Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0399855	(X3) Date Survey Completed 11/21/2018
Name of Provider or Supplier Allina Health Apple Valley Clinic	**Street Address, City, State** 14655 Galaxie Ave, Apple Valley, MN	

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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry, Urinalysis and Toxicology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/21/18 at 8:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received non-graded results from API due to no consensus in Chemistry, Urinalysis and Toxicology for the events and tests listed below. Event = 2016 - Chemistry / Group 2 - 3rd Event Sample ID = UDS-05 Test = Benzodiazapine Event = 2017 - Chemistry / Core - 1st Event Sample ID = CH-01 Test = LDL Cholesterol (Calculated) Event = 2017 - Hematology / Coagulation - 1st Event Sample ID = UA-02 Test = Urobilinogen Event = 2017 - Hematology / Coagulation - 2nd Event Sample ID = UA-03 Test = Urobilinogen Event = 2018 - Chemistry / Miscellaneous - 1st Event Sample ID = UDS-02 Test = Opiates 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 11/21/18 at 10:30 a.m., Testing Personnel 9 (TP9) confirmed the above findings. .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty

	assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/21/18 at 8:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received non-graded results from API due to no consensus in Chemistry for the events and tests listed below. Event = 2016 - Chemistry / Group 2 - 3rd Event Sample ID = CH-13 Test = Free Thyroxine, TSH* Event = 2017 - Chemistry / Core - 1st Event Sample ID = CH-01 Test = Free Thyroxine, Triglycerides 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 11/21/18 at 10:30 a.m., Testing Personnel 9 (TP9) confirmed the above findings. * TSH = thyroid Stimulating Hormone .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform and/or document required maintenance on equipment used for Immunology testing. Findings are as follows: 1. The laboratory performed Immunology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/21/18 at 8:05 a.m. 2. Various digital timers were observed as present and available for use during the tour of the lab. 2. A requirement for checking the accuracy of timers was established in the Clock & Timer Quarterly Check procedure, located in the Laboratory Procedure Manual. 4. Documentation of accuracy of timers was not found for the following periods during review of laboratory records: 2016 - Calendar Quarters 3 & 4 2017 - Calendar Quarters 1,2 & 3 The laboratory was unable to provide documentation of this function check upon request. 5. In an interview on 11 /21/18 at 1:30 p.m., Testing Personnel 9 (TP9) confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure quality control (QC) was performed each day of qualitative Immunology patient specimen testing. Findings are as follows: 1. The laboratory performed Serum Qualitative HCG* under the specialty of Immunology as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/21/18 at 8:05 a. m. 2. QC performance for Serum Qualitative HCG* was established in the Consult Diagnostics hcG Combo Test Cassette manufacturer Instruction for Use (IFU) found in the QC Log Book. 3. Laboratory records confirmed Serum Qualitative HCG* QC had been performed upon opening of each new kit in the timeframe reviewed: October, 2016 - November, 2018. 4. An Individualized Quality Control Plan (IQCP) for Serum Qualitative HCG* was not found in laboratory records. The laboratory was unable to provide an IQCP upon request. 5. In an interview on 11/21/18 at 2:30 p.m., Testing Personnel 9 (TP9) confirmed the above findings. * HCG = Human chorionic gonadotropin .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure accurate reference ranges were listed on Urinalysis and Chemistry test reports reviewed during the survey. Findings are as follows: A) Urinalysis 1. The laboratory performed Urinalysis testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/21/18 at 8:05 a.m. 2. A Siemens Clinitek Advantus urinalysis analyzer was observed as present and available for use during the tour. 3. The reference ranges found in the Urinalysis Table located in the Laboratory Procedure Manual, and the Urinalysis - Complete UA, Dipstick UA and Microalbumin procedure located in the Cliniteks (Advantus / Status +) Manual, were not consistent with that included on the test report (Male - 60 years, Date of testing = 6 /7/18) reviewed on the date of survey, as follows: Parameter: Table: Procedure: Test Report: pH 5.0 - 8.5 4.6 - 8.0 5.0 - 9.0 Specific --- 1.001 - 1.035 1.001 - 1.030 Gravity WBC / hpf* --- None Given 0 - 4 RBC / hpf* --- None Given 0 Casts / lpf* --- None Given Negative Epithelial / lpf*--- None Given Negative Bacteria / lpf* --- None Given Negative Mucous / lpf* --- None Given Negative 4. In an interview on 11/21 /18 at 2:30 p.m., Testing Personnel 9 (TP9) confirmed the above findings. * hpf = High Power Field * lpf = Low Power Field B) Chemistry 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/21/18 at 8:05 a.m. 2. A Siemens Dimension EXL chemistry analyzer was observed as present and available for use during the tour. 3. The reference ranges found in the Dimension EXL Testing Table located in the Chemistry Procedure Manual, and the Chemistry Reference Range Table located in the Laboratory Procedure Manual, were not consistent with that included on the test report (Female - 58 years, Date of testing = 11/20/18) reviewed on the date of survey, as follows: Parameter: = Glucose Dimension EXL Testing Table = 74 - 106 Chemistry Reference Range Table = 70 - 99 Patient Report = 70 - 110 4. In an interview on 11/21/18 at 2: 30 p.m., Testing Personnel 9 (TP9) confirmed the above findings. .