STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS A complaint survey was completed on December 29, 2021. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F.R. § 493.1230 Condition: General laboratory systems 42 C.F.R. § 493.1250 Condition: Analytic systems 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing; laboratory director	D 000		
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observations and an interview with the Testing Personnel (TP), the laboratory failed to follow the manufacturer's instructions for the Quidel QuickVue SARS antigen kits utilized for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal (AN) swab specimens. This deficient practice had the potential to affect all patient SARS-CoV-2 tested at this location. Findings Include:- Item 1- Northshore Clinical Laboratory offsite laboratory location located at 5519 Bigger Road, Dayton, Ohio.	D1001		

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D1001	Continued From page 1 1. On 10/26/2021 at 9:45 AM a review of the manufacturer's instructions for the Quidel QuickVue SARS Antigen rapid test kit found the following statements: "Conditions of Authorization for the Laboratory and Patient Care Setting...must be appropriately trained in performing and interpreting the results..." "Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight." "Prior to collecting the anterior nares swab, the patient should be instructed to blow their nose." "Anterior nares test procedure...Keep swab in the tube for one (1) minute...at ten (10) minutes, remove the Test Strip, and read result within five (5) minutes..." "Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements" 2. Documentation of training was requested from the TP on 10/26/2021 at 9:45 AM. The TP stated only two to three hours of peer testing observation was conducted prior to independent testing of patients. No documentation of training was performed and the TP was unable to provide the requested information. 3. Storage of Quidel QuickVue SARS Antigen rapid test kits was discovered on 10/26/2021 at 9:46 AM in a large back area conference room in the original shipping boxes. On 10/26/2021 at 9:47 AM TP confirmed no temperature monitoring	D1001		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D1001	Continued From page 2	D1001		

of the storage area was performed.

4. Observation of specimen processing on 10/26/2021 from 10:15 to 10:35 AM revealed no instructions given to the patient to blow their nose prior to AN swabbing.

5. Observation also revealed after specimen collection the swab was placed into the reagent tube for incubation and swirled for an indeterminate amount of time. The swab was then removed, disposed of in a general waste bin, and a test strip was placed into the reagent tube. The TP periodically checked the test strip for any reaction. After an indeterminate amount of time the test strip was removed and resulted. No timer was used for specimen processing.

6. On 10/26/2021 at 10:40 AM the TP verified a timer was not used for the testing procedure and the facility did not have any any segregated hazardous waste containers.

7. The surveyor requested a listing of all of the offsite laboratory locations for Northshore Clinical Laboratory The list was provided on December 8, 2021 at 1:10 PM. Including on the list is the following:
a) MLC Dayton- A1
b) 5519 Bigger Road, Dayton, Ohio

Item 2 - Northshore Clinical Laboratories offsite testing location in the Butera Market store at 815 Center St., Grayslake, Illinois 60030.

1. The surveyor showed Staff OX a photo of COVID-19 testing and PCR collection table directly in the path of the exit door of the grocery store facility. The table area did not have any

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D1001	Continued From page 3	D1001		

barrier or screen to provide confidentiality for those who wish to be tested and provide protection for those departing from the grocery store, and a thermometer to monitor room temperatures to ensure optimal test performing conditions.

2. Staff OX confirmed the Butera Market facility is one of their offsite testing locations on December 08, 2021 at 10:08 AM.

Item 3. Northshore Clinical Laboratories located at 4751 N. Kedzie Ave., Chicago, Illinois 60625.

1. On December 8, 2021 at 10:05 AM, the surveyor requested the training documents used for employees performing COVID-19 testing and PCR collection at the collection site locations. Staff OX provided the following documents.

Northshore Clinical Shift Check List
Opening Duties
On-site Protocol
CDC Anterior Nasal Swab Specimen Collection Instructions
GenBoy COVID-19 Ag
CareStart COVID-19 Antigen test
Quidel QuickVue SARS Antigen test
BinaxNOW COVID-19 Ag Card test
Closing Duties

2. Review of the four Emergency Use Authorization (EUA) test instructions revealed that each test system required the documented training of all testing personnel and the distribution of an informational "FACT SHEET" to each patient receiving testing.

3. On December 8, 2021 at 10:30 AM, Staff OX

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D1001	Continued From page 4 and HP confirmed the laboratory did not provide training to those testing at the collection sites and did not provide each site with the information FACT SHEETS associated with the EUA COVID-19 test the collection site was using.	D1001		
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory test records, direct observation and interview, the laboratory failed to retain records of test requisitions and test authorizations for at least 2 years for one of one patient test report reviewed. Findings include: 1) Review of patient test report NSCL-MLCD1XXXX collected on September 23, 2021 at 4:24 PM shows the following patient test result: a) Test Name- SARS-C0V-2 b) Result- NEGATIVE c) Units- Index d) Flag- (No information noted on report) e) Reference Range/Cutoff- Normal=Negative 2) 1) Review of patient test report NSCL-MLCD1XXXX collected on September 23, 2021 at 4:24 PM shows the following patient identification and demographic information: a) Patient: AXXXXXXX, XXXXX	D3027		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D3027	Continued From page 5 b) Birth: X/XX/20XX c) Age: 1X XXXXXX f) Gender: XXXXX 3) The surveyor requested the test requisition and test authorization for patient test report NSCL-MLCD1XXXX on December 8, 2021 at 10:55 AM. Staff OX stated, "we shred original order," The conversation occured on December 8, 2021 at 10:55 AM. 4) On a laboratory tour on December 8, 2021 at 1:26 PM, the surveyor directly observed, in the lower level of the laboratory accessed through an open unsecured passageway from the laboratory testing area located on the first floor, 14 uncovered containers in various sizes containing numerous patient test requistions which contained patient demographic information. 5) The laboratory was not able to provide the surveyor with the orginal or copy of test requistion for patient sample NSCL-MLCDXXXX.	D3027		
D5200 140H	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in §493.1239 for each specialty and subspecialty of testing performed.	D5200		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5200	Continued From page 6 This CONDITION is not met as evidenced by: Based on direct observation and interview, the laboratory failed to meet the general laboratory system requirments in 42 CFR 493.1231 through 42 CFR 493.1236. Findings include: 1) Failure to ensure confidentiality of patient information: See D5201 2) Failure to ensure positive patient identification. See D5203 3) Failure to have a policy in place to document complaints or problems communicated to the laboratory. See D5205	D5200		
D5201 140H	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on direct observation and interview, the laboratory failed to ensure confidentiality of patient information for 14 of 14 patient test requisitions of patient samples submitted for testing that were reviewed. Findings include: 1) On a laboratory tour on December 8, 2021 at 1:31 PM, the surveyor directly observed, in the lower level of the laboratory, which was accessed	D5201		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5201	Continued From page 7	D5201		

through an open unsecured passageway from the laboratory testing area located on the first floor, 14 uncovered containers in various sizes containing numerous patient test requisitions which contained patient demographic information. The surveyor retrieved the following 14 test test requisitions from a sampling of the 14 uncovered containers:

a) Collection Date: 11/7/2021 Patient Name: NXXXXXX, SXXXXXXXX Identification number: No information

b) Collection Date: 11/7/2021 Patent Name: ZXXXXX, EXXXXXXXX Identification number: No information

c) Collection Date: 11/7/2021 Patient Name: GXXXX, GXXXXX Identification number: No information

d) Collection Date: No date Patient Name: DXXXXX, GXXXXXXXX Identification number: No information

e) Collection Date: No date Patient Name: AXXX, KXXXXXXXXXX Identification number: No Information

f) Collection Date: No date Patient Name: PXXXX, DXXXX Identification number: No Information

g) Collection Date: No date Patient Name: RXXXXXXXX, BXXXX Identification number: No Information

h) Collection Date: No date Patient Name: PXX, CXXXXXXXX Identification number: ncsltsfb10XXX

i) Collection Date: 12/5/21 Patient Name: FXXXXX, BXXXX Identification number: ncslcvs12XXX

j) Collection Date: 12/3/21 Patient Name: WXXXXXX, FXXX Identification number: ncslcvs12XXX

k) Collection Date: 12/5/21 Patient Name:

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5201	Continued From page 8 FXXXXX, BXXXX Identification number: ncslcvs12XXX l) Collection Date: 12/5/21 Patient Name: GXXXXXX, AXXX Identification number: ncslcvs12XXX m) Collection Date: 12/5/21 Patient Name: GXXXXXXX,GXXXXXXX Identification number: AIO67XXX i) Collection Date: 12/5/21 Patient Name: DXXXXX, LXXX Identification number: AIO67XXX 2) The laboratory failed to ensure confidentiality of patient demographic information by storing patient test requistions in an unsecured area in uncovered storage containers in various sizes. 3) Staff HP confirmed the above findings in a conversation on December 8, 2021 at 1:31 PM.	D5201		
D5203 140H	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on direct observation and interview, the laboratory failed to establish and follow written procedures that ensure positive identification of patients specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results for 1 of 1 patient sample and 1 of 1 Federal Express shipping box reviewed.	D5203		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5203	Continued From page 9	D5203		

Findings include:

Item 1

1). Direct observation on December 9, 2021 at 11:10 AM, the surveyor observed a hallway with shelves and carts of patients' specimens from courier drop-offs and Fedex shipment packages. Staff HP opened a randomly selected Fedex package labeled from the following location:

BXXXXXXX XXXX
Grand Dominion Testing
2305 W Springfield
Champaign, IL 61821

The surveyor observed in the box, 14 bagged specimen tubes that were not labeled with any patient name or any other type of identifying information.

2). Staff HP confirmed the above findings on December 9, 2021 at 11:15 AM.

Item 2

1). Direct observation on December 9, 2021 at 11:58 AM, the surveyor observed staff X1 register, add collection dates, generate computer labels, and order SARS-CoV-2 PCR tests for six specimen tubes that were submitted without their Northshore Clinical Laboratories requisition cards. The surveyor observed each specimen had a patient's name and no collection date. Staff X1 explained that these specimens did not require requisition cards because they were from a school location with a standing order. The survey asked Staff X1 how often were the specimen pick-ups at this site. Staff X1 stated once per week. Staff X1 could not verify the actual collection date of the specimens and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5203	Continued From page 10 further stated the collection date issued was the date before the specimen was received in the laboratory. 2) Staff OX confirmed the above findings on December 9, 2021 at 12:00 PM. Item 3 1) The surveyor directly observed staff BJ register, generate computer label 1957XXX and order a SARS-CoV-2 PCR test for a specimen tube that was not labeled with any patient name or any other type of identifying information. The direct observation occurred on December 9, 2021 at 12:00 PM. 2) Staff HP confirmed the above findings on December 9, 2021 at 12:00 PM.	D5203		
D5205 140H	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of laboratory documents and interview, the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory for 1 of 1 patient test report reviewed. 1) Review of patient test report 1254XXX shows the telephone number of the laboratory listed as 773-570-6510.	D5205		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5205	Continued From page 11 2) The surveyor requested the complaint policy or procedure in use for complaints or problems communicated to the laboratory at the listed laboratory telphone number of 773-570-6510. Staff HP replied, "Do not have policy on that level." The conversation occured on December 9, 2021 at 9:40 AM. Item 2. 1. Surveyor requested on December 8 2021 at 9:55 AM, to Staff X1 for the McHenry health department reporting confirmation of 20 patient results. McHenry health department reported that the laboratory was sending duplicate final patient results which interferred with their contact tracing process. Staff OX stated the laboratory contracted with Lifepoint Informatics to report all COVID-19 results to local health departments. XXXXX0009 XXXXX0063 XXXXX0071 XXXXX0065 XXXXX0080 XXXXX0046 XXXXX0053 XXXXX0066 XXXXX0063 XXXXX0081 XXXXX0010 XXXXX0064 XXXXX0070 XXXXX0066 XXXXX0079 XXXXX0047 XXXXX0054 XXXXX0065 XXXXX0464	D5205		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5205	Continued From page 12 XXXXX0082 2. On December 8 2021 at 10:45 AM, Staff X1 stated Lifepoint did have reporting issues with McHenry health department on September 30, 2021. Lifepoint did not document the reporting complaint and the patient results involved and did not notify the laboratory. Staff X1 stated that they did not have a policy or procedure for Lifepoint to document issues that occur with patient reporting results to the health departments.	D5205		
D5309 140H	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to ensure test requisition or authorized information is transcribed or entered accurately into the laboratory information system (LIS) for four out of four patient results. Findings Include: 1. The Specimen receiving, Labeling, and Storage; the COVID-19 Data Entry SOP for LabDaQ, and specimen rejection criteria policy and procedure, patients' electronic record and final reports were reviewed. 2. Review of two patients' electronic printout and test reports showed the following:	D5309		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5309	Continued From page 13	D5309		

Electronic Record
Patient A4 #XXX25 - date of birth (DOB): XX/X9/2009; Collection date: 11/17/2021
Patient J4 #XXX24 - DOB: XX/X9/2009; Collection date: 11/17/2021
Patient A4 #XXX63 - DOB: XX/X9/2009; Collection date: 11/20/2021
Patient J4 #XXX64 - DOB: XX/X9/2009; Collection date: 11/20/2021

Final test Reports
Patient A4 #XXX25 - DOB: XX/X3/2007; Coll. date: 11/17/2021; Rapid Antigen = Negative; SARS-CoV-2 = Positive.
Patient J4 #XXX24 - DOB: XX/X9/2009; Coll. date: 11/17/2021; Rapid Antigen = Negative; SARS-CoV-2 = Negative
Patient A4 #XXX63 - DOB: XX/X3/2007; Coll. date: 11/20/2021; Rapid Antigen = Positive; SARS-CoV-2 = Positive
Patient J4 #XXX64 - DOB: XX/X9/2009; Coll. date: 11/20/2021; Rapid Antigen = Positive; SARS-CoV-2 = Positive

3. On December 8, 2021 at 2:00PM, the surveyor requested for the requisitions received from Grapefruit testing for Patients' A4 and J4. Staff OX stated patient specimens submitted by GraXXXX Testing (located in New Jersey) have a standing order and do not require a requisition with their specimen.

4. The Specimen receiving, Labeling, and Storage policy stated "Specimens received in the lab should be matched with the requisition for primary and secondary identifications (First name, Last name, and Date of Birth)."

5. The COVID-19 Data Entry SOP for LaXXXX

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5309	Continued From page 14 stated "Verify that the Last and First Name match the patient's requisition form..." 6. Review of the specimen rejection criteria policy revealed the procedure does not list 'specimens received without requisition card' as a criteria for rejection. 7. Staff OX and Staff HF confirmed the above findings on December 8, 2021 at 2:30 PM.	D5309		
D5400 140H	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observations, record review, procedure's manual, and interviews, the laboratory failed to have complete written procedures for the SARS-CoV-2 Pooled Real-Time Reverse Transcriptase (RT)-Integrated DNA Test (IDT) -Polymerase Chain Reaction (PCR) Assay testing performed (D5403); failed to establish and document performance specifications of the laboratory developed test (LDT) SARS-COV-2 Pooled PCR test (D5423); and failed to establish and document control procedures (D5453) to ensure reliable and	D5400		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5400	Continued From page 15 accurate test results affecting 1,738,443 patients tests.	D5400		
D5403 140H	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in §493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for	D5403		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5403	Continued From page 16	D5403		

reporting imminently life threatening results, or panic, or alert values.
(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on direct observation, record review, lack of documentation, and interview, the laboratory's procedure manual failed to include all the applicable requirements specified in §493.1251 (b)(1) - (14) for the SARS-CoV-2 Pooled Real-Time Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) tests performed by the laboratory, affecting 1,738,443 reported patients tests.

Findings Include:

Item 1

The laboratory tested patients' nasopharyngeal swabs with a laboratory developed test using pooled specimens to identify SARS-CoV-2 Ribonucleic Acid (RNA).

1. The Specimen receiving, Labeling, and Storage; the COVID-19 Data Entry SOP for LabDaq, the specimen rejection criteria policies and procedure, the SARS CoV-2 Real-Time RT-PCR IDT Assay procedure manual, and the Clinical Laboratory Improvement Amendments (CLIA) application (CMS-116) were reviewed.

2. The procedure manual failed to include the following requirements:

*Requirements for patient preparation; specimen collection, storage, preservation, transportation, processing, and referral; and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5403	Continued From page 17	D5403		

criteria for specimen acceptability and rejection as described in §493.1242.

*Step-by-Step performance of the procedure. Direct observation on December 8, 2021 at 12:09 PM, surveyor observed Staff X2 seated at Hood #4 overseeing the INTEGRA barcode reader and auto-pipettor pipetting and pooling patient specimens from a specimen rack into a 96-well plate. The completed 96-well was sent to another station and the pipetted racked specimens was given a number and set aside until testing was complete. This process was continued until four pooled 96-well plates were pipetted. The pooled plates are heated treated and then added to 384-well plate for RT-PCR. The numbered rack was entered onto a log sheet that listed the specimen in position A1 and H1 and the name of the collection site the specimens were from. When the 384-well RNA-PCR test plate was completed and positive well positions identified, Staff X4 pulled the four patient specimens pooled in the identified positive well for retest. The retest or rerun of the patient specimens separately, determined the actual positive patient(s). The laboratory failed to include this process in the procedure.

* Preparation and storage of 96-well and 384-well plates, solutions, calibrators, controls, reagents, stains, dyes, and other materials used in testing, as applicable.

* Calibration, calibration verification, and maintenance procedures for four SimpliAmp and four QuantStudio 12K Thermocyclers.

*The reportable range for test results for the test system as established or verified in

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5403	Continued From page 18 §493.1253. *Control procedures - How are controls added to test plates and additional required control procedures. See D5453. *Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. *Limitations in the test methodology. This is a Laboratory Developed Test (LDT), the Emergency Use Authorization (EUA) for TaqPath COVID-19 RNA specifications cannot be used without empirical comparison data. * Imminently life-threatening test results, or panic or alert values. * The literature the LDT is based upon must be provided and reference. * The step-by-step procedure for entering results in the patient record and reporting patient results to patients and health departments. * Description of the course of action to take if a test system becomes inoperable. 3. The CMS-116 signed by the owner and laboratory director attested the laboratory performed 5,000,000 patient tests for SARS-CoV-2 RNA. 4. Via email on January 3, 2022 at 4:37 PM, Staff HP stated the laboratory performed 1,738,443 tests using the LDT from May 1, 2021 to December 30, 2021.	D5403		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5403	Continued From page 19 5. Staff HP, Staff OX, and Staff JS confirmed the above findings on 12/09/2021 at 1:30PM. Item 2 1) Review of patient test report 125XXXX shows the following: a) Result- SARS CoV-2- Negative b) Collection date: 10/16/2021 c) Received date: 11/8/2021 2) The laboratory reported SARS CoV-2 patient test results for sample 125XXXX without establishing requirements for patient preparation; specimen collection, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242. 3) Staff PX confirmed the above findings on 12/08/21 at 1:45 PM.	D5403		
D5423 140H	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision.	D5423		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5423	Continued From page 20	D5423		

(2)(iii) Analytical sensitivity.
(2)(iv) Analytical specificity to include interfering substances.
(2)(v) Reportable range of test results for the test system.
(2)(vi) Reference intervals (normal values).
(2)(vii) Any other performance characteristic required for test performance.
This STANDARD is not met as evidenced by:
Based on direct observation, records review, and interviews; the laboratory failed to establish and verify the performance specifications of the laboratory developed test (LDT) that used pooled specimens to identify SARS-CoV-2 prior to testing patients, affecting 1,738,443 reported patients tests.

Findings Include:

1. Direct observation on December 8, 2021, at 12:09 PM, the surveyor observed four SimpliAmps and four QuantStudio 12K Thermocyclers. Staff HP and JS stated these thermocyclers were used to identify SARS-CoV-2 Ribonucleic Acid (RNA) in a laboratory developed test called Real-Time Reverse-Transcriptase (RT)-Polymerase Chain Reaction (PCR)-IDT assay.

2. Review of the SARS-CoV-2 TaqPath RNA-PCR Emergency Use Authorization (EUA) and RT-IDT-PCR procedures manuals, proficiency testing records for 2021, and performance verification records revealed the following:
*The laboratory's performance verification for the TaqPath COVID-19 EUA was conducted in May of 2021.
*The proficiency testing results for events 2

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5423	Continued From page 21	D5423		

and 3 of 2021 were based on the TaqPath COVID-19 EUA test system.

*The date the RT-IDT-PCR procedure began to be used for patient testing could not be determined.

*On December 8, 2021 at 12:16 PM, Staff HP stated the laboratory used this LDT assay when TaqPath supplies are unavailable.

*No visible evidence the RT-IDT-PCR assay procedure had been approved by the laboratory director or performance specifications determined, or test system comparison with the TaqPath EUA performed, prior to use for patient testing.

3. Further review of the provided documentation revealed the laboratory failed to perform and document the following performance studies for the LDT named SARS-CoV-2 Real-Time RT-PCR-IDT Assay:

a). Specimen stability studies for patient specimens shipped through all weather conditions.

b). Specimen Pooling studies. Studies no longer exempt since the laboratory is not following TaqPath EUA protocol.

c. Accuracy; Comparison of IDT-PCR assay to TaqPath EUA

d. Precision

d. Analytical specificity to include interfering substances. Must provided empirical proof and summary

e. Reportable range of test results for the test system.

f. Reference intervals (normal values).

g. Any other performance characteristic required for test performance.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5423	Continued From page 22 4. Via email on January 3, 2022 at 4:37 PM, Staff HP stated the laboratory performed 1,738,443 tests using the LDT from May 1, 2021 to December 30, 2021. 5. Staff HP, Staff JS and Staff OX confirmed the above findings on 12/09/2021 at 1:30 PM.	D5423		
D5453 140H	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to include two control materials of which one is capable of detecting errors in the extraction process, at least once a day patient specimens are assayed, when performing tests, for two out of two days of patient testing. Findings: 1. The SARS-CoV-2 Ribonucleic Acid (RNA) Real-Time Reverse-Transcriptase	D5453		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5453	Continued From page 23 (RT)-Polymerase Chain Reaction (PCR)-IDT assay procedure manual, quality control (QC) records, and patients' final reports from November 19 and 24, 2021 were reviewed. 2. The laboratory used the laboratory developed test (LDT) pooled RT-IDT-PCR assay to identify SARS-CoV-2 in patients' nasopharyngeal swabs. 3. The QC data revealed the lack of any documented extraction controls on each test date reviewed. 3. Interview on December 8, 2021 at 12:35 PM, Staff JX stated the controls included in a 'run' were two positives, and a negative. The runs did not include any extraction phase control. 4. The laboratory manual failed to establish, perform, and document control procedures that include at least one control detecting errors in the SARS-CoV-2 RNA-PCR extraction process, at least once each day of patient testing. 5. Staff HP, Staff JS and Staff OX confirmed the above findings on 12/09/2021 at 1:30PM.	D5453		
D5805 140H	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate.	D5805		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5805	Continued From page 24 (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure test reports indicate the test result and correct interpretation for four out of four patient reports. Findings include: 1. Four patients' final reports and the SARS-CoV-2 Ribonucleic Acid (RNA) Real-Time Reverse-Transcriptase (RT)-Polymerase Chain Reaction (PCR)-IDT assay manual were reviewed. 2. The 4 patients' (patients D1, D2, D3 and D4) results reviewed were reported on November 20, 2021 and November 24, 2021. 3. The four reports failed to disclaim the following statement: "The performance characteristics of this test were determined by National Clinical Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration". 4. On a Complaint survey conducted on December 9, 2021 at 1:30 PM, Staff HP and Staff OX confirmed the above findings.	D5805		
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets	D6076		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6076	Continued From page 25 the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory director (LD) failed to meets the qualification requirements for providing overall management and direction in a high complexity laboratory (D6078).	D6076		
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or	D6078		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6078	Continued From page 26 (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March	D6078		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6078	Continued From page 27	D6078		

14, 1990 at 55 FR 9538, on or before February 28, 1992; or

(b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or

(b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.
This STANDARD is not met as evidenced by:
Based on record review, the Laboratory Personnel Report (CMS 209), and interview with staff, the laboratory director (LD) failed to be eligible to operate, manage and direct the laboratory and its personnel performing the SARS-CoV-2 Real-Time Reverse Transcriptase (RT) - Polymerase Chain Reaction (PCR) laboratory developed test (LDT) system, affecting 5,000,000 patient tests.

Findings:

1. The CMS 209, the Clinical Laboratory Improvement Amendments (CMS 116) application, and the personnel files of Staff NQ were reviewed.

2. The Staff NQ files revealed the following:
a). June 28, 1976 credential evaluation stating NQ education from University of Karachi, Pakistan is equivalent to a Bachelor Science degree with a major in Biochemistry.
b). Unevaluated Master of Science Diploma and an Unevaluated Doctor of Medicine Diploma.
c). Resume stating laboratory director of

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D0426602	A. BUILDING _____ B. WING _____	12/29/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHSHORE CLINICAL LABORATORIES, INC	4751 N KEDZIE AVE CHICAGO, IL 60625

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6078	Continued From page 28	D6078		

moderately complex laboratory in 1995 to present and doctor of medicine in June of 1985 from the University of Santo Domingo in Dominican Republic.

d). Interview with Staff NQ on December 8, 2021 at 9:30AM, stated he was not a licensed Doctor of Medicine in the State of Illinois.

3. On the CMS 116, the owner and Staff NQ attested 5,000,000 patient tests have been performed during the year of 2021.

4. Staff NQ and HP confirmed the above findings on December 8, 2021 at 9:45 AM.