

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1010918	(X3) Date Survey Completed 02/03/2025
Name of Provider or Supplier City Medical	Street Address, City, State 30581 Stephenson Hwy, Madison Heights, 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
D0000	An unannounced revisit survey was performed on February 3, 2025 as a follow-up to the September 16, 2024 recertification survey. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined it is out of compliance with the following conditions: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to have the date and time of specimen collection on the test request for three (Patients 1, 3, and 4) of four patient test records reviewed. Findings include: 1. A review of three patient test records revealed a lack of time the laboratory received the specimens: a. Patient #1 had their test request placed on 12/31/24 at the Southgate</p>

	<p>location and test results reported on 1/6/25. b. Patient #3 had their test request placed on 1/13/25 at the Southgate location and test results reported on 1/16/25. c. Patient #4 had their test request placed on 1/17/25 at the Southgate location and test results reported on 1/23/25. 2. An interview on 2/3/25 at 11:33 am with the Technical Consultant and Testing Personnel confirmed the test requests for the patients listed above did not have the date and time of specimen collection.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to verify the reference intervals for its urine pH testing on the Siemens Viva Pro E analyzer for one (January 2025) of one month since the laboratory started testing urine pH. Findings include: 1. An interview on 2/3/25 at 10:10 am with the Testing Personnel revealed the laboratory started testing patient specimens for urine pH at the beginning of January 2025 using the Siemens Viva Pro E analyzer. 2. A review of the laboratory's verification of performance specification records for its pH test kit with the Siemens Viva Pro E analyzer revealed a lack of verification of reference intervals. 3. An interview on 2/3/25 at 10:29 am with the Technical Consultant confirmed the laboratory had not verified the manufacturer's reference intervals prior to testing patient specimens.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant and Testing Personnel, the laboratory failed to include reference intervals for its urine pH testing on test reports for three (Patients 1, 3, and 4) of four patient test reports reviewed. Findings include: 1. A review of four patient test reports revealed Patients 1, 3, and 4 had urine pH testing performed and no reference intervals were included on the test report for interpretation. 2. An interview on 2/3/25 at 11:33 am with the Technical Consultant and Testing Personnel confirmed reference intervals were not included on the test report.</p>
<p>D6012</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(i)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care;

This STANDARD is not met as evidenced by:

. Based on record review and interviews, the Laboratory Director failed to ensure verification of the reference intervals was performed and acceptable for its urine pH testing on the Siemens Viva Pro E analyzer. Refer to D5421.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant and Testing Personnel, the Laboratory Director failed to ensure reference intervals for its urine pH testing were included on test reports. Refer to D5807.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

. Based on record review and interviews, the Laboratory Director failed to ensure procedures for performing pH testing were approved, signed, and dated by the laboratory director before use. Refer to D5407.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

. Based on record review and interviews, the Technical Consultant failed to verify the reference intervals for its urine pH testing on the Siemens Viva Pro E analyzer. Refer to D5421.