

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0304601	<b>(X3) Date Survey Completed</b>  10/08/2020
<b>Name of Provider or Supplier</b>  Clay County Hospital Laboratory	<b>Street Address, City, State</b>  83825 Highway 9, 1st Floor South Hall, Ashland, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2173</b>	<p>COMPATIBILITY TESTING CFR(s): 493.863(a)</p> <p>Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records for 2018 - 2020, and an interview with the Laboratory Manager, the surveyor determined the laboratory failed to satisfactorily perform the crossmatch testing for Immunohematology, Event #1, 2020. The laboratory scored eighty percent (80 %), a failing score. This affected one of eight Immunohematology events reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records for 2020 revealed the laboratory scored 80 % for the crossmatch for Event #1. For Immunohematology, this is considered a failing score. 2. In an interview on 10/08 /2020 at 2:55 PM - 3:25 PM, the laboratory manager confirmed the score and acknowledged understanding of the failure.</p>
<b>D5413</b>	<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>

This STANDARD is not met as evidenced by:  
Based on a review of the 2018 - 2020 temperature and humidity logs for the Respiratory Unit (Arterial Blood Gas testing) and an interview with the laboratory manager, the surveyor determined the laboratory failed to document room temperature and humidity for several days in July and August of 2020. This affected two months in 2020, from January to October 8, 2020 (exit day of the survey). The findings include: 1. A review of the temperature and humidity logs revealed the following missing documentation: a) The laboratory did not document the room temperature (established 15 - 31 degrees Celsius) on August 3, 4 and 6; and July 23, 25 and 26, 2020. b) The laboratory did not document the humidity (established 15 - 20 percent) on August 4 and 5; and July 23, 25 and 26 of 2020. 2. In an interview on 10/06/2020 at 3:46 PM, the laboratory manager of the Respiratory Unit stated he was out from July 31 to August 13, 2020; however the other employees should have monitored and documented the temperatures and humidity. In the exit interview on 10/08/2020 at 2:55 PM - 3:25 PM, the laboratory manager confirmed the above noted findings.

**D5417**

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on a review of the 2019 - 2020 monthly quality control records (Roche Diagnostics Quality Assurance Reports) for the Arterial Blood Gases (ABGs), a review of the manufacturer's package inserts for the quality control, and an interview with the laboratory manager of the Respiratory Unit, the surveyor determined the laboratory staff failed to ensure quality control material was not used beyond the expiration dates. In March of 2019, the laboratory analyzed patient samples with three levels of controls; however two levels (Level 1 and 2) had exceeded their expiration dates. This affected one month in 2019 of twenty four months reviewed by the surveyor. The findings include: 1. A review of the Roche Diagnostics Quality Assurance Reports for 2019 revealed only Auto-Trol Level 3 quality control was uploaded to the monitoring system for March. 2. Further review of the Roche Diagnostics Quality Assurance Reports revealed in March of 2019, the three levels of quality control in use were as follows: 21480959 Level 3; 21460854 Level 2 expired 12/2018; and 21470758 Level 1 expired 02/2019. 3. An attached corrective action note indicated Levels 1 and 2 had expired, prior to March 2019, and the staff were not aware, when the patient specimens were run in March. The laboratory manager became aware (no date given), when he attempted to upload the data, and the system would only accept the quality control data of the material with a current date, Level 3. According to this note, the laboratory staff was advised by the Roche representative the patients were acceptable, as long as the controls were within acceptable range; although two of the three levels had expired. 4. In an interview on 10/06/2020 at 3:46 PM, the laboratory manager of the Respiratory Unit confirmed the above noted findings. When asked how many patients were tested, using only one level of quality control material, deemed acceptable to use, the laboratory manager replied, ten patients were run. In a follow-up interview at exit on 10/08/2020 at 2:55 PM, the laboratory manager again confirmed the above noted findings. .

## CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the calibration verification records for the Siemens Dimension - EXL 200, and an interview with the laboratory manager (also serving as the Technical Consultant), the surveyor determined the laboratory failed to perform the calibration verifications for electrolytes, at least every six months, from July 2018 - March 2019. This affected one of seven calibration verifications reviewed by the surveyor. The findings include: 1. A review of the Chemistry calibration verification records for the Siemens Dimension revealed the laboratory performed a calibration verification on July 26, 2018 and then on March 15, 2019, almost an eight month time-frame. A review of the records revealed the laboratory's usual practice was to perform the calibration verification every four months. 2. In an interview on 10/08/2020 at 2:55 - 3:25 PM, the laboratory manager stated he had been trying to keep up and perform the calibration verification about every four months. The surveyor reviewed the calibration verifications with the laboratory manager and asked if there was a written policy for the calibration verifications to include the required frequency. The laboratory manager stated he did not have a written policy and procedure. Again, the laboratory manager stated he had been performing the verifications more frequently than every six months, and he was not sure what happened between July 2018 and March 2019. The laboratory manager stated there should have been another between the dates. .