

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0503694	(X3) Date Survey Completed 09/23/2024
Name of Provider or Supplier Harlingen Pediatrics Associates	Street Address, City, State 321 South 21st Street, Harlingen, 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 national database and verified with the proficiency testing company. The facility was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 obtained from the CMS (Center

	for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Institute (API), 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 had unsuccessful participation in the specialty of hematology for the analyte White Blood Cell Differential (refer to D2130).
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 the CMS 155 report and proficiency testing records from American Proficiency Institute (API), the laboratory failed to successfully participate for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Hematology for the analyte White Blood Cell Differential resulting in an initial proficiency testing failure. The findings include: 1. A review of the CMS 155 report revealed the laboratory received the following unsatisfactory scores (passing = >80%) for the analyte White Blood Cell Differential: First testing event 2024 60% Second testing event 2024 73% 2. A desk review of the laboratory's American Proficiency Institute (API) results from the first and the second events of 2024 confirmed the proficiency testing scores: First testing event 2024 60% Second testing event 2024 73%
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, 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, the laboratory director failed to

ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program (refer to D2130).