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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0701010 | (X3) Date Survey Completed 12/07/2021 |
| Name of Provider or Supplier Pearland Pediatrics Pa | Street Address, City, State 2017 East Broadway Suite A, Pearland, 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 |
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| D0000 | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. |
| D2006 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records from 2020-2021, and confirmed in interview, the laboratory failed to analyze proficiency testing materials the same as patient samples for Complete Blood Count (CBC) analysis for six of six testing events in 2020 and 2021. Findings were: 1. Review of the laboratory policy Medonic M Series CBC testing (SOP #1, Revision #2) under Result Interpretation/Troubleshooting revealed "do not report flagged results to the physician. If a flag appears, run prime cycle if needed, let specimen sit for 5 minutes, mix specimen well, and repeat testing if enough sample allows for repeat." 2. Review of the CAP proficiency testing records from 2020 and 2021 revealed the following TM flags (too many WBC populations</p> |

found; slide review advised) for 6 of 6 testing events with no documentation of the repeat analysis. FH2-A 2020 FH2-3 "TM" FH2-B 2020 FH2-08 "TM" FH2-C 2020 FH2-11 "TM"; FH2-13 "TM"; FH2-14 "TM" FH2-A 2021 FH2-02 "TM"; FH2-03 "TM" FH2-B 2021 FH2-06 "TM" FH2-C 2021 FH2-12 "TM" 3. An interview with lab coordinator and technical consultant on 12/7/21 at 1030 hours in the break room confirmed the above findings.