Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2098042	11/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
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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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documentation for review and interview with the Technical Supervisor (TS), the laboratory failed to retain documentation of Quality Control (QC) results performed on the Sciex API 5000 LC/MS analyzer for at least 2 years. Findings include: 1. The laboratory began urine drug screen and drug confirmation testing on the Sciex API 5000 LC/MS analyzer on 2/25/2022. At the time of the survey conducted on 11/29/2022, the laboratory had only performed patient testing on one day, 2/25/2022. Approximately 78 patient tests were performed on that date. 2. The laboratory's QC process for each test plate (test run) includes a low and high level of QC at the beginning and the end of the run and 11 standards. 3. The laboratory failed to provide evidence of QC documentation from the analyzer for testing that occurred on 2/25/2022. 4. The TS interviewed on 11/29/2022 at 10:35am confirmed the laboratory could not produce documentation from the analyzer of QC performance for the testing date referenced above. The TS stated that the instrument was inoperable at the time of the survey and the laboratory was unable to retrieve the QC records from the analyzer.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on review of the laboratory records and lack of documentation for verification of accuracy, and interview with the technical consultant on November 29, 2022, the laboratory failed to perform the verification of accuracy at least twice annually for SARS CoV-2 testing. Findings include: 1. The laboratory began patient testing using the SARS-CoV-2 (COVID-19) assay on the Solana instrument in March 2021, which received the Food and Drug Administration (FDA) approval under an Emergency Use Authorization (EUA) for CLIA-certified laboratories authorized to perform moderate or high complexity testing. 2. The laboratory failed to perform and document twice annual verification of accuracy for SARS-CoV-2 testing in 2021. 3. The laboratory failed to establish a policy or procedure for performing twice annual verification of accuracy for SARS-CoV-2 testing. 4. The technical consultant confirmed by interview on November 29, 2022 at 10:10 am, the lack of performing twice annual verification of accuracy for the SARS-CoV-2 test. 5. The laboratory reported performing 100 COVID-19 tests annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory's established QA policies and procedures failed to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of records from 2021 and 2022 for the verification of accuracy for testing performed in the sub-specialty of Virology. See D5217 for findings. 2. The facility personnel interviewed on 11/29/2022 at 12:25pm confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems associated with the general laboratory systems.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the facility personnel, the laboratory failed to have a written or electronic request for all patients tested for SARS-CoV-2 (COVID-19) on the Quidel Solana analyzer. Findings include: 1. The laboratory began patient testing for SARS-CoV-2 (COVID-19) testing on the Quidel Solana analyzer in March 2021. 2. No written or electronic request for COVID-19 testing was presented for review for each patient tested by the laboratory from March 2021 through the date of the survey, 11/29/2022. The laboratory

	performed approximately 100 patient tests during that time. 3. The facility personnel interviewed on 11/29/22 at 11:47am confirmed that the laboratory failed to have an electronic or written test requisition for each patient tested for COVID-19 by the laboratory.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory's established QA policies and procedures failed to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of test requisitions for Solana SARS-CoV-2 Assay testing performed in the sub-specialty of Virology. See D5301 for findings. 2. The facility personnel interviewed on 11/29/2022 at 12:25pm confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems associated with the preanalytic laboratory systems.
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 the number and severity of deficiencies cited for quality practices identified during the survey conducted on November 29, 2022, it was determined that the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283, and failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the sub-specialty of Virology. See D5413, D5445 and D5791 for findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of temperature logs for review, review of the manufacturer's Instructions For Use (IFU) for the Solana SARS-CoV-2 Assay(COVID-19) and interview with the facility personnel, the laboratory failed to document the refrigerator temperature where test reagents are stored, and failed to document the temperature of the heat block used during the test procedure. Findings include: 1. The laboratory began patient testing using the SARS-CoV-2 (COVID-19) assay on the Solana instrument in March 2021, which received the Food and Drug Administration (FDA) approval under an Emergency Use Authorization (EUA) for CLIA-certified laboratories authorized to perform moderate or high complexity testing. 2. The manufacturer's IFU for the Solana SARS-CoV-2 Assay reviewed during the survey states, "The Assay Kit should be stored at 2 C to 8 C until the expiration date listed on the outer kit box." 3. No documentation was presented for review during the survey to indicate the laboratory monitored and recorded the refrigerator temperature where test kits are stored on the following dates in July 2021: 14-17, 19-24, and 26-31. 4. The test procedure listed in the manufacturer's IFU for the Solana SARS-CoV-2 Assay states, "Heat the Process Buffer Tubes at 95 2 C for 5 minutes and then vortex the Tubes for 5 seconds." 5. No documentation was presented for review during the survey to indicate the laboratory monitored and recorded the temperature of the heat block used to heat the Process Buffer Tubes as indicated above (see #4) from March 2021 through the date of the survey conducted on 11/29/22. 6. At 12:10pm on 11/29 /2022, the facility personnel interviewed confirmed that the laboratory failed to monitor and document the refrigerator temperature and heat block temperature as indicated above. 7. The laboratory began COVID-19 testing in March 2021 and performs approximately 100 tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation, review of the manufacturer's instructions and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency specified by the manufacturer for SARS-CoV-2 (COVID-19) testing performed on the Quidel Solana analyzer. Findings include: 1. The laboratory began patient testing using the SARS-CoV-2 (COVID-19) assay on the Solana instrument in March 2021, which received the Food and Drug Administration (FDA) approval under an Emergency Use Authorization (EUA) for CLIA-certified laboratories authorized to perform moderate

	or high complexity testing. 2. The manufacturer's instructions for the Solana SARS-CoV- 2 assay state, "Authorized laboratories using the Solana SARS-CoV-2 Assay will use the Solana SARS-CoV-2 Assay as outlined in the 'Solana SARS-CoV-2 Assay' Instructions For Use...A positive control (such as a positive patient sample) should be processed and tested with each batch of specimens. The external positive control (containing SARS-CoV-2 Synthetic RNA) may be treated as a patient specimen. The control should be sampled and tested as if it were a patient specimen and processed as described above in the Assay Procedure. The external positive control is intended to monitor substantial reagent and instrument failure. The external negative control may be treated as a patient specimen. The control should be sampled and tested as if it were a patient specimen and processed as described above in the Assay Procedure. The external negative control is used to detect reagent or environmental contamination (or carry-over) by SARS-CoV-2 RNA or amplification." 3. During the survey conducted on 11/29/2022, no QC documentation was provided for review for the Solana SARS-CoV-2 Assay, to indicate the laboratory performed a positive and negative external control per test run as required by the manufacturer. 4. The laboratory tested approximately 100 patients from March 2021 through the date of the survey, 11/29/2022. 5. The facility personnel interviewed on 11/29/22 at 11: 35am confirmed that the laboratory did not perform and document external positive and negative controls with each test run as required by the manufacturer.
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 review of Quality Assessment (QA) policies and procedures, analytic test records, and interview with the facility personnel, the laboratory's established QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified in the analytic systems. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of Quality Control (QC) records for testing performed in the sub-specialties of Virology and Toxicology. See D3031 and D5445 for findings. 2. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of temperature measurements for the refrigerator and heat block as required for the Solana SARS-CoV-2 Assay. See D5413 for findings. 3. The facility personnel interviewed on 11/29 /2022 at 12:25pm confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems associated with the analytic systems.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported

	from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the Technical Supervisor (TS), the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the laboratory's information system (LIS). Findings include: 1. The laboratory performs toxicology testing on urine specimens using the Sciex API 5000 LC/MS analyzer, with an approximate annual test volume of 250. The laboratory began patient testing on 2/25/2022. 2. The laboratory performs SARS-CoV-2 (COVID-19) testing on the Quidel Solana analyzer, with an approximate annual test volume of 100. The laboratory began patient testing in March 2021. 3. The test results from the Sciex API 5000 LC/MS analyzer and the Quidel Solana analyzer are electronically interfaced into the Laboratory Information System (LIS), Polymed. 4. No documentation was presented for review during the survey conducted on November 29, 2022 to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced into the LIS. 5. The TS interviewed on 11/29/22 at 10:55am confirmed the laboratory failed to have a system in place to verify the accuracy of the patient test results that are electronically sent from the analyzers to the LIS.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation and interview with the technical consultant (TC), the TC failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one testing personnel who began SARS-CoV-2 testing on the Solana instrument in March 2021. 2. The technical consultant interviewed on 11/29/22 at 9:55am confirmed that the laboratory failed to have documentation of a semiannual competency evaluation for the testing personnel indicated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review and interview with

	the technical consultant (TC), the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on November 29, 2022, no annual competency evaluation documentation was presented for review for one testing personnel who began SARS-CoV-2 (COVID-19) testing in March 2021 on the Solana instrument. 2. The technical consultant interviewed on 11/29/22 at 9:55am confirmed the laboratory failed to provide documentation of an annual competency evaluation for the testing personnel indicated above.
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: The Condition of Laboratory Director is not met as evidenced by the failure to provide overall management and direction in accordance with 493.1445 of this subpart. See D6087, D6093, D6094 and D6102 for specific findings.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Solana SARS-CoV-2 assay and review of laboratory records, the laboratory director failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. Findings include: 1. The Solana SARS-CoV-2 manufacturer's instructions for use (IFU) states, "Only use the protocol described in this package insert. Deviations from the protocol may give erroneous results." 2. The laboratory director failed to ensure that laboratory personnel are performing the Solana SARS-CoV-2 Assay in accordance with the manufacturer's instructions as required for accurate and reliable results. See D5413, D5445, D6053 and D6054 for specific findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 lack of quality control records, the laboratory director failed to ensure that

	quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D3031 and D5445 for 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 lack of quality assessment (QA) documentation for review, the laboratory director failed to ensure that a QA program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5391 and D5791 for 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 lack of initial training documentation for one testing personnel who performs testing in the specialty of toxicology and interview with the technical supervisor, the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for one testing personnel who began patient testing on 2/25/2022 in the sub-specialty of Toxicology on the Sciex API 5000 LC/MS analyzer. 2. The technical supervisor interviewed on 11/29/22 at 9: 47am confirmed the laboratory failed to have documentation of initial training for the testing personnel indicated above.