

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2074398	(X3) Date Survey Completed 04/10/2025
Name of Provider or Supplier Unity Health Wcmc	Street Address, City, State 3214 East Race Street, Searcy, AR	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of policy and procedure and interview it was determined that the laboratory failed to define control procedures to calculate the standard deviations used for acceptable range of chemistry control runs. Findings follow: A. Upon request, the laboratory could not produce policies and procedures for calculation of standard deviations for chemistry controls. B. In an interview on 4/9/2025, at 9:39am the technical supervisor confirmed that policies and procedures for calculating standard deviations for chemistry controls were not available.</p>

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based upon review of the laboratory's policy and procedure for "Coagulation Quality Control (QC) PT and PTT", "Sysmex CA-2500 QC Printouts" report, the corrective action report for coagulation, patient results, lack of documentation, and interview, the laboratory failed to evaluate patient results back to the last successful Prothrombin Time (PT) QC results when quality control (QC) results were outside of the laboratory's acceptable range. Findings follow: A) Review of the "Sysmex CA-2500 QC Printouts" report for November 2024 revealed that QC01 lot# 564891 with a laboratory defined acceptable range of 11.0 to 12.2 seconds was reported 10.9 on 11/12/24 at 00:58 hours, 10.9 on 11/12/24 at 01:11 hours, before being acceptable on 11/12/24 at 02:04 hours and, QC03 lot # 556587 with a laboratory defined acceptable range of 45.4 to 51.8 seconds was reported 42.3 on 11/12/24 at 00:58 hours, 42.4 on 11/12/24 at 01:11 hours, before being acceptable on 11/12/24 at 02:05 hours. B) Review of the "Sysmex CA-2500 QC Printouts" report for November 2024 revealed that the last successful QC results occurred on 1/11/23 at 16:55 hours. C) Review of the coagulation testing corrective action sheet revealed the corrective action taken to bring QC results into acceptable range was "New Inn(ovin) no patients ran". The replacement of innovin (the PT assay reagent) represented a change in the testing system. D) Review of patient results revealed that eleven PT tests were performed and reported on patients, identified as numbers 1 through 11 on a separate patient identification list, from 11/11/24 at 16:55 hours until 11/12/24 at 00:58 hours. D) Upon request, the laboratory was unable to provide documentation that the patient results identified above had been evaluated. E) In an interview on 4/9/25 at 09:55 a.m. the laboratory staff members (# 2 on the CMS form 209) confirmed that PT tests were performed and reported on patients identified above and had not been evaluated.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. Through a review of personnel records of nineteen testing personnel performing moderately complex laboratory assays and interviews with laboratory staff, it was determined the laboratory director failed to give written authorization for seven of nineteen testing personnel to perform moderately complex procedures without direct

supervision. Survey findings follow: A) A review of personnel records of nineteen randomly selected testing personnel, who have completed training for performing moderately complex procedures, revealed that seven (#38, #49, #51, #52, #55, #53, #61 (as listed on the form CMS-209) failed to have the laboratory director's written authorization to perform moderately complex testing without supervision. B) In an interview, at 1:20 p.m. on 4/8/25, laboratory employee (#2 as listed on the form CMS-209) confirmed the lack of written authorizations for the seven personnel identified above and that they performed moderately complex testing for Arterial Blood Gas and /or Activated Clotting time Determinations.