Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2117612	10/02/2019
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 complaint survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 10/2/19. Areas surveyed included proficiency testing enrollment and staff training. The Quickhealth Urgent Care LLC laboratory was found not in compliance with the following requirements: D2000, D2016, D2130, D5801, D6015, and D6028.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: 39179 Based on proficiency testing (PT) record review and interview with the laboratory director, the laboratory failed to enroll in hematology PT for 2019. Findings include: 1. Review of 2019 Hematology first event scores from the American Proficiency Institute (API) revealed scores of 0% each for: white blood count, red blood count, hemoglobin, hematocrit, platelet, and automated differential analytes. Review of API's 2019 Hematology second event scores revealed no record of the laboratory participating. Information provided by the laboratory director per email on 9/7/19 revealed: *Upon returning from an out-of-country trip on 1/28/19 she was unable to get in contact with someone to send her information regarding what PT results had been submitted to API. *The laboratory had a lot of personnel changes including management and most staff who performed hematology testing.

	*Laboratory financial challenges had occurred resulting in payment for laboratory related items including the 2019 PT subscription not being made. Information provided by API per email on 9/13/19 revealed the laboratory had ordered a 2019 Hematology module in September 2018. The first hematology event was placed on hold due to nonpayment. The 2019 order was eventually canceled due to nonpayment. The accounts receivable department of API had made several notifications to the laboratory with no response. Interview per telephone with the laboratory director on 10 /2/19 at 4:00 p.m. revealed she had contacted the laboratory several times after she returned from an out-of-country trip in January 2019 to arrange an on-site visit. She had received no response back.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: 04790 Based on proficiency testing (PT) record review and interview with the laboratory director, the laboratory failed to achieve satisfactory performance in PT for the speciality of hematology in two of three PT events (2019 first and second events). That failure resulted in unsuccessful PT participation. Findings include: 1. Review of the 2019 Hematology first event scores from the American Proficiency Institute (API) revealed scores of 0% each for six of six hematology analytes: white blood cell count, red blood cell count, hemoglobin, hematocrit, platelet, and automated differential. Those scores had resulted in a hematology specialty overall score of 0%. Review of API's 2019 Hematology second event scores revealed no record of the laboratory participating. Information provided by the laboratory director per email on 9/7/19 revealed: *Upon returning from an out-of-country trip on 1/28/19 she was unable to get in contact with someone to send her the PT results that had been submitted to API. *The laboratory had a lot of personnel changes including a management and most staff who performed hematology testing. *It was her understanding the invoice for the 2019 Hematology PT subscription had not been paid. *Laboratory financial challenges had been occurring which resulted in payment for laboratory related items not being made. Information provided by API per email on 9/13/19 revealed the laboratory had ordered a 2019 Hematology module in September 2018. The first hematology event was placed on hold due to nonpayment. The 2019 order was eventually canceled due to nonpayment resulting in the second event not being

	shipped. The accounts receivable department of API had made several notifications to the laboratory with no response.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: 04790 Based on review of CASPER reports, proficiency testing (PT) reports, and interview with the laboratory director, the laboratory failed to achieve satisfactory PT performance for the specialty of hematology in two of three events (2019 Hematology first and second events) resulting in unsuccessful performance. Findings include: 1. Review of the laboratory's CASPER Reports 153D and 155D PT results revealed a score of 0% had been received for each of the six hematology analytes: white blood cell count, red blood cell count, hemoglobin, hematocrit, platelet, and automated differential in the first hematology event. Those 0% scores had resulted in a hematology speciality overall score of 0%. There were no scores for the second hematology event. An 80% score was required to pass a hematology specialty event and each analyte per CLIA regulations. Refer to D2016.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of quality control (QC), quality assessment (QA) records, patient reports, and interview with the lead laboratory staff, the laboratory failed to ensure printed reports were legible for five of five months (May 2019 through September 2019). The printed patient reports had been utilized by practitioners for treatment determinations. Findings include: 1. Review of the following records revealed the print had varying degrees of faintness with some print to the point of being unable to be read: *QC records for September 2, 3, 4, 5, 6, 7, 8 , 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 23, 24, 25, 26, 27, 28, and 29. *QC records for random days in May and June 2019. *Patient test reports: 9/30/19-sample #16270, 9/29/19-sample #17635, 7/12/19-sample #17655, 7/17/19-sample #6589, and 5/1/19-sample #2973. Review of QA studies dated 9/7/19 and signed by the laboratory director revealed patient test reports had been reviewed. However there was no notation of those reports being illegible due to poor print quality. Interview with the lead laboratory staff person on 10/2/19 at 2:00 p.m. revealed: *The ink cartridge had been replaced approximately three weeks ago, but the printing did not improve. *The hematology analyzer had not been used from 7/19/19 to 8/16/19 due to lack of reagents.

D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: 04790 Based on proficiency testing (PT) record review and interview with the laboratory director, the director failed to ensure the laboratory had been enrolled and participated in an approved PT program for hematology for two of two events reviewed (2019 Hematology first and second events). Findings include: 1. The laboratory failed to enroll in PT testing for 2019. Refer to D2000.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: 04790 Based on review of training records, form CMS-209, and interview with the lead laboratory person, the director failed to ensure 17 of 18 laboratory staff (A, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, and R) had been trained to accurately perform tests and report tests results prior to testing patient samples and reporting patient test results. Findings include: 1. Review of the CMS-209 form revealed staff C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, and R had no documentation of having been trained to run patient complete blood count (CBC) samples on the hematology analyzer. Review of training records revealed: *Staff A had been trained on the hematology analyzer on 9/7/19. *No record of when the staff identified above had started performing patient CBC testing. Interview with the lead laboratory staff person on 10/2/19 during the survey revealed: *Staff A had been performing patient CBCs prior to 9/7/19. *She had been trained on the hematology analyzer on 9/7/19 but had not performed any patient CBCs prior to that. *She was unaware of where training records had been kept before she started working at that site.