

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0685520	(X3) Date Survey Completed 11/26/2018
Name of Provider or Supplier Coliseum Pediatric & Adolescent Care	Street Address, City, State 145 N Crest Boulevard, Macon, GA	
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 proficiency testing desk review was completed on November 26, 2018. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Report 155 and review of the laboratory's proficiency testing (PT) reports from the College of American Pathologists (CAP), the laboratory failed to maintain satisfactory performance in four of seven consecutive events (3rd event of</p>

	<p>2016, 1st event of 2017, and 1st and 3rd events of 2018), for analyte # 765, automated white blood cell (WBC) differential resulting in the second unsuccessful PT occurrence for WBC differential. Findings include: Refer to D 2130</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and review of the laboratory's 2016, 2017 and 2018 proficiency testing (PT) evaluation reports from CAP, the laboratory failed to maintain satisfactory performance on four of seven consecutive proficiency testing events for the automated white blood cell (WBC) differential resulting in the second unsuccessful PT occurrence for WBC differential. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory automated WBC differential scores: 2016 event three 40%, 2017 event one 0%, 2018 event one 40% and 2018 event three 60%. 2. Review of the 2016 event three evaluation report from CAP revealed an overall score of 60% with unacceptable scores for Granulocytes % on sample numbers FH1-11 and FH1-14 and Lymphocytes % on sample numbers FH1-11, 14 and 15. 3. Review of the 2017 event one evaluation report revealed an overall score of 0% with unacceptable scores for Granulocytes %, Lymphocytes % and Monocyte/Mid% on sample numbers FH1-1, 2, 3, 4, & 5 4. Review of the 2018 event one evaluation report revealed an overall score of 40% with unacceptable scores for Granulocytes % on sample numbers FH1-2, 4 and 5 and Lymphocytes % on sample numbers FH1-1, 2, 4 and 5. 5. Review of the 2018 event three evaluation report revealed an overall score of 60% with unacceptable scores for Granulocytes % and Lymphocytes % on sample numbers FH1-13 and 14.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports from the College of American Pathologists (CAP), the laboratory director failed to ensure the laboratory maintained satisfactory performance in four of seven consecutive events (3rd event of 2016, 1st event of 2017, and 1st and 3rd events of 2018), for analyte # 765, automated white blood cell (WBC) differential resulting in the second unsuccessful PT occurrence for WBC differential. Findings include: Refer to D 6016</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p>

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 a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and review of the laboratory's 2016, 2017 and 2018 proficiency testing (PT) evaluation reports from CAP, the laboratory director failed to ensure the laboratory maintained satisfactory performance on four of seven consecutive proficiency testing events for the automated white blood cell (WBC) differential resulting in the second unsuccessful PT occurrence for WBC differential. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory automated WBC differential scores: 2016 event three 40%, 2017 event one 0%, 2018 event one 40% and 2018 event three 60%. 2. Review of the 2016 event three evaluation report from CAP revealed an overall score of 60% with unacceptable scores for Granulocytes % on sample numbers FH1-11 and FH1-14 and Lymphocytes % on sample numbers FH1-11, 14 and 15. 3. Review of the 2017 event one evaluation report revealed an overall score of 0% with unacceptable scores for Granulocytes %, Lymphocytes % and Monocyte/Mid% on sample numbers FH1-1, 2, 3, 4, & 5 4. Review of the 2018 event one evaluation report revealed an overall score of 40% with unacceptable scores for Granulocytes % on sample numbers FH1-2, 4 and 5 and Lymphocytes % on sample numbers FH1-1, 2, 4 and 5. 5. Review of the 2018 event three evaluation report revealed an overall score of 60% with unacceptable scores for Granulocytes % and Lymphocytes % on sample numbers FH1-13 and 14.