

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0662031	(X3) Date Survey Completed 11/10/2023
Name of Provider or Supplier Odd Fellow Home	Street Address, City, State 1229 S Jackson St, Green Bay, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Item 1: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Application for Certification (Form CMS-116) and documents on file with the Wisconsin CLIA State Agency and interview with the nursing home Chief Executive Officer (CEO), the laboratory did not inform HHS (Health and Human Services) or its designee within thirty days of the change in laboratory director on August 21, 2023, and did not meet the notification requirements at 493.39(b)(4) in subpart B, Certificate of Waiver. Findings include: 1. Review of the Form CMS-116 on file with the State Agency showed Staff D was the laboratory director. 2. Review of documents at the State Agency showed Staff D left employment with the facility on August 17, 2023. Further review showed attempts were made by the State Agency via email and phone to contact the laboratory requesting the name of the laboratory director on August 16 and 22 and September 15 and 27, 2023. No response was received from the laboratory. 3. Interview with the nursing home CEO (Staff A) on November 10, 2023, at 9:10 AM confirmed Staff D had not been employed since August 17, 2023. Further interview revealed staff B was the laboratory director as of August 21, 2023, and revealed Staff B was no longer employed at the nursing home. The current interim laboratory director (staff C) had been in place since October 24, 2023. Staff A also confirmed there was no documentation to show the laboratory contacted the state agency within thirty days of August 21, 2023, when the laboratory changed directors.</p> <p>Item 2: Based on surveyor observation of glucose control solutions, review of manufacturer's instructions, and interview with the interim laboratory director, the laboratory did not follow the manufacturer's instructions for two of two vials of</p>

control solutions to ensure manufacturer instructions were followed and expired controls were not used for testing. Findings include: 1. Observation of the Assure Prism Control Solutions on November 10, 2023, at 10:10 AM revealed the control lot numbers and expiration dates were (lot number / expiration date): Vial A: CSTB12AN / 2023-05-11 Vial B: CSTN10AM / 2023-06-09 Neither the box or vials were labeled with opened dates or discard dates. 2. Review of the manufacturer's instructions for use of the Assure Prism Control Solutions revealed the following instructions: "Check the expiration date shown on the bottle label. Do not use if expired." "Do not use beyond 3 months (90 days) after opening the bottle. Record the discard date (3 months from the day the bottle was opened) on the bottle label." 3. Interview with the interim laboratory director (staff C) on November 10, 2023, at 10:15 AM confirmed the control vials were available for use by testing personnel, were expired, and were not labeled with discard dates as required by the manufacturer. Item 3: Based on surveyor observation of glucose testing supplies, review of manufacturer's instructions and laboratory quality control logs, and correspondence with the CEO and administrator, the laboratory did not follow the manufacturer's instructions to ensure control results for two of two meters used on the 'C' wing were acceptable before performing resident testing. Findings include: 1. Review of the manufacturer's instructions for use of the Assure Prism Control Solutions revealed the following instructions: "If the control solution test results are outside the range printed on the test strip bottle/box, do not use the system to test blood until you have resolved the problem." 2. Observation of the test strips and a glucose test analyzer available on the 'C' wing medical cart on November 10, 2023, at 10:00 AM revealed an Assure Prism Glucose Meter and test strips available for use. Staff had previously opened the vial but had not labeled the vial with the opened date. The vial of test strips showed lot UD12MAHPA and showed the following acceptable ranges for controls: Control level 1 / 105-158 mg/dL Control level 2 / 186-279 mg/dL. 3. Email correspondence from November 10, 2023, at 2:41 PM from the administrator (staff E) included copies of three completed 'Glucose Meter Control Solution Checks' logs from 'C' wing with the most recent control testing performed. The logs did not identify which meter was used for testing control solutions or which lot number of strips were tested. Two logs showed the most recent control testing was performed on October 25, 2023; the third log showed testing performed on October 27, 2023. No test results were available for November. The logs include instructions to test controls when a new bottle of strips is opened. The logs showed the following documented control values in mg/dL (milligrams per deciliter): Log / Date tested / High Value / Low Value Log 1 / October 25, 2023 / 226 / 60 Log 2 / October 25, 2023 / 229 / 59 Log 3 / October 27, 2023 / 227 / 62 Values for the Low Control (Level 1) were not within the acceptable range listed on the current vial of test strips available for use. The records showed no evidence staff recognized the control values were not acceptable or that corrective actions were taken. 4. Email from the CEO (staff A) on November 13, 2023, at 12:41 PM confirmed testing personnel on 'C' wing used two meters for glucose testing. The email also confirmed the records did not include meter identification, the test strip lot numbers, and did not identify the testing personnel.