Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661948	(X3) Date Survey Completed 11/20/2020
Name of Provider or Supplier Medical College Of Wisconsin	**Street Address, City, State** Cri Room C-3383 Tbrc-Cri 3rd Floor, Milwaukee, 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
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 surveyor review of laboratory policies and procedures and interview with the technical supervisor, the laboratory did not establish procedures to assess employee competency. Findings include: 1. Review of laboratory procedures showed no evidence of a procedure for assessing employee competency. 2. Interview with the technical supervisor on November 20, 2020 at 3:00 PM confirmed the laboratory did not establish procedures for assessing employee competency.
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 surveyor review of the "Alpha 1 Antitrypsin Assay" and interview with the technical supervisor, the procedure did not include step-by-step instructions for using a diffusion plate for more than one day of testing, did not include control procedures or corrective actions to take when controls are not acceptable, and did not include instructions for reporting patient results. Findings include: 1. Step one of the Petri Plate Set-up in the "Alpha 1 Antitrypsin Assay" procedure showed the instructions direct testing personnel to start with a new Petri Plate. There are no instructions for using a previously used diffusion plate for additional testing. 2. Review of the "Alpha 1 Antitrypsin Assay" procedure showed no reference to the type, number, or frequency of controls run with the procedure. Further review showed no course of action to take if controls were not acceptable. 3. The procedure did not include instructions for reporting patient test results. 4. Interview with the technical supervisor on November 20, 2020 at 2:00 PM confirmed the procedure did not allow for use of a diffusion plate for more than one day of testing and did not include any information about the use of quality control materials or for reporting Alpha 1 Antitrypsin test results.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical supervisor, the laboratory did not test two control materials of different concentrations each day of patient Alpha 1 Antitrypsin Assay testing. Findings include: 1. Review of Alpha 1 Antitrypsin Assay records showed the laboratory used a single agar diffusion plate for testing on multiple days. The records showed only one set of control material results for the plate. 2. Interview with the technical supervisor on November 20, 2020 at 2:00 PM confirmed the laboratory did not test control materials each day of patient testing for Alpha 1 Antitrypsin.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on surveyor review of quality assessment records and interview with the technical supervisor, the director had not ensured maintenance of the quality assessment program and had not evaluated the accuracy of the Disaccharidases or pancreatic enzymes test system in comparison with DuPont Hospital for Children in 2020. Findings include: 1. Review of results of a specimen exchange for disaccharides and pancreatic enzyme panels with DuPont Hospital for Children from March 2020 showed no evidence of review by the technical supervisor or the laboratory director. 2. Interview with the technical supervisor on November 20, 2020 at 2:45 PM confirmed the director did not review the 2020 comparison report from DuPont Hospital for Children to ensure the test systems provided quality results.