

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0681245	(X3) Date Survey Completed 01/29/2019
Name of Provider or Supplier A Dahhan Md Fccp	Street Address, City, State 120 Professional Lane Ste 101, Harlan, KY	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the TOSOH manufacturer's Operator's manual, review of Daily Environmental logs, and staff interview on 01/29/2019, the laboratory failed to follow established procedure in the daily recording of humidity readings. Findings include: Review of the Operator's manual revealed the manufacturer stated "Take refrigerator and room temperature readings along with relative humidity reading daily". Review of the Daily Environmental Log provided by the manufacturer revealed the facility failed to document humidity readings from 05/12/2017 through 01/28/2019. Interview with Testing personnel #1 at 2:40 PM on 01/29/2019, confirmed the laboratory failed to have a system in place to ensure policy was followed and humidity readings were documented each day of patient testing.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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)</p>

(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 record review and staff interview on 01/29/2019, the laboratory failed to ensure the laboratory director review, approve, sign, and date the performance specifications for the TOSOH Chemistry analyzer prior to routine patient testing. Findings include: Record review revealed performance specifications (precision, accuracy, reportable range verification, reference range verification) were established for the TOSOH analyzer 04/17/2017. There was no documentation of review by the laboratory director prior to the start of patient testing on 05/12/2017. Interview with Testing Personnel #1 at 2:40 PM on 01/29/2019, confirmed the laboratory failed to have a policy in place to ensure performance specifications for each nonwaived unmodified test system were reviewed, approved, signed, and dated prior to reporting patient test results.