

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2246682	<b>(X3) Date Survey Completed</b>  12/13/2023
<b>Name of Provider or Supplier</b>  Pro Diagnostics Lab	<b>Street Address, City, State</b>  7124 W 83rd St Unit D, Bridgeview, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by:</p> <p>A. Based on surveyor's review of laboratory records and interview with the technical supervisor (TS) and the laboratory owner; the laboratory failed to enroll in an approved proficiency testing (PT) program for the subspecialty of virology (SARS-CoV-2) in 2021 through 2023; 13 chemistry analytes in 2021 and 2023; and six hematology analytes in 2021 and 2023. Finding Include: 1. On 12/13/2023, at 9:50 a. m., an interview with the TS revealed the laboratory performed testing in the subspecialty of virology (SARS-CoV-2), routine chemistry for 13 regulated chemistry analytes (Sodium, Potassium, Chloride, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Total Protein, Albumin, Aspartate Aminotransferase / Serum Glutamic Oxaloacetic Transaminase (AST / SGOT), Alanine Aminotransferase / Serum Glutamic-Pyruvic Transaminase (ALT / SGPT), Alkaline Phosphatase, Total Bilirubin), and six hematology analytes (red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential) in 2021; SARS-CoV-2 testing only in 2022; the laboratory performed SARS-CoV-2, 13 regulated chemistry and six hematology analyte tests in 2023. 2. Review of the laboratory's proficiency testing records found no documentation of enrollment in a Centers for Medicare &amp; Medicaid Services (CMS) approved PT program for testing virology subspecialty</p>

SARS-CoV-2 for Event 3 2021; Event 1, Event 2, and Event 3 in 2022; and Event 1, Event 2, and Event 3 in 2023. 3. Review of the laboratory's proficiency testing records found no documentation of enrollment in a Centers for Medicare & Medicaid Services (CMS) approved PT program for testing 13 of 13 (Sodium, Potassium, Chloride, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Total Protein, Albumin, Aspartate Aminotransferase / Serum Glutamic Oxaloacetic Transaminase (AST / SGOT), Alanine Aminotransferase / Serum Glutamic-Pyruvic Transaminase (ALT / SGPT), Alkaline Phosphatase, Total Bilirubin) regulated chemistry analytes for Event 3 2021 and Event 1 in 2023. 4. Review of the laboratory's proficiency testing records found no documentation of enrollment in a Centers for Medicare & Medicaid Services (CMS) approved PT program for testing six of six (red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential) regulated hematology analytes for Event 3 2021 and Event 1 in 2023. 5. On 12/13/2023, at 11:06 a.m., the TS and laboratory owner confirmed the above findings. B. Based on surveyor's review of laboratory records and interview with the technical supervisor (TS) and the laboratory owner; the laboratory failed to attain satisfactory participation in proficiency testing for two regulated chemistry analytes (Calcium and Sodium), and one regulated hematology analyte (Hematocrit) in 2023. Findings include: 1. The laboratory failed to attain a score of at least 80 percent for two of two regulated chemistry analytes Calcium and Sodium in 2023. (Refer to D2087). 2. The laboratory failed to attain a score of at least 80 percent for the regulated hematology analyte Hematocrit in 2023. (Refer to D2121). 3. On 12/13/2023, at 11:06 a.m., the TS and laboratory owner confirmed the above findings.

**D2087**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:  
Based on review of the Centers for Medicare & Medicaid Services CASPER Report 0155D and interview with the technical supervisor (TS), the laboratory failed to attain a score of at least 80 percent for the regulated chemistry analyte Calcium for proficiency testing (PT) Event 2, 2023 and regulated chemistry analyte Sodium for PT Event 3, 2023. Findings Include: 1. Review of the "CASPER Report 0155D" revealed the following unsatisfactory scores for the regulated PT analytes calcium (CA) and sodium (NA). a) "Event 2 Score 2023: Analyte # 0345 CA, TOTAL 60\*" b) "Event 3 Score 2023: Analyte # 0475 NA, 60\*" 2. On 12/13/2023, at 1:30 p.m., an interview with the TS confirmed the above finding.

**D2121**

**HEMATOLOGY**  
CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:  
Based on review of the Centers for Medicare & Medicaid Services CASPER Report 0155D and interview with the technical supervisor (TS) revealed the laboratory failed to attain a score of at least 80 percent for regulated hematology analyte Hematocrit for

proficiency testing (PT) Event 3, 2023. Findings Include: 1. Review of the "CASPER Report 0155D" revealed the following unsatisfactory score for the regulated PT analyte hematocrit (HCT). a) "Event 3 Score 2023: Analyte # 0785 HCT (NON-WAIVED) 60\*" 2. On 12/13/2023, at 1:30 p.m., an interview with the TS confirmed the above finding.

**D3000**

**FACILITY ADMINISTRATION**  
CFR(s): 493.1100

Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:  
Based on surveyor's direct observation, laboratory documentation, and interview with the technical supervisor (TS), the laboratory failed to meet the requirements of this condition. The laboratory failed to provide a unidirectional workflow for molecular amplification procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies. (Refer to D3005).

**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's direct observation, laboratory records, and interview with the technical supervisor (TS), the laboratory failed to maintain a uni-directional workflow for molecular amplification procedures to prevent potential cross-contamination in specimen processing, preparation, amplification, and detection for SARS-CoV-2 in 2021, 2022 and 2023. Findings Include: 1. Review of the laboratory's "RT PCR Test Near Me" procedures manual stated the following information: "General Considerations" "2. Maintain separate areas and dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips, gowns and gloves) for assay reagent setup and handling of processed samples." "3. Workflow must always be from the clean area to the dirty area." 2. On 12/13/2023 at 8:27 a.m., direct observation of the TS demonstrating the testing procedures for the "iAMP - COVID19-100" (iAMP) assay revealed the laboratory failed to follow the general considerations outlined in the laboratory's procedure manual. a. The preparation of extraction buffer reagent, the transfer of patient samples to the patient testing plates, and the addition of positive and negative control samples to the patient testing plates all performed in one biosafety cabinet ("ESCO Class II Biological Safety Cabinet Serial: 2021-176601"). b. The testing pipettes stored on a rack outside of the biosafety

	<p>cabinet. c. Proficiency testing kit (AAB Medical Laboratory Evaluation), completed patient samples, and new patient samples (iAMP and blood) stored in one refrigerator ("ATOSA Model: MCF8705GR"). d. Positive and negative (iAMP) controls stored in one freezer ("ATOSA"). 3. On 12/13/2023, at 8:27 a.m., the TS confirmed the above findings.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the technical supervisor (TS) and the laboratory owner, the laboratory failed to evaluate the biannual method accuracy for Carbon Dioxide (CO2) chemistry analyte testing at least twice a year in 2023. Findings Include: 1. Review of the PT record "AAB Chemistry M3 2023 - Pro Diagnostics Lab CLIA: 14D2246682" revealed the laboratory performed CO2 testing in 2023. 2. Review of laboratory records and lack of documentation revealed the laboratory failed to evaluate and document the biannual method accuracy for CO2 testing at least twice a year in 2023. 3. On 12/13/2023, at 11:40 a.m., interview with the TS and the laboratory owner confirmed the above findings.</p>
<p><b>D5789</b></p>	<p><b>TEST RECORDS</b> CFR(s): 493.1283(b)</p> <p>Records of patient testing including, if applicable, instrument printouts, must be retained.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the technical supervisor (TS) and the laboratory owner, the laboratory failed to retain patient test records for 12 of 12 months in 2021. Findings Include: 1. Review of laboratory records, patient test results and lack of documentation revealed the laboratory failed to retain patient testing records and instrument printouts for 12 of 12 months in 2021. 2. On 12/13/2023, at 11:40 a.m., interview with the TS and the laboratory owner revealed: "Change of ownership on 10/16/2023; old owner removed instruments and laboratory records."</p>
<p><b>D6092</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare &amp; Medicaid Services CASPER Report 0155D, laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to ensure corrective actions were taken for three</p>

of three unsatisfactory proficiency testing analyte scores in 2023. Findings Include: 1. The laboratory failed to document the corrective actions taken for failing to attain a score of at least 80 percent for calcium proficiency testing (PT) for Event 2, 2023 and sodium PT for Event 3, 2023. (Refer to D2087). 2. The laboratory failed to document the corrective actions taken for failing to attain a score of at least 80 percent for hematocrit proficiency testing (PT) for Event 3, 2023. (Refer to D2121).