

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442194	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Doctor's Clinic	Street Address, City, State 106 W 12th, Caruthersville, MO	
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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS 96 proficiency report, interview with the laboratory director and phone interview with the proficiency testing(PT) program, the laboratory failed to authorize the PT program to release the data to HHS. Findings: 1. Review of the CMS 96 proficiency report, pulled by the state surveyor, showed no results for proficiency testing. 2. Interview with the laboratory director on January 15, 2019 at 11:00 AM confirmed the laboratory failed to authorize the PT program to release the results to HHS. 3. Phone interview with American Proficiency Institute(API) on January 16, 2019 at 10:AM confirmed the laboratory did not authorize API to release proficiency data to HHS.</p>
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 2016, 2017, 2018 proficiency testing(PT) records, personnel documentation and interview with the laboratory director, the laboratory failed to</p>

include 3 of 4 testing personnel in the PT samples testing process. Findings: 1. Review of the CMS 209 personnel form revealed 4 testing personnel, who routinely perform testing in the laboratory. 2. Review of PT attestation sheets for complete blood cell counts(CBC) showed testing person #1 performed the third event for 2016, the second and third events for 2017, and the first and second event of 2018. 3. Interview with the laboratory director on January 15, 2019 at 11:30 AM confirmed, the laboratory failed to include 3 of 4 testing personnel, who routinely test patient samples, in the rotation for PT during 2016, 2017 and 2018.

D2016

SUCCESSFUL PARTICIPATION
CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:
Based on onsite review of 2016, 2017, 2018 hematology proficiency testing (PT) from the provider and interview with the laboratory director, the laboratory failed to successfully participate in PT. Refer D2130, unsatisfactory performance for analytes: granulocytes, monocytes and lymphocytes. Refer D2131, failure to achieve an overall testing event score of satisfactory performance for white blood cell(WBC) autodifferential.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on onsite review of 2016, 2017, 2018 hematology proficiency testing(PT) results reported by the PT provider and interview with the laboratory director, the laboratory failed to achieve a satisfactory testing performance for the analytes: granulocytes, lymphocytes, and monocytes. Findings: 1. Review of third event of 2016 showed a score of 20 percent for the analyte, monocytes. 2. Review of the second event of 2017 showed a score of 0 percent for the analytes: granulocytes, lymphocytes and monocytes. 3. Review of the first event of 2018 showed a score of 0

percent for the analytes: granulocytes and lymphocytes. 4. Interview with the laboratory director on January 15, 2019 at 11:30 confirmed the laboratory failed to achieve satisfactory performance for granulocytes, lymphocytes and monocytes.

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on onsite review of hematology proficiency testing(PT) results provided by the PT provider and interview with the laboratory director, the laboratory failed to achieve an overall satisfactory testing performance for white blood cell(WBC) autodifferential. Findings: 1. Review of third event of 2016 showed an overall score of 73 percent for WBC differential. 2. Review of the second event of 2017 showed an overall score of 0 percent for WBC differential 3. Review of the first event of 2018 showed an overall score of 0 percent for WBC differential. 4. Interview with the laboratory director on January 15, 2019 at 11:30 confirmed the laboratory failed to achieve an overall score of satisfactory performance.

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 review of the Drew 3 hematology manufacturer's manual and interview with the laboratory director, the laboratory failed to monitor and document the room temperature and humidity of the laboratory. 1. Review of the Drew 3 hematology analyzer manufacturer's manual for performance specifications revealed to operate the analyzer in a temperature range of 18-32 degrees Celsius with a relative humidity of 50-80 percent. 2. Review of the temperature documentation logs showed the laboratory failed to document room temperature and humidity. 3. Interview with the laboratory director on January 15, 2019 at 11:00 AM confirmed the laboratory failed to document the room temperature and humidity in the laboratory where the Drew 3 hematology analyzer was in operation.