Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2117103	07/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Innovative Health Labs	9755 Patuxent Woods Dr, Ste 100, Columbia, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the laboratory supervisor, the laboratory did not ensure that the all PT records were being saved, PT summary's were being reviewed and that PT samples were tested in the same manner at the patients. Findings: 1. The PT records from 2017 and 2018 (4 events) were reviewed. The events included PT for Chemistry- Core, Chemistry- Miscellaneous, Immunology and Hematology. 2. The PT records from the first event of 2017 did not include instrument printouts for the Chemistry- Miscellaneous event, there was no documented review of Immunology kits 1 and 2, and the Hematology instrument printouts showed that 4 of 5 PT specimens had been tested in duplicate. 3. The PT records from the second event of 2017 did not include instrument printouts, attestation sheet and PT worksheet for the Chemistry- Core event and no instrument printouts for the Immunology event. 4. The PT records from the third event of 2017 did not include the instrument printouts, attestation sheet, PT worksheet and documented review of the summary sheet for the Chemistry Miscellaneous event and the Hematology instrument printouts showed that 5 of 5 PT specimens had been tested

	in duplicate. 5. The PT records from the first event of 2018 did not include the instrument printouts, attestation sheet, PT worksheet and documented review of the summary sheet for the Hematology event and there were no instrument printouts and no documented review of the summary sheet for the Immunology event. 6. During the survey on 07/10/2018 at 11:30 AM the laboratory supervisor confirmed that instrument printouts, attestation sheet, PT worksheet and documented review of the summary sheet for the multiple events were not available and that the Hematology PT specimens had periodically been tested in duplicate and not tested in the same manner as patient specimens.
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 review of the hematology records and interview with the new technical consultant, the laboratory did not follow the manufacturer's instructions for calibration of the AcT 5diff AL (hematology analyzer). Findings: 1. The manufacturer's instructions require the user to calibrate the hematology analyzer every six months. 2. The technical consultant explained that the hematology analyzer holds the documentation of the calibrations in the "Calibration Logs" file on the analyzer. When the "Calibration Logs" file on the analyzer was viewed the actual calibration was labeled "Supervisor." The new technical consultant explained that the analyzer had been calibrated on 05/19/17 and 08/01/17. 3. There were no other records within the hematology analyzer showing that the calibration had been performed since 08/01/17. 4. During the survey on 07/10/18 at 11:30 AM the new technical consultant confirmed that the analyzer had not been calibrated every six months as required by the manufacturer.
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 patients final reports and interview with the supervisor, the laboratory did not ensure that the final test report listed the name of the laboratory listed on the CLIA certificate. Findings: 1. The name of the laboratory listed on the CLIA certificate is "Matsunaga Pain Management, LLC." Review of the final patient reports shows that the name of the laboratory is "Innovative Health Labs." 2. During

	the survey on 07/10/18 at 11:30 AM the laboratory supervisor confirmed that the final reports did not include the name of the laboratory listed on the current CLIA certificate.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A. Based on review of the quality control (QC) records and interview with the new technical consultant, the laboratory director did not ensure that the chemistry controls were verified from lot to lot per the policy and procedure manual. Findings: 1. The "Quality Control" procedure states "New lots of QC products are obtained with sufficient lead-time to complete product evaluation in parallel with current lot." and "Using current calibration method, analyze each new lot of assayed quality control material (minimum of n = 6) over at least two analytical events. Calculate the mean, standard deviation (SD) and coefficient of variation (%CV) for each new quality control material." 2. The chemistry department uses 3 different sets of QC materials. Each set was started on the following dates: 07/13/17, 06/19/17, and 06/25/17. All 3 sets of QC materials were started after the initial CLIA survey conducted on 03/29/17. 3. During the survey on 07/10/18 at 11:30 AM the new technical consultant confirmed that there was no documentation showing that the 3 sets of new chemistry controls had each been tested 6 times in parallel per the procedure with old lots prior to being used for patient testing. B. Based on review of the QC records and interview with the new technical consultant, the laboratory director did not ensure that the pipette calibrations were performed every six months per the policy and procedure manual. Findings: 1. The "Pipette Calibration & Maintenance" procedure states "All pipetting devices used for quantitative analytical work shall be calibrated before being placed into service, then every 6 months or whenever maintenance is required." 2. When the surveyor asked to review the pipette calibration records the new technical consultant stated that the pipettes were not calibrated. Instead of calibration the laboratory decided to purchase new pipettes. 3. During the survey on 07/10/18 at 11:30 AM the new technical consultant confirmed that there was no documentation showing that the pipettes had been calibrated every 6 months per the "Pipette Calibration & Maintenance" procedure. C. Based on review of the quality assurance (QA) records and interview with the new technical consultant, the laboratory director did not ensure that the monthly maintenance was reviewed and monthly QA records were maintained per the policy and procedure manual. Findings: 1. Review of the monthly analyzer maintenance records for 2017 and 2018 showed that the records were not documented as having been reviewed for the monthly of September, October and November 2017. 2. Review of the monthly "Quality Management Meeting Minutes" for 2017 and 2018 showed that the monthly of April, May and June of 2017 and the month of March 2018 were missing from the binders. 3. During the survey on 07/10/18 at 11:30 AM the new technical consultant confirmed that the monthly analyzer maintenance records and the "Quality Management Meeting Minutes" were not available at the time of the survey.

D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the competency assessment of the new technical consultant and interview with the laboratory supervisor, the laboratory director did not ensure that the competency assessment for the new technical consultant had been completed prior to performing patient testing. Findings: 1. Review of the "Competency Checklist for AC*T 5 Diff AL" (hematology analyzer) showed that the following tasks had not been completed: identify and briefly explain function of analyzer components, overview of screens and software, management reagents and consumables, Startup & Shutdown procedures, QA/QC procedures (7 of 12 tasks), and process samples (10 of 10 tasks) and perform system reset cycle. 2. Review of the "Competency Checklist AU 480 Chemistry Analyzer" showed that the following tasks had not been completed: load ISE reagents, Assign a reagent to fixed position, and Maintenance (7 of 8 tasks). 3. The new technical consultant stated that the her training started in March 2018 but she did not start working until April 2018. 4. During the survey on 07/10/18 at 11:30 AM the laboratory supervisor confirmed that the training of the new technical consultant had not been completed prior to performing patient testing.