

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2215033	(X3) Date Survey Completed 08/04/2023
Name of Provider or Supplier Prophase Diagnostics, Ny, Inc	Street Address, City, State 711 Stewart Avenue, 2nd Fl, Ste 200, Garden City, NY	
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	<p>An announced CLIA exempt-state validation survey was conducted at the ProPhase Diagnostics laboratory on August 3-4 2023, by the CMS Boston CLIA federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory is not in compliance with condition-level CLIA requirements this includes standard-level deficiencies. The survey findings are cited as the following:</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: A. Based on record review, written laboratory procedures, patient test requisition, final patient report, and interview with the Chief Operating Officer (COO) and the Quality Director, the laboratory failed to ensure specimen integrity was maintained during transport per their own written procedures for nine of nine patients. Findings include: 1. Interview on 08/03/2023 at 09:35 AM with the COO confirmed the laboratory performed SARS-CoV-2 testing on eight QuantStudio 12K Flex analyzers (identified as #4, #5, #6, #7, #8, #9, #10, #11). 2. On 08/04/2023, a review of the written laboratory procedure titled, "RT-PCR SOP for PhoenixDx SARS-CoV-2 Multiplex" under section "6. Specimen Handling" stated, "Transport Temperature Saline/VTM - Refrigerated (2-8C)". 3. On 08/03/2023, a review of nine patient requisitions and patient final test reports from 01/10/2023 through 08/01/2023 revealed no documentation of the temperature during transportation for nine of nine</p>

patients: a. Patient #01074-PZ-23009 - Nasopharyngeal Swab collected on 01/09/2023, received on 01/10/2023, and reported on 01/10/2023 b. Patient #01730-06-23011 - Nasopharyngeal Swab collected on 01/11/2023, received on 01/13/2023, and reported on 01/14/2023 c. Patient #01718-PZ-23012 - Nasopharyngeal Swab collected on 01/12/2023, received on 01/12/2023, and reported on 01/14/2023 d. Patient #01566-00-23066 - Nasopharyngeal Swab collected on 03/07/2023, received on 03/08/2023, and reported on 03/08/2023 e. Patient #01593-00-23066 - Nasopharyngeal Swab collected on 03/07/2023, received on 03/07/2023, and reported on 03/09/2023 f. Patient #01196-00-23172 - Nasopharyngeal Swab collected on 06/21/2023, received on 06/21/2023, and reported on 06/28/2023 g. Patient #0205500-23198 - Nasopharyngeal Swab collected on 07/17/2023, received on 07/18/2023, and reported on 07/18/2023 h. Patient #01064-00-23208 - Nasopharyngeal Swab collected on 07/28/2023, received on 07/30/2023, and reported on 07/31/2023 i. Patient #01091-00-23207 - Nasopharyngeal Swab collected on 07/28/2023, received on 07/31/2023, and reported on 08/01/2023 4. Interview on 08/04/2023 at 10:45 AM with the Quality Director, confirmed the above findings. B. Based on record review, written laboratory procedures, patient test requisition, final patient report, and interview with the Chief Operating Officer (COO) and the Quality Director, the laboratory failed to ensure specimen integrity was maintained during transport per their own written procedures for two of two patients. Findings include: 1. Interview on 08/03/2023 at 09:35 AM with the COO confirmed the laboratory performed COVID-19, Flu A, Flu B combination testing on three QuantStudio 7K Flex analyzers (identified as #7-1, #7-2, #7-3). 2. On 08/03/2023 a review of the written laboratory procedure titled, "TaqPath SARS-CoV-2, Flu A, Flu B Combo RT-PCR Assay Manual v2.0" under section "6. Specimen Handling" stated: a. "Transport Temperature Saline/VTM - Refrigerated (2-8C)*" b. "*Transport specimen stability for patient samples collected in Viral Transport Media (VTM) has been demonstrated at 15-30C for up to 72 hours." 3. On 08/04/2023, a review of two patient requisitions and patient final test reports from 07/17/2023 revealed no documentation of the temperature during transportation for two of two patients: a. Patient #02050-00-23198 - Nasopharyngeal Swab collected on 07/17/2023, received on 07/18/2023, and reported on 07/18/2023 b. Patient #02075-00-23198 - Nasopharyngeal Swab collected on 07/17/2023, received on 07/18/2023, and reported on 07/18/2023 4. Interview on 08/04/2023 at 10:45 AM with the Quality Director, confirmed the above findings.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on record review and interview with the Chief Operating Officer (COO) and the Information Technology (IT) Director, the laboratory failed to ensure the Laboratory Information System (LIS) had been approved, signed, and dated by the Laboratory Director (LD) before put into use. Findings include: 1. Interview on 08/03/2023 at 09:35 AM with the COO confirmed the laboratory performed: a. SARS-CoV-2 testing on eight QuantStudio 12K Flex analyzers (identified as #4, #5, #6, #7, #8, #9, #10, #11) b. COVID-19, Flu A, Flu B combination testing on three QuantStudio 7K Flex analyzers (identified as #7-1, #7-2, #7-3) 2. Interview on 08/04/2023 at 09:00 AM with the IT Director confirmed the laboratory used the Orchard LIS to organize and track patient specimens throughout the phases of testing. 3. On 08/04/2023, a

record review of the Orchard LIS installation revealed no evidence the laboratory director approved, signed, and dated before put into use on 04/15/2023. 4. Interview on 08/04/2023 at 01:10 PM with the COO confirmed the laboratory could not locate any documentation to prove the LD approved, signed, and dated the LIS.

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 laboratory failed to have a Laboratory Director who meets the qualification requirements of high complexity testing before patient testing for one of one patient. Refer to D6078

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 (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 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 email correspondence and interview with the Chief Operating Officer (COO) and the laboratory owner, the laboratory failed to have a Laboratory Director (LD) who meets the qualification requirements of high complexity testing before patient testing for one of one patient. Findings include: 1. Interview on 08/03/2023 at 09:35 AM with the COO confirmed the laboratory performed the following: a. SARS-CoV-2 testing on eight QuantStudio 12K Flex analyzers (identified as #4, #5, #6, #7, #8, #9, #10, #11) b. COVID-19, Flu A, Flu B combination testing on three QuantStudio 7K Flex analyzers (identified as #7-1, #7-2, #7-3) 2. On 08/03/2023, a review of personnel records and email correspondence to human resources from the LD listed on the CMS 209 form revealed the LD resigned on 07/31/2023. 3. Interview on 08/03/2023 at 10:25 AM with the COO confirmed the laboratory tested one patient after the LD resignation on 07/31/2023: a. Patient 01091-00-23207 - Specimen collected 07/26/2023, received into the laboratory 07/31/2023, and reported on 08/01/2023 4. Interview on 08/03/2023 at 11:03 AM with the Laboratory Owner confirmed the LD resignation and provided a letter to the surveyor dated 08/03/2023 stating, " ... We will cease testing until NYSDOH has approved the update on HCS. All testing will be routed to NJ until NYSDOH approves the changes ...". 5. Email correspondence dated 08/03/2023 at 02:22 PM from the laboratory to the New York State Department of Health (NYSDOH) Clinical Laboratory Evaluation Program (CLEP) confirmed the laboratory's submission and change of high complexity laboratory director during the first day of the survey (08/03/2023).