Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1000952	02/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Randy S Morris, Md, Sc	3 N Washington St, Naperville, IL	

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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, lack of documentation, and interview with the general supervisor (GS); the laboratory failed to ensure attestation statements were completed for endocrinology analytes, covid antibody testing, and semen analysis as required per 493.801 in 2022 and 2023. Findings Include: 1. Review of the American Association of Bioanalysis - Medical Laboratory Evaluation (AAB-MLE) PT records for 2022 and 2023 revealed a lack of attestation statements for six of six endocrinology events, including the seven analytes listed below; six of six covid antibody events; and four of four semen analysis events. Endocrinology analytes: Human chorionic gonadotropin (hCG), Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Estradiol, Thyroid Stimulating Hormone (TSH), Vitamin D, and Progesterone. 2. On survey date 11/29/2023, at 09:24 am, an interview with the GS confirmed these findings.
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 records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to have a competency policy /procedure in place to assess employee competency as required per 493.1235. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the lack of a competency assessment policy/procedure in place as required per 493.1235. 2. On survey date 02/27/2024, at 12:47 pm, the LD confirmed the laboratory failed to have a competency policy/procedure in place to assess employee competency.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, lack of documentation, American Association of Bioanalysis - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interviews with the general supervisor (GS) and laboratory director (LD); the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified regarding PT as required per 493.1239. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the lack of a proficiency testing policy/procedure in place to establish guidelines for acceptable proficiency testing practices, including: a. Testing the PT samples in the same manner as it tests patient specimens. b. PT samples must be examined with the laboratory's regular patient workload by routine personnel and methods. c. The testing individual and the LD must attest to the routine integration of the PT samples into the patient workload (see D2009). d. Testing the PT samples the same number of times it routinely tests patient samples. e. Laboratories must not engage in any inter-laboratory communications pertaining to the results of PT samples until after the due date. f. Laboratories must not send PT samples to another laboratory for any analysis. g. PT testing must be fully documented and retained for a minimum of two years. 2. On survey date 02-27-2024, at 12:47 pm, the LD confirmed the laboratory failed to have a proficiency testing policy/procedure in place to establish guidelines for acceptable proficiency testing practices.
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 review of laboratory's policy and procedure manual, lack of documentation, and interview with general supervisor (GS); the laboratory failed to outline all components of test procedures for the subspecialty of Endocrinology. Findings Include: 1. Review of the policy and procedure manual for endocrinology testing identified the policy "Standard Operation Procedure....Analyzer Roche e411", which failed to outline the following required components of a test procedure: a. Calibration verification procedures. b. The reportable range for test results for the test system as established or verified in 493.1253. c. Limitations in the test methodology, including interfering substances. d. Reference intervals (normal values). e. Description of the course of action to take if a test system becomes inoperable. 2. During survey date 02 /28/2024, at 12:47 pm, the above findings were confirmed by the GS.
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 review of the laboratory's calibration records, lack of documentation, and interview with the general supervisor (GS); the laboratory failed to conduct calibration verifications for endocrinology and covid antibody testing on the Roche Cobas e411 analyzer as required per 493.1255. Findings include: 1. Review of the "Standard Operation Procedure" for "Analyzer Roche e411" revealed the laboratory utilizing this analyzer for the following eight analytes; Human chorionic gonadotropin

	(hCG), Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Estradiol, Thyroid Stimulating Hormone (TSH), Vitamin D, Progesterone, and Covid Antibody. 2. Review of the "Standard Operation Procedure" for "Analyzer Roche e411" also revealed the laboratory failed to include calibration verification procedures for the above-mentioned analytes. 3. Ten of ten patient test results reviewed found no calibration verification had been performed on the Roche Cobas e411 analyzer. Patient ID: Analyte: Date of testing: 64627 hCG, TSH, 07/17/2023 Vitamin D 64372 hCG 12/5/2023 70042 Estradiol, 12/5/2023 Vitamin D, Progesterone 69322 TSH, 04 /21/2023 Covid antibody 67501 Estradiol 04/21/2023 67501 Vitamin D 01/10/2023 64625 LH and FSH 01/10/2023 66627 Progesterone 08/19/2022 Covid antibody 54467 LH and FSH 08/19/2022 63913 Estradiol, 05/25/2022 Progesterone 4. Interview with the GS on 02/28/2024 at 10:07 am confirmed no calibration verifications have been performed on the Roche Cobas e411 analyzer for endocrinology and covid antibody testing in the years of 2021 through the survey date of 02/28/2024.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of a random sampling of patient test results and interviews with the general supervisor (GS) and the laboratory director (LD); the laboratory test reports failed to include interpretation information for endocrinology testing, including Human Chorionic Gonadotropin (hCG), Thyroid Stimulating Hormone (TSH), Vitamin D, Estradiol, and Progesterone analytes. Findings Include: 1. A random sample of four of five patient testing dates found the laboratory failed to indicate interpretation information for the following endocrinology tests: Patient ID: Testing Date: Test Performed: 64627 01/10/2023 Vitamin D 69322 04/21/2023 TSH 64627 07 /17/2023 hCG, TSH, Vitamin D 70042 12/05/2023 Estradiol, Progesterone 2. Interview with the GS and LD on 02/28/2024, at 12:47 pm, confirmed the above findings.