Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2144527	(X3) Date Survey Completed 11/01/2023
Name of Provider or Supplier Ripley Medical Clinic	**Street Address, City, State** 202 Tucker Street, Ripley, TN	
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of complete blood count (CBC) quality control (QC) records, and staff interview, the laboratory failed to retain QC ranges used for each QC lot number from the date of the last survey on 03/23/22 until 09/19/23. The findings include: 1. Observation of the laboratory on 11/01/23 at 8 am revealed the Sysmex KX-21N CBC instrument in use for patient testing. 2. Review of the laboratory's quality control records revealed the following: Lot 2193 (Low, Normal and High) in use from 07/18/22 to 10/12/22. Lot 2361 (Low, Normal and High) in use from 01/11/23 until 04/03/23. The QC records did not include the QC ranges as set in the instrument during the periods when the lots were in use. 3. Interview with the technical consultant on 11/01/23 at 11:45 am revealed the following: The laboratory puts the QC limits calculated from the package insert in the instrument when the lots are placed into use. The daily printouts that are retained as the laboratory's QC records do not include the QC ranges. The laboratory could not provide proof of the QC ranges used for the selected lot numbers. The laboratory did not have records of QC ranges in use from the date of the last survey to 09/19/23 when the current lot was placed into use. This confirmed the laboratory failed to retain QC ranges for a period of at least two years.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory and staff interview during observation, review of the laboratory's quality control (QC) records, manufacturer instructions for calculating QC limits, patient CBC reports, the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) and interview with the technical consultant, the laboratory failed to use correct manufacturer QC limits for twenty-four of twenty-four QC lots reviewed from 03/24/22 until the date of the survey on 11/01/23, with approximately 3,496 patients reported. The findings include: 1. Observation of the laboratory on 11/01/23 at 8 am revealed the Sysmex KX-21N CBC instrument in use for patient testing (Serial # A6173). Control lots observed in use were 3248 (Levels one, two and three). During observation, the lead testing person stated the laboratory uses the manufacturer package insert ranges for quality control. 2. Review of the laboratory's current QC lot (32480-Level one, two and three) revealed the following manufacturer ranges and ranges in use by the laboratory for selected parameters: Level one (32480710) Manufacturer Laboratory White Blood Cell 3.0-4.0 2.5-4.5 Red Blood Cell 2.19-2.59 1.99-2.79 Hemoglobin 6.2-7.0 5.8-7.4 Hematocrit 16.9-19.7 15.5-21.1 Platelet 63-103 43-123 Level two (32480711) Manufacturer Laboratory White Blood Cell 6.5-7.9 5.8-8.6 Red Blood Cell 4.18-4.70 3.92-4.96 Hemoglobin 12.5-13.9 11.8-14.6 Hematocrit 33.6-38.2 31.3-40.5 Platelet 189-271 148-312 Level three (32480712) Manufacturer Laboratory White Blood Cell16.8-20.4 15.0-22.2 Red Blood Cell 5.10-5.62 4.84-5.88 Hemoglobin 16.2-17.8 15.4-18.6 Hematocrit 42.6-49.8 39.0-53.4 Platelet 482-620 413-689 3. Review of a document provided by the manufacturer and received via email from the technical consultant on 11/03/23 at 9:12 am revealed specific instructions for calculation of QC limits. 4. Review of the manufacturer QC assay sheets revealed the laboratory used an incorrect method of calculating the QC ranges that were entered into the instrument from the date of the last survey to the current survey date (11/01/23) for the low, normal and high QC levels for each lot. The limits as calculated on the QC assay sheets were two times the correct limits. For Lot 2277, the assay sheet with the calculations also indicated the use of QC values for the POCHi instrument instead of the KX-21N instrument. Lot 2025 in use on 03/24/22 until 04/21/22 Lot 2029 in use from 04/22/22 until 07/15/22 Lot 2193 in use on 07/18/22 until 10/12/22 Lot 2277 in use on 10/13/22 until 01/10/23 (Use of values for POCHi instrument) Lot 2361 in use on 01/11/23 until 04/03/23 Lot 3080 in use on 04/04/23 until 06/27/23 Lot 3164 in use on 06/28/23 until 09/19/23 Lot 3248 in use on 09/19/23 until survey date 5. Review of patient CBC final test reports revealed reporting of patient CBC during periods when incorrect QC limits were in use as follows: Patient 28311 reported on 09/12/22 Patient 25994 reported on 03/07/23 Patient 20206 reported on 08/04/23 6. Review of the Form CMS-116 revealed the laboratory reports approximately 184 patients per month, resulting in approximately

	3,496 patient CBCs reported during the period when incorrect QC limits were in use. 7. Electronic interview via text message received on 11/03/23 at 8:23 am confirmed the laboratory had incorrectly calculated the appropriate QC ranges according to manufacturer instructions since the last survey on 03/23/22 to the current survey date (11/01/23).
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's ranges for monitoring of humidity, recorded humidity values, and interview with the technical consultant, the laboratory form for monitoring of humidity for the Sysmex KX-21N Complete Blood Count (CBC) instrument was inconsistent with manufacturer ranges and laboratory policy, resulting in potential use of the instrument on dates when the humidity was outside the established ranges in 2022 and 2023, and ineffective quality assessment with no corrective action performed. The findings include: 1. Observation of the laboratory on 11/01/23 at 8 am revealed the Sysmex KX-21N CBC instrument in use for patient testing (serial #A6173). 2. Review of humidity ranges for the laboratory revealed the following: Manufacturer range = 30 - 85% Laboratory policy = 30 - 85% Monitoring forms = 10 - 80% 3. Review of recorded humidity ranges for the months of September 2022, March 2023 and August 2023 revealed humidity that was out of the manufacturer range for 20 of 67 days as follows: Recorded humidity for the month of September 2022 was outside the range required by the manufacturer and laboratory policy for twelve of twenty-one days (09/14/22, 09/16/22, 09/19/22, 09/20/22, 09/21/22, 09/22/22, 09/23/22, 09/26/22, 09/27/22, 09/28/22, 09/29/22, 09/30/22) Recorded humidity for the month of March 2023 was outside the range required by the manufacturer and laboratory policy for eight of twenty-three days (03/13/23,03/14/23, 03/15/23, 03/16/23, 03/17/23, 03/20/23, 03/21/23, 03/22/23) 4. Interview with the technical consultant on 11/01/23 at 11:45 am confirmed the laboratory's form for monitoring humidity was not consistent with manufacturer ranges or the range stated in laboratory policy in 2022 or 2023, resulting in ineffective quality assessment review of the laboratory's environmental conditions with no corrective action action performed. Word Key Percent = %