

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2155292	(X3) Date Survey Completed 01/14/2021
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
D0000	A recertification survey was conducted on January 14, 2021. Your Kids Urgent Care clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to attest to the routine integration of the proficiency testing (PT) samples into the patient workload using the laboratory's routine methods by signing the attestation for 1 (2020 3rd) out of 3 (2019 2nd, 3rd, and 2020 3rd) event attestations examined for the specialty of Hematology. Findings: Review of the laboratory's proficiency testing records with American Proficiency Institution (API) for the 2020 3rd event showed the Laboratory Director did not sign the attestation. Review of the laboratory's procedure manual noted, "The "Attestation sheet" must be signed by both the Laboratory Director and the testing personnel in a timely manner." During an interview on 1/14/21 at 5:50 PM, the Testing Personnel - A stated the laboratory director did not sign the attestation.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p>

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to run proficiency testing (PT) samples the same number of times, as it routinely tests patient samples for 3 out of 3 (2019 2nd, 3rd and 2020 3rd) event attestations examined for the specialty of Hematology. Findings: 1. Review of the laboratory's proficiency testing records with American Proficiency Institution (API) for the 2019 2nd event showed the due date to submit results to API was 7/26/19. Review of the attestation for the 2019 2nd event showed Testing Personnel (TP) - A ran sample #6 on 7/25/19 and former TP - E ran sample #6 on 7/25/19. 2. Review of the laboratory's proficiency testing records with API for the 2019 3rd event showed the due date to submit results to API was 12/2/19. Review of the attestation for the 2019 3rd event showed TP - A ran sample #14 and #15 on 11/24/19, former TP - F ran sample #14 and #15 on 11/24/19 and former TP - G ran sample #14 on 11/24/19. 3. Review of the laboratory's proficiency testing records with API for the 2020 3rd event showed the due date to submit results to API was 11/24/20. Review of the attestation for the 2019 3rd event showed TP - A ran sample #11, #12, #13, #14 and #15 on 11/11/20, TP - C ran sample #11, #12, #13, #14 and #15 on 11/16/20, and TP - D ran sample #11, #12, #13, #14 and #15 on 11/22/20. Review of the laboratory's Proficiency Testing procedure noted "The PT samples must be handled exactly like patient specimens, utilizing usual testing methods, instruments and personnel. Repeated analysis of PT samples shall not be permitted unless the lab performs the same repetitive analysis in the routine analysis of patient specimens." During an interview on 1/14/21 at 5:53 PM, TP - A stated patient samples were not routinely run multiple times and some PT samples were run more than once.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
 CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to maintain a copy of all proficiency testing program report forms for 2 (2020 1st, 2nd) out of 5 (2019 2nd, 3rd, and 2020 1st, 2nd, 3rd) events for the specialty of Hematology. Findings: Review of the laboratory's proficiency testing records with American Proficiency Institution (API) for the 2020 1st event showed the laboratory did not have the attestation and the record of proficiency testing results. Review of the laboratory's proficiency testing records for the 2020 2nd event showed the laboratory did not have the attestation, the record of proficiency testing results, and the PT performance evaluation form. Review of the laboratory's Proficiency Testing procedure noted ""All records must be maintained for 2 years." During an interview on 1/14/21 at 5:53 PM, Testing Personnel - A stated she was not able to locate the above mentioned PT records.

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 record review and interview, the laboratory failed to document the review and evaluation of proficiency testing (PT) for 1 (2020 3rd) out of 4 (2019 2nd, 3rd and 2020 1st, 3rd) event performance evaluations examined for the specialty of hematology. Findings: Review of the American Proficiency Institute (API) PT showed the Laboratory Director failed to sign "Proficiency Testing Performance Evaluation" forms for 3rd event in 2020. Review of the laboratory's Proficiency Testing procedure noted, "The Laboratory Director and testing staff must sign the review and any corrective action documentation within 30 Days of receipt of PT evaluation report." Review of the API PT evaluation form "Proficiency Testing Performance Evaluation" noted, "After reviewing the evaluation reports, complete the information below and retain this form along with the enclosed reports." The form provided a place for the Laboratory Director or designee to sign and date the form. The Laboratory Personnel Report, signed and dated by the Laboratory Director on 1/14/21, showed the Laboratory Director was the only Clinical Consultant and Technical Consultant. The Laboratory Director was the only person qualified to sign the PT performance evaluation for this laboratory. During an interview on 1/14/21 at 5:55 PM, Testing Personnel - A stated the performance evaluation was not signed by the Laboratory Director.

D5805

TEST REPORT

CFR(s): 493.1291(c)

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 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 procedure notes failed to provide all required information for laboratory test reports for 3 out of 3 (#1, #2, #3) patients. Findings: Review of the patient notes given to the patients, showed the units of measurements and the reference range (normal values) for the White Blood Cell count were not reported. During an interview on 1/14/20 at 5:41 PM, Testing Personnel - A stated the patient notes given to patients did not contain the units of measurements and the normal values.

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 of the laboratory. Findings: Cross Reference D6016: Based on record review and interview, the Laboratory Director failed to ensure that proficiency testing was performed according to CLIA regulations. Cross Reference D6018: Based on record review and interview, the Laboratory Directory failed to review the laboratory's performance of proficiency testing results.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that proficiency testing was performed according to CLIA regulations. Findings: The Laboratory Director failed to attest to the routine integration of the proficiency testing (PT) samples into the patient workload using the laboratory's routine methods by signing the attestation for 1 (2020 3rd) out of 3 (2019 2nd, 3rd, and 2020 3rd) event attestations examined for the specialty of Hematology. (See D2009) The Laboratory Director failed to ensure the laboratory ran proficiency testing (PT) samples the same number of times, as it routinely tested patient samples for 3 out of 3 (2019 2nd, 3rd and 2020 3rd) event attestations examined for the specialty of Hematology. (See D2010) The Laboratory Director failed to ensure the laboratory maintained a copy of all proficiency testing program report forms for 2 (2020 1st, 2nd) out of 5 (2019 2nd, 3rd, and 2020 1st, 2nd, 3rd) events for the specialty of Hematology. (See D2015)

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:

Based on record review and interview, the Laboratory Directory failed to review the laboratory's performance of proficiency testing results. Findings: The Laboratory

Director failed to document the review and evaluation of proficiency testing (PT) for 1 (2020 3rd) out of 4 (2019 2nd, 3rd and 2020 1st, 3rd) event performance evaluations examined for the specialty of hematology. (See D5211)

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Technical Consultant failed to assess the competency of Testing Personnel listed on the Laboratory's Personnel Report for 4 out of 4 personnel (A, B, C, D) from 1/1/2019 to 1/14/2020. Findings: Review of the CMS-209 form titled, "Laboratory Personnel Report (CLIA)" signed and dated by the Laboratory Director on 1/14/21, showed the Laboratory Director served as the Technical Consultant. 1. Review of the competency assessment records for Testing Personnel (TP) - A showed no competency assessment for 2019 was available for review. The competency assessment for TP - A dated 1/2020, showed the competency assessment was not signed by the Laboratory Director. 2. Review of the competency assessment for TP - B dated 12/28/19 showed the competency assessment was not signed by the Laboratory Director. A second competency assessment for TP - B that was not dated, showed the competency assessment was signed by TP - A and was not signed by the Laboratory Director. 3. Review of the initial training competency assessment for TP - C dated 4/18/20 showed the competency assessment was not signed by the Laboratory Director. The six month competency assessment for TP - C dated 11/1/20 showed the competency assessment was signed by TP - A and was not signed by the Laboratory Director. 4. Review of the competency assessment records for TP - D showed no competency assessment for 2019 was available for review. The competency assessments for TP - D dated 1/5/20 and 6/18/20, showed the competency assessments was not signed by the Laboratory Director. During an interview on 1/14/20 at 6:01 PM, TP - A stated the competency assessments were not signed by the Laboratory Director.