing and proper procedures that must be followed. Personnel will update tracking log on a daily basis with patient information and results. b. Written SOPs have been created and reviewed by Laboratory Director. c. All new and existing staff are to be trained on proper implementation of patient tracking log.	

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			d. FedEx tracking log will be set up to include tracking number with patient's specimens sent in each clinical container. e. Patients will be given a rapid result stating that it was given in the state of Nevada, not Illinois. Results will be sent in a secure HIPAA-compliant email. 3. The corrective action is being monitored in the following ways to ensure the deficient practices do not recur: a. Laboratory has implemented written SOPs to train and retrain staff with for Rapid and PCR testing and proper procedures that must be followed. b. Laboratory Director or Designee will monitor the patient log on a daily basis to ensure log is being updated daily with proper patient information 4. The Laboratory Director and Director of Operations shall be responsible for ensuring the plan of correction is implemented. 5. This corrective action has been initiated as of the submission date, and shall be completed by March 1, 2022. Laboratory will	

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			continue to monitor for compliance. 6. 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	