

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0652812	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier New Hampshire Public Health Lab	Street Address, City, State 29 Hazen Dr, Concord, 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
D2009	<p>TESTING OF PROFICIENCY SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to attest that proficiency testing (PT) samples were integrated into the patient workload using the laboratory's routine methods. Findings include: 1. Record review conducted on 11/28/18 of 2017 and 2018 College of American Pathologist (CAP) Immunology, Syphilis Serology, and Virology PT documentation revealed that the LD failed to sign the 2017 and 2018 CAP PT attestation statements. The record review further revealed that the Technical Supervisor (TS1) signed the 2017 and 2018 (CAP) Immunology, Syphilis Serology, and Virology PT attestation statements instead of the LD. 2. Record review conducted on 11/29/18 of 2017 and 2018 College of American Pathologist (CAP) Bacteriology, Mycology, Parasitology, and Mycobacteriology PT documentation revealed that the LD failed to sign the 2017 and 2018 CAP PT attestation statements. The record review further revealed that the Technical Supervisor (TS2) signed the 2017 and 2018 (CAP) Bacteriology, Mycology, Parasitology, and Mycobacteriology PT attestation statements instead of the LD. 3. Staff interviews conducted on with the TS1 on 11/28/18 at 11:45 AM and with the TS2 on 11/29/18 10:30 AM confirmed the above findings. 4. Staff interview with the Quality Assurance Manager on 11/29/18 at 1:30 PM confirmed the above findings and further revealed that the LD failed to delegate in writing the responsibility of signing the attestation statements to TS meeting the qualifications of 493.1447.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p>

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to review and evaluate an unacceptable VDRL, CSF Proficiency Test titer score the laboratory received for the College of American Pathologists (CAP), G-A 2018 Syphilis Serology proficiency testing (PT) event. Findings include: 1. Record review conducted on 11/26/2018 of the CAP G-A Syphilis Serology evaluation report revealed that the laboratory reported an unacceptable titer result of 1:2 for sample G-01. The CAP G-A Syphilis Serology evaluation report included an acceptable titer range of 1:4 to 1:32 for sample G-01. 2. Record review conducted on 11/28/18 of 2017 and 2018 PT records revealed no documented review or evaluation of the unacceptable VDRL, CSF 1:2 titer result reported for sample G-01 in the CAP Syphilis Serology G-A 2018 event. 3. Interview with the technical supervisor (TS) on 11/28/18 at 10:45 AM confirmed the above findings.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on staff interview and record review, the Urine Multi-element by Inductively Coupled Plasma- Mass Spectrometry (ICP-MS) and Cobas Ampliprep Cobas Taqman HCV RNA v2.0 Procedures were not signed and approved by the current laboratory director (LD) before use. Findings include: 1. Record review conducted on 11/28 /2018 of the Urine Multi-element by ICP-MS, Document ID: QU-Template-SOPCH-B-SOP-401, Revision 6, effective 11/16/2018, and Cobas Ampliprep Cobas Taqman HVC RNA v2.0, Document ID: VI-MO-SOP-011, Revision 1, effective 04/05/2018, revealed that the procedures were not signed and approved by the current LD prior to use. 2. Interview with the Quality Assurance Manager (QAM) on 11/28/18 at 3:30 PM confirmed these findings. 3. Interview with the QAM on 11/28/18 at 3:30 PM further revealed that Qualtrax document control system folder assignments were modified after July 2017 and the LD folder assignment was removed.

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 of 2017 and 2018 new employee competency assessment

records and interviews with the Virology, Chemistry, and Bacteriology Technical Supervisors (TS), the laboratory failed to evaluate and document the competency of 6 out of 9 new testing personnel (TP) semi-annually during their first year performing high complexity testing. Findings include: 1. Record review conducted on 11/26/18, 11/28/18, and 11/29/18 of employee competency documentation of new TPs hired in the specialties of Bacteriology, Virology, and Chemistry between 10/01/16 through 11/21/18 revealed that 6 out of the 9 new TP were not evaluated semi-annually during their first year performing high complexity testing. 2. Interviews conducted with the Chemistry TS and Bacteriology TS on 11/29/18 10:45 AM and the Virology TS on 11/28/18 10:00 AM confirmed the above findings.