

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0722293	(X3) Date Survey Completed 02/27/2020
Name of Provider or Supplier Jonesboro Pediatrics	Street Address, City, State 236 Arrowhead Blvd, Jonesboro, 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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 27, 2020. The laboratory was found not in compliance with all applicable CLIA requirements found at 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 Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (Events 2 & 3 of 2019), resulting in the first</p>

	<p>unsuccessful occurrence for Hematocrit (HCT) #0785. Findings include: Refer to D2130</p>
D2130	<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 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, the laboratory failed to maintain satisfactory performance in two consecutive events (Events 2 & 3 of 2019), resulting in the first unsuccessful occurrence for Hematocrit (HCT) #0785. The findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed hematocrit (HCT) on Event 2 of 2019 with a score of 40% and Event 3 of 2019 with a score of 60%. 2. The criteria for acceptable performance for the specialty of Hematology is a score of 80%. 2. Desk review of the laboratory's proficiency testing reports from the American Academy of Family Physicians (AAFP) confirmed the laboratory failed HCT on Events 2 & 3 of 2019 resulting in the first unsuccessful performance.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP), quality assurance (QA) records, and interview with the testing personnel the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory. Th findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to be taken to identify and correct problems, nor efforts to prevent recurrences and necessary procedures to prevent reoccurrence of problems in the laboratory. Corrective actions are being performed in the laboratory but are not documented. 2. The testing personnel confirmed on 02/27/20, at 12:30 PM, in the laboratory, that the laboratory is performing corrective actions but not documenting them. TP#1 also confirmed that the QA policy does not adequately assess and identify problems in the laboratory.</p>
D6000	<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>

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, the laboratory failed to maintain satisfactory performance in two consecutive events (Events 2 & 3 of 2019), resulting in the first unsuccessful occurrence for Hematocrit (HCT) #0785. Findings include: Refer to D6016

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 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, the laboratory failed to maintain satisfactory performance in two consecutive events (Events 2 & 3 of 2019), resulting in the first unsuccessful occurrence for Hematocrit (HCT) #0785. The findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed hematocrit (HCT) on Event 2 of 2019 with a score of 40% and Event 3 of 2019 with a score of 60%. 2. The criteria for acceptable performance for the specialty of Hematology is a score of 80%. 2. Desk review of the laboratory's proficiency testing reports from the American Academy of Family Physicians (AAFP) confirmed the laboratory failed HCT on Events 2 & 3 of 2019 resulting in the first unsuccessful performance.

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 surveyor review of personnel records and interview with the testing personnel, the Technical Consultant failed to assess the six competency assessment criteria for testing personnel for Hematology test procedures performed in the laboratory for April 2017 through February 2020. The findings include: 1. A review of testing personnel records revealed that a comprehension assessment was performed for moderately complex procedures in the laboratory, but the assessment did not address the six competency assessment criteria or the procedure for performing for the specialty of Hematology. 2. Competency assessments were not being performed and signed off by the Technical Consultant (TC) or Laboratory Director (LD) from March 2017 through February 2020. 3. An interview with the office manager and testing

personnel in the office on 2/27/2020 at 1:30 PM confirmed that annual competencies did not contain the six competency assessment criteria for testing personnel in the specialty of Hematology and were not being performed by the TC or LD.