Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0661948	06/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Medical College Of Wisconsin	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 the Centers for Medicare and Medicaid Services (CSM) Form 209 and competence assessment records and interview with the Technical Supervisor (Staff A), the laboratory had not assessed one of two testing personnel annually in 2023. Findings include: 1. Review of Form CMS-209 'Laboratory Personnel Report (CLIA)' submitted for this survey and signed by the director on June 24, 2024, showed the form identified two testing personnel in the laboratory (Staff A and B). 2. Review of testing personnel competence assessment records showed Staff A had no testing personnel competence assessment documented in 2023. 3. Interview with Staff A on June 24, 2024, at 1:45 PM confirmed the laboratory had not evaluated the competence of staff A in performing their responsibilities as a testing person. This is a repeat deficiency previously cited on November 20, 2020.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Technical Supervisor (Staff A), the laboratory did not document the actual time of receipt for

	seventeen of seventeen specimens reviewed for disaccharidase testing received in June 2024. Findings include: 1. Review of laboratory requisitions showed the form included a space to record the date and time (with AM or PM) when personnel received the specimen in the laboratory. Seventeen requisitions reviewed from June 2024 for disaccharidase testing showed the testing person marked AM or PM but did not record the actual time of receipt. 2. Interview with Staff A on June 24, 2024, at 2: 00 PM confirmed testing personnel did not record the specific time they received the specimen and confirmed personnel only marked the requisition as AM or PM.
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 laboratory procedures and interview with the Technical Supervisor (Staff A), one of one immunology procedure did not include all the required elements that were applicable to the test procedure. Findings include: 1. Review of the 'Alpha 1 Antitrypsin Assay' immunology procedure showed the following: a. The procedure did not include complete step-by-step instructions: In Step 5 of the "Petri Plate Set-Up", the procedure stated, "add 150 uL (microliters) of antibody (depends on the antibody)". The procedure did not identify what antibody to use and did not provide instruction on when or how personnel would adjust the amount of antibody added. In Step 9, the procedure did not define what standard personnel were to use. The procedure did not include the calculations used to interpret results. b. The procedure did not define the full calibration process: The procedure did not include the calculations used to create the standard curve. The procedure did not define how testing personnel should evaluate the results of the standards to determine whether the results were acceptable and did not define how personnel should evaluate the resulting standard curve to determine acceptability prior to use for patient result calculations. c. The procedure did not define the reportable range for the test system. d. The procedure did not define the quality control process. The procedure did not identify the type of control used (specific manufacturer or made in-house). The procedure did not define the number and frequency of controls required. e. The procedure did not define the corrective actions to take when calibration or control results were not acceptable. f. The procedure did not provide the reference intervals

	(normal range) for the test. g. The procedure did not provide instructions for reporting patient results: The procedure did not show how personnel create the patient report. The procedure did not define how testing personnel evaluate the duplicate test results for each sample. The procedure did not define how testing personnel determine the patient result from the tested dilutions. The procedure did not include the calculations used to determine the patient results. h. The procedure did not identify what to do if any part of the process becomes inoperable. 2. Interview with Staff A on June 24, 2024, at 2:15 PM confirmed the procedure did not include the reference intervals and did not define the control procedures. This is a repeat deficiency previously cited on November 20, 2020.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, manufacturer instructions, and laboratory procedures and interview with the Technical Supervisor (Staff A), the laboratory did not evaluate statistical parameters for each batch and lot number of control samples and did not perform concurrent testing of new lot numbers of unassayed controls for three of three analytes evaluated. Findings include: 1. Review of laboratory quality control (QC) records for the Alpha 1 Antitrypsin Assay, glucose assay, and protein assay showed the laboratory used formulas built in Excel worksheets to calculate statistical parameters for the control results and to determine if daily QC results were acceptable. Review of the Excel spreadsheet, 'Disaccharidase Calculations', showed the spreadsheet file included pages for 'Protein Control Raw' and Glucose Control Raw'. Review of the 'Protein Control Raw' page showed the laboratory recorded daily QC results for protein testing in dated rows. Testing personnel started a new row for each day of testing. Personnel recorded control results in column D for level one and column E for level two. The sheet included calculations for average, standard deviation (SD), and high and low acceptable values for each control level based on results from June 13, 2016, to August 17, 2020 (lines 6 through 987). The sheet had functions built in to evaluate subsequent control results to determine whether the control values entered on a given day were over or under the acceptable limits. The acceptability determinations were based on the results documented in lines 6 through 987. The worksheet showed results entered through June 2024 (row 1888) and showed the acceptability of these results were also determined using the ranges based on the results in lines 6 - 987. The worksheet included documentation of historic QC material lot number changes, but personnel did not document any changes in QC lot number in the last two years. Review of the

	Excel spreadsheet for glucose QC showed the same design as the protein worksheet. The worksheet calculated the average, SD, and high and low acceptable values using internal formulas based on results from June 13, 2016, through September 23, 2020 (lines 6 through 997). The sheet showed testing personnel entered results through June 2024 (row 1857) and showed the acceptability of results were determined using the ranges based on the results in lines 6 - 997. Testing personnel did not document any changes in lot number in the QC records in the last two years. Review of laboratory quality control (QC) records for the Alpha 1 Antitrypsin assay showed the average and SD used by personnel to evaluate control results included all control results obtained from March 2014 through June 2024 without consideration of the batch of controls used. 2. Review of the manufacturer's instructions for the Sekure DC-TROL Chemistry Control material showed the provided glucose and protein assay values are for test systems using SEKISUI Diagnostics' reagents. The instructions showed no control ranges for testing performed with other manufacturer's chemistry reagents. 3. Review of the 'Bio-Rad Total Protein' procedures showed the laboratory used Bio-Rad total protein reagents. The 'Glucose Trinder Microplate Assay' and the 'Small Bowel Bx Set-Up for Disaccharidases' procedures did not identify the Glucose reagent used. Review of the 'Quality Control' procedure that addressed control practices for glucose and protein testing showed the procedure included instructions for determining the mean and standard deviation of new lot numbers of controls for the protein and glucose assays. The procedure did not address concurrent testing of new lot numbers of controls. 4. Interview with Staff A on June 24, 2024, at 3:00 PM revealed the laboratory used Biotron glucose reagent and confirmed the laboratory did not use SEKISUI reagents for the protein or glucose test. Interview also confirmed the laboratory pooled patient samples to create batched controls for the Alpha 1 Antitrypsin test. Staff A further confirmed the laboratory had not followed the quality control procedure for glucose and protein testing and did not evaluate the statistical parameters for each new lot number received or batch and had not performed concurrent testing before using a new lot number or batch of controls.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of procedures and quality control (QC) records and interview with the Technical Supervisor (Staff A), the laboratory did not take and document corrective actions when protein QC results did not meet the laboratory's established criteria for acceptability on eleven of eleven days in April 2024. Findings include: 1. Review of the procedure, 'Quality Control', showed a glucose or protein test run is "considered valid if both controls fall between two standard deviations of the mean. If one or both of the controls fall outside 2 standard deviations of the mean of the averages, the test may need to be repeated". 2. Review of the 'Protein Control Raw' page in the 'Disaccharidase Calculations' Excel spreadsheet revealed QC results for 20 days of testing in April 2024. The spreadsheet identified ten of the twenty data

	points for level one as 'OVER' showing the result was above the acceptable range. The spreadsheet identified one of the twenty points for level two as 'OVER'. No record of corrective actions was available. 3. Interview with Staff A on June 24, 2024, at 3:00 PM confirmed staff did not document corrective actions when control results were not acceptable.
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 twice annual accuracy verification records from 2023 and 2024 and interview with the Technical Supervisor (Staff A), the laboratory director did not ensure review of the quality assessment program results to ensure accuracy of results for two of two events reviewed. Findings include: 1. Review of the interlaboratory 'Panc External Proficiency Test Reports' from 2023 and 2024 showed no documented review of the results. The report from the February 2023 showed discrepant results between this laboratory (MCW) and the comparison laboratory (NCH) for sample NCH DE3: Test results: Test / MCW / NCH Amylase / 1.1 / 135.5 Lipase / 100 / 404.5 Trypsin / 207.7 / 1280.8 Protein / 3.2 / 5.5 Reference Values: Test / MCW / NCH Amylase / >32 / 10.3 Lipase / >146 / 165.2 Trypsin / >55.4 / 306.9 Protein: not provided on the report The MCW laboratory interpreted the results for this sample as "low amylase, lipase, normal Trypsin". The NCH laboratory interpreted the results as normal. 2. Interview with the Technical Supervisor on June 24, 2024, at 4:00 PM confirmed the records did not show documented review of the results from the interlaboratory comparison testing used twice annually to evaluate accuracy. Further interview confirmed the records of evaluation and determination of the root cause of the discrepant results for sample NCH DE3 in 2023 were not available. This is a repeat deficiency previously cited on November 20, 2020.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form 209, laboratory records, and interview with Technical Supervisor (Staff A), the laboratory director has not specified, in writing, the responsibilities and duties of the general supervisor. Findings include: 1. Review of Form CMS-209, 'Laboratory Personnel Report (CLIA)', signed by the laboratory director on June 24, 2024, and submitted for this survey, showed the report did not identify a general supervisor. 2.

	Review of laboratory records showed no documentation of the assigned responsibilities of the general supervisor. 3. Interview with Staff A on June 24, 2024, at 1:45 PM confirmed the laboratory director had not delegated the responsibilities and duties of the general supervisor in writing to staff filling those responsibilities.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of procedures and quality control (QC) records and interview with the Technical Supervisor (Staff A), testing personnel did not follow quality control policies eleven of twenty days for protein testing and eight of nineteen days for glucose testing in April 2024. Findings include: 1. Review of the 'Quality Control' Procedure showed both levels of QC material tested for glucose and protein must be in the acceptable range for the run to be accepted. 2. Review of the Protein and Glucose control pages in the 'Disaccharidase Calculations' Excel Spreadsheet showed testing personnel documented twenty protein runs and nineteen glucose runs in April 2024. The Glucose page showed six days with control level 1 and two days with control level 2 below the acceptable range. The protein page showed ten runs with control level 1 and one run with control level 2 above the acceptable range. 3. Interview with Staff A on June 24, 2024, at 3:30 PM confirmed testing personnel did not follow the laboratory's policy and accepted the test runs without evaluating and resolving the cause of the unacceptable control results.