

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D1059581	(X3) Date Survey Completed 04/12/2018
Name of Provider or Supplier Elliot Poct Lab At Londonderry Urgent Care	Street Address, City, State 40 Buttrick Rd, Londonderry, NH	
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
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to ensure that the quality control program for hematology and chemistry testing was maintained in 2017 and 2018. Findings include: 1) Review on 4/12/2018 of the laboratory's control procedure titled "I STAT IQCP STUDY" signed and approved by the laboratory director on 1/5/2015 revealed instruction to perform quality control testing for Prothrombin (PT/INR) and Chem 8+ (analytes include sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, and creatinine) test cartridges upon arrival and every 30 days. 2) Review on 4/12/2018 of control records from April 2017 to April 2018 for PT/INR and Chem 8+ revealed control testing was performed monthly. There was no documentation that the laboratory performed control testing for PT/INR and Chem 8+ reagent test cartridges upon arrival of new shipments at this laboratory. 3) Interview on 4/12/2018 at 12:45 p.m. with the technical consultants confirmed the above findings. 4) The laboratory performs an estimated 2,804 sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine tests and 136 PT/INR tests annually.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical consultant failed to evaluate personnel performing hematology and chemistry testing semiannually in their first year of testing in 2016 and 2017. Findings include: 1) Review on 4/12/2018 of three personnel records from 2016, 2017, and 2018 revealed two of the three personnel were not assessed for competency for a second semiannual evaluation in their first year of performing hematology and chemistry patient testing at this laboratory under this (CLIA ID) and the third personnel received no semiannual evaluation for competency assessment in their first year of performing hematology and chemistry patient testing at this laboratory under this (CLIA ID). 2) Interview on 4/12/2018 at 10:50 a.m. with the technical consultants (TC) confirmed the above finding. The TCs revealed that competency assessments performed at other laboratories under different CLIA ID's were often used to document competency assessment for shared testing personnel at this laboratory.