Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2105916	09/10/2018
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Revisit 09/04/2018 New Deficiency. Based on review of the laboratory's policy, "QUALITY ASSURANCE PROFICIENCY TESTING PATHOLOGY" records, and confirmed in interview, the laboratory failed to ensure accuracy was verified for histopathology in 08/2018 (not included in subpart I of this part). Findings included: 1. Review of the laboratory's policy "PROFICIENCY TESTING PROGRAM (IN-HOUSE)" stated, "Every 6 months, the histotechnologists will pick a case that has already been reported and will send all slides for review to a Doctor, the histotechnologist needs to put the complete Doctor's name and address. Upon receipt of the pathology report from the Doctor, diagnosis of the slide specimen will be matched to the in-house diagnosis by Laboratory Director. If diagnosis match, the reports are attached and placed in the proficiency testing section of the Quality Control Log." 2. Review of "QUALITY ASSURANCE PROFICIENCY TESTING PATHOLOGY" record dated 08/24/2018 included review for Case #PHD18-3803. The record stated, "Enclosed is a case randomly selected from biopsy case diagnosed during the month of August. I am requesting your professional evaluation to verify diagnosis made by my in-house pathologist as well as the quality of work performed by my lab personnel." Slides (#1, 2, 3, 4) were sent to an outside pathologist for review and included the pathologist documentation of "Diagnosis: Negative/agree..." and at the bottom of the record the comment "Agree with results: Yes" was circled. This included the outside pathologist signature/date (08/30/2018) and above it included the Chief Operating Officer's (COO) signature/date (08/24/2018) ("Dr" beneath the signature was crossed out). This record did not include the laboratory

	director's signature, who is responsible for the QA program [CFR 493.1445(e)(5)] and was the "in-house" pathologist (who was also the technical supervisor, general supervisor and testing person). Note: The COO was not listed on the CMS 209, was not the "in-house" pathologist who made the diagnosis and the COO does not have pathologist credentials. 3. During an interview on 09/04/2018 at 10:55 am, Testing Person - 2 was asked about the process for submitting the slides to an outside pathologist (for QA/PT), she stated, "The slides are submitted to Dr (name), sent with the diagnosis and will document if there is agreement." The laboratory did not ensure slides without the diagnosis (answer to slides) were submitted to ensure verification of accuracy of all histopathology processes performed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Revisit 09/04/2018 New Deficiency. Based on review of quality control logs, laboratory occurrence reports and confirmed in interview, the laboratory failed to document corrective actions taken when patient slides were not within acceptable limits for 11 patients in 06/2018 and 07/2018. Findings included: 1. The laboratory's practice was processing specimens (toenails) and preparing/staining slides to send for interpretation and diagnosis by pathologists read off-site (Greenville, TX). "Histology Quality Control Log" records accompanied groups of patient slides. 2. Review of the "Histology Quality Control Log" records from 06/2018 and 07/2018 revealed the following: 06/06/2018 - "CASE #'S" included "PH18-2811A" and a documented comment, "No coverslip." 06/11/2018 - "CASE #'S" included "2596 A, D" and a documented comment, "Suboptimal stain." 07/09/2018 - "CASE #'S" included "3278, 3289, 3787, 3234, 3235, 3252, 3253, 3264" and a documented comment, "green contrast has to be more prominent (washed off stain)" and for "CASE #'S" "slides 3253,3254, 3255, 3256A" with a documented comment, "are very pale." 07/09/2018 - "CASE #'S" included "PD18:0001-0007" and a documented comment, "suboptimal sectioning - quality" and at bottom of record stated, "Notes: quality of sections are suboptimal especially cases .01 .03, thick, many folds and many shatters." The above records were returned from the pathologists who read the slides off-site. The laboratory did not document corrective actions taken for the above problems. 3. Review of a "Laboratory Occurrence Report" included patient specimen demographics, "Corrective Action," and the following: "_Tissue poorly oriented _Slides and/or blocks incorrectly numbered _Requisitions and slides and/or blocks do not match _Stain needed to be repeated due to performance _Gross needed to be repeated due to poor performance _Specimens measurements entered incorrectly _Specimen lost during processing _Tissue placed in wrong fixative/bottle size _Specimen gross measurement missing _Specimen container(s) improperly labeled _Specimen container(s) received empty _Specimen measurements entered incorrectly

	_Other:" "CORRECTIVE ACTION LOG" documents were blank for 06/2018 and 07 /2018. Other Corrective action forms were part of their QA plan. The laboratory did not have documentation of "Laboratory Occurrence Report" records or correction action forms for 06/2018 and 07/2018. 4. During an interview on 09/04/2018 at 3:15 pm, Testing Person - 4 was asked for documented corrective actions taken for the problems identified, documentation of corrective action taken was not provided.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Revisit 09/04/2018 New Deficiency. Based on review of laboratory's policy, temperature records and confirmed in interview, the laboratory failed to document corrective actions taken when room temperatures were not within the defined range for 8 of 46 documented days (07/2018 and 08/2018) and when equipment temperatures were not within defined range for 10 of 38 documented days (08/2018) to ensure quality laboratory services. Findings included: 1. Review of the laboratory's policy for temperatures stated, "If the temperature is found to be out of control, corrective action must be taken and documented. Temperatures must be checked and written on the corresponding daily log sheet. 1. Room Temperature...3. Instrument Dependent on Regulated Temperatures...Normal instrument temperatures ranges are as follows:...5. Embedding Center: 68 +1-2 Celsius 6. Cold Plate: -5 Celsius." The embedding center log was not consistent with the policy (Fahrenheit versus Celsius). 2. Review of the room temperature and embedding center temperature (paraffin chamber & hot plate, cold plate) records for 07/2018 and 08/2018 revealed the laboratory did not document corrective actions taken for the following days temperatures were not within range: Embedding Center ("68 degrees +/- 2 degrees Fahrenheit [a line was drawn through "Celsius"] for Paraffin Chamber & Hot Plate"): 08/21/2018: 60 08/22/2018: 60 08/23/2018: 60 08/24/2018: 60 08/27/2018: 65 08/28 /2018: 65 All temperatures were circled. Embedding Center (-5 degrees Celsius for Cold Plate): 08/22/2018: -6 08/23/2018: -7 08/27/2018: -6 08/29/2018: -6 Archival Room Temperature (20-25 degrees Celsius): 07/20/2018: 26.5 07/30/2018: 19.8 07/31 /2018: 19.4 08/01/2018: 19.5 08/02/2018: 19.4 08/03/2018: 19.5 08/06/2018: 19.7 08 /10/2018: 19.8 3. During an interview on 09/04/2018 at 11:00 am, Testing Person - 2 was asked for documentation of corrective actions taken for the above temperatures not within range, documentation could not be provided.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Revisit 09/04/2018. New Deficiency. Based on review of laboratory's policies, corrective action records, temperature charts, and quality control logs, the laboratory

	director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics were identified, as evidenced by: 1. The laboratory failed to document corrective actions taken when patient slides were not within acceptable limits for 11 patients in 06/2018 and 07/2018. Refer to D5781. 2. The laboratory failed to document corrective actions taken when room temperatures were not within the defined range for 8 of 46 documented days (07/2018 and 08/2018) and when equipment temperatures were not within defined range for 10 of 38 documented days (08/2018) to ensure quality laboratory services. Refer to D5785.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Revisit 09/04/2018 New Deficiency. Based on review of the CMS 209, personnel records and in interview with staff, the laboratory director did not specify, in writing, the responsibilities and duties of each consultant, as well as each person engaged in the performance of all phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, and whether supervisory review is required, as evidenced by: Findings included: 1. Review of the CMS 209 form listed the consultant as Testing Person - 2 (who was crossed out), who performs grossing for all specimens received. According to the consultant on 09/04/2018 at 10:00 am, she began working for the laboratory 01/2018 and her and Testing Person -3 were the ones grossing specimens. Note: The laboratory never submitted a CMS 209 form signed by the laboratory director, as requested and required. 2. Review of Testing Person -2 "JOB RESPONSIBILITIES" included duties of "Performing the 'Gross Procedure' and other specimen processes. This was signed by Testing Person - 2 and dated 04/27/2018, but not signed by the laboratory director. Note: Testing Person - 2/consultant would require review of gross examinations within 24 hours by the qualifying general supervisor/technical supervisor (who is not onsite). Review of Testing Person - 4 (histology manager; started 07/2018) records did not include written duties and responsibilities by the laboratory director. The laboratory director did not specify, in writing, the responsibilities and duties of each consultant, as well as each person engaged in the performance of all phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, and whether supervisory review is required.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case,

	prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Revisit 09/04/2018 New Deficiency. Based on review of the laboratory's policy, CMS 209 form and personnel records, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity (gross examinations) testing at least annually after the first year for 1 of 4 Testing Persons (TP-3). Findings included: 1. Review of the laboratory's policy stated, "Laboratory Manager/Supervisor: 1) Ensures that there are sufficient personnel with adequate documented training and experience to meet the needs of the laboratory." According to CFR 493.1445(e)(11), this is the responsibility of the laboratory director, not the "Laboratory Manager/Supervisor." The policy also stated, "Laboratory Manager /Supervisor: 2) Develops and administers a competency evaluation for testing personnel...3) Assesses and evaluates competency evaluations for testing personnel which includes the following criteria..." The policy on competency included all required components. 2. Review of the CMS 209 form listed TP-3 as one who performs grossing for all specimens received. 3. Annual competency record for TP-3 was filled and dated 08/28/2018 and signed by TP-4 (histology manager), not the laboratory director/technical supervisor. The technical supervisor failed to evaluate and document the performance of TP-3 responsible for high complexity (gross examinations) testing.