Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2154013	(X3) Date Survey Completed 08/13/2019
Name of Provider or Supplier Gold Cross Family Clinic	**Street Address, City, State** 500 N Main, Junction City, 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
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 validation documentation for the FastPak T4 and TSH assays, lack of documentation, a review of laboratory billing records, and interviews with staff, it was determined the laboratory failed to validate precision and normal range for the T4 assay and failed to validate the normal range of the TSH assay. Survey findings include: A. A review of validation documentation dated 10/10/2018, for tests performed on the FastPak immunoassay analyzer, (TSH and T4) revealed the laboratory did not have documentation of validation of the normal range for patient results for either TSH or T4. Through the review it was also determined there was no documentation of validation of the precision for the T4 analyte. The laboratory had documentation of running quality control material five times for each level but the form titled, "Calculating Accuracy and Precision" was not completed for the T4 analyte. B. During an interview, at 3:09 on 8/13/2019, the laboratory director confirmed the validation of the instrument did not include a validation of the precision for the T4 analyte. She further stated that the normal range was determined by looking at information from other facilities, the manufacturer's recommendations, and written references and that the laboratory did not validate the normal ranges on their instrument. C. Billing records show the laboratory reported 15 T4 patient results and 7 TSH patient results since the laboratory began using the FastPak test system.