

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0707540	(X3) Date Survey Completed 01/17/2018
Name of Provider or Supplier Child Care Consultants Inc	Street Address, City, State 5957 Cleveland Avenue Suite A, Columbus, OH	
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
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 an interview with Testing Personnel (TP), the laboratory failed to ensure TP attested to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods. Findings Include: 1. Review of five out of seven of the laboratory's 2016-2017 PT records provided on the date of the inspection, did not find TP signatures attesting to the routine integration of PT samples into the patient workload using the laboratory's routine methods on the following TP records: WSLH PT ID #2014020 June 22, 2016 MLE ID #014457 November 9, 2016 MLE ID #014457 February 24, 2017 MLE ID #014457 June 2, 2017 MLE ID #014457 September 29, 2017 2. TS#9 confirmed the TP did not provide signatures attesting to the routine integration of PT samples into the patient workload using the laboratory's routine methods and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/17/2018 at 10:59 AM.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and</p>

rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual and an interview, the laboratory failed to establish written policies and procedures for specimen rejection. Findings Include: 1. Review of the laboratory's procedure manual titled "Laboratory Procedure Manual North Office", did not find a policy and procedure for specimen rejections. 2. Testing Personnel #9 confirmed that the laboratory's procedure manual did not have a specimen rejection procedure. The interview occurred 01/17/2018 at 11:18 AM.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) documentation, quality assessment documentation, and an interview with Testing Personnel (TP), the Laboratory Director failed to ensure that an approved corrective action plan is followed when any PT results are below 80%, unacceptable or unsatisfactory. Findings Include: 1. Review of the laboratory's PT documentation, provided on the date of survey, did not find records of any evaluation for the following subspecialties: 2016 MLE-M1 #014457, Bacteriology current score 60% 2016 MLE-M2 #014457, Hematology current score 63% 3. The Surveyor requested evaluation documentation of the laboratory's PT scores that were below 80%, unacceptable or unsatisfactory. TP#9 confirmed the laboratory did not follow a corrective action plan for PT scores less than 80%, unacceptable or unsatisfactory, and was unable to provide the requested documentation on the date of survey. The interviews occurred on 01/17 /2018 at 10:59 AM.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's competency assessment documentation, and an interview with Testing Personnel (TP), the Laboratory Director failed to ensure that

prior to testing patients' specimens, TP had the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results. Findings Include: 1. Review of the laboratory's initial competency assessment documentation for TP#16, revealed TP#16 did not have documentation of an initial competency assessment. 2. The Surveyor requested the laboratory's initial competency assessment documentation for TP#16. TP#9 confirmed the laboratory did not have initial training documents for TP#16, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/17/2018 at 10:26 AM.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based upon a review of the policy and procedure manual and staff interview, the Laboratory Director, (LD), failed to approve written test procedures found in the lab's procedure manual. Findings were as follows: 1. Review of the laboratory's policy and procedure manual titled "Laboratory Procedure Manual, North Office", revealed the lab director failed to approve written test procedures, by signature, and provide the date in which they were approved for 2016. 2. An interview with Testing Personnel #9 verified the policy and procedure manual had not been approved by signature and date by the LD for 2016.