

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0002728	(X3) Date Survey Completed 05/08/2019
Name of Provider or Supplier Concord Hospital - Laconia	Street Address, City, State 80 Highland St, Laconia, 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
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to promptly notify the authorized person ordering the test or the individual using the test results of reporting errors for chemistry tests in 2019. Findings include: 1) Review on 5/8/2019 of corrected reports from January through March 2019 revealed results for a comprehensive metabolic profile (CMP) (includes chemistry analytes: glucose, creatinine, calcium, sodium, potassium, chloride, carbon dioxide, alkaline phosphatase, total bilirubin, albumin, total protein, alanine aminotransferase, and aspartate aminotransferase) was first reported on 12/1/2018. This report had been corrected on 3/8/2019 at 9:13 a.m. by personnel in the IT department. The correction to the report included changes to the normal reference ranges and result flags (low, normal, high) for the CMP analytes. There was no documentation that the personnel from IT had notified someone of the correction (e.g. the ordering provider, personnel responsible for providing care to the patient, or the laboratory). 2) Interview with the General Supervisor (GS) on 5/8/2019 at 8:30 a.m. confirmed the above finding. The GS revealed the corrected report was due to the correction of either the gender or date of birth entered during the registration process which resulted in changes to the CMP analytes' normal reference ranges and the result flags.</p>
D6063	LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to obtain documentation of qualifications for 2 of 4 testing personnel performing moderately complex chemistry and hematology testing in 2017, 2018, and 2019. Refer to tag D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed ensure 2 of 4 testing personnel met qualification requirements prior to performing moderately complex chemistry and hematology testing in 2017, 2018 and 2019. Findings include: 1) Review on 5/7/2019 of 4 personnel records for testing personnel performing moderately complex chemistry and hematology testing revealed 2 of 4 of testing personnel files had no documentation of educational qualifications. 2) Interview with the General Supervisor and human resources personnel on 5/7/2019 at 1:00 p.m. confirmed the personnel records for 2 of the 4 testing personnel did not include educational qualifications.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to ensure

policies and procedures used by the information technology (IT) personnel to correct patient test reports were corrected promptly and proficiently in 2019. Findings include: 1) Review on 5/8/2019 of corrected reports from January through March 2019 revealed results for a comprehensive metabolic profile (CMP) (includes chemistry analytes: glucose, creatinine, calcium, sodium, potassium, chloride, carbon dioxide, alkaline phosphatase, total bilirubin, albumin, total protein, alanine aminotransferase, and aspartate aminotransferase) was first reported on 12/1/2018. This report had been corrected on 3/8/2019 at 9:13 a.m. by personnel in the IT department. The correction to the report included changes to the normal reference ranges and result flags (low, normal, high) for the CMP analytes. There was no documentation that the personnel from IT had notified someone of the correction (e.g. the ordering provider, personnel responsible for providing care to the patient, or the laboratory). Further review revealed on 3/8/2019 at 10:20 a.m. the laboratory's information system (LIS) changed the reference ranges (and result flags) back to what had originally reported on 12/1/2019. 2) Interview with the General Supervisor (GS) on 5/8/2019 at 8:30 a.m. confirmed the above finding. The GS revealed the corrected report was due to the correction of either the gender or date of birth entered during the registration process which resulted in changes to the normal reference ranges and the result flags. The GS could not explain at the time of survey why the IT department and not laboratory personnel changed the results of the normal reference range or why the LIS changed the results back.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to ensure qualifications were met for 5 of 6 testing personnel performing high complexity hematology, immunohematology, and microbiology testing in 2017, 2018, and 2019. Refer to tag D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory

training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed ensure 5 of 6 testing personnel met qualification requirements prior to performing high complexity hematology, immunohematology, and microbiology testing in 2017, 2018 and 2019. Findings include: 1) Review on 5/7/2019 of 6 personnel records for testing personnel performing high complexity hematology, immunohematology, and microbiology testing revealed 5 of 6 testing personnel files had no documentation of educational qualifications. 2) Interview with the General Supervisor and human resources personnel on 5/7/2019 at 1:00 p.m. confirmed the personnel records for 5 of the 6 testing personnel did not include educational qualifications.