Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0963940	(X3) Date Survey Completed 11/07/2022
Name of Provider or Supplier Syed A A Zaidi Md Pllc	**Street Address, City, State** 868 Highway 51 South, 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
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 observation of the laboratory, review of patient records, review of validation records, instrument printouts and final patient test results and interview with the laboratory director, the laboratory failed to verify normal ranges for the Sysmex XN 330 Complete Blood Count (CBC) instrument from the time patient testing began on 07/28/21 until the date of the survey on 11/07/22. The findings include: 1. Observation of the laboratory on 11/07/22 at 8:30 am revealed the Sysmex XN 330 in use for patient testing for CBC with Differential (new since the last survey date). 2. Review of the first patient CBC performed (ID # 641214930) revealed the instrument was placed into use on 07/28/2021. 3. Review of validation records for the Sysmex XN 330 revealed no normal range study was performed to verify the laboratory's ranges. 4. Interview with the laboratory director on 11/07/22 at 2:30 pm confirmed the laboratory failed to verify the laboratory normal ranges for the Sysmex XN 330 CBC instrument since patient testing began on 07/28/21 until the date of the survey on 11/07/22.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)

	(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, instrument validation and testing personnel records, and interview with the technical consultant, the technical consultant failed to ensure testing person number two was trained for the use of the Sysmex XN 330 Complete Blood Count (CBC) instrument in 2021 (one of three testing personnel). The findings include: 1. Observation of the laboratory on 11 /07/22 at 8:30 am revealed the Sysmex XN 330 CBC instrument (serial # 13380) in use for patient testing (new since the last survey date). 2. Review of the first patient CBC reported revealed patient testing began on 07/28/21. 3. Review of instrument validation and testing personnel records revealed no documentation of training for one of three testing personnel (testing personnel # two) for the Sysmex XN 330. 4. Interview with the technical consultant on 11/07/22 at 2:30 pm confirmed the technical consultant failed to ensure testing person number two received training for the use of the Sysmex XN 330 CBC instrument in 2021.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, instrument validation and testing personnel records, and interview with the technical consultant, the technical consultant failed to assess testing personnel competency for the use of the Sysmex XN 330 Complete Blood Count (CBC) instrument prior to patient testing in 2021 for three of three testing personnel. The findings include: 1. Observation of the laboratory on 11/07/22 at 8:30 am revealed the Sysmex XN 330 CBC instrument (serial # 13380) in use for patient testing (new since the last survey date). 2. Review of the first patient CBC reported revealed patient testing began on 07/28/21. 3. Review of instrument validation and testing personnel records revealed no documentation of competency assessment for three of three testing personnel for the new instrument prior to patient testing. 4. Interview with the technical consultant on 11 /07/22 at 2:30 pm confirmed the technical consultant failed to assess testing personnel competency for use of the Sysmex XN 330 CBC instrument prior to patient testing in 2021 for three of three testing personnel.