

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2181522	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Mi Health Clinic	Street Address, City, State 4707 Mcleod Drive East, Saginaw, 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
D5207	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the laboratory director, the laboratory failed to identify and document issues when receiving urine specimens for testing that was no longer performed by the laboratory because of a breakdown in communication with ordering providers for three (Patient Specimens 1-3) urine specimens with urinalysis testing ordered present in the laboratory. Findings include: 1. A review of the laboratory's allegation of compliance for D5401 revealed a section stating the laboratory has "permanently discontinued all urinalysis testing effective March 27, 2025" and "The LIS has been updated to block test orders. All relevant personnel were informed, and future urinalysis requests are referred externally." 2. The surveyor observed three urine specimens in the refrigerator on 5/14/25 at 11:09 am with urinalysis testing ordered after 3/27/25: a. Patient Specimen 1, order date 4/11/25 for "Urinalysis complete W Reflex Culture panel- Urine." b. Patient Specimen 2, order date 4/23/25 for "Urinalysis complete W Reflex Culture panel- Urine." c. Patient Specimen 3, order date 5/2/25 for "Urinalysis complete W Reflex Culture panel- Urine." 3. The surveyor requested documentation showing the laboratory referred testing to an external laboratory on 5/14/25 at 11:09 am and it was not provided. 4. An interview on 5/14/25 at 12:21 pm with the laboratory director revealed the laboratory did not notify the ordering providers for the patients listed above that urinalysis testing would not be performed on the specimens submitted.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

. Based on observation and interview with the laboratory director, the laboratory failed to ensure its Thermo Scientific Cytoseal 60 coverslipping medium had not exceeded expiration dates for the two bottles observed. Findings include: 1. The surveyor observed the following expired Thermo Scientific Cytoseal 60 coverslipping medium with the expiration date of 11/2022 materials during a tour of the laboratory on 5/14/25 at 11:08 am. 2. A review of the Siemens Clinitek Status analyzer data revealed a total of seven patients had testing performed using the Siemens Multistix 10 SG urinalysis strips on 3/16/25. 3. An interview on 5/14/25 at 11:08 am with the laboratory director confirmed its Thermo Scientific Cytoseal 60 coverslipping medium was expired.