| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D0988967 | 07/24/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ringgold Pediatric Clinic, Pc | 7494 Battlefield Parkway, Ringgold, GA | |

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** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 24, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of proficiency test (PT) documents and staff interview, the laboratory failed to test the PT samples in the same manner as their routine patients' specimens. Findings include: For more details refer to D2007 and D2009 . |
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods |

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| | This STANDARD is not met as evidenced by:<br>Based on review of proficiency test (PT) documents and staff interview, the laboratory failed to examine the PT samples with the laboratory's regular patient workload by testing personnel (TP) who routinely perform the laboratory testing as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed all Hematology PT events for 2017, 2018, and 2019 thus far were performed by Staff #2 (CMS 209). 2. An interview with Staff #2 (CMS 209) on 7/24 /2019 in a medical office at approximately 11:30 a.m. confirmed the aforementioned PT events were performed by Staff #2 (CMS 209). |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD did not sign the attestation statements for the following Hematology PT events: 2017( Event Three); 2018 (Events One through Three); 2019 (Event One). 2. An interview with Staff #2 in a medical office on 7/24 /2019 at approximately 11:30 a.m. confirmed the LD did not sign the aforementioned attestation statements. This is a REPEAT deficiency. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on maintenance document review and staff interview, the laboratory failed to monitor and document laboratory humidity as required. Findings include: 1. Maintenance document review revealed there were no humidity logs available at the time of survey for the following dates: 2017 (July - December); 2018,and 2019 thus far. 2. An interview in a medical office with Staff #2 (CMS 209) on 7/24/2019 at approximately 11:30 a.m. confirmed there were no humidity logs available for the aforementioned dates. |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<br><br>The laboratory director is responsible for the overall operation and administration of |

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| | 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory failed to delegate laboratory duties and responsibilities to qualified testing personnel (TP) as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD designated unqualified TP, due to lack of educational qualifications, to attest for the LD for the following Hematology PT Events: 2017 - Event One; 2018 - Events One through Three; 2019 - Event One. 2. American Proficiency Institute (API) PT document review revealed the LD designated unqualified TP, due to lack of educational qualifications, to review the 2018 Hematology (Third Event) PT report. 3. An interview with Staff #2 (CMS 209) in a medical office on 7/24/2019 at approximately 11:30 a.m. confirmed the aforementioned PT documents were signed by unqualified TP due to lack of educational qualifications. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure that all PT reports were reviewed by the appropriate staff as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD failed to review the Hematology 2018 (Third Event) PT report. 2. An interview with Staff #2 (CMS 209) on 7/24/2019 in a medical office at approximately 11:30 a.m. confirmed the LD did not review the aforementioned PT report. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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)(14) Specify, in writing, the responsibilities and duties of each |

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| | consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing as required. Findings include: 1. SOP review revealed the laboratory SOP did not contain a duties and responsibilities policy an procedure at the time of survey. 2. An interview in a medical office Staff #2 (CMS 209) on 7/24/2019 at approximately 11:30 a.m. confirmed the missing duties and responsibilities policy and procedure from the SOP. This is a REPEAT DEFICIENCY. |