Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0722940	07/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Med Now Inc	2709 Airport Rd Suite 101, Dalton, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on July 2, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD did not sign the 2019 Hematology Third Event attestation statement. 2. An interview with the laboratory supervisor in her office on 7/2/2019 at approximately 12:00 p.m. confirmed the LD did not sign the aforementioned attestation statement. REPEAT DEFICIENCY
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 proficiency test (PT) document review and staff interview, the laboratory failed to maintain copies of all PT documents as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed there was not a 2019 Hematology first event attestation statement available at the time of the survey. 2. An interview with the laboratory supervisor in her office on 7/2/2019 at approximately 10:00 a.m. confirmed that there was no attestation statement available at the time of survey for the aforementioned PT event.
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 the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to follow the policies and procedures as required. Findings include: 1. SOP review revealed the policy and procedure was not followed for 2017, 2018 and 2019 thus far for the laboratory director/technical consultant's (LD /TC) duties and responsibilities. 2. An interview with the laboratory supervisor in her office on 7/2/2019 at approximately 12:00 p.m. confirmed the LD/TC duties and responsibilities policy and procedure in the SOP were not followed for 2017, 2018, and 2019 thus far.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of proficiency test documents, review of testing personnel documents, and staff interview, the laboratory director/technical consultant (LD/TC) failed to provide overall management and direction of the laboratory as required. Findings include: For details refer to D2009, D6004, and D6018
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review, proficiency test (PT) document review, and staff interview, the laboratory director/technical consultant (LD/TC) failed to delegate TC duties and responsibilities to qualified TP as required. Findings include: 1. Review of TP competency documents revealed 2019 initial training competencies for Staff #3 (CMS 209) and Staff #6 (CMS 209) were performed by unqualified TP due to lack of educational qualifications. 2. American Proficiency Institute (API) PT document review revealed an unqualified TP (due to lack of educational qualifications) signed the attestation statement for the 2017 Hematology third event instead of the LD/TC. 2. An interview with the laboratory supervisor in her office on 7/2/2019 at approximately 12:00 p.m. confirmed the aforementioned initial competencies were performed by unqualified TP due to lack of educational qualifications. During the same interview, the laboratory supervisor confirmed an unqualified TP signed the aforementioned PT attestation statement instead of the LD /TC. REPEAT DEFICIENCY
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 test (PT) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to review all PT reports received as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD/TC failed to review the PT reports for the following Hematology PT events: 2018 -- Events two and three; 2019 -- Event one. 2. An interview with the laboratory supervisor in her office on 7/2/1019 at approximately 12: 00 p.m confirmed the LD/TC did not review the aforementioned PT reports. REPEAT DEFICIENCY
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to evaluate and document annual TP performance as required. Findings include: 1. TP competency document review revealed the LD/TC did not perform an annual competency for Staff #4 (CMS 209) in 2018. 2. An interview with the laboratory supervisor in her office on 7/2/2019 at approximately 12:00 p.m. confirmed the LD/TC did not perform an annual competency in 2018 for the aforementioned TP.