Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0910592	(X3) Date Survey Completed 05/28/2019
Name of Provider or Supplier American Health Network Of Ohio, Llc	**Street Address, City, State** 3825 Trueman Court, Hilliard, OH	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory failed to document the handling, preparation, processing, examination and each step in the testing and reporting of proficiency testing results. All patients tested at this lab have the potential to be affected. Findings Include: 1. Review of the laboratory's 'Procedure Manual', on 5/28/19, failed to find any proficiency testing policies and procedures. 2. An interview with the Laboratory Manager, on 5/28/19 at 12:57 pm, confirmed that, although the laboratory did establish a protocol for each step in the handling, preparation, processing, examination and reporting of proficiency testing results, the laboratory failed to include a Laboratory Director approved Proficiency Testing policy and procedure in the 'Procedure Manual.'
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 record review, and an interview with the Laboratory Manager, the laboratory failed to establish a written policy and procedure to assess competency of the Technical Consultant (TC), as specified in the personnel requirements in subpart M. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Laboratory Director on 4/16/19, found 1 person, in addition to the Laboratory Director, serving as the TC. 2. Review of the laboratory's Competency Assessment policy and procedure failed to find a policy and procedure for assessing the competency of the TC based on the regulatory responsibility of that role, at a frequency determined by the laboratory. 3. An interview with the Laboratory Manager, on 5/28/19 at 1:39 pm, confirmed that the lab failed to establish a policy and procedure for assessing the competency based on the regulatory responsibility of those roles, at a frequency determined by the laboratory.
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 an interview with the Laboratory Manager the laboratory failed to include approved reference intervals, in the specialty of hematology, in the procedure manual for reporting patient test results. All patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of the laboratory's 'Procedure Manual' failed to find Laboratory Director approved reference ranges, in the specialty of hematology, for reporting patient results. 2. An interview with the Laboratory Manager, on 5/28/19 at 1:47 pm, confirmed, that although the lab did establish and verify reference ranges for hematology, the lab failed to include Laboratory Director approved ranges in the procedure manual.