Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0126129	03/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Prophase Diagnostic Laboratory	42 Throckmorton Ln, Old Bridge, NJ	

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
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on surveyor observation of the work area where Molecular testing was performed and interview with the Laboratory Supervisor (LS), the laboratory failed to minimize contamination of patient specimens, equipment, reagents, and instrumentation for SARS-COV-2 (COVID 19) PCR tests from 4/8/20 to the date of the survey. The findings include: 1. Observation of the work area revealed the laboratory did not have a closed system to prevent contamination of Molecular tests. 2. The product was prepared and detected while moving between two work spaces using the same entrance and exit. 3. Patient specimens and reagents were received, prepared, extracted and amplified in the same work space. 4. The laboratory processed 1000 to 1500 Molecular SARS-COV-2 PCR tests per day. 5. The LS confirmed on 3 /31/21 at 12:10 pm the laboratory was not arranged to minimize contamination.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on surveyor observation of the area where Molecular amplification procedures

	were performed and interview with the Laboratory Supervisor (LS), the laboratory failed to have a unidirectional workflow for specimen preparation, reagent preparation, product detection and amplification from 4/8/20 to the date of the survey. The laboratory processed 1000 to 1500 Molecular SARS-COV-2 (COVID 19) PCR tests per day. The LS confirmed on 3/31/21 at 12:00 pm the laboratory did not have a unidirectional work flow.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: a. Based on an in-office review of the laboratory's requirements for a NJ State License, the laboratory failed to renew their New Jersey State Clinical Laboratory License for 2021. The Supervisor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 3/30/21 that the laboratory did not renew its CLIS license for 2021. b. Based on surveyor review of the NJ State license and interview with the state surveyor, the Laboratory Director failed to be in compliance with the State of New Jersey requirements to get approval from the state before performing patient samples for SARS-COV-2 (COVID 19) PCR saliva tests. The laboratory performed 81,278 saliva tests from 12/11/20 to 3/20/21. The Laboratory Supervisor confirmed on 3/31 /21 at 12:00 pm the laboratory did not have a CLIS license for saliva tests.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on lack of Performance Specification (PS) records and interview with the Laboratory Supervisor (LS), the laboratory failed to retain PS records for the QuantStudio 12K Flex analyzer used to perform SARS-COV-2 (COVID 19) PCR tests from 4/8/20 to the date of survey. The finding includes: 1. The were no work records, raw data or instrument print outs on site to confirm the data in four separate validations found on site. 2. The LS confirmed there were none of the above records for the validations performed.
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 the lack of Competency Assessment (CA) records and interview with the

	Laboratory Supervisor (LS), the laboratory failed to follow written procedures to perform a CA on the Technical Supervisor, General Supervisor and twelve Testing Personnel form 4/8/20 to the date of survey. The LS confirmed on 3/31/21 at 12:00 pm that the CA was not performed.
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 surveyor review of the Procedure Manual (PM) and interview with the Laboratory Supervisor (LS), the laboratory failed to follow the PM for Molecular tests from 4/8/20 to the date of the survey. The findings include: 1. The PM stated under Prophase Covid-19 Real Time (RT-PCR) Assay Manual: "Assay tests nasopharyngeal swab, nasopharyngeal aspirate, and bronchial lavage specimens." 2. Page 27 of the PM Section 21.0 States: "other specimen types have not been evaluated and should not be tested with this assay. 3. The laboratory performed 81,278 RT-PCR using saliva specimens. 4. The TS confirmed 3/31/21 at 12:30 pm that the laboratory did not follow the PM.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Laboratory Supervisor (LS), the laboratory failed to perform comparison studies for the QuantStudio Flex 12K instruments in use from 4/8/20 to the date of the survey. The finding includes: 1. There was no documented evidence the laboratory performed comparison studies between the four analyzers stated above during the validation or prior to patient testing. 2. The LS confirmed on 3/31/21 at 11:00 am that the laboratory failed to perform comparison studies.
D5805	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. (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 surveyor review of the Test Report (TR) and interview with the Laboratory Supervisor (LS), the laboratory failed to report qualitative Molecular SARS-COV-2 (COVID 19) PCR tests results accurately from 4/8/20 to the date of survey. The finding includes: 1. A review of 20 TR revealed 20 out of 20 did not have a specimen source. 2. The laboratory performed non Food and Drug Administration (FDA) cleared tests and there was no statement stating "This test has not been FDA cleared or approved. This test has not been authorized by the FDA under an Emergency Use Authorization (EUA). 3. The laboratory failed to provide all of the manufacturer reporting disclaimers as required in their package insert and the four disclaimers that the FDA lists in pathway D of the "FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency" since all of the testing performed was a laboratory developed test (LDT). 4. The LS confirmed on 3/31/21 at 10:45 am that tests SARS-COV-2 (COVID 19) PCR were not reported accurately.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Report (TR) and interview with the Laboratory Supervisor (LS) the laboratory failed to assess and correct problems on the TR for SARS-CoV-2 RT PCR tests results from 4/8/20 to the date of survey. The finding includes: 1. The review of four FR revealed: a. Two of four : Collection time and received time was 12:00 am but the laboratory was not open at 12:00 am. b. One of four: No collection time was recorded c. One sample received from Texas was collected at 4:49 pm, received at 8:14 pm, and resulted at 11:42 pm on 3/10/21. Timing is not possible. d. Accession 686 stated: Testing location: P4 Clinical - 25 Riverside Drive, Pine Brook, NJ at bottom of the report but under Testing Methodology it stated " This sample was tested and interpreted at Prophase Diagnostic. 2. Statement on TR said Prophase Diagnostics is "using nasopharyngeal swabs and nasal swabs" but omitted saline specimens. 3. The Laboratory Director (LD) on the TR was DR, not the LD listed in the CMS 116. 4. Disclaimer stated " This test has been authorized by the Clinical Laboratory Improvement Services (CLIS) of NJ State Licensure Review Program/PT Review Program and the laboratory must abide by all applicable regulations regarding testing under a FDA /EUA." but CLIS did not license them for saliva testing and the test did not receive an EUA at the time of the survey. It was a laboratory developed test. 5. The laboratory performed 81,278 SARS-CoV-2 RT PCR saliva tests and 17,223 tests using swabs in saline from 10/10/20 to 3/20/21. 6. The LS stated on 3/31/21 at 1:45 pm that the laboratory failed to assess and correct problems of the FR.
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 an surveyors review of the laboratory's records, procedures, Quality Control (QC), Quality Assurance (QA), Performance Specifications (PS) and interviews with the Laboratory Supervisor (LS) the Laboratory Director (LD), the LD failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily for Molecular SARS-COV-2 RT PCR tests and in compliance with the CLIA regulations from 4/8/20 to the date of the survey. 1. The LD failed to ensure the laboratory was constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. Cross Refer to D 3003 2. The LD failed to ensure Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. Cross Refer to D 3005. 3. The LD failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed on the date of the survey. Cross Refer to D 6079 4. The LD listed on the CMS 116 failed to be accessible by telephone or electronically. Cross Refer to D 6080 5. The LD failed to ensure PS were adequate to perform test. Cross Refer to D 6086. 6. The LD failed to ensure the laboratory established an accurate QA program. Cross Refer to D 6094. 7. The LD failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education. Cross Refer to D 6102.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of written policies and procedures, record review, surveyor interviews and observation, it was determined that the Laboratory Director (LD) failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed on the date of the survey. The findings include: 1. A CMS 116 was received from the laboratory requesting a LD change to SM, MD on 12/16/2020. 2. The change was made in the Aspen Data base on 12/16/2020. 3. The Laboratory Supervisor and staff on site the day of the survey stated the LD was DR, MD. 4. The manuals listed below were on site the day of the survey: a. Laboratory Policy Manual (LPM): Molecular Virology Version 1 Covid -

	19 Assay Validation, LPM: Covid-19 Real Time (RT-PCR) Assay Manual both dated 11/20/2020, Final Reports and Laboratory PM were signed by DR, MD. b. Prophase Diagnostic Covid -19 Validation 2020 approved by SM, MD. c. Prophase Diagnostic Covid -19 Validation 2021, Molecular Version 1 approved by CB/AV, neither are listed on the CMS 209 or are employed at this Prophase NJ location. d. Prophase Diagnostic Quality Control in PCR Department Molecular Virology Version 1 2020 approved by CB. e. Prophase Diagnostic Laboratories COVID-19 Real-Time (RT-PCR) Assay Manual 2021 approved by CB/AV 5. There is no LD approval on items 7, 8 and 9 6. There were no education records or training records for the technical supervisor, clinical consultant, general supervisor or testing personnel from 4/8/20 to the date of the survey.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on surveyor visit to the laboratory and interview with the Laboratory Supervisor (LS), the Laboratory Director (LD) listed on the CMS 116 was not on site at the time of the initial survey or accessible by telephone or electronically. It was stated by office personnel "the LD listed on the CMS 116 was not the LD". The LD confirmed on 3/31/21 at 9:50 am the LD was not available.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Supervisor (LS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Molecular SARS COV 2 RT PCR tests on the QuantStudio 12K flex analyzer from 4/8/20 to the date of survey. The findings include: 1. There was no documented evidence validation was performed for: a. Saliva tests. The laboratory performed 81,278 saliva tests from 10/20/20 to 3/30/21. b. The stability of the specimen. Room Temperature, Refrigerated and Frozen c. The expiration date of reagents, working solutions and controls d. The performance of the MagMax Viral/Pathogen II Nucleic Acid Isolation Kit. e. There was no verification of the Lucigen Extraction f. Accuracy of concentration techniques and aliquoting g. Time and temperature of the thermocyclers. h. Quality Control i. Software used or transmitted results 2. Raw data to confirm nasopharyngeal swab validation was not found on site at the time of the survey. 3. The validation was performed on swabs in transport media but swabs are received in saline in the laboratory. 4. There was no documented evidence found on site at the day of the surveyor to show the validation was done in the laboratory or by laboratory staff. 5. Validation data was submitted by CB or CB and AV. The LS stated they work in New York. 6. The LS confirmed on 3 /30/21 at 1:50 pm that PS were not adequate.

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 surveyor review of the laboratory Procedure Manual (PM) and interview with the Laboratory Supervisor(LS), the Laboratory Director failed to ensure a Quality Assurance (QA) program was accurately established to assure quality of laboratory services for Molecular SARS-COV-2 RT PCR tests provided from 4/8/20 to the date of the survey. The findings include: 1. The QA procedure did not include review of: a. Positivity rate monitoring for contamination b. False positive and negative results in reference to patients history. c. Rejected samples d. Daily Quality Control (QC) and extraction QC e. Requestions received 2. The LS confirmed on 3/30 /20 at 2:45 pm that a QA program was not accurately established.
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 Personnel Records (PR) and interview with, the Laboratory Supervisor (LS), the Laboratory Director (LD) failed to ensure that education and training was adequate to perform Molecular tests for twelve Testing Personnel from 4 /8/20 to the date of the survey. The LS confirmed on 3/31/21 at 1:10 pm that all education and training records were not available to ensure Testing Personnel had the proper education and training to perform testing.