

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1043255	(X3) Date Survey Completed 01/09/2019
Name of Provider or Supplier Albaree Health Services Llc	Street Address, City, State 900 Tom Frazier Way, Ste 200, Salyersville, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results from the American Proficiency Institute proficiency testing agency and staff interview on 01/09/2019, the laboratory failed to ensure Hematology proficiency testing samples were tested by all testing personnel who routinely perform Complete Blood Cell (CBC) patient testing. Findings include: Review of attestation statements revealed there was only one of four testing personnel listed on the CMS Form 209 tested proficiency samples for three testing events in 2017 and three testing events in 2018. Testing personnel acknowledged in an interview at 11:30 AM on 01/09/2019, the laboratory failed to establish a policy to ensure proficiency testing samples were rotated among all testing personnel responsible for CBC testing.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test</p>

system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of records from the American Proficiency Institute proficiency testing agency, and staff interview on 01/09/2019, the laboratory failed to ensure attestation sheets were signed by the director and analyst verifying proficiency testing samples were tested in the same manner as patient testing. Findings include: Attestation forms were not available for review for the second and third hematology testing events of 2018. Testing personnel acknowledged in an interview at 11:30 AM on 01/09/2019, the laboratory failed to establish a policy to ensure all attestation forms provided by the proficiency testing agency were signed by the director and testing personnel.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 01/09/2019, the laboratory failed to monitor and document humidity in the laboratory where testing was performed on the Sysmex XP-300 Hematology analyzer from 01/26/2017 through 01/08/2019. Findings include: The Manufacturer's operations manual for the Sysmex XP-300 analyzer lists an operating range for relative humidity between thirty percent (30%) and eighty-five percent (85%). The laboratory failed to provide documentation of humidity being monitored from 01/26/2017 through 01/08/2019. Testing personnel revealed in an interview at 11:30 AM on 01/09/2019, the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 01/09/2019, the Technical Consultant failed to fulfill the responsibility of performing and documenting competency assessments on four of four testing personnel in 2018 and 2019. Findings include: Review of annual competency evaluations performed in 2018 and 2019 revealed peer testing personnel performed and documented the six mandated procedures required for assessment of competency. There was no evidence of participation by the

Technical Consultant. Testing personnel revealed in an interview at 11:30 AM on 01/09/2019, the laboratory failed to have a system in place to ensure the Technical Consultant perform and document competency assessments on all testing personnel.