

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2107090	(X3) Date Survey Completed 11/13/2023
Name of Provider or Supplier Thomas Kizy Md Pllc	Street Address, City, State 329 Columbia Street, Algonac, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</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 a test request for patients receiving urine qualitative toxicology testing for 8 (Patients 1-8) of 8 patient test records reviewed: 1. A review of patient test records revealed the following patients had urine qualitative toxicology testing without a test request: a. Patient 1 had testing reported on 3/21/23. b. Patient 2 had testing reported on 4/19/23. c. Patient 3 had testing reported on 5/4/23. d. Patient 4 had testing reported on 6/15/23. e. Patient 5 had testing reported on 7/26/23. f. Patient 6 had testing reported on 9/13/23. g. Patient 7 had testing reported on 10/18/23. h. Patient 8 had testing reported on 11/2/23. 2. An interview on 11/13/23 at 11:50 am with the Technical Consultant confirmed the laboratory did not have test requests for the patient testing listed above.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant, the laboratory failed to document the date and time of specimen collection for 8 (Patient 1-8) of 8 patient test records reviewed. Findings include: 1. A review of patient urine qualitative toxicology test records revealed a lack of specimen collection date and time on test requests for the following patients: a. Patient 1 had testing performed 3/21/23. b. Patient 2 had testing performed 4/19/23. c. Patient 3 had testing performed 5/4/23. d. Patient 4 had testing performed 6/15/23. e. Patient 5 had testing performed 7/26/23. f. Patient 6 had testing performed 9/13/23. g. Patient 7 had testing reported 10/18/23. h. Patient 8 had testing reported 11/2/23. 2. An interview on 11/13/23 at 11:50 am with the Technical Consultant confirmed the laboratory had not included the specimen collection date and time.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

. Based on observation and interviews, the laboratory failed to label its Medica Easy RA reagent with the expiration date for 1 onboard reagent observed. Findings include: 1. The surveyor observed the laboratory's Medica Easy RA instrument with reagent labeled with "11/7/23." 2. An interview on 10:02 am with the Testing Personnel revealed 11/7/23 was the preparation date when the surfactant is added to deionized water and the instrument records the expiration date of 30 days. 3. An observation of the laboratory's surfactant reagent revealed it had an expiration date of 11/28/23. 4. An interview on 11/13/23 at 10:03 am with the Technical Consultant confirmed the surfactant used in the preparation of the reagent would expire prior to 30 days and the expiration date was not indicated on the reagent.