Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1038322	01/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Hendrix Medical Clinic	2709 West Kingshighway, Suite 6, Paragould, AR	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Through a review of manufacturer's instructions for the Medonic M Series hematology analyzer, a review of the laboratory policy and procedure manual, a review of five randomly selected patient complete blood count reports, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to follow manufacturer's instructions, and laboratory policies for Medonic analyzer flags on complete blood count (CBC) results. Survey findings include: A. Manufacturer's instructions for the Medonic M Series hematology analyzer state that if the WBC differential is flagged with "OM" the action required is to follow the laboratory's protocol for verification of results. B. The laboratory protocol for verifying differential results flagged by the Medonic analyzer, as listed in the policy and procedure manual, is as follows: 1. Check there specimen for clots or agglutination. Recollect if clots are found; 2. If no clots are detected, the specimen will be re-mixed and re-tested; 3. If flags persist, at the discretion of the physician, send the specimen to the reference lab. C. In a review of five randomly selected patient CBC reports, it was determined that two of the five reports included OM flags present on the WBC differential. It was further determined that there was no documentation that the laboratory protocol had been followed on two out of two CBC reports with flags. D. In an interview, at 3:11 p.m. on 1/19/2021, lab employee #4 (as listed on the form CMS-209) confirmed the lack of documented actions for the flagged CBC results.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Through a review of new instrument validation documentation for the Vitros 350 Chemistry analyzer and interviews with staff, it was determined the laboratory failed to validate the reportable range in use for eight of sixteen chemistry tests reviewed. Survey findings include: A. The surveyor reviewed new instrument validation documentation for the Vitros 350 Chemistry Analyzer dated 10/30/2019. In a review of the validation documentation for reportable range, it was determined eight chemistry tests out of sixteen reviewed, failed to have the reportable range in use validated. The following test reportable ranges were not validated: Alanine Aminotransferase (ALT) - the reportable range in use is 6 - 100 but was only validated from 21 to 919; Chloride - the reportable range in use is 50 - 175 but was only validated to 142.5; Glucose - the reportable range in use is 20 - 625 but was only validated to 583.5; Potassium - the reportable range in use is 1 - 14 but was only validated to 10.55; Sodium - the reportable range in use is 75 - 250 but was only validated to 203.5; Total Bilirubin - the reportable range in use is 0.1 - 27 but was only validated to 18.35; Urea - the reportable range in use is 2 - 120 but was only validated to 106; and Triglyceride - the reportable range in use is 10 - 525 but was only validated to 473. B. In an interview at 1:12 p.m. on 1/19/2021, laboratory employee #4 (as listed on the form CMS-209) confirmed the reportable ranges in use by the laboratory had not been fully validated.