Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2144527	11/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ripley Medical Clinic	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
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on laboratory observation, review of patient test reports, staff interview, and electronic mail communication, the White Blood Cell differential was inaccurately reported on the final patient test report from the date patient testing began on the Sysmex XN 330 Complete Blood Count with White Blood Cell Differential (CBC w /Diff) instrument on 03/12/24 until the date of the survey on 11/12/24 with approximately 1,357 patients reported during the period. The findings include: 1. Laboratory observation on 11/12/24 at 8:40 a.m. revealed the Sysmex XN 330 instrument (serial number 16313) used for performing patient testing for CBC w/Diff. 2. A review of the first patient CBC w/Diff reported from the Sysmex XN 330 on 03 /12/24 for patient MRN 28142 revealed the following: The instrument printout from the Sysmex XN 330 contained WBC differential parameters for monocytes, eosinophils, basophils, and immature granulocytes. The final patient test report did not include the monocytes, eosinophils, basophils and immature granulocytes. The monocyte percent (%) and monocyte absolute count (#) from the instrument printout were reported under MXD% and MXD# parameters. 3. A review of patient MRN 32296, reported on 11/12/24 (the survey date), revealed the following: The instrument printout from the Sysmex XN 330 contained WBC differential parameters for

	monocytes, eosinophils, basophils, and immature granulocytes. The final patient test report did not include results for monocytes, eosinophils, basophils, and immature granulocytes. The monocyte % and monocyte # from the instrument printout were reported under MXD% and MXD# parameters. 4. An interview with the technical consultant on 11/12/24 at 12:00 p.m. revealed that the laboratory implemented the Sysmex XN 330 instrument on 03/12/24. The final patient test report in the EMR was not updated to reflect the differential parameters reported by the Sysmex XN 330 instrument. This confirmed the survey findings. 5. According to an electronic mail communication received on 11/15/24 at 4:57 p.m., 1,357 patient WBC differentials were reported incorrectly from the time the laboratory began testing on the Sysmex XN 330 on 03/12/24 until the date of the survey on 11/12/24. Word Key: MRN=Medical Record Number EMR=Electronic Medical Record WBC=White Blood Cell