

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393580	(X3) Date Survey Completed 04/19/2021
Name of Provider or Supplier Ghc East Clinic	Street Address, City, State 5249 East Terrace Dr, Madison, WI	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality control procedures and records and interview with the technical consultant, the laboratory did not follow their procedures to test two levels of external quality control material when they opened a new lot number of the OSOM Mono test on March 1, 2021 or prior to testing a patient sample on March 12, 2021. Findings include: 1. Review of the laboratory's Individualized Quality Control Plan showed the laboratory required testing two levels of external control material (one positive and one negative) with each new lot number of OSOM Mono test kits prior to testing patient samples. 2. Review of electronic quality records showed OSOM Mono lot E201070 expired February 28, 2021 and the system started lot E201268 on March 1, 2021. Electronic quality control records showed the laboratory first tested external quality control samples on lot E201268 on March 26, 2021. 3. Review of test records showed the laboratory tested one patient (patient 1) on March 12, 2021. 4. Interview with the technical consultant on April 19, 2021 at 11:37 AM confirmed the laboratory records showed the laboratory had not tested two levels of external quality control material with OSOM Mono test lot E201268 prior to performing an OSOM Mono test on patient 1 on March 12, 2021.</p>