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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D0991967 | (X3) Date Survey Completed 03/15/2021 |
| Name of Provider or Supplier Richmond Pediatrics Associates, Inc | Street Address, City, State 7521 Right Flank Road - Suite 100, Mechanicsville, VA | |
| 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 |
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| D0000 | <p>An unannounced, off-site CLIA proficiency testing desk review was conducted for Richmond Pediatrics Associates, Inc on March 15, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D2016 - 42 CFR. 493.803 Condition: Successful Participation. Specific deficiencies cited are as follows.</p> |
| 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:</p> |

Based on an off-site desk review of the laboratory's proficiency testing (PT) records (2020 Second, 2020 Third Event and 2021 First Event), and interview, the laboratory failed to attain a score of at least eighty percent of acceptable responses for Platelets (PLT) for two (2) of three (3) Hematology testing events resulting in unsuccessful PT performance. See 2121.

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 an off-site desk review of the laboratory's proficiency testing (PT) records, and interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Platelets (PLT) in two (2) of three (3) hematology testing events reviewed, resulting in an unsuccessful PT performance. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) records 2020 FH1-B Event 2, 2020 FH1-C Event 3 and 2021 FH1-A Event 1 revealed PLT scores of less than 80% for the following 2 events: CAP 2020 Hematology Auto Differentials FH1-B Event 2 - PLT = 60%; CAP 2021 Hematology Auto Differentials FH1-A Event 1 - PLT = 60 %; resulting in an unsuccessful PT performance. 2. In a telephone interview with the primary testing personnel on March 15, 2021 at approximately 8:00 AM, the above findings were confirmed.