Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1042451	03/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jonesboro Pediatrics	210 West Camp Ground Road, Mcdonough, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on proficiency testing review using the Centers for Medicare and Medicaid (CMS) Casper Report 096 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (2nd event of 2019 and 3rd event of 2019), resulting in the first unsuccessful occurrence for Hematology # 760 including hematocrit(HCT) #785. Findings include: Refer to D 2130
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on proficiency testing review using the Centers for Medicare and Medicaid (CMS) Casper Report 096 and review of the laboratory's proficiency testing (PT) reports from the American Academy of Family Physicians (AAFP), the laboratory failed to maintain satisfactory performance in two consecutive events (2nd and 3rd events of 2019), resulting in the first unsuccessful occurrence for hematocrit (HCT), analyte # 785. Findings include: 1. Review of Casper Report 096 disclosed the laboratory failed analyte #785 HCT on event 2 of 2019 with a score of 40% and event 3 of 2019 with a score of 60%. 2. Review of the laboratory's proficiency testing reports from AAFP confirms the laboratory failed HCT on events 2 and 3 of 2019, resulting in the first unsuccessful performance. 3. Interview with staff #2 (CMS 209) on 03/30/21 in the lab at approximately 11:30 AM confirmed the 2 consecutive PT failures.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) reports review from the American Academy of Family Physicians (AAFP) and staff interview, the laboratory failed to review unsatisfactory scores and document the corrective actions taken in two consecutive events (2nd and 3rd events of 2019) for hematocrit (HCT), analyte # 785. Findings include: 1. Review of AAFP PT reports reveal the laboratory failed analyte #785 HCT on event 2 of 2019 with a score of 40% and event 3 of 2019 with a score of 60%. 2. Review of the laboratory's proficiency testing reports from AAFP reveals the laboratory failed to review and document corrective actions taken for the failed HCT on events 2 and 3 of 2019. 3. Interview with staff #2 (CMS 209) on 03/30/21 in the lab at approximately 11:30 AM confirmed the lab's failure to review and document corrective actions for PT failures.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected

	by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on calibration document review and staff interview, the lab failed to calibrate the Cell-Dyn Emerald analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data revealed the Emerald was calibrated 11 /7/18, 4/10/19, 5/22/19, 01/08/20, and 11/02/20, resulting in an 8 month span (05/22 /19 - 01/08/20) and a 10 month span (01/08/20 - 11/02/20). 2. Interview with staff #2 (CMS 209 form) on 03/30/21 at approximately 12 PM in the lab, confirmed the time spans.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on lab report reviews and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of patient lab reports # 110126 and #110934 reveal the reports did not include reference intervals or appropriate units of measurement. 2. Interview with staff #2 (CMS 209 form) on 03/30/21 at approximately 12 PM in the lab, confirmed the lack of reference intervals or appropriate units of measurement on the patient lab reports.
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 proficiency testing review using the Centers for Medicare and Medicaid (CMS) Casper Report 096 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two consecutive events (2nd and 3rd events of 2019), resulting in the first unsuccessful occurrence for hematocrit (HCT), analyte # 785. Findings include: Refer to D 6016
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 (PT) review using the Centers for Medicare and Medicaid (CMS) Casper Report 096, review of the laboratory's proficiency testing (PT) reports, and staff interview, the laboratory director (LD) failed to ensure the laboratory maintained satisfactory performance in two consecutive events (2nd and 3rd events of 2019) for hematocrit (HCT), analyte # 785. Findings include: 1. Review of Casper Report 096 disclosed the laboratory failed analyte #785, HCT on event 2 of 2019 with a score of 40% and event 3 of 2019 with a score of 60%. 2. Review of the laboratory's proficiency testing reports from American Academy of Family Physicians (AAFP) confirmed the laboratory failed HCT on Events 2 and 3 of 2019. 3. Interview with staff #2 (CMS 209) on 03/30/21 in the lab at approximately 11:30 AM confirmed the LD's failure to ensure the laboratory maintained satisfactory performance in PT.