Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2105916	**(X3) Date Survey Completed** 08/22/2023
Name of Provider or Supplier Pro Health Diagnostic, Llc	**Street Address, City, State** 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on laboratory policy, patient requisitions and confirmed in interview, the laboratory failed to confirm the specimen source was included on the patient requisitions prior to patient specimen processing for 33 of 35 patients tested in June 2023. Findings Included: 1. Review of laboratory policy, "Criteria for Rejection of Unacceptable Specimens" (Approved by the Laboratory Director on 04/11/2023) revealed the following: "Criteria For Rejections: ...Improper labeling or absence of requisitions 1. Lack of Surgical Pathology Requisition 2. Improperly completed requisition/order" 2. Random review of patient requisitions received in June 2023,

	revealed the following 33 of 35 improperly completed patient requisitions that failed to include a specimen source: June 2023 Patient Accession Numbers: PHD23-0176; PHD23-0177; PHD23-0178; PHD23-0179; PHD23-0219; PHD23-0222; PHD23-0224; PHD23-0226; PHD23-0227; PHD23-0228; PHD23-0229; PHD23-0230; PHD23-0238; PHD23-0239; PHD23-0240; PHD23-0242; PHD23-0243; PHD23-0244; PHD23-0248; PHD23-0251; PHD23-0252; PHD23-0253; PHD23-0254; PHD23-0255; PHD23-0256; PHD23-0257; PHD23-0258; PHD23-0259; PHD23-0260; PHD23-0263; PHD23-0265; PHD23-0268; PHD23-0269 3. During an interview on 08/22/2023 at 01:20 p.m., in the facility break room with the office manager, the office manager confirmed the above findings.
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 policy, validation records, and confirmed in staff interview, the laboratory failed to follow its own written policy for performing a validation study on 1 of 1 tissue processors in 2023. Findings included: 1. Review of the laboratory's policy titled "Tissue Processor" revealed: "QUALITY CONTROL: A validation will be performed any time a new processor is put in place, there is an equipment failure, or if there is a change in a processing program. See Processor Validation." 2. Review of the laboratory's validation records revealed the laboratory did not perform a validation study on the laboratory's Tissue Tek VIP tissue processor Serial number 52150394. The laboratory was asked to provide a validation study, and none was provided. 3. During an interview on 08/22/2023 at 12:32 pm, the Laboratory Consultant after review of records confirmed the laboratory failed to perform a validation study on their tissue processor.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instruction, and confirmed in staff interview, the laboratory failed to follow the manufacturer's instructions for covering 1 of 1 microscope when not in use in 2023 (August). Findings included: 1. During a tour of the laboratory's processing room on 08/22/2023 at 12:15 pm, the surveyor observed a Labomed CxL microscope uncovered on a table next to the fume hood. 2. Review of the Labomed CxL microscope user' manual revealed: "2 Maintenance and Storage ... 4. When not using them microscope, ensure the frame is fully cooled and store the unit in a dry locker or cover with a dust cover (provided)." The laboratory failed to follow the manufacturer's instructions for covering the

	microscope when not in use. 3. During an interview on 08/22/2023 at 1:28 pm, the Laboratory Consultant confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's maintenance policy, manufacturer's instructions, maintenance records and confirmed in interview, the laboratory failed to ensure annual maintenance was performed for 1 of 1 Tissue-Tek VIP tissue processor 1 of 1 Leica Autostainer XL, 1 of 1 Leica CV5030 coverslipper, 1 of 1 Leica EG 1150c embedder, 1 of 1 Tissue-Tek TEC embedder, 2 of 2 Bockel ovens, 2 of 2 Reichert-Jung microtomes, 1 of 1 Avantik 630 fume hood, and 1 of 1 Labomed CxL microscope (utilized in histopathology testing) that is necessary for accurate and reliable test results for 2023. Findings included: 1. During a tour of the laboratory on 08/22/2023 at 11:59 am, the following was observed to be stored and ready for use: Staining Room: Tissue-Tek VIP (Serial #52150394) labeled with a preventative maintenance (PM) sticker "Medical Equipment Source - PM (was checked off as completed), Date: 5/17/22, Next Due: 5/17/23" Leica Autostainer XL (Serial #XL01041) labeled with a preventative maintenance (PM) sticker "Medical Equipment Source - PM (was checked off as completed), Date: 4/13/22, Next Due: 4 /13/23" Leica CV5030 cover slipper (Serial #2215107.201) labeled with a preventative maintenance (PM) sticker "Medical Equipment Source - PM (was checked off as completed), Date: 4/13/22, Next Due: 4/13/23" Microtomy Room: Leica EG 1150c embedder (Serial #3346) labeled with a preventative maintenance (PM) sticker "Medical Equipment Source - PM (was checked off as completed), Date: 4/13/22, Next Due: 4/13/023" Tissue-Tek TEC embedder (Serial #51010401) labeled with a preventative maintenance (PM) sticker "Medical Equipment Source - PM (was checked off as completed), Date: 4/13/22, Next Due: 4/13/23" Bockel oven labeled with a preventative (PM) sticker "Orion - electrical safety check and PM were checked off as completed), Date illegible. There was another PM sticker under the first PM sticker labeled: "Electrical Safety Test- Pass Date: 4/13/22; Next Due: 4/13 /23 Reichert-Jung Microtome #1 (Serial #304119) labeled with a preventative maintenance (PM) sticker "Medical Equipment Source - PM (was checked off as completed), Date: 5/18/22, Next Due: 5/18/23" Reichert-Jung Microtome #2 (Serial #152853) labeled with a preventative maintenance (PM) sticker "Medical Equipment Source - PM (was checked off as completed), Date: 4/13/22, Next Due: 4/13/23" Specimen Processing Room: Labomed CxL microscope labeled with a preventative maintenance (PM) sticker "micronix - Date: 10/30/2015, Next Due: 10/30/2016" Avantik 630 fume hood, labeled with a preventative (PM) sticker "Electrical Safety Test- Pass Date: 4/13/22; Next Due: 4/13/23 Bockel oven labeled with a preventative (PM) sticker "Electrical Safety Test- Pass Date: 4/13/22; Next Due: 4/13/23 2. Review of the laboratory's policy titled "Tissue Processor" revealed: "MAINTENANCE ... 4. The annual PM and maintenance are performed. All issues and maintenance

	performed are documented on the Equipment Maintenance History log along with a copy of the invoice." 3. Review of Labomed CxL microscope user's manual revealed: "4 Care and Maintenance ... 4. Periodical checking: To maintain the performance of the instrument, we recommend customers have their microscopes serviced periodically by a factory authorized dealer/rep. For details, contact your nearest dealer or Labo America's main office in California." 4. Review of the laboratory's maintenance logs for May 2023 revealed: Leica Autostainer XL log: "Preventative Maintenance (annually due by 4/13)" A handwritten note dated 06/14/2023 by the laboratory director stating: "NEED PM ASAP. Discussed with [XX] & [XX]." Leica CV5030 log: "Preventative Maintenance (annually due by 4/13)" A handwritten note dated 06/14/2023 by the laboratory director stating: "NEED PM ASAP! Discussed with [XX] & [XX]." Leica EG 1150C log: "ANNUAL PREVENTATIVE MAINTENANCE: Due NOW" A handwritten note dated 06/14/2023 by the laboratory director stating: "NEED PM ASAP. Discussed with [XX] & [XX]." Boekel Oven Log: "Annual PM completed: Now Due" Handwritten notes dated 06/14/2023 by the laboratory director stating: "Need PM!" "NEED PM ASAP! Discussed with [XX] & [XX]." Microtome #1/ Water Bath Log: "Annual PM performance date: Now Due" A handwritten note dated 06/14/2023 by the laboratory director stating: "Need PM ASAP! Discussed with [XX] & [XX]." Microtome #2 / Water Bath Log: "Annual PM performance date: 5/18/22" A handwritten note dated 06/14/2023 by the laboratory director stating: "NEED PM ASAP! Discussed with [XX] & [XX]." Avantik Biogroup Fume Hood Log: "Annual PM completed: Now Due" A handwritten note dated 06/14/2023 by the laboratory director stating: "NEED PM ASAP! Discussed with [XX] & [XX]." 5. During an interview on 08/22/2023 at 1:28 pm, the Laboratory Consultant confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy manual, CMS (Centers for Medicare and Medicaid Services) form 209, personnel records, and interview with staff, the Technical Supervisor (TS-1) failed to evaluate initial competency of 1 of 3 testing persons (TP-3) responsible for high complexity testing in 2023. Findings Included: 1. Review of laboratory policy manual revealed the following job description signed by TS-1 on 03/03/2020, "Job Category: Technical Supervisor; Department/Group: Pro Health Diagnostics Job Description: Manage periodic activities in lab 1. Identifying training needs and providing in-service training and education 2. Evaluating competency of all testing personnel 3. Evaluating and documenting the performance of individuals responsible for high complexity testing." 2. Review of the CMS 209 form submitted at time of survey, revealed 1 Technical Supervisor (TS-1) and 3 Testing Personnel (TP-1, TP-2, TP-3) performing high complexity testing. 3. Review of TP-3 personnel forms revealed an initial competency performed on 02/17/2023, by TP-2. The Technical Supervisor failed to evaluate initial competency of 1 of 3 testing persons (TP-3) responsible for high complexity testing in 2023. 4. During an interview on 08/22/2023 at 01:20 p.m., in the facility break room with the office manager, the office manager confirmed the above findings.

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 CMS (Center for Medicare & Medicaid Services) 209 form submitted at time of survey, laboratory policy, laboratory specimen grossing review forms, patient requisitions and confirmed in interview, the general supervisor failed to ensure complete gross examinations for patient specimens performed by testing persons, were reviewed within 24 hours for 82 of 82 randomly reviewed patient specimens grossed in May 2023. Findings Included: 1. Review of the CMS 209 form listed the laboratory director as the clinical consultant, technical supervisor (TS), and general supervisor (GS). The 209 included three testing persons (TP-1, TP-2 and TP-3) who performed the gross examinations of specimens received in the laboratory. The laboratory director/ technical supervisor/ general supervisor was not onsite. TP-2 and TP-3 did not qualify as a technical supervisor or general supervisor, requiring gross review within 24 hours. 2. Review of laboratory policy, "Histotechnologist Training for Macroscopic Evaluation" (Approved by the Laboratory Director on 06/14 /2023) revealed the following: "Specimen Grossing Review: Gross descriptions from the requisitions are reviewed by a pathologist prior to microscopic examination within 24 hours, excluding holidays and weekends. All requisitions are scanned and emailed to the medical director. This is documented by the pathologist on the "Specimen Grossing Review Form"." 3. Review of laboratory specimen grossing review forms, revealed the following statement: "All specimen gross descriptions have been reviewed in 24 hours, excluding weekends and holidays, by the General Supervisor /Technical Supervisor prior to microscopic examination." Also contained on the form was a section for the General Supervisor's acknowledgement/signature to the above statement. The surveyor inquired on 08/22/2023 at 11:55 a.m., in the facility break room with the office manager, as to what information the GS received when reviewing patient specimen grossing. The office manager stated the GS only received the patient requisition with the grossing description, and the grossing review form. No other documentation was provided to the GS for review. The general supervisor failed to ensure complete gross examinations for patient specimens performed by testing persons, were reviewed within 24 hours for 84 of 84 patient specimens grossed in May and June 2023. 4. Review of patient final reports revealed the following patients grossed in May 2023 that did not have review within 24 hours of grossing: May 2023 a. Date Grossed by TP-3: 05/04/2023; Accession Numbers: PHD23-0017; PHD23-0018; PHD23-0019; PHD23-0020; PHD23-0021; PHD23-0022; PHD23-0023; PHD23-0024; PHD23-0025; PHD23-0026; PHD23-0027; PHD23-0028; PHD23-0029 b. Date Grossed by TP-3: 05/08/2023; Accession Numbers: PHD23-0042; PHD23-0043; PHD23-0044; PHD23-0045; PHD23-0046; PHD23-0047; PHD23-0048; PHD23-0049; PHD23-0050 c. Date Grossed by TP-3: 05/09/2023; Accession Numbers: PHD23-0053; PHD23-0054; PHD23-0055; PHD23-0056; PHD23-0057; PHD23-0058; PHD23-0060; PHD23-0061; PHD23-0062; PHD23-0063; PHD23-0064 d. Date Grossed by TP-3: 05/11/2023; Accession Numbers: PHD23-0059; PHD23-0065; PHD23-0066; PHD23-0070; PHD23-0071; PHD23-0072; PHD23-0073; PHD23-0074; PHD23-0075 e. Date Grossed by TP-3: 05/17/2023; Accession Numbers: PHD23-0086; PHD23-0087; PHD23-0088; PHD23-0089; PHD23-0089; PHD23-0090 f. Date Grossed by TP-3: 05/18/2023; Accession Numbers: PHD23-0095; PHD23-0096; PHD23-0097; PHD23-0098; PHD23-0099; PHD23-0100 g. Date Grossed by TP-3: 05/22/2023; Accession Numbers: PHD23-0108; PHD23-0109; PHD23-0110; PHD23-0111 h. Date Grossed by TP-3: 05/23/2023; Accession Numbers: PHD23-0112; PHD23-0113; PHD23-0114; PHD23-0115; PHD23-0116; PHD23-0117; PHD23-0118; PHD23-0119; PHD23-0120 i. Date Grossed by TP-3: 05 /26/2023; Accession Numbers: PHD23-0121; PHD23-0122; PHD23-0123; PHD23-0124; PHD23-0125; PHD23-0126 j. Date Grossed by TP-3: 05/31/2023; Accession

	Numbers: PHD23-0127; PHD23-0128; PHD23-0129; PHD23-0130; PHD23-0131; PHD23-0132; PHD23-0133; PHD23-0134; PHD23-0135 5. During a phone interview with the Laboratory Director/GS on 08/22/2023 at 11:58 a.m., the GS stated the only documentation reviewed for grossing were the patient requisitions with gross descriptions. No other information, including digital images, was provided of the grossing. This confirmed the above findings.