Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2201417	05/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Labelite	5824 N Northwest Hwy, Chicago, IL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Due to a current criminal investigation the State Agency was unable to obtain necessary documentation in order to substantiate complaints and complete the survey investigation.
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 records review, lack of documentation, and interview, the laboratory failed to retain eight of eight days of test requisitions and test authorizations for at least two years. Findings include: Item 1. 1. The laboratory's procedures manual, SARS-CoV-2 test data from 12/06/2021, Toxicology patient results from the weeks of 12/15/2021; 01/22/2022; and 02/16/2022 were reviewed. 2. The laboratory performed Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) assay to identify and detect SARS-CoV-2 virus and Liquid Chromatography Mass Spectrometry (LCMS) for Drugs of Abuse confirmation. 3. On May 10 2022 at 3:35 PM, the surveyor requested Staff #1 to select one RT-PCR test plate run from each of the following dates listed and provide requisitions and final reports of the patients within the selected plate runs. 12/06/2021 12/10/2021 12/23/2021 12/24/2021 12/30/2021 4. On May 19, 2022 at 3: 18 PM, the surveyor received from Staff #1 "12-06-21 7th COVID Run Example"" data from a 384-well test plate run. The laboratory failed to provide the requisitions or authorizations from 382 of 382 patients results tested and reported from this run. 5. Further review of the data received showed that the laboratory failed to provide any test data and requisitions from the remaining four dates (12/10/21; 12/23/21; 12/24 /21; and 12/30/21) as requested. Item 2. 6. On May 10, 2022 at 3:35 PM, the surveyor requested Staff #1 to provide requisitions and final reports from the following RT-

	PCR patients: Patient X1 - ID #XX29, swab collected on 12/24/2021 and swab collected on 12/30/2021; Patient X2 - ID #XX30, swab collected on 12/24/2021 and swab collected on 12/30/2021; Patient FT - swab collected on 12/06/2021; and Patient M9 - swab collected on 12/23/2021. 7. On May 12, 2022 at 1:43 PM, the surveyor received from Staff #1 "Requested PCR test results". The laboratory failed to provide the requisitions or authorizations for five of six patients listed in findings #6. Item 3. 8. On May 10 2022 at 3:35 PM, the surveyor requested Staff #1 to provide requisitions and final reports from Toxicology patients tested during the following weeks: 12/15/2021; 01/22/2022; and 02/16/2022. 9. On May 18, 2022 at 12:52 PM, the surveyor received from Staff #1 "Toxicology Test Reports 1 and 2". The laboratory failed to provide the requisitions or written authorizations for 22 of 22 patients results tested and reported from the weeks listed in finding #8.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to establish and follow written policies and procedures to assess one of one individual (Staff #C) performing Liquid Chromatography Mass Spectrometry (LCMS) used in Toxicology, affecting 1232 patients' tests. Findings include: 1. On May 10, 2022 at 9:56 AM during a tour of the laboratory, the surveyor observed two LCMS instruments; Agilent Technologies 6460 Triple Quad LC/MS marked LCMS1 and LCMS2. 2. The laboratory's test menu, test volume worksheet dated from January 2021 through April 2022, and competency documentation were reviewed. 3. The test menu showed the LCMS instruments were used to confirm the detection and identification of Drugs of Abuse. 4. The competency documents provided failed to include any training and competency procedures for performing LCMS analysis. 5. On May 10, 2022 at 1:25 PM, the surveyor requested for the competencies and training of the laboratory personnel. 6. Interview with Staff #1 and Staff #2 on May 10, 2022 at 9:58 AM, stated the laboratory did not have any testing personnel documentation and the employee who performed LCMS analysis (Staff #C) resigned in April 2022. 7. 1232 patients were tested during the time period reviewed by Staff #C. 8. On May 19, 2022 at 3:35 PM, Staff #1 and Staff #2 confirmed the above findings.
D5400	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 record review, lack of documentation, and interviews, the laboratory failed to establish written procedures for the Northshore Clinical Labs' (NS COVID-19 Master Mix) SARS-CoV-2 RNA Reverse Transcriptase (RT)-Polymerase Chain Reaction (PCR) assay performed (D5401); failed to establish and document performance specifications of the NC COVID-19 Master Mix RT-PCR test (D5423); failed to establish and document control procedures (D5441); failed to document the lot numbers and expiration dates of the kits and reagents used in the test system (D5471); failed to have patient testing data for the RT-PCR tests performed (D5789); and failed to establish and document written policies and procedures to monitor, assess, and when indicated, correct problems identified in the SARS-CoV-2 RNA-PCR system (D5791) to ensure reliable and accurate test results, affecting 177,789 patients results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and interview, the laboratory failed to have a written procedure for the NS COVID-19 Master Mix Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) assay performed on 86 of 86 days of testing, affecting 190,000 tests. Findings Include: 1. The laboratory's procedure manual, manufacturer's invoices, and RT-PCR validation data were reviewed. 2. The laboratory performed RT-PCR analysis to detect and identify the SARS-CoV-2 virus. 3. The laboratory manufacture invoices and validation/verification data revealed the following: *The laboratory began testing with the Emergency Use Authorized (EUA) Thermofisher's Taqpath SARS-CoV-2 RT-PCR assay in April of 2021. *The first documented shipment of NS COVID-19 Master Mix RT-PCR assay was received on 10/20/2021 from Northshore Clinical Labs. *The "New test method Verification" results were accepted by the laboratory director (LD) on 10/24/2021. *Laboratory received four shipments of the NS COVID-19 Master Mix kits totaling 190,000 reactions or tests. *The first documented shipment of the EUA LumiraDx SARS-CoV-2 RNA STAR Complete was received on 01/3/2022. *The validation of the LumiraDx was approved by the LD on 01/14/2022. *The laboratory tested patients with the NS COVID-19 Master Mix RT-PCR assay for 86 days. 4. The procedures and documents provided showed the laboratory failed to include any written procedure for the laboratory developed NS COVID-19 Master Mix RT-PCR assay. 5. Due to the lack of documentation, the number of patients tested during the 86 days could not be determined. 6. On May 19, 2022 at 3:18 PM, Staff #1 confirmed the above findings.
D5423	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. (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 record review, lack of documentation, and interview, the laboratory failed to establish the performance specifications for the laboratory developed Northshore (NS) SARS-CoV-2 RNA Reverse Transcriptase (RT)-Polymerase Chain Reaction (PCR) test used on two of two QuantStudio RT-PCR analyzers prior to testing patients, affecting 190,000 tests. Findings Include: 1. The laboratory's procedure manual, manufacturer's invoices, and RT-PCR validation/verification data were reviewed. 2. The laboratory performed RT-PCR analysis to detect and identify the SARS-CoV-2 virus. 3. The laboratory manufacture invoices and validation/verification data revealed the following: *The first documented shipment of NS COVID-19 Master Mix RT-PCR assay was received on 10/20/21 from Northshore Clinical Labs. *New test method Verification results were accepted by the laboratory director (LD) on 10/24/21 for Quantstudio 5 analyzers S/N-272532335 & S/N-272532738. *Laboratory received four shipments of the NS COVID-19 Master Mix kits totaling 190,000 reactions or tests. 4. Further review of the verification data showed the documentation provided failed to include the establishment of the following performance specifications for the NS COVID-19 Master Mix laboratory developed test (LDT): a. Accuracy. b. Precision. c. Analytical sensitivity. d. Analytical specificity to include interfering substances. e. Reportable range of test results for the test system. f. Reference intervals (normal values). g. Any other performance characteristic required for test performance. 5. On a Validation and Complaint Investigation survey ending on May 19, 2022 at 3:18 pm, Staff #1 confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 establish control procedures for the laboratory developed Northshore (NS) Clinical Labs SARS-CoV-2 RNA Reverse Transcriptase (RT)-Polymerase Chain Reaction (PCR) test used on two of two QuantStudio RT-PCR analyzers prior to testing patients, affecting 190,000 tests. Findings Include: 1. The laboratory's procedure manual, manufacturer's invoices, and RT-PCR validation data were reviewed. 2. The laboratory performed RT-PCR analysis to detect and identify the SARS-CoV-2 virus.

	3. The manual and documents provided failed to include a written procedure for the laboratory developed test (LDT) called NS COVID-19 Master Mix RT-PCR assay. See D5401. 4. The manufacturer's invoices and validation/verification data revealed the laboratory director approved the use of the NS COVID-19 Master Mix assay on October 24, 2021 and received four shipments of the NS COVID-19 Master Mix Assay kits totaling 190,000 reactions or tests. See D5423. 5. The laboratory failed to define control procedures that monitor the accuracy and precision of the complete analytic process of the NS COVID-19 Master Mix RT-PCR assay prior to testing patients. 6. On a Validation and Complaint Investigation survey ending on May 19, 2022 at 3:18 pm, Staff #1 confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (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 document for five of five patient test dates reviewed, the lot number of each commercially prepared reagent, plate, and solutions used in the SARS-CoV-2 identification systems, affecting 177,789 patients' tests. Findings include: 1. The laboratory procedures manual, the test volume worksheet dated from January 2021 through April 2022, and test data from 12/06/2021 were reviewed. 2. The laboratory used the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedure to detect and identify SARS-CoV-2 in patients' nasopharyngeal swab samples. 3. On May 10, 2022, at 3:35 PM, the surveyor requested Staff #1 to select one RT-PCR test plate run from each of the following dates listed and provide the quality control records and reagent logs for each of the selected runs. 12/06/2021 12 /10/2021 12/23/2021 12/24/2021 12/30/2021 4. Review of the plate data dated 12/06 /2021 "7th Plate" revealed the test plate included 382 patients tests and two controls, the lot numbers of reagents, kits, solutions and controls used in the run were not recorded. 5. Further review of the documents provided on May 10 through May 19, 2022, showed the laboratory failed to document any the lot numbers and expiration dates of the reagents and controls for five of five dates the surveyor selected for review. 6. The laboratory's manual failed to include a method to document the above information. 7. 177,789 patient specimens were tested during the period reviewed. 8. On a Validation and Complaint survey ending on May 19, 2022, at 3:18 PM, Staff #1 confirmed the above findings.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

	This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain four of five days of patients' testing records, affecting 177,789 patients' tests. Findings include: Item 1. 1. The laboratory procedures manual, the test volume worksheet dated from January 2021 through April 2022, and test data from 12/06 /2021 were reviewed. 2. The laboratory used the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedure to detect and identify SARS-CoV-2 in patients' nasopharyngeal swab samples. 3. On May 10 2022 at 3:35 PM, the surveyor requested Staff #1 to select one RT-PCR test plate run from each of the following dates listed and provide the test data and final reports of the patients within the selected runs. 12/06/2021 12/10/2021 12/23/2021 12/24/2021 12/30/2021 4. Review of the documents provided on May 10 through May 19, 2022 showed Staff #1 retrieved patients' test data for one of five days requested by the surveyor. The number of patients tested on the four dates requested but not received could not be determined. 5. 177,789 patient specimens were tested during the period reviewed. Item 2. 6. On May 10 2022 at 3:35 PM, the surveyor requested Staff #1 to provide requisitions and final reports from the following RT-PCR patients: Patient X1 - ID #XX29, swab collected on 12/24/2021 and swab collected on 12/30/2021; Patient X2 - ID #XX30, swab collected on 12/24/2021 and swab collected on 12/30/2021 Patient FT - swab collected on 12/06/2021; and Patient M9 - swab collected on 12/23/2021. 7. On May 12, 2022 at 1:43 PM, the surveyor received from Staff #1 "Requested PCR test results". Review of the patients' reports revealed the laboratory failed to provide the result from the swab collected on 12/24/21 for Patient X1 and swabs collected on 12/24/21 and 12/30/21 for Patient X2. 8. On a Validation and Complaint Investigation ending on May 19, 2022 at 3:18 PM, Staff #1 confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to establish and follow written policies and procedures to perform quality assessment (QA) for the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) SARS-CoV-2 testing performed, affecting 177,789 patient tests. Findings Include: 1. The laboratory's procedures manual, the RT-PCR records, and test volume worksheet from January 2021 through April 2022 were reviewed. 2. Review of the Taqpath Quant Studio validation records showed the laboratory began performing the SARS-CoV-2 RNA RT-PCR test on April 7, 2021. 3. The procedures manual revealed the laboratory policies and procedures failed to include an ongoing mechanism to monitor, assess, and when indicated, correct identified problems that occur when performing RT-PCR tests. 4. Further review showed the laboratory failed to document any ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions. 5. 177,789 patient specimens were tested during the period reviewed. 6. On a Validation and Complaint survey ending on May 19, 2022 at 3;18 PM, Staff #1 confirmed the above findings.
D6076	LABORATORY DIRECTOR

	CFR(s): 493.1441 The laboratory must have a director who meets 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, the laboratory personnel report (CMS-209), and interview the laboratory director (LD) failed to ensure that the laboratory developed test (LDT) used for SARS-CoV-2 detection and identification provide quality laboratory services (D6082); failed to ensure that quality assessment programs are established and maintained (D6094); failed to ensure all personnel had the appropriate training for the testing performed (See D6102) in the subspecialties of Virology and Toxicology, affecting 179,021 patients' tests.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure that the laboratory developed test (LDT) NS COVID-19 Master Mix RT-PCR assay used for SARS-CoV-2 detection and identification provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing, affecting 177,789 patients' tests. Findings: 1. The procedures manuals, manufacturer's invoices, test volume worksheet from January 2021 and April 2022, and Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) validation data were reviewed 2. The LD failed to ensure all test performance in the analytic phase for RT-PCR testing provided accurate and reliable results. See D5401, D5423, D5441, D5471, and D5789, prior to testing patients. 3. The laboratory reported 177,789 patients results during the time period reviewed. 4. On a Validation and Complaint survey ending on May 19, 2022, at 3:18 PM, Staff #1 confirmed the above findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to establish quality assessment (QA) programs to assure the quality of laboratory services provided and to identify failures in quality as they occur for tests performed in the subspecialties of Virology and Toxicology, affecting 179,021 patients' test. Findings:

	1. The laboratory's test data and validation records, procedures manuals, and test volume worksheet from January 2021 through April 2022 were reviewed. 2. On May 10 2022 at 3:35 PM, the surveyor requested Staff #1 to provide the QA records, policies and procedures for the SARS-CoV-2 and Toxicology testing. 3. Review of the documents provided on May 10, 2022 through May 19, 2022 showed the LD failed to establish and implement any QA procedures for Pre-analytic, Analytic, and Post-analytic phases of the laboratory. 4. 179,021 patient specimens were tested during the period reviewed. 5. On a Validation and Complaint survey ending on May 19, 2022 at 3:18 PM, Staff #1 confirmed the above findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure prior to testing patients, all personnel have the appropriate education and training and have demonstrated that they can perform all testing operations reliably to provide and report accurate results for four out of four laboratory personnel. Findings include: 1. The test volume worksheet, the Laboratory Personnel Report (CMS 209), and the laboratory's competency policy and procedures were reviewed. 2. The CMS 209 listed one technical supervisor (TS), one general supervisor (GS) and two testing personnel (TP) performing Virology and Toxicology in the laboratory. 3. On May 10, 2022 at 1: 25 PM, the surveyor requested Staff #1 to provide the education, training, and competency of all the laboratory personnel. The laboratory failed to provide any personnel records for four of four TP listed on the CMS-209. 4. 179,021 patient specimens were tested during the period reviewed. 5. On a Validation and Complaint survey ending on May 19, 2022 at 3:18 PM, Staff #1 confirmed the above findings.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on record review, the Laboratory personnel report (CMS 209), and interview, the laboratory failed to have an employee who meets the qualification requirements and provide clinical consultation (CC) for the Virology and Toxicology (D6057) testing performed, affecting 179,021 patients' tests.
D6136	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1457 The clinical consultant provides consultation regarding the appropriateness of the

	testing ordered and interpretation of test results. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to employ one of one clinical consultant (CC) for the Virology and Toxicology testing performed in the laboratory, affecting 179,021 patients' tests. Findings: 1. The CMS 209, and test volume worksheet were reviewed. 2. The CMS 209 revealed the laboratory director failed to designate a CC. 3. 179,021 patient specimens were tested during the period reviewed. 4. On a Validation and Complaint survey ending on May 19, 2022 at 3:18 PM, Staff #1 confirmed the above findings.