

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661948	(X3) Date Survey Completed 08/01/2022
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical supervisor, the current laboratory director did not approve, sign and date the procedures being used for patient testing. Findings include: 1. Review of the laboratory procedures showed no evidence the procedures were approved by the current laboratory director. 2. Interview with the technical supervisor on August 1, 2022, at 9:50 AM confirmed staff A became that laboratory director in February 2022. Further interview confirmed the laboratory had no documentation to show the current laboratory director approved, signed and dated the procedures used for patient testing.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of temperature logs and interview with the technical supervisor, the laboratory did not document corrective action when the temperature readings were outside the defined acceptable range on the GI LAB Refrigerator #1 for thirty-nine of two hundred fifty-three days in 2021. Findings include: 1. Review of GI LAB Refrigerator #1 temperature logs revealed no documentation of corrective action on temperature readings outside the acceptable range of 2-6 degrees Celsius (C) on the following days in 2021: January 6, 8, 18, 27 February 23, 24 March 3, 23, 30 April 6, 15, 30 May 5, 18, 20, 26 June 8, 14, 18, 22, 25 July 1, 12, 13, 19 August 7, 18, 19 October 7, 8, 21 November 15, 18, 22, 29, 30 December 1, 6, 8, 2. Interview with the technical supervisor on August 1, 2022, at 11:00 AM confirmed the laboratory did not document corrective action when the temperature readings were outside the defined acceptable range on the GI LAB Refrigerator #1 for thirty-nine of two hundred fifty-three days in 2021.