Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0014230	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier University Of Md Health Center Laboratory	**Street Address, City, State** Campus Drive Bldg 140 #1163, College Park, MD	

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
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 procedure manual review and interview with testing person (TP) #1, the laboratory did not provide the TP with written policies and procedures for performing serum pregnancy testing. Findings: 1. The laboratory uses the "ICON 25 hCG" test kit to perform pregnancy testing using both urine and serum. 2. Procedure manual review showed that the "ICON 25-HCG-Rapid Immunoassay For The Qualitative Detection of HCG in Urine for POCT" procedure gave instructions for how to perform the waived urine pregnancy testing. The laboratory did not have a procedure for using the kit with serum. 3. During an interview on 04/19/2023 at 12:15 PM, TP #1 confirmed

	that the procedure manual did not contain a procedure for how to perform pregnancy testing using serum.
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 quality control (QC) record review and interview with testing person (TP) #1, the laboratory did not ensure that both an external positive and negative control are run each day of patient testing with the "ICON 25 hCG" test kit. Findings: 1. The laboratory uses the "ICON 25 hCG" test kit to perform qualitative pregnancy testing using serum. 2. A review of pregnancy test QC records from 11/30/2022 to 04/04 /2023 showed that the laboratory performed QC weekly. 3. Record review showed that the laboratory does not have an IQCP in place to reduce the amount of QC required when performing testing with the "ICON 25 hCG" test kit. This was confirmed during an interview with TP #1 at 10:15 AM on the day of the survey. 4. During an interview on 04/19/2023 at 12:15 PM, TP #1 confirmed that the laboratory did not ensure that a negative and positive control was performed at least once a day patient specimens are assayed or examined.