

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2119423	(X3) Date Survey Completed 09/02/2021
Name of Provider or Supplier White River Health Family Care	Street Address, City, State 1217 Batesville Blvd, Batesville, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the laboratory policy and procedures, temperature logs for 2020, lack of documentation and interviews with staff, it was determined the laboratory failed to monitor and document room temperatures, refrigerator temperatures and humidity conditions that are essential for the proper storage of reagents and supplies. Survey findings follow: A. A review of the laboratory policy and procedure revealed: "The temperature and humidity of the laboratory must be monitored and kept between the posted acceptable ranges to ensure the proper storage and/or testing environment for all reagents and patient specimens used. Testing personnel will check daily and recorded on the temperature logs. Refrigerator range 2-8 degrees Celsius: Room Temperature Range 18-25 degrees Celsius and humidity 20-80%." B. A review of the refrigerator temperatures for January- December 2020 (twelve of twelve months) revealed the laboratory failed to monitor and document refrigerator and humidity temperatures on one of thirty-one days in March; four of thirty days in April; one of thirty-one days in October and two of thirty-one days in December. C. In an interview on 9/2/2021 at 10:30, the technical consultant confirmed the laboratory failed to monitor or document room temperature and humidity on the days mentioned.</p>

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

. Through a review of the temperature records for 2020 and 2021, lack of documentation, and interviews with staff, it was determined the laboratory failed to document corrective actions taken when refrigerator temperatures and humidity were outside of the laboratory's acceptable criteria. Survey findings follow: A. A review of temperature logs for 2020 and 2021 revealed the laboratory refrigerator temperature acceptable range was listed as 2 to 8 degrees Celsius and humidity range 20-80%. B. A review of the temperature logs for twelve of twelve months in 2020 revealed the refrigerator temperature was documented outside the acceptable criteria and no corrective actions were performed. On July 25, 2020 refrigerator temperature was documented at 11 degrees Celsius outside of acceptable range. C. A review of the temperature logs for eight of eight months in 2021 revealed the humidity were documented (16.0%) outside the acceptable criteria and no corrective actions were performed on five of twenty-eight days in February 2021. D. In an interview at 10:30 on 9/2/2021, the technical consultant confirmed the lack of documented corrective actions for refrigerator temperatures and humidity outside acceptable criteria.