

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659663	(X3) Date Survey Completed 02/12/2019
Name of Provider or Supplier Collom & Carney Clinic Laboratory	Street Address, City, State 5002 Cowhorn Creek Rd, Texarkana, TX	
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
D2153	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a)</p> <p>Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on review of College of American Pathologists (CAP) proficiency testing (PT) documentation for 2017 - 2018 and staff interview, the laboratory failed to attain a score of a least 100 percent in one of three events for the year of 2017 in the specialty of immunohematology, subspecialty ABO Group. Findings: 1. CAP PT documentation was reviewed. The evaluation sheet for sample set J-C 2017 in the 3rd event 2017 showed a score of 0 of 5 for ABO Group. 2. In an interview at the site on 02-12-2019, laboratory technical supervisor # 2 (CMS form 209) stated that, although she had reviewed and signed the results, she had not noticed the unsatisfactory score. .</p>
D2154	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(b)</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 review of CAP PT documentation and staff interview, the laboratory failed to attain an overall testing score of at least 100 percent for immunohematology (ABO Group/Rh Type) in the third event of 2017. Findings: 1. Review of CAP PT documentation for the third event 2017, sample set J-C 2017 Transfusion Medicine, revealed a score of 0 of 5 for ABO Group/Rh Type, resulting in a proficiency event</p>

	<p>score of 50. 2. In an interview at the site on 02-12-2019, technical supervisor # 2 confirmed the PT score as unsatisfactory. 3. The CAP evaluation included a notation, "A score of zero has been given due to the lack of response." No explanation could be offered at the time of the survey. .</p>
<p>D2160</p>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(e)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on review of CAP PT documentation and staff interview, the laboratory failed to take or document remedial action for an unsatisfactory score for ABO Group/Rh Type in the third testing event of 2017. Findings: 1. A review of CAP PT documentation for 2017 revealed an unsatisfactory score for ABO Group/Rh Type in the third event 2017. Refer to D2154. 2. No documentation of remedial action was found or could be made available during the survey. 3. In an interview at the site on 02-12-2019, technical supervisor # 2 stated that she had not noticed the score during result review, and to her knowledge no remedial action had been taken. .</p>
<p>D3003</p>	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: . Based on surveyor observation and staff interview, the laboratory failed to minimize the risk of contamination by patient specimens in the staff break room. Findings: 1. The space provided for document review and interview was a staff break room equipped with tables, a refrigerator for food storage and a sink. Against a wall near the exit was a refrigerator bearing a sign with the notice, "Biohazard: Caution-- Biological Hazard." 2. During the survey on 02-12-2019, at 2:35 PM CDT, a laboratory staff member entered the room, opened the biohazard-marked refrigerator, retrieved a rack of blood tubes containing patient specimens and set it on the table. The staff member located a particular specimen in the rack, removed it, replaced the rack in the marked refrigerator and left the room. Both the laboratory director and technical supervisor # 2 were present at the time. Approximately five minutes later another staff member entered the break room, removed a container of food from the non-marked refrigerator, set it on the table in the same area recently occupied by the specimen rack and proceeded to eat. 3. In the exit interview on 02-12-2019 at 4:45 PM CDT, the laboratory director and technical supervisor # 2 acknowledged they had seen the staff member place the tube rack on the table. Technical supervisor # 2 stated she had told the staff "a million times not to do that." .</p>