

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0699416	(X3) Date Survey Completed 09/24/2024
Name of Provider or Supplier Michigan Medical Group, Pc	Street Address, City, State 22348 Wick Road, Taylor, MI	
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>. A. Based on observation and interview with the owner, the laboratory failed to notify the state agency when it changed laboratory directors for one (August 2024 to September 2024) of one month since the laboratory director notified the laboratory they were not serving in the laboratory director role. 1. An interview with the owner on 9/24/24 at 1:39 pm revealed the laboratory director listed on the laboratory's CLIA certificate had contacted the laboratory via phone call and text message about a month ago to notify them he was listed on their CLIA certificate in error and was not serving as laboratory director. 2. The surveyor requested documentation showing the laboratory had notified the state agency of the change in laboratory director on 9/24/24 at 1:39 pm and it was not made available. 3. An interview on 9/24/24 at 1:39 pm with the owner confirmed the laboratory had not notified the state agency when there was a change in laboratory director in accordance with Subpart B 493.39 Notification requirements for laboratories issued a certificate of waiver. B. Based on observation, record review, and interview with the office manager, the laboratory failed to follow manufacturers' instructions for quality control performance for its Siemens Multistix 10 SG urinalysis testing using the Clinitek Status + for two (September 2022 to September 2024) of two years. Findings include: 1. The surveyor observed the laboratory on 9/24/24 at 1:00 pm and saw a Siemens Multistix 10 SG bottle with test strips next to the Clinitek Status + urinalysis analyzer. 2. The surveyor requested the Siemens Multistix 10 SG and Clinitek Status + manufacturer's instructions on 9/24/24 at 1:00 pm and the documents were not made available. 3. A review of the "Siemens Multistix 10 SG" instructions for use obtained from Siemens revealed a section titled</p>

"Quality Control" stating, "Test negative and positive controls when you first open a new bottle. Water should NOT be used as a negative control. Each laboratory should establish its own goals for adequate standards of performance" and a section titled "CLIA Waived Laboratories" stating, "Test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days." 4. An interview on 9/24/24 at 1:30 pm with the testing personnel confirmed the laboratory had not performed and documented quality control. C. Based on observation, record review, and interview with the testing personnel, the laboratory failed to follow manufacturer's instructions for using its Siemens Multistix 10 SG urinalysis dipsticks for one of one bottle in use observed. Findings include: 1. The surveyor observed the laboratory on 9/24/24 at 1:00 pm and saw a Siemens Multistix 10 SG bottle with test strips next to the Clinitek Status + urinalysis analyzer without a cap on the bottle. 2. The surveyor requested the Siemens Multistix 10 SG and Clinitek Status + manufacturer's instructions on 9/24/24 at 1:00 pm and the documents were not made available. 3. A review of the "Siemens Multistix 10 SG" instructions for use obtained from Siemens revealed a section stating, "Do not remove the strip from the bottle until immediately before it is to be used for testing. Replace the cap immediately and tightly after removing the reagent strip." 4. An interview on 9/24/24 at 1:30 pm with the testing personnel confirmed the Siemens Multistix 10 SG urinalysis dipsticks bottle was uncapped and the cap was missing.