Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1023296	11/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics, Carla J Cole, Do, Pa	323 N Shiloh Road, Garland, TX	

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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Centers for Medicare and Medicaid Services) national database and verified with the proficiency testing company, American Proficiency Institute (API). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 Successful participation in a proficiency testing program 493.807 Reinstatement of laboratory performing nonwaived testing 493.1403 Laboratory Director, Moderate Complexity
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 a desk review of proficiency testing records, it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of hematology for the analyte WBC (White Blood Cell). Refer to D2130. Note: Initial unsuccessful participation was cited on 12/19/2016. Review of the CMS 0155 report revealed the following results for American Proficiency Institute (API) proficiency testing: API 2016 - 1st Event laboratory received an unsatisfactory score of 60 % for WBC. API 2016 - 3rd Event laboratory received an unsatisfactory score of 60 % for WBC. API 2017 - 2nd Event laboratory received an unsatisfactory score of 20 % for WBC.
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on a desk review of Centers for Medicare and Medicaid Services (CMS) form 0155 and American Proficiency Institute (API)proficiency testing records, it was determined the laboratory had not successfully participated in proficiency testing for the satisfactory performance in a specialty of hematology for the WBC (White Blood Cell) analyte. Findings included: 1. Review of the CMS 0155 report revealed the following results: API 2018 - 3rd Event laboratory received an unsatisfactory score of 40% for WBC. API 2019 - 2nd Event laboratory received an unsatisfactory score of 0% for WBC. 2. Review of the laboratory's API proficiency testing records revealed the following results: API 2018 - 3rd Event laboratory received an unsatisfactory score of 40% for WBC. API 2019 - 2nd Event laboratory received an unsatisfactory score of 0% for WBC. 3. The laboratory must demonstrate sustained satisfactory performance (>/= 80%) on two consecutive testing events for reinstatement. Note: Noninitial unsuccessful participation was cited on 10/03/2017. Review of the CMS 0155 report revealed the following results for American Proficiency Institute (API) proficiency testing: API 2016 - 1st Event laboratory received an unsatisfactory score of 60 % for WBC. API 2016 - 3rd Event laboratory received an unsatisfactory score of 60 % for WBC. API 2017 - 2nd Event laboratory received an unsatisfactory score of 20 % for WBC.
D2121	HEMATOLOGY CFR(s): 493.851(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and American Proficiency Institute (API) records, the laboratory failed to attain a score of at least 80% acceptable responses for each analyte in the specialty of hematology. Findings included: 1. Review of the CMS 0155 report revealed the following results: API 2018 - 3rd Event laboratory received an unsatisfactory score of 40% for WBC. API 2019 - 2nd Event laboratory received an unsatisfactory score of 0% for WBC Diff, Hematocrit, Hemoglobin, WBC and Platelets. 2. Review of the laboratory's API proficiency testing records revealed the following results: API 2018 - 3rd Event laboratory received an unsatisfactory score of 40% for WBC. API 2019 - 2nd Event laboratory received an unsatisfactory score of 0% for WBC Diff, Hematocrit, Hemoglobin, WBC and Platelets. Word Key: WBC Diff=White blood cell differential WBC=White blood cell
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and American Proficiency Institute (API) records from 2017 (1st, 2nd, and 3rd Events), 2018 (1st, 2nd, and 3rd Events), 2019 (1st and 2ndEvents), it was revealed that the laboratory failed to attain an overall testing event score of at least 80% for the 2nd testing event of 2019 for hematology resulting in an unsatisfactory performance. Findings included: 1. Review of the CMS 0155 report revealed the following results: API 2019 - 2nd Event laboratory received an overall event score of 0% for hematology. 2. Review of the laboratory's API proficiency testing records revealed the following results: API 2019 - 2nd Event laboratory received an overall event score of 0% for hematology.
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 a desk review of CMS 0155 form and American Proficiency Institute (API) proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or better) for the same analyte in the specialty of hematology in two consecutive testing events or two out of three consecutive testing events. Two out of three unsatisfactory scores result in unsuccessful PT performance. Findings included: 1. Review of the CMS 0155 report revealed the following results: API 2018 - 3rd Event laboratory received an unsatisfactory score of 40% for WBC. API 2019 - 2nd Event laboratory received an unsatisfactory score of 0% for WBC. 2. Review of the laboratory's API proficiency testing records revealed the following

	results: API 2018 - 3rd Event laboratory received an unsatisfactory score of 40% for WBC. API 2019 - 2nd Event laboratory received an unsatisfactory score of 0% for WBC. Note: Initial unsuccessful participation was cited on 12/19/2016. Review of the CMS 0155 report revealed the following results for American Proficiency Institute (API) proficiency testing: API 2016 - 1st Event laboratory received an unsatisfactory score of 60 % for WBC. API 2016 - 3rd Event laboratory received an unsatisfactory score of 60 % for WBC. API 2017 - 2nd Event laboratory received an unsatisfactory score of 20 % for WBC.
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 a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. 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 a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2130.