Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2105916	05/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pro Health Diagnostic, Llc	2695 Villa Creek Dr Suite B109, Farmers Branch, TX	

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	An entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of laboratory policies, Center for Medicare & Medicaid Services (CMS) 209 form, patient test requisitions, specimen grossing review forms, and confirmed in interview, the laboratory failed to follow its own written policy for grossing of histology specimens for 44 of 44 patient specimens in 2020 (02/2020). Findings: 1. Review of the laboratory's policy "Policy# SP-106" revealed:

	"Accessioning ... Documenting Gross Dictation: All specimens are grossed by histotechnicians under the direct supervision of the Pathologist/Medical Director. Each specimen is grossed one at a time. All required information on the requisition is checked against specimen container for verification. Specimens are grossed documenting the measurements and noting any discolorations or lesions." 2. Review of the CMS 209 form listed the laboratory director as the clinical consultant, general supervisor (GS), technical supervisor (TS) and testing person (TP). The form included two additional general supervisors/testing persons (GS-2/TP-5, GS-3/TP-6) who perform reading and interpretation of the slides and also included six additional testing persons (TP-2, TP-3, TP-4, TP-7, TP-8, TP-9), who performed the gross examinations of specimens received from outside clients. The laboratory director /general supervisor/technical supervisor was not onsite. GS-2/TP-5 and GS-3/TP-6 were also not onsite. TP-2, TP-3, TP-4, TP-7, TP-8, TP-9 did not qualify as general supervisors or technical supervisors, requiring review within 24 hours. Gross examination included all documented physical examination/descriptions including measurement of the specimen. 3. During an interview on 05/18/2021 at 10:17 am, TP-2 stated that grossing was reviewed by the pathologists (general supervisors) when they would come into the laboratory to pick up slides. She stated that the pathologist would review the grossing by reviewing the specimen blocks. During an interview on 05/18/2021 at 10:32 am, TP-2 stated that the only direct supervision of grossing was during training and no other direct supervision of grossing was performed on a day to day basis. The laboratory failed to perform direct supervision of grossing, as required by their own written policy. 4. Review of patient test requisitions revealed gross examinations were documented on the requisitions and included initials of TP-7. Review of the Specimen Grossing Log revealed gross examinations were reviewed and signed by the LD/GS-1 and/or GS-2/TP-5. The following patient specimens were grossed without direct supervision in 2020, as required by their own written policy: Grossing date: 02/11/2020; Grossing review date: 02/17/2020 Specimen #: PHD20-0001, PHD20-0002, PHD20-0003, PHD20-0004, PHD20-0005, PHD20-0006, PHD20-0007, PHD20-0008, PHD20-0009, PHD20-0010 Grossing date: 02/12/2020; Grossing review date: 02/12/2020 Specimen #: PHD20-0011, PHD20-0012, PHD20-0013, PHD20-0014, PHD20-0015, PHD20-0016, PHD20-0017, PHD20-0018, PHD20-0019, PHD20-0020, PHD20-0021, PHD20-0022, PHD20-0023, PHD20-0024, PHD20-0025, PHD20-0026, PHD20-0027, PHD20-0028 Grossing date: 02/18 /2020; Grossing review date: 02/18/2020 Specimen #: PHD20-0029, PHD20-0030, PHD20-0031, PHD20-0032, PHD20-0033, PHD20-0034, PHD20-0035, PHD20-0036, PHD20-0037, PHD20-0038, PHD20-0039, PHD20-0040, PHD20-0041, PHD20-0042, PHD20-0043, PHD20-0044 5. During the exit interview on 05/18/2021 at 2:05 pm, TP-2 confirmed the laboratory failed to follow their own written policy for direct observation of grossing by the pathologist.
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 review of laboratory policy, patient records, and interview with staff, it was revealed that the laboratory failed to ensure the laboratory name and address for all tests performed was on the final reports for 10 of 10 patients. Findings included: 1. The laboratory policy titled, "General Instructions for Obtaining Surgical Specimens" (Signed by the laboratory director 04/22/2020), stated, "All specimens are sent to Precise Diagnostics... Specimen overflow from Precise will then be referred to Pro Health Diagnostics for routine histology..." 2. A random review of patient requisitions and patient final reports from 02/10/2020 through 02/14/2020 revealed the following 10 of 10 patients in which the test requisition form was submitted to Pro Health Diagnostics, the patient final report was issued through Precise Diagnostics, and the patient final report failed to include the name and address of the laboratory where the professional component of the test (pathologist's review of the tissue slide) was performed: Date: 02/10/2020; Patient PHD20-001 Date: 02/10/2020; Patient PHD20-003 Date: 02/10/2020; Patient PHD20-0010 Date: 02/10/2020; Patient PHD20-0013 Date: 02/10/2020; Patient PHD20-0021 Date: 02/10/2020; Patient PHD20-0024 Date: 02/14/2020; Patient PHD20-0033 Date: 02/14/2020; Patient PHD20-0035 Date: 02/14 /2020; Patient PHD20-0038 Date: 02/14/2020; Patient PHD20-0041 3. In an interview on 05/18/2021 at 1:33 pm in the breakroom, Testing Person #2 was asked if only the grossing component of testing was performed at Pro Health Diagnostics, as indicated on the patient final report. She stated that both the grossing and slide review by the pathologist were performed by Pro Health Diagnostics. After review of the patient final reports, testing person #2 confirmed that the laboratory failed to include the name and address of the laboratory to include all components of testing.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by

HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of laboratory policies, Center for Medicare & Medicaid Services (CMS) 209 form, patient test requisitions, specimen grossing review forms, and confirmed in interview, the general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were reviewed within 24 hours for 10 of 10 patient specimens in 2020 (February). Findings: 1. Review of the laboratory's policy titled "Policy# SP-107" revealed: "Specimen Grossing Review: All specimen blocks and gross descriptions from the requisitions are reviewed and verified to match by the pathologist prior to microscopic examination within 24 hours. This is documented by the pathologist on the "Specimen Grossing Review Form"". 2. Review of the CMS 209 form listed the laboratory director as the clinical consultant, general supervisor (GS), technical supervisor (TS) and testing person (TP). The form included two additional general supervisors/testing persons (GS-2/TP-5, GS-3/TP-6) who perform reading and interpretation of the slides and also included six additional testing persons (TP-2, TP-3, TP-4, TP-7, TP-8, TP-9), who performed the gross examinations of specimens received from outside clients. The laboratory director /general supervisor/technical supervisor was not onsite. GS-2/TP-5 and GS-3/TP-6 were also not onsite. TP-2, TP-3, TP-4, TP-7, TP-8, TP-9 did not qualify as general supervisors or technical supervisors, requiring review within 24 hours. Gross examination included all documented physical examination/descriptions including measurement of the specimen. 3. During an interview on 05/18/2021 at 10:17 am, TP-2 stated that grossing was reviewed by the pathologists (general supervisors) when they would come into the laboratory to pick up slides. She stated that the pathologist would review the grossing by reviewing the specimen blocks. 4. Review of patient test requisitions revealed gross examinations were documented on the requisitions and included initials of TP-7. Review of the Specimen Grossing Log revealed gross

	examinations were reviewed and signed by the LD/GS-1 and/or GS-2/TP-5. There was no documentation of the TS/GS review of the specimen blocks within 24 hours of the gross examinations for TP-7. The following patient specimens were not reviewed within 24 hours in 2020 as required: Specimen #: PHD20-0001 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17/2020, indicating review of grossing. Specimen #: PHD20-0002 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17/2020, indicating review of grossing. Specimen #: PHD20-0003 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17 /2020, indicating review of grossing. Specimen #: PHD20-0004 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17/2020, indicating review of grossing. Specimen #: PHD20-0005 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17/2020, indicating review of grossing. Specimen #: PHD20-0006 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17 /2020, indicating review of grossing. Specimen #: PHD20-0007 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17/2020, indicating review of grossing. Specimen #: PHD20-0008 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17/2020, indicating review of grossing. Specimen #: PHD20-0009 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17 /2020, indicating review of grossing. Specimen #: PHD20-0010 Test requisition date received: 02/10/2020, test requisition included grossing examination, TP-7 initials and date (02/11; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 02/17/2020, indicating review of grossing. The laboratory did not ensure specimen blocks were reviewed and documented within 24 hours by the TS /GS, as required. 5. During an interview on 05/18/2021 at 10:17 am, TP-2 confirmed the above findings.