

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1026323	(X3) Date Survey Completed 02/20/2019
Name of Provider or Supplier Medicare Express-North Charleston Llc	Street Address, City, State 8740 Rivers Ave, N Charleston, 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
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> <p>This STANDARD is not met as evidenced by: Based on American Academy of Family Practitioners (AAFP) proficiency testing record review, and testing personnel interview, the laboratory failed to review and evaluate proficiency testing results for 4 of 7 proficiency testing events reviewed from 2017 through 2018 (2017, Events A, B, and C; 2018, Events A). Findings include: 1. Review of proficiency testing results revealed the following scores: a. 2017, Event A; 60% for hematocrit a. 2017, Event B; 60% for thyroid stimulating hormone, 0% for testosterone a. 2017, Event C; 60% for red blood cell count, 0% for hematocrit a. 2018, Event A; 20% for white blood cell count, 40% for lymphocyte, 40% for granulocyte, 20% for red blood cell count, 20% for hemoglobin, 20% for hematocrit, 60% mean corpuscular volume, 40% platelet There was no documentation of director review and evaluation or corrective action for the failure. 2. Testing personnel confirmed during onsite interview on 02/20/2019 at 3:30pm, that the laboratory had failed to review and evaluate proficiency testing results.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.</p>

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on 02/20/2019, based on procedure manual review and confirmation by testing personnel, the laboratory failed to establish and maintain a description of the course of action to take if the hematology analyzer became inoperable and also failed to establish and define hematology critical test values. Findings include: 1. The laboratory's procedure manual did not include documented critical values or an established or approved procedure for the actions to take if the hematology became inoperable. 2. Testing personnel confirmed during an onsite interview on 02/20/2019 at 3:15pm that there were no defined critical values or an established protocol if the hematology became inoperable.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on instrument operator manual review, instrument maintenance record review and testing personnel interview, it was determined that the laboratory failed to document semi-annual maintenance on the Cell- Dyn hematology instrument for two of two years reviewed (2017 through 2018). 1. Review of the Cell-Dyn hematology analyzer revealed that all operators should routinely perform scheduled maintenance to ensure optimum performance of the instrument including a monthly rinse of the lyse inlet reagent line and semi-annual cleaning of the printer. 2. Review of the Cell-Dyn hematology analyzer maintenance logs on 02/20/2019 at 11:15am revealed that the monthly rinse of the lyse inlet reagent line and semi-annual cleaning of the printer had not been documented for two of two years reviewed (2017 through 2018). 3. Testing personnel confirmed during an onsite interview on 02/20/2019 at 3:30pm that the monthly and semi-annual maintenance had not been performed for the reviewed years.

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:

Based on the laboratory procedure manual, lack of documentation and testing personnel interview, the laboratory failed to ensure that documentation 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 10 patients who had CBC laboratory procedures requested would be selected and reviewed by the laboratory quarterly 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. 2. Documentation of a quarterly 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 02/20/2018 at 3:00pm that the laboratory had failed to ensure that a complete blood count (CBC) test result comparison was performed as required.