Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2101596	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Amoskeag Women's Health	1650 Elm St, Ste 302, Manchester, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of microbiology testing at least twice annually in 2016 and 2017. Findings include: 1) Review on 7/25/2018 of proficiency testing (PT) records from 2016 and 2017 revealed the laboratory was not enrolled in and did not perform PT for Candida, Gardnerella vaginalis, and Trichomonas in 2016 and 2017. 2) Interview on 7/25/2018 at 11:45 a.m. with Staff A (technical consultant) and Staff B (testing personnel) confirmed the above finding. Staff A and Staff B revealed the laboratory did not verify the accuracy of candida, bacterial vaginosis, and trichomonas testing at least twice annually in 2016 and 2017.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless

	the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform calibration verification procedures at least every six months for chemistry testing in 2016 and 2017. Findings include: 1) Review on 7/25/2018 of calibration verification records from 2018 revealed calibration procedures were performed on 6/20/2018 for quantitative pregnancy (hCG), prolactin, and follicle stimulating hormone (FSH) analytes. The laboratory had no documentation for calibration verification procedures performed in 2016 and 2017 for hCG, prolactin and FSH. 2) Interview on 7/25/2018 at 12:30 p.m. with Staff A (technical consultant) and Staff B (testing personnel) revealed the laboratory failed to perform calibration verification procedures for hCG, prolactin, and FSH every six months in 2016 and 2017.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the manufacturer's stated values for hematology control materials in 2016, 2017 and 2018. Findings in include: 1) Review on 7/25/2018 of package inserts for complete blood count (CBC) control materials (three levels) revealed stated ranges for the commercially assayed control materials. 2) Review on 7/25/2018 of CBC control records from June 2018 revealed a new lot number of control material was put into use on 6/18/2018. There was no documentation that the laboratory verified the assayed ranges of the new lot of control material prior to putting it into use. Further review revealed each lot number of control material was used over a period of two months. The laboratory put into use approximately six new lot numbers of CBC control material each year in 2016, 2017 and up to June 18, 2018. 3) Interview on 7/25 /2018 at 1:00 p.m. with Staff B (testing personnel) revealed the laboratory did not

	verify the assayed ranges for new lot numbers of CBC control materials prior to putting them into use in 2016, 2017, and in 2018. Staff B confirmed prior to 6/18 /2018 each lot number of CBC control material was used over a two month period.
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 on July 25, 2018 the laboratory failed to ensure qualification requirements were met for one of two new testing personnel prior to performing moderately complex microbiology, diagnostic immunology, chemistry, and hematology testing in 2017 and 2018. 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 to ensure one of two new testing personnel met qualification requirements prior to performing moderately complex microbiology, and hematology testing in 2017 and 2018. Findings include: 1) Review of personnel records on 7/25/2018 revealed two new testing personnel; Staff C (testing personnel) started in July 2017, and the other testing personnel started in May 2018. Review of the personnel records for Staff C revealed no documentation of educational qualifications. Training documentation revealed Staff C completed training in September 2017 to perform Candida, Gardnerella vaginalis, and Trichomonas, and complete blood count (CBC) testing. Further review of personnel records revealed Staff C left the laboratory in May 2018. 2) Interview on 7/25/2018 at 10:00 a.m. with Staff A (technical consultant) and Staff B (testing personnel) confirmed Staff C performed the above microbiology and hematology tests in 2017 and 2018 and the laboratory did not obtain and review Staff C's educational qualifications.