Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0002717	(X3) Date Survey Completed 11/15/2018
Name of Provider or Supplier Concord Hospital - Franklin	**Street Address, City, State** 15 Aiken Ave, Franklin, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. (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 record review and staff interview the laboratory's procedure manual failed to include normal values used for routine chemistry and toxicology testing in 2018. Findings include: 1) Review on 11/15/2018 of two patient test reports from 2018 revealed the normal values were included on test report (dated 1/27/2018) for an arterial blood specimen and a test report (dated 11/10/2018) for a venous blood specimen included a different set of normal values. Both arterial and venous blood gas test reports included results and normal values for hydrogen concentration (pH), carbon dioxide partial pressure (pCO2), oxygen partial pressure (pO2), oxygen

	saturation (O2Sat), oxyhemoglobin (O2Hb), carboxyhemoglobin (COHb), methemoglobin (MetHb), bicarbonate (HCO3), and base excess (BE). 2) Review on 11/15/2018 of the laboratory's procedure titled "ABG Normal Range Values" last revised 5/2013 revealed normal values for the following reported arterial blood gas analytes: pH, pCO2, pO2, COHb, MetHb, and O2Hb. The procedure failed to include normal values for all reported venous blood gas analytes and failed to include normal values for reported arterial blood gas O2Sat, HCO3, and BE analytes. 3) Interview on 11/15/2018 at 11:00 a.m. with the technical supervisor confirmed normal blood gas values for venous blood specimens were not included in the laboratory procedure.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 on 11/14/2018, the technical supervisors failed to evaluate the performance of testing personnel performing general immunology, chemistry, hematology and immunohematology testing semiannually within their first year of performing testing on patient specimens in 2017 and 2018. Findings include: 1) Review on 11/14/2018 of five personnel records revealed three new testing personnel began performing general immunology, chemistry, hematology and immunohematology testing patient specimens in 2017 and 2018. Review of competency evaluation records for each of the three new testing personnel revealed an initial competency evaluation performed as part of training and an annual competency evaluation. 2) Review on 11/14/2018 of the laboratory's procedure titled "Competency Assessment Policy" last revised 7/2018 revealed "Competency of newly hired staff will be performed twice within the first year of employment and then annually thereafter." 3) Interview on 11/14/2018 at 12:00 p.m. with the technical supervisors confirmed the above findings. The technical supervisors revealed new testing personnel must pass the initial competency assessments in order to complete training and to be allowed to perform testing on their own (without trainer supervision) and then the first semiannual competency is performed a year later (annual).