

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0262516	(X3) Date Survey Completed 05/14/2024
Name of Provider or Supplier Chi Memorial Family Practice Associates - Ringgold	Street Address, City, State 4700 Battlefield Parkway, Suite 200, 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
D0000	A recertification survey was performed on May 14, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on review of standard operations procedure manual (SOP) and interview with testing personnel (TP), the laboratory failed to have the proper procedure in place for the Sysmex XN-430 or the date of the initial use of the procedure. Findings: 1. Review of the SOP revealed the procedure in place was for the previous analyzer, the Beckman Coulter ACT Diff II, not the analyzer currently in use, the Sysmex XN-430. The initial date of use was also absent for the Sysmex XN-430. 2. Interview with TP #1 (CMS 209) on 5/14/24 at 12 Noon in the breakroom, confirmed the aforementioned finding(s).</p>
D6024	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</p> <p>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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,</p>

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and testing personnel (TP) interview, the laboratory director failed to ensure corrective actions were documented for any failed PT scores. Findings: 1. Review of the API PT documents for 2023 Hematology Event #1 revealed red blood cell (RBC) received a score of 80%. No corrective actions were documented for the missed RBC parameter. 2. Interview with TP #1 (CMS 209) on 5/14/24 at 9:36 AM in the breakroom, confirmed the missing corrective action for the missed RBC parameter.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of testing personnel (TP) documents and an interview with testing personnel confirmed the technical consultant failed to perform semiannual competency on all testing personnel. Findings: 1. Review of TP competency documents revealed TP #3 (CMS 209) did not have a 6 month competency completed in March 2023. (No documentation available) 2. Interview with TP# 1 (CMS 209) in the breakroom on 5/14/24 at 10:20 AM, confirmed the aforementioned finding.