| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 49D0889860 | 05/29/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Rva Pediatrics, Pc | 10410 Ridgefield Pkwy, Richmond, 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** | An announced CLIA Recertification survey was conducted at RVA Pediatrics, PC on 05/29/24 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of quality control (QC) records, lack of documentation, and interview, the laboratory failed to retain the "Cell Dyn 18 Plus" manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for three of seven lot numbers used from 10/01/22 up to the date of survey on 05/29/24. Findings include: 1. Review of the laboratory's hematology QC records from 10/01/22 up to the date of survey on 05/29/24 revealed the laboratory received and used seven lot numbers of the "Cell Dyn 18 Plus Hematology Control": 2262, 2340, 3065, 3149, 3233, 3317 and 4036. The following three QC lot numbers lacked documentation of acceptable ranges or manufacturer's package inserts: 3149, 3233 and 4036. The inspector requested to review the package inserts. The documentation was not available for review. 2. An exit interview with the laboratory supervisor on 05 /29/24 at 1530 confirmed the findings. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an |

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| | ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's monthly hematology quality control (QC) records, quality assurance (QA) checklists, policy and procedures (P&P), lack of documentation, and an interview, the laboratory failed to provide documentation of an approved QA policy at the date of the survey on 05/29/24. Findings include: 1. Review of the laboratory's monthly hematology QC records revealed a QA checklist that included categories of review for pre-analytical, analytical, and post-analytical categories such as, but not limited to: testing personnel, proficiency testing, quality control materials, and patient test result reviews. 2. The inspector requested to review the QA policy that provided instructions for conducting the reviews and corrective actions to be performed for the categories found on the QA checklists. In an interview with the laboratory supervisor on 05/29/24 at 1500, they stated, "I don't think we have a policy, we have the checklists." 3. An exit interview with the laboratory supervisor on 05/29/24 at 1530 confirmed the findings. |