Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2117103	06/10/2021
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that the laboratory director (LD) signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of Chemistry-Miscellaneous PT records from 3 events in 2019 showed that the LD did not sign the attestation statement from the 2nd PT event; and 2. A review of Immunology PT records from 3 events in 2020 showed that the LD did not sign the attestation statement from the 3rd PT event. 3. During an interview on 6/10/2021 at 11:30 AM, the TC confirmed that the attestation statements were not signed by the LD.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on record review and interview with the technical consultant, the laboratory failed to document all components of the investigation of failed proficiency testing (PT) results and the corrective actions taken to prevent recurrence of PT failures (D5221).
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to document all components of the investigation of failed proficiency testing (PT) results and the corrective actions taken to prevent recurrence of PT failures. Findings: 1. The laboratory received a score of 50% on General Immunology PT for the analyte C-reactive protein (CRP) performed during the 2nd event of 2020. The corrective actions documented on the "Proficiency Testing Performance Evaluation" form stated, "The quantity of PT specimen does not allow for repeat testing. In future I will ensure that CRP is calibrated w/in 10 days of API testing". The documentation did not indicate if CRP calibrations or quality control had been acceptable around the time of the PT, or if patient results had been affected. 2. The laboratory received a score of 50% on General Immunology PT for CRP performed during the 3rd event of 2020. 3. In an email from 5/20/2021 the TC stated that after this most recent PT failure the laboratory had consulted Beckman Coulter (the instrument manufacturer) concerning the problem with CRP PT results and that a technician had found that "the lot number of the calibrator had not been changed in the proper place." The TC provided a letter dated 5/27/2021 from the "Complaints Handling Unit" at Beckman Coulter which stated, "After reviewing the provided data, it was determined that the incorrect calibrator set points was being used. The calibrator that the operator was using was ODC0026 Lot#1060A but the set points for the Non-Latex calibrator ODR3021 was loaded. The issue was resolved after updating the set points to the ODC0026 Lot#1060A." 4. During a phone interview on 6/10 /2021 at 11:30 AM the TC stated that the service technician had told them that patient results "would be off by about 2%." 5. PT record review showed that there was nothing written under "Performance Review and Corrective Action" on the "Proficiency Testing Performance Evaluation" form for this event, and that there was no documentation of the steps taken to correct the problem or of an investigation being performed to evaluate whether patient results had been affected by this issue. 6. During an interview on 6/10/2021 at 11:30 AM, the TC confirmed that the laboratory had failed to document all corrective actions taken for the failed PT.
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 procedure manual and quality control (QC) record review and interview

	with the technical consultant (TC), the laboratory did not follow written procedures for performing quality assurance. Findings: 1. The procedure "Quality Management Plan," "9.1 Quality assurance monitors" states, "9.1.4. On a quarterly basis, a small sampling of calculated test results will be reviewed for accuracy." In an email from 5/20/2021, the TC stated, "This has actually been revised/removed from SOP as of 6/20/2018." 2. Procedure manual review showed that the "Quality Management Plan" procedure containing this information had been approved by the laboratory director on 2/25/2021. 3. Section 9.3.7., "Process Verification" in the same procedure states, "A quarterly review of at least 1 random accession numbers (from a Positive specimen) will be performed to document any deviations from established policy. This is a system whereby the entire test process can be recreated through document review for purposes of substantiating the reported test finding." When asked in an email for documentation of this process, the TC stated on 5/20/2021 that "This is not being performed." 4. The procedure "Quality Control" states, "New lots of QC products are obtained with sufficient lead-time to complete product evaluation in parallel with current lots" and "Using current calibration method, analyze each new lot of assayed quality control material (minimum of n=6) over at least two analytical events." 5. A review of QC records from 2019 and 2020 did not show documentation that parallel testing had been performed with the new lot number of chemistry QC. 6. In an email response on 5/20/2021 to questions posed on 4/28/2021, the TC stated, "Unfortunately, I did not run parallel studies in 2020, when the new lot was brought in." 7. During an interview on 6/10/2021 at 11:30 AM, the TC confirmed that the written procedure manual did not accurately reflect the actual practice of the laboratory.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that PT results are returned within the timeframes established by the PT program. Findings: 1. PT record review showed that the laboratory scored 0% in hematology for the 1st event of 2020. 2. During a phone interview on 2/10/2021 at 2:30 PM, the TC stated that the laboratory had "missed the deadline to send results in." 3. During an interview on 6/10/2021 at 11:30 AM, the TC confirmed that the LD failed to ensure that PT results were returned before the deadline.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory director (LD) did not ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. A review of PT records from 2019 to 2020 showed that the PT "Performance Evaluation" form which reports the results of PT was not reviewed and signed by the LD for 2 of 4 events for Chemistry-Miscellaneous PT in 2019 and 2020, and for 1 of 3 events for Immunology PT in 2020. 2. During an interview on 6/10/2021 at 11:30 AM, the TC confirmed that the PT results reports were not reviewed and signed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective actions.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with technical consultant, the laboratory director did not ensure that corrective action was taken and documented for failed immunology PT for the 3rd event of 2020. Cross refer to D5221