Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1078964	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Winona Health Urgent Care	420 E Sarnia Suite 1600, Winona, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director or designee failed to review and evaluate proficiency testing (PT) results for 1 of 1 PT events with Unacceptable results in 2017. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, Microbiology, Urinalysis and Parasitology / Mycology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 4/5/18 at 10:05 a.m. 2. The laboratory performed Proficiency Testing (PT) using American Proficiency Institute (API) as the provider. 3. Review of API PT documents revealed the following result was graded as unacceptable: Year: 2017 Survey: Microbiology Event: 3rd Sample: VIR-14 Test: Influenza A 4. Documentation of review, internal evaluation and corrective actions for the unacceptable result was not found. The laboratory was unable to provide the above record upon request. 5. In an interview at 11:15 a.m. on 4/5/18, TP-1 confirmed the above findings. .
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 document review and interview with laboratory personnel, the laboratory failed to ensure accurate reference ranges were listed on Chemistry final test reports. Findings are as follows: 1. Reference range discrepancies were revealed during review of test procedures and patient test reports for the following tests: A) Chemistry The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 4/5/18 at 10:05 a.m. - Glucose: The "Normal Adult Expected Range" Table, located in the Laboratory Procedure manual, listed the Glucose reference range = 70 - 100 mg/dl. A final Test Report, performed 7/25/2016 on a Male/86 years, listed the Glucose reference range = 70 - 99 mg/dl. - Creatinine The "Normal Adult Expected Range" Table, located in the Laboratory Procedure manual, listed the Creatinine reference range = 0.6 - 1.2 mg/dl. A final Test Report, performed 7/25/2016 on a Male/86 years, listed the Creatinine reference range = 0.7 - 1.3 mg/dl. A) Hematology The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 4/5/18 at 10:05 a.m. - Red Blood Cells (RBC): The "Normal Adult Expected Range" Table, located in the Laboratory Procedure manual, listed the RBC reference range = 4.70 - 6.00 cells/mcL A final Test Report, performed 11/2/2016 on a Female/22 years, listed the the RBC reference range = 4.20 - 5.40 cells/mcL - Hemoglobin (Hgb) The "Normal Adult Expected Range" Table, located in the Laboratory Procedure manual, listed the Hgb reference range = 13.5 - 17.5 g/dl. A final Test Report, performed 11/2 /2016 on a Female/22 years, listed the Hgb reference range = 12.0 - 16.0 g/dl. - Hematocrit (Hct) The "Normal Adult Expected Range" Table, located in the Laboratory Procedure manual, listed the Hct reference range = 41.0 - 53.0 %. A final Test Report, performed 11/2/2016 on a Female/22 years, listed the Hct reference range = 36.0 - 46.0 %. - Red Cell Distribution Width (RDW) The "Normal Adult Expected Range" Table, located in the Laboratory Procedure manual, listed the RDW reference range = 11.8 - 15.6 %. A final Test Report, performed 11/2/2016 on a Female/22 years, listed the RDW reference range = 11.9 - 15.5 %. 2. In an interview on 4/5/18 at 1:30 p.m., TP-1 confirmed the above findings. .
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: LD FAILED TO REVIEW AND EVALUATE P.T. RESULTS ON SURVEYS WHERE ALL RESULTS = ACCEPTABLE Based on document review and interview with laboratory personnel, the Laboratory Director failed to review and evaluate proficiency testing (PT) results for 25 of 25 events reviewed. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, Microbiology, Urinalysis and Parasitology / Mycology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 4/5/18 at 10:05 a.m. 2. The laboratory performed Proficiency Testing (PT) using American Proficiency Institute (API) as the provider. 3. The results for the following PT events were found during review of laboratory documents, but did not provide evidence that they had been reviewed and

	evaluated by the Laboratory Director (LD). Year Event 2016 Chemistry - Group 1 / 1st Event Chemistry - Group 1 / 2nd Event Chemistry - Group 1 / 3rd Event 2016 Chemistry - Group 2 / 1st Event Chemistry - Group 2 / 2nd Event Chemistry - Group 2 / 3rd Event 2016 Heme & Coag / 1st Event Heme & Coag / 2nd Event Heme & Coag / 3rd Event 2016 Micro / 1st Event Micro / 2nd Event Micro / 3rd Event 2017 Chemistry - Core / 1st Event Chemistry - Core / 2nd Event 2017 Chemistry - Miscellaneous / 1st Event Chemistry - Miscellaneous / 2nd Event Chemistry - Miscellaneous / 3rd Event 2017 Heme & Coag / 1st Event Heme & Coag / 2nd Event Heme & Coag / 3rd Event 2017 Micro / 1st Event Micro / 2nd Event Micro / 3rd Event 4. The laboratory was unable to provide the evaluations upon request. 5. In an interview at 11:15 a.m. on 4/5/18, TP-1 confirmed the above findings.