Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2050127	02/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Medcare Express-North Charleston Llc	2863 N Hwy 17, Mt Pleasant, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: This STANDARD is not met as evidenced by: During an onsite recertification survey on 2/14/20, based on proficiency testing review, lack of documentation, and staff interview, it was determined that the staff failed to sign attestation statements from 3 of 3 events of 2018 proficiency testing (2018, Events 1, 2, and 3). Findings include: 1. Review of 2018 proficiency testing records revealed that the attestation statements for the 1st, 2nd, and 3rd events of 2018 were not signed by testing personnel or by the lab director. There was no corrective action for the missing signatures. 2. Testing personnel confirmed during an onsite interview on 02/14/20 that the reviewed attestation forms were not signed as required.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems

	identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: This STANDARD is not met as evidenced by: During an onsite recertification survey on 02/14/20, based on a review of policy and procedure manual, observation, and staff interview, it was determined that the staff failed to document quality assessment (QA) activities for 2 of 2 years reviewed (2018, 2019). Findings include: 1. The laboratory policy and procedure manual stated that a QA plan must be reviewed and documented with employees anually. 2. Based on an onsite record review on 02/14/20, no documentation of a QA plan or its review was made available for the years of 2018 and 2019. No corrective action for the missing QA review was available for review. 3. Testing personnel confirmed during an onsite interview on 02/14/20, that no QA plan was reviewed or documented for the years 2018 and 2019.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: This STANDARD is not met as evidenced by: During an onsite recertification survey on 02/14/20, based on review of Cell Dyn 1800 operator's guide, calibration record review, and testing personnel interview, it was determined that the staff failed to ensure that a calibration was performed on the analyzer at least every six months as required by the manufacturer for two of two years reviewed (2018 and 2019). Findings include: 1. The Cell Dyn 1800 operator's guide stated that a calibration should be performed at least every six months. 2. Calibration records for the years 2018 and 2019 were not available for review survey. There was no corrective action documented for the missing calibrations. 3. Testing personnel confirmed during an onsite interview on 02/14/20 that calibrations for the years 2018 and 2019 were not performed as required.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by:

	Surveyor: Roshan Benson This standard is NOT MET as evidenced by: During an onsite recertification survey on 02/14/2020, based on the laboratory procedure manual, lack of documentation and testing personnel interview, the laboratory failed to ensure that testing personnel were evaluated annually after the first year of testing patient specimens for 6 of 6 testing personnel listed on the CMS 209(employees 1 through 6) for the years 2018 and 2019 . Findings include: 1. The laboratory listed 6 testing personnel on the CMS-209 on the day of the survey. 2. Documentation of an annual training and evaluation for the years 2018 and 2019 was unavailable for review on the day of the survey for 6 of 6 testing personnel (employees 1 through 6) . 3. Testing personnel confirmed during an onsite interview that the laboratory had failed to ensure that testing personnel were evaluated at least annually after the first year of testing patient specimens.