

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2155292	(X3) Date Survey Completed 06/25/2019
Name of Provider or Supplier Your Kids Urgent Care	Street Address, City, State 4586 East Michigan Street, Orlando, FL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in proficiency testing with an approved proficiency testing program from 11/10/18 to 6/25/19. Findings: Review of the "Laboratory Test Log" showed that the laboratory started testing for White Blood Cell Counts (WBC) on 11/10/18. No documentation of proficiency testing records were available for inspection. During an interview on 6/25/19 at 1:49 PM, the Administrator stated they had not enrolled in proficiency testing for WBC's.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview, the laboratory's procedure manual failed to have a written procedure on employee competency. Findings: Review of the laboratory's procedure manual, signed by the laboratory director, showed that there was no procedure on employee competency. During an interview on 6/25/19 at 3:17 PM, the Administrator acknowledged that they did not have a procedure on employee competency.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on observation, record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Cross Referenc D5403. Based on record review and interview, the laboratory's written procedure manual was incomplete. Cross Referenc D5429. Based on record review and interview, the laboratory failed to document the daily maintenance performed on the HemoCue White Blood Cell (WBC) analyzer from 11/10/18 to 6/25/19. Cross Referenc D5481. Based on record review and interview, the laboratory failed to perform and document the running of daily Quality Controls (QC) on the HemoCue White Blood Cell (WBC) analyzer form 11/10/19 to 6/9/19.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

	<p>Based on record review and interview, the laboratory's written procedure manual was incomplete. Findings: Review of the laboratory's procedure manual, signed by the laboratory directory, showed that there was no procedure on proficiency testing. During an interview on 6/25/19 at 3:17 PM, the Administrator acknowledged that they did not have a procedure on proficiency testing.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the daily maintenance performed on the HemoCue White Blood Cell (WBC) analyzer from 11/10/18 to 6/25/19. Findings: Review of the "Laboratory Test Log" showed that the laboratory started testing for White Blood Cell Counts (WBC) on 11/10/18. The HemoCue WBC Operations Manual states "Clean the cuvette holder after each day of use." No documentation of instrument maintenance was available for inspection. During an interview on 6/25/19 at 3:15 PM, the Administrator acknowledged they had not recorded the maintenance.</p>
<p>D5481</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform and document the running of daily Quality Controls (QC) on the HemoCue White Blood Cell (WBC) analyzer from 11/10/19 to 6/9/19. Findings: Review of the "Laboratory Test Log" showed that the laboratory performed testing for WBC's on 11/10/18, 12/14/18, 12/15/18, 12/21/18, 1/4/19, 1/5/19, 1/8/19, 1/30/19, 2/2/19, 2/8/19, 2/9/19, 2/16/19, 3/1/19, 3/9/19, 3/17/19, 3/19/19, 4/22/19, 5/5/19, 5/9/19, 5/14/19, 5/17/19, 5/23/19, 5/24/19, 6/2/19, 6/3/19, 6/4/19, 6/5/19, 6/7/19, and 6/9/19. Review of the "Hemocue WBC Daily QC Report" showed that there were no QC reports dated with the above mentioned dates. During an interview on 12/15/19 at 0:00 AM, the Administrator acknowledged that they had no run QC on every day of testing.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the</p>

condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory's patient notes failed to list the correct address of the location where the White Blood Cell (WBC) counts were performed 3 out of 3 patient notes examined (#1, #2 and #3). Findings: The laboratory uses the Patient Notes as their final report that is given upon request to the patient. Review of the Patient Notes showed for patient #1, #2 and #3 that the laboratory's address was incorrect. During an interview on 6/25/19 at 3:45 PM, the Administrator acknowledged that the Patient Notes are given to patients upon request, and that the address was incorrect.

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 record review and interview, the Laboratory Director failed to provide overall management and direction. Cross References D6007. Based on record review and interview, and record review, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and postanalytical phases of testing from 11/01/18 to 6/25/19. Cross References D6015. Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing with an approved proficiency testing program from 11/10/18 to 6/25/19. Cross References D6030. Based on record review and interview, the Laboratory Director failed to ensure that the laboratory's procedure manual have a written procedure on employee competency.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on record review and interview, and record review, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and postanalytical phases of testing from 11/01/18 to 6/25/19. Analytical: 1. Based on record review and

interview, the laboratory's written procedure manual was incomplete. Findings: Review of the laboratory's procedure manual, signed by the laboratory directory, showed that there was no procedure on proficiency testing. During an interview on 6/25/19 at 3:17 PM, the Administrator acknowledged that they did not have a procedure on proficiency testing. 2. Based on record review and interview, the laboratory failed to document the daily maintenance performed on the HemoCue White Blood Cell (WBC) analyzer from 11/10/18 to 6/25/19. Findings: Review of the "Laboratory Test Log" showed that the laboratory started testing for White Blood Cell Counts (WBC) on 11/10/18. The HemoCue WBC Operations Manual states "Clean the cuvette holder after each day of use." No documentation of instrument maintenance was available for inspection. During an interview on 6/25/19 at 3:15 PM, the Administrator acknowledged they had not recorded the maintenance. 3. Based on record review and interview, the laboratory failed to perform and document the running of daily Quality Controls (QC) on the HemoCue White Blood Cell (WBC) analyzer from 11/10/19 to 6/25/19. Findings: Review of the "Laboratory Test Log" showed that the laboratory performed testing for WBC's on 11/10/18, 12/14/18, 12/15/18, 12/21/18, 1/4/19, 1/5/19, 1/8/19, 1/30/19, 2/2/19, 2/8/19, 2/9/19, 2/16/19, 3/1/19, 3/9/19, 3/17/19, 3/19/19, 4/22/19, 5/5/19, 5/9/19, 5/14/19, 5/17/19, 5/23/19, 5/24/19, 6/2/19, 6/3/19, 6/4/19, 6/5/19, 6/7/19, and 6/9/19. Review of the "Hemocue WBC Daily QC Report" showed that there were no QC reports dated with the above mentioned dates. During an interview on 12/15/19 at 0:00 AM, the Administrator acknowledged that they had not run QC on every day of testing. Postanalytical: Based on record review and interview, the laboratory's Patient Notes failed to list the correct address of the location where the White Blood Cell (WBC) counts were performed 3 out of 3 Patient Notes examined (#1, #2 and #3). Findings: The laboratory uses the Patient Notes as their final report that is given upon request to the patient. Review of the Patient Notes showed for patient #1, #2 and #3 the laboratory's address was incorrect. During an interview on 6/25/19 at 3:45 PM, the Administrator acknowledged that the Patient Notes are given to patients upon request, and that the address was incorrect.

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:
 Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing with an approved proficiency testing program from 11/10/18 to 6/25/19. Findings: Review of the "Laboratory Test Log" showed that the laboratory started testing for White Blood Cell Counts (WBC) on 11/10/18. No documentation of proficiency testing records were available for inspection. During an interview on 6/25/19 at 1:49 PM, the Administrator stated they had not enrolled in proficiency testing for WBC's.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to ensure that the laboratory's procedure manual have a written procedure on employee competency. Findings: Review of the laboratory's procedure manual, signed by the laboratory directory, showed that there was no procedure on employee competency. During an interview on 6/25/19 at 3:17 PM, the Administrator acknowledged that they did not have a procedure on employee competency.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory failed to verify the educational qualifications of 3 (E, F and G) out of 8 (A, B, C, D, E, F, G, and H) Testing Personnel. (Cross Reference D6065)

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to verify the educational qualifications of 3 (E, F and G) out of 8 (A, B, C, D, E, F, G, and H) Testing Personnel. Findings Included: Review of the CMS 209, Laboratory Personnel Report,

signed by the Laboratory Director on 6/1/19 revealed Employee E, F, and G held the position of Testing Personnel for moderate complexity. Review of personnel documentation revealed no documentation of the educational qualifications for Testing Personnel E, F, and G. During an interview on 6/25/19 at 2:37 PM , the Administrator acknowledged that the laboratory did not have proof of education for E, F, and G.