

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2127130	<b>(X3) Date Survey Completed</b>  05/22/2024
<b>Name of Provider or Supplier</b>  Umc West Clinic	<b>Street Address, City, State</b>  6600 North Desert Blvd, El Paso, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed and found to be in substantial compliance with the conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780 during the onsite validation inspection conducted May 22, 2024.
<b>D5305</b>	<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 a random review of patient order requisitions and staff interview, the laboratory failed to ensure the address of the authorized person requesting the test was included on the order requisitions for four of twelve patient's requisitions reviewed from December 2023 to February 2024. Findings include: 1. A random review of patient order requisitions from December 2023 and February 2024 revealed the following 4 requisitions failed to include the address of the authorized person requesting the test: Patient ID: 000001589300 Order date: 12/20/23 Patient ID: 000001938842 Order date: 1/5/24 Patient ID: 000001519695 Order date: 1/5/24</p>

Patient ID: 000000857825 Order date: 2/14/24 2. In an interview on 5/22/24 at 5:10 p. m. in the conference room, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy, manufacturer's instructions for use (IFU) and confirmed in interview, the laboratory failed to have a written policy for establishing patient geometric mean when using the NEOPLATINE CI PLUS ASSAY for Prothrombin Time with INR (PT w/INR). Findings included: 1. Review of the laboratory's policy titled "STA - NEOPLATINE CI PLUS ASSAY Determination of Prothrombin Time (PT) ON STA Satellite" found: "The INR corresponds to the value of the ratio of the patient's PT and the geometric mean PT of the normal reference population raised to the ISI (International Sensitivity Index) power:" 2. Review of the manufacturer's IFU "NEOPLASTINE CI PLUS Determination of Prothrombin Time (PT) found: "The INR value corresponds to the value of the ratio of the patient's PT to that of the standard PT raised to the ISI (International Sensitivity Index) power of the thromboplastin used:" 3. Technical Consultant-1 (as listed on the CMS-209 form) confirmed the findings during an interview on 05/22/2024 at 1605 hours in the conference room. Key: CMS - Centers for Medicare and Medicaid Services

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
I. Based on a review of the laboratory's policies, a random review of patient test reports, and staff interview, the laboratory failed to ensure the reference intervals for three chemistry analytes (Iron, Creatinine, Alkaline Phosphatase) were correct on five of nine random patient test reports reviewed from January 2024. Findings include: 1. A review of the laboratory's policy titled 'DXC Iron (FE)' revealed the following: "Reference Intervals UMC established reference intervals follow. Serum (Adult Male) 76 - 198 ug/dL Serum (Adult Female) 26 - 170 ug/dL" 2. A review of the laboratory's policy titled 'DXC Creatinine' revealed the following: "Reference Intervals UMC established reference intervals follow. Serum or Plasma Adult >= 18 yrs old 0.6 - 1.3 mg/dL" 3. A review of the laboratory's policy titled 'DXC Alkaline Phosphatase

(ALP)' revealed the following: "Reference Intervals UMC established reference intervals follow. Female 13 - 14 yrs 49 - 190 IU/L" 4. A random review of patient test reports from January 2024 revealed the following reference intervals for Iron, Creatinine, Alkaline Phosphatase, all of which did not match the intervals defined in the laboratory's policies: Patient ID: 000001519695 17 year old Male tested on 1/5/24 Reference interval for Iron = 45 - 189 MCG/dL \*the laboratory's policy failed to define a reference interval for children Patient ID: 000001993582 23 year old Female tested on 1/19/24 Reference interval for Iron = 28 - 170 MCG/dL Patient ID: 000000873155 45 year old female tested on 1/5/24 Reference interval for Creatinine = 0.50 - 1.20 mg/dL Patient ID: 0000019993582 23 year old female tested on 1/19/24 Reference interval for Creatinine = 0.50 - 1.20 mg/dL Patient ID: 000001467681 14 year old female tested on 1/16/24 Reference interval for Alkaline Phosphatase = 37 - 200 IU/L 5. In an interview on 5/22/24 at 4:40 p.m. in the conference room, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings. 36914 II. Based on review of patient final reports and confirmed in interview, the laboratory failed to include reference ranges for hematology testing for two of two patients reviewed in January 2024. Findings included: 1. Review of patient final reports found the laboratory failed to include reference ranges for the following hematology tests: Patient ID: 000000857825 a) NRBC Percent b) Segmented Neutrophil Percent c) Lymphocyte Percent d) Monocyte Percent e) Eosinophil Percent f) Basophil Percent g) Absolute Metamyelocyte h) Absolute Myelocyte i) Absolute Promyelocyte j) Promyelocyte Percent k) Neutrophil Bands Percent l) Metamyelocyte Percent m) Reactive Lymphocytes n) Other Percent Patient ID: 000001590756 a) NRBC Percent b) Segmented Neutrophil Percent c) Lymphocyte Percent d) Monocyte Percent e) Eosinophil Percent f) Basophil Percent g) Absolute Metamyelocyte h) Absolute Myelocyte i) Absolute Promyelocyte j) Promyelocyte Percent k) Neutrophil Bands Percent l) Metamyelocyte Percent m) Reactive Lymphocytes n) Other Percent 2. Technical Consultant-1 (as listed on the CMS-209 form) confirmed the findings in an interview on 05/22/2023 at 1650 hours in the conference room. Key: NRBC - Nucleated Red Blood Cell CMS - Centers for Medicare and Medicaid Services