Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2236474	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Gautam Jha M D	1325 W Whittaker - Ste D, Salem, IL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedures and interview with the laboratory director (LD): the laboratory failed to establish and follow written policies and procedures to assess the competency for one of one technical consultant (TC) at the site. Findings include: 1. Review of the laboratory policy and procedure manual found no policy in place to monitor the competency of technical consultants. 2. Interview with LD at 04:02 pm on 01-14-2025, confirmed the laboratory had failed to establish and follow a competency evaluation for one of one technical consultant.
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: Based on review of laboratory policy and procedures, direct observation, review of

	laboratory validation records, and interview with testing personnel (TP) #1 and the Laboratory Director (LD); the laboratory failed to demonstrate that it obtained performance specifications comparable to those established by the laboratory for the reportable range for two of six analytes [red blood cell test (RBC) and hematocrit testing (HCT)] for the Sysmex XN-530 test system. Findings include: 1. During a tour of the laboratory with TP #1 at 11:10 on 01-14-2025 the surveyor confirmed that the Sysmex XN-530 (serial number: 12414) is used for hematology testing. 2. Review of laboratory policy and procedure identified the policy, "Method Verification Protocols" which stated the following: "Reportable range The reportable range study determines the lowest and highest test results that are reliable and can be reported directly from the analyzer. " 3. Review of the laboratory validation document titled "certificate of reportable range verification" identified the highest test result data for the reportable range study for the following analytes: RBC: 8.31 HCT: 63.8 4. Review of the laboratory police and procedure identified the policy titled "Reportable Ranges" stated under the section titled "Sysmex XN 530" Validated reportable range RBC: 0.02 to 8.60 HCT: 0.2 to 71.7 5. Interview with the LD and TP #1 at 04:05 on 01-14-2025, confirmed that the laboratory had failed to demonstrate the validated reportable ranges for RBC and HCT.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, lack of documentation, and interview with testing personnel (TP) #1 and Laboratory Director (LD), the laboratory failed to perform the control procedures for the evaluation of test methods for six of six hematology analytes on the Sysmex XN-530 analyzer, as specified by the laboratory procedure. Findings include: 1. Review of laboratory policy and procedure identified the document titled "Evaluation of Test Methods" which stated the following: "V. Method comparison Method comparison studies are performed to determine the relative bias (accuracy) between the method under evaluation and the method currently in use, if another method or analyzer is being used in the laboratory .... 1. Analyze specimens from approximately 10-20 patients ... 3. Analyze all samples by both methods. 4. Determine bias by statistical methods." 2. Review of laboratory validation records for the Sysmex XN-530 analyzer identified documents titled "correlation studies" which lacked the required statistical analysis documentation showing method comparison for six of six analytes which include: A. White Blood Cell Count (WBC) B. White Blood Cell differential (WBC-D) C. Red Blood Cell Count (RBC) D. Hemoglobin (HGB) E. Hematocrit (HCT) F. Platelet Count 3. Interview with the LD and TP #1 at 04:10 on 01-14-2025, confirmed that the laboratory had failed to complete the statistical analysis for six of six analytes for the Sysmex XN-530 analyzer as established by the laboratories control procedure.