Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2117612	07/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Quickhealth Urgent Care Llc	7600 S Louise Avenue Ste 150, Sioux Falls, SD	

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 recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 7/17/18. The Quickhealth Urgent Care LLC laboratory was found not in compliance with the following requirement(s): D5807 and D5821.
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 review of patient electronic medical records (EMR) and interview with laboratory staff, the laboratory failed to provide normal patient ranges for % neutrophil, % lymphocyte, % monocyte, % mixed cell, absolute neutrophil count, absolute lymphocyte count, absolute monocyte count, absolute mixed cell count, red cell distribution width-standard deviation (RDW-SD), and red cell distribution width coefficient of variation (RDW-CV) for one of one sampled patient specimen (specimen dated 6/25/18 for patient sample number 40489). In addition during the twelve month timeframe of 1/1/17 through 12/31/17 there were 2334 laboratory patient test results reported without the normal patient ranges for automated white blood cell differentials. Findings include: 1. Observations at 2:10 p.m. on 7/17/18 and review of the test results for patient sample numbber 40489's complete blood count test dated 6/25/18 revealed no normal patient range for % neutrophil, % lymphocyte, % monocyte, % mixed cell, absolute neutrophil count, absolute lymphocyte count, absolute monocyte count, absolute mixed cell count, RDW-SD, and RDW-CV. Interview with testing personnel A at 2:10 p.m. on 7/17/18 revealed all results were manually entered into the EMR. She was unaware the differential normal patient ranges for the % neutrophil, % lymphocyte, % monocyte, % mixed cell, absolute

	neutrophil count, absolute lymphocyte count, absolute monocyte count, absolute mixed cell count, RDW-SD, and RDW-CV test results were not on the patient test report in the EMR.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of patient electronic medical records (EMR), the hematology quality assurance (QA) form, and interview with laboratory staff, the laboratory failed to clearly identify corrected patient test results for one of one sampled patient specimen (sample dated 6/25/18 for specimen number 40489). Findings include: 1. Observations at 2:10 p.m. on 7/17/18 and review of the hematology QA form revealed specimen number 40489 complete blood count (CBC) test results had been corrected in the EMR. Review of specimen number 40489's complete blood count results in the EMR revealed no documentation of the incorrect test results, the corrected test results, or notification to the provider of the corrected results. Interview with testing personnel A at 2:10 p.m. on 7/17/18 revealed: *The Sysmex XP hematology analyzer was not interfaced to the EMR. *All patient results were manually entered into the EMR by testing personnel upon completion of patient testing. *She reviews CBC reports for accuracy in the EMR as part of the laboratory's QA plan. *If errors were found, she corrected the report. She did not document the corrections or notification to the provider. She was not aware documentation of the correction and notification was necessary.