

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466470	(X3) Date Survey Completed 03/05/2025
Name of Provider or Supplier St Vincent Morrilton Lab	Street Address, City, State #4 Hospital Drive, Morrilton, 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instruction, the laboratory's procedure manual, patient test records, and interview with staff the laboratory failed to establish a policy to ensure 2 of 19 patient lactate samples were centrifuged within 15 minutes of collection from 2/21/25 though 3/4/25. A) Manufacturer's instructions ("Siemens Dimension Clinical Chemistry System Flex Reagent Cartridges" Lactate, REF DF16, Issue Date 2019-04-01) for the lactate analysis performed in the laboratory, stated: "Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes." B) The Laboratory's General Policy manual did not contain specific policies for lactate, but referred to "following manufacturer's instructions and /or package inserts". C) A query of Lactate sample turnaround time records from 2/21/25 through 3/4/25 revealed 2 of 19 samples took longer than 15 minutes from collection to result. Centrifuge times were not documented. D) During interview 3/5/25 at 2:53pm, the General Supervisor (as listed on the CMS-209 form) confirmed that the lab documented collection times and report times; but not centrifuge times.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interview with laboratory staff, the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 3/5/25 at 2:37pm, one (of one) container of Siemens Ictotest Reagent Tablets (lot (10)284115A, SMN 10337316, Siemens, expiration date 12/31/24) was observed in the laboratory, available for use beyond the expiration date. B) During a tour of the laboratory on 3/5/25 at 2:32pm, six (of six) Sofia RSV test kits (lot 160853, Item 1197500 RSV FIA, Quidel, expiration date 12/29/24) was observed in the laboratory, available for use beyond the expiration date. C) In an interview on 3/5/25 at 2:37pm testing personnel #7 (as listed on the CMS-209 form), confirmed that the items, identified above, had exceeded their expiration dates and were available for use in the laboratory.