

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0462290	(X3) Date Survey Completed 09/22/2026
Name of Provider or Supplier Hospital Service District Of West Feliciana, The	Street Address, City, State 5266 Commerce Street, Saint Francisville, LA	
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	A validation survey was conducted on September 22, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's written policies and procedures, client services manual, patient testing records, and interview with the Technical Supervisor (TS) of the laboratory, the laboratory failed to establish and follow written policies and procedures for conditions of specimen transportation (temperature) for 3 of 3 patient specimens transported to the laboratory between April to August 11th, 2026 (Random review). Findings Included: 1) Review of the laboratory's policy titled 'West Feliciana Parish Hospital Clinical Laboratory Specimen Transportation' did not state conditions of specimen transportation (temperature) requirements for outpatient Clostridium difficile (C. diff) stool specimens and blood tubes collected by home health nurses. The policy stated the following on page 3 of 4: "e. Customer Service Representative (couriers) Procedures ... i. Pick up specimens from the designated location in the client office at scheduled pickup time or as dispatched ... iii. Place frozen specimens in the compartment of cooler designated for frozen specimens. iv. Place specimens requirement refrigeration in the compartment of cooler that is designated for refrigerated specimens. V. Place specimens to be maintained at room temperature in

the container designated for ambient specimens. vii. Check the specimens to be sure the appropriate temperature was maintained during transport ... f. Specimen Management Procedures for laboratory personnel i. Check the specimens upon receipt in the department to be sure the appropriate temperature was maintained during transport ... 2) Review of the laboratory's client services manual titled 'Client Services Manual West Feliciana Hospital Laboratory' did not state specimen transportation temperature requirements for blood tubes and fecal specimens sent to the laboratory for testing. 3) Review of patient test records between April and August 11th, 2026 revealed 3 of the following specimens sent to the laboratory without specimen transportation temperatures established, and no record of temperature verification upon receipt: a. Patient MRN: 059406; Test: C. diff; Type: Fecal Collection Sterile Container or Parapak C&S b. Patient MRN: 030400; Test: C. diff; Type: Fecal Collection Sterile Container or Parapak C&S c. Patient MRN: 437-78-9355; Tests: Comprehensive Metabolic Panel (CMP), Hemoglobin A1C (Hgb A1C); Type: Serum Separator Tube (SST), Lavender Top Tube (EDTA) 4) In an interview on 9/22/2026 at 4:30 PM, the TS confirmed the findings the laboratory failed to establish and follow conditions of specimen transportation (temperature) for blood and fecal specimens brought to the laboratory by patients and/or home health nurses.

D5413

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

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on direct observation, review of the laboratory's temperature records, manufacturer's instructions, test records, and interview with the Technical Supervisor (TS) of the laboratory, the laboratory failed to define room temperature in accordance with manufacturer's instructions of the Siemens Dimension analyzer for 2 of 2 years (2025 and 2026). Findings Included: 1) During a tour of the laboratory on 9/22/26 at 4:04 PM, one Siemens Dimension EXL 200 analyzer was observed in use. 2) Review of the laboratory's temperature records between 2025 and 2026 revealed an acceptable room temperature range of 18 to 25 degrees Celsius. 3) Review of the manufacturer's instruction for the Siemens Dimension Clinical Chemistry analyzer stated the following room temperature requirements for specimen stability for Acetaminophen (ACTM), Aspartate Aminotransferase (AST), Digoxin (DGNA) and N-terminal Pro-Brian Natriuretic Peptide (NTP): a. ACTM - "Separated specimens are stable for 8 hours at 20 to 25 degrees Celsius ..." b. AST - "Separated specimens are stable for 3 days at 20 to 25 degrees Celsius ..." c. DGNA - "Separated specimens are stable for 8 hours at 20 to 25 degrees Celsius ..." d. NTP - "Separated specimens are stable for three days when stored at 20 to 25 degrees Celsius" 4) In an interview on 9/22/26 at 4:04 PM, the TS confirmed the laboratory kept specimens on racks for undefined periods, at room temperature prior to running, and that room temperatures were not defined in accordance with the manufacturer's instructions. However, specimens were tested as soon as possible. II. Based on direct observation, review of manufacturer's

instructions, review of the laboratory's temperature records, and interview with the Technical Supervisor (TS) of the laboratory, the laboratory failed to define, monitor and document temperatures for the Phlebotomy room where temperature dependent supplies were stored for 2 of 2 years (2025 and 2026). Findings Included: 1) During a tour of the facility on 9/22/26 at 4:04 PM in the phlebotomy room, the following temperature dependent laboratory supplies were seen stored without temperatures defined, monitored and documented: a. 13 Becton Dickinson (BD) Vacutainer Tiger-Top tubes, Lot Number 5325094, Manufacturer storage temperature requirements 4 to 25 degrees Celsius b. 2 BD Vacutainer Grey Top Tubes, Lot Number 5260203, Manufacturer storage temperature requirements 4 to 25 degrees Celsius c. 2 BD Vacutainer Blue Top Tubes, Lot Number 5293144, Manufacturer storage temperature requirements 4 to 25 degrees Celsius 2) Review of the laboratory's temperature records revealed no temperatures defined, monitored and documented for 2025 and 2026 in the Phlebotomy room. 3) In an interview on 9/22/26 at 4:05 PM, the TS confirmed the phlebotomy room containing temperature dependent supplies did not have temperatures defined, monitored and documented.