

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2042041	(X3) Date Survey Completed 01/24/2019
Name of Provider or Supplier Doctors Care City Of Columbia	Street Address, City, State 2012 Harden St, Suite112, Columbia, SC	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 01/24/2019, based on procedure manual review, proficiency testing review, and testing personnel review, the laboratory failed to ensure that proficiency testing (PT) for complete blood count (CBC) testing were routinely tested the same number of times as patient samples for 1 of 7 PT events reviewed from 2017 to 2019 (2018 Event 3). Findings include: 1. The laboratory procedure defined the following values as panic values: a. WBC (white blood cell count) less than 3 or greater than 15 b. Hgb (hemoglobin) less than 10 or greater than 20 c. Plt (platelet count) less than 100 or greater than 600 d. Hct (hematocrit) less than 30 or greater than 60 The procedure manual stated that all panic values would be rerun to ensure accuracy. 2. Review of the American Proficiency Institute (API) proficiency testing events from 2017 to 2019 revealed the following proficiency testing events with critical values that were reported and not repeated according to laboratory policy. a. 2018, Event 3: i. sample 12- WBC 17.0; ii. sample 14- WBC 2.8; Hgb 6.0; Hct 17.7; Plt 64 3. Testing personnel confirmed during an onsite interview on 01/24/2019 at 1:00pm that the laboratory failed to ensure that proficiency testing samples were routinely tested the same number of times as patient samples.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
During an onsite recertification survey on 01/24/2019, based on proficiency testing record review, and testing personnel interview, the laboratory failed to review and evaluate proficiency testing results for 1 of 7 proficiency testing events reviewed from 2017 through 2019 (2018, Event 3). Findings include: 1. Review of proficiency testing results revealed the following scores: a. 2018, Event 3; 0% for vaginal wet prep identification There was no documentation of director review and evaluation or corrective action for the failure. 2. Testing personnel confirmed during onsite interview on 01/24/2019 at 01:00pm, that the laboratory had failed to review and evaluate proficiency testing results.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
During an onsite recertification survey on 01/24/2019, based on laboratory procedure manual review, direct observation, and confirmation by the laboratory testing personnel, the laboratory failed to follow their written procedures for patient specimen labeling for 3 of 5 observed specimens. Findings include: 1. The laboratory procedure manual stated that all patient specimens would be labeled with the following information prior to testing; patient name, date of birth, and medical record number. 2. During a laboratory walkthrough on 01/24/2019 at 10:15 am, five patient specimens were observed on the CBC testing rack. Three of the five specimens did not include the required labeling information (patient name, date of birth and medical record number). The laboratory manager stated that the specimens had been processed and results were released. 3. Testing personnel confirmed during interview on 01/24/2019 at 1:00pm, that the laboratory had failed to follow their written procedures for labeling patient specimens prior to testing.

D5777

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(b)(c)

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
During an onsite recertification survey on 01/24/2019, based on the laboratory procedure manual, lack of documentation and testing personnel interview, the laboratory failed to ensure that documentation of the laboratory director's review of complete blood count (CBC) test result comparison procedures was performed for 2 of 2 years reviewed (2017 and 2018). Findings include: 1. The laboratory procedure

manual stated that the records of 6 patients who had CBC laboratory procedures requested would be selected and reviewed by the laboratory bi-annually to ensure the following criteria were consistent: (1) patient age, (2) sex, (3) diagnosis or pertinent clinical data, (4) distribution of patient test results, (5) relationship with other test parameters. The procedure manual stated that this review would be signed and dated by the laboratory director. 2. Documentation of the laboratory's director signature of the bi-annual patient record review for CBC testing was unavailable for review on the day of the survey for the years 2017 and 2018. 3. Testing personnel confirmed during an onsite interview on 01/24/2018 at 1:00pm that the laboratory had failed to ensure that documentation of the laboratory director's review of complete blood count (CBC) test result comparison procedures was performed as required for the years 2017 and 2018.