Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0191390	03/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Northeastern Laboratory Medicine Inc	271 North Cedar Street, Hazleton, PA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the technical supervisor (TS), the laboratory failed to establish a competency assessment policy to assess the competency of 1 of 1 TS from 2018 to the day of survey. Findings Include: 1. On the day of survey, 03/11/2019, the laboratory failed to provide a competency assessment policy to assess the competency of 1 of 1 TS (also listed on the CMS Laboratory personnel from as the technical consultant and general supervisor) in 2018 and 2019. 2. The laboratory could not provide documentation of the competency assessment performed on the TS in 2018 and 2019. 3. The TS confirmed the finding above on 03/11/2019 around 9:30 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with technical Supervisor

	(TS), the laboratory failed to include a negative and positive quality control (QC) material, each day of patient testing for serum Human chorionic gonadotropin (hCG) testing performed on the Consult Diagnostic hCG combo cassette kits used from 2018 to 2019. Findings include: 1. On the day of survey, 03/11/2020, review of hCG QC records revealed the laboratory did not perform external QC on the Consult Diagnostic hCG combo cassette kits each day of patient testing for hCG serum performed from 2018 to 2019. 2. In 2018, 99 serum hCG tests were analyzed. 3. In 2019, 50 serum hCG tests were analyzed. 4. The TS confirmed the findings above on 03/11/2020 around 11:30 am.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the Technical supervisor (TS) and testing personnel (TP) #4 , the laboratory failed to check and document each batch or shipment of Thermo Scientific Remel media for sterility, its ability to support growth, select or inhibit specific organisms, and/or produce a biochemical response (end user QC) in 2018 and 2019. Findings Include: 1. On the day of survey, 03/11/2020, review of QC records revealed, the laboratory did not perform end user QC on the following Thermo Scientific Remel media used for throat and urine cultures in 2018 and 2019: - Chocolate media. - Blood media. - CNA media. - MacConkey media. - MacConkey Agar with Sorbitol media. - XLD media. 2. In 2018: 31 throat cultures and 2,403 urine cultures were examined. 3. In 2019: 36 throat cultures and 2,879 urine cultures were examined. 4. The medical assistant confirmed the findings above on 03/11/2020 around 12:00 pm.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical supervisor (TS), the LD failed to ensure a quality assessment (QA) program was established to assure the quality of laboratory services provided from 2018 and 2019. Findings Include: 1. On the date of survey, 03/11/2020, the TS could not provide a QA procedure or documentation of periodic evaluation of the laboratory, that assessed its pre-analytical, analytical, and post-analytical processes from 03/11/2018 to 12/31 /2020. 2. The TS confirmed on 03/11/2020 around 9:15 am that a QA policy did not exist before 01/2020.

D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, personnel competency assessment records, and interview of the technical supervisor (TS), the TS failed to evaluate the competency of 6 of 6 testing personnel performing each test procedure in the departments of Bacteriology, Clinical Chemistry, Hematology, Serology and for microscopic urinalysis examinations in 2018 and 2019. Findings Include: 1. On the day of survey, 03/11/2020, the TS could not provide documentation of competency assessments for 6 of 6 TP who performed each test type of testing in the departments of Bacteriology, Clinical Chemistry, Hematology, Serology and for microscopic urinalysis examinations in 2018 and 2019 2. The TS confirmed the findings above on 03/11/2020 around 9:35 am.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency assessment records and interview with the technical supervisor (TS), the TS failed to assess the competency of 3 of 6 TP through external proficiency testing samples or internal blind testing samples for Bacteriology, Clinical Chemistry, Hematology, Serology and for microscopic urinalysis examinations performed in 2018 and 2019. Findings Include: 1. On the day of survey, 03/11/2020, review of TP competency assessment records, revealed, the TS did not assess the competency of 3 of 6 TP through external proficiency testing samples or internal blind testing samples for Bacteriology, Clinical Chemistry, Hematology, Serology and for microscopic urinalysis examinations in 2018 and 2019. 2. The TS confirmed the finding above on 03/11/2020 around 10:15 am.