Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D1087809	02/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Grace Community Health Center, Inc D/B/A	14662 N Us Highway 25e, Corbin, KY	

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 Initial Certification Survey was conducted on 02/24/2025. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (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. This STANDARD is not met as evidenced by: Based on observation, document reviews, review of the laboratory policies, and interview, the laboratory failed to establish a written procedure for specimen labeling requirements and failed to establish panic or alert values for complete blood count

	(CBC) non-waived tests. Findings include: During the laboratory walkthrough observation on 02/24/2025 at 10:15 AM, two CBC specimens were observed that were both labeled with a first and last name and a date. The dates observed on the specimens did not indicate if they referred to the date of collection or the date of birth. Random patient test records reviewed on 02/24/2025 at 12:45 PM, revealed the following two CBC test results with CBC test values that included an exclamation point behind the value. - Test Record #1 - Hemoglobin (Hgb) value of 10.2g/dL! - Test Record #2 - Mean Corpuscular Volume (MCV) value of 103.4 fL! The Centers for Medicare and Medicaid Services (CMS)-116 form revealed the laboratory performed one non-waived test with a total estimated annual test volume of 5,000. A review of the laboratory procedure manual on 02/24/2025 at 11:08 AM revealed no evidence there was a procedure that specified the requirements for specimen labeling or evidence of established panic or alert values for the CBC test. A review of the laboratory policy titled "CBC Reference Ranges Newborn to Adult," undated, revealed, "CBC reports are given directly to the Physician/Provider [sic] any critical value shall be interpreted and acted upon in the examination room." There was no evidence of established panic or alert values. During an interview on 02/24/2025 at 11: 17 AM, Testing Personnel #1 stated all CBC specimens should be labeled with a sticker that included the patient's name, medical record number, date of birth, and date of collection; but was unable to confirm the laboratory had an established procedure for specimen labeling requirements for the CBC test. During an additional interview on 02/24/2025 at 12:50 PM, Testing Personnel #1 stated the exclamation point on the CBC test values indicated an out of normal range value but was unable to confirm if the values were critical and was unable to confirm that the laboratory had established panic or alert values for the CBC test.