

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0049984	(X3) Date Survey Completed 02/10/2022
Name of Provider or Supplier Stone County Medical Center	Street Address, City, State 2106 East Main Street, Mountain View, 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
D3025	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d)</p> <p>Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.</p> <p>This STANDARD is not met as evidenced by: Based upon a review of the Nursing policy titled, "Administering Blood and Blood Components", a review of eight blood administration records, and interviews with staff, it was determined the facility failed to ensure transfusion reaction policies are followed. Findings follow: A. Through a review of the Nursing policy titled, "Administering Blood and Blood Components", it was determined the policy stated, "The initial vital signs and subsequent vital signs should be noted on the Blood Bank Crossmatch/Transfusion Form or Anesthesia Record. Any negative or adverse patient response to the transfusion will be made aware by the nurse to the patient's attending physician, and documented in the nurses notes or anesthesia record." B. The policy titled, "Transfusion Reaction Protocol" states steps to follow if a transfusion reaction is suspected. The first four steps listed are: 1. Stop the Blood; 2. Keep the line open with normal saline; 3. Notify the patient's attending physician or physician on call and initiate any treatment ordered.; 4. Report the suspected reaction to the Laboratory Blood Bank Immediately. The first sign or symptom of a possible transfusion reaction listed in the policy is Fever (temperature rise of 1.5 degrees - 2 degrees over the patient's beginning temperature. C. Through a review of eight patient blood administration records for patients receiving blood between September 2021 and January 2022, it was determined that one of eight patient transfusions included symptoms of possible transfusion reaction, as listed in the Transfusion Reaction Protocol. Patient #36308 received packed red blood cells (unit #W091021419944) on 11/23/2021. At 20:15 the pretransfusion patient temperature was documented as 97.6</p>

degrees F. At 20:20 (five minutes after the transfusion started) the patient temperature was documented as 99.4 degrees F (1.8 degree rise in temperature). According to the policy a 1.5 to 2 degree rise in temperature should initiate the transfusion reaction protocol. There was no documentation that the transfusion protocol had been initiated at that time. D. In an interview at 12:50 on 2/10/2022, laboratory employee #4 (as listed on the form CMS-209) confirmed the temperature change should have initiated the transfusion reaction protocol and that there was no documentation of a transfusion reaction investigation.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Through a review of the quality control policy and Procalcitonin quality control documentation, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to monitor, over time, the accuracy and precision of Procalcitonin quality control results. Survey findings include: A. A review of the policy titled, "Daily Review of Patient and Quality Control Results" revealed the policy stated, "The Quality Control is reviewed at least once per month by the Laboratory Supervisor to monitor for shifts and trends in the Quality Control." B. During a review of Procalcitonin quality control for July, October, and December 2021, it was determined the laboratory did not have quality control results in a graph format (such as Levey-Jennings graphs) in order to identify shifts or trends in Quality Control over time. Zero of three months had documentation of evaluating for shifts and trends. C. In an interview, at 12:26 on 2/10/2022, laboratory employee #4 (as listed on the form CMS-209) confirmed that the laboratory had no method for evaluating Procalcitonin quality control results for changes over time.