

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2122410	(X3) Date Survey Completed 12/12/2018
Name of Provider or Supplier Kidzcare Pediatrics	Street Address, City, State 4233 Us 411 Ste B, Madisonville, TN	
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
D5481	<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:</p> <p>===== Based on review of Laboratory Quality Control (QC) Procedure, review of August and September 2017 Complete Blood Count (CBC) Quality Control Reports, review of 2 patient reports and interview with the primary testing person and the Laboratory Director, determined the laboratory failed to follow their quality control criteria for acceptability prior to reporting patient results. The findings include: 1. Review of the QC procedure for corrective action for "out of control" results for CBC testing states: 1. Re-run the same control sample: a. If result is acceptable, patient samples may be tested and reported. b. If control results indicate a problem, appropriate action must be taken and documented and control retested. - Check all reagents and control for signs of deterioration or contamination - Check instrument maintenance logs to be sure that service and calibration are current - Check with the manufacturer for possible problems with QC lot number - Contact manufacturer for technical assistance 2. Document corrective actions and repeat controls 3. If that control is not acceptable, repeat using a fresh vial of control 4. Recalibrate instrument and re-run controls 5. If problem cannot be corrected within a clinically useful time, notify lab director. 2. Review of August and September 2017 quality control reports revealed from 8/28/17 to 9/21/17 normal and high qc materials were ran many, many times in order to get acceptable qc results. 3. Review of 2 patient reports for August and September 2017 revealed patients were tested and reported. 4. An interview with the current primary testing person and Laboratory Director at approximately 1:00 p.m. 12/12/18 confirmed upon review of the quality control reports the laboratory failed to follow</p>

procedure on handling "out of control" CBC quality control results for August and September 2017 prior to reporting patient results.
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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 review of 5 random patient CBC (Complete Blood Count) reports for: August and September of 2017, January, April and November of 2018 and interview with current primary testing person, determined the test report failed to contain positive patient identification. The findings include: 1. Review of 5 random patient CBC reports for August and September of 2017 and January, April and November of 2018 revealed the CBC reports lacked 2 patient identifiers. 2. Interview at approximately 1:00 p.m. 12/12/18 with the current primary testing person confirmed the CBC reports reviewed lacked 2 patient identifiers. =====

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

===== Based on review of monthly Quality Control (QC) Policy Monitor for 2017 Quality Assurance, review of corrective action procedure for "out of control" CBC QC, review of CBC QC for August and September of 2017 and interview with the current primary testing person and Laboratory Director, determined the director failed to ensure remedial actions were taken when there were significant deviations from the laboratory's established CBC quality control performance for August and September of 2017. The findings include: 1. Review of the monthly Quality Control Policy Monitor for 2017 revealed that laboratory director had reviewed QC reports for August and September 2017 with no documentation of corrective action. 2. Review of corrective action procedure for "out of control" CBC QC revealed policy was not followed for significant deviations for CBC QC for August and September of 2017 (reference D5481). 3. Review of CBC

QC for August and September of 2017 revealed significant deviations for "out of control" QC with quality controls being ran multiple times to get an acceptable result which deviated from policy with no remedial actions documented. 4. An interview at approximately 1:00 p.m. 12/12/18 with the current primary testing person and the laboratory director confirmed the director failed to ensure remedial actions were taken when significant deviations from the laboratory's established performance specifications for CBC QC were identified for August and September of 2017.
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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 review of competency records for 4 of 4 testing personnel which lacked competency documentation for 2 of 4 testing personnel for 2017 and 2018 and upon interview with the current primary testing person, determined the technical consultant failed to document competency for 2 of 4 testing personnel for CBC testing. The findings include: 1. Review of competency records for 4 of 4 testing personnel revealed 2 of 4 personnel lacked competency documentation for 2017 and 2018. 2. An interview at approximately 1:00 p.m. 12/12/18 with the current primary testing person confirmed that 2 of 4 testing personnel lacked competency documentation for 2017 and 2018 for CBC testing.
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