

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1085608	(X3) Date Survey Completed 05/29/2025
Name of Provider or Supplier White River Medical Center	Street Address, City, State 1710 Harrison Street, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based upon a review of laboratory policy and procedure " H&E/Diff Quick Stain QC" , lack of documentation, a review of patient test records for 2022 and interviews with laboratory staff, the laboratory failed to document stain quality on twenty-seven of twenty-seven performances of frozen section examinations in which patient histopathology slides were stained and examined. Survey finding include: A) A review of the laboratory's policy and procedure "H&E/Diff Quick Stain QC" revealed "evaluation will be performed on each day of use by the interpreting pathologist and documented on the attached form". B) The laboratory provided reports of twenty-seven frozen section examinations that were performed on patients in 2024 (identified as numbers one through twenty-seven on a separate patient identification list) . C) Upon request, the laboratory was unable to provide H&E quality control (QC) documentation for the days when the frozen sections were performed on the patients identified above D) In an interview, at 2:00 p.m. on 9/29/25, laboratory staff member (#1, as listed on form CMS 209), confirmed that stain quality was not documented and "it is possible that it has fallen by the wayside"..</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the</p>

staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based upon a review of personnel records for eleven testing personnel listed on the form CMS-209, and through interviews with laboratory staff, the technical consultant failed to perform competency assessments using the six required methods for eleven of twenty-seven testing personnel reviewed. Survey findings include: A) Review of personnel records for eleven testing personnel (Numbers 36, 37, 38, 39, 40, 43, 45, 46, 47, 49, 60 on Form CMS 209) revealed competencies were documented by a check mark placed next to a statement of duty elements without an indication of any of the six required methods for assessing personnel competency identified. B) During an interview, at 1:45 p.m. on 5/29/25, laboratory staff members (numbers #2, 3, 4, 5, 6 on form CMS 209) confirmed the methods of competency assessment were not documented on personnel competency records identified above.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based upon review of personnel competency records for 27 employees listed on the CMS 209 form, authorizations to perform tests, and interview the laboratory did not assess the competency of one employee semiannually during the first year of employment. Findings follow: A) Review of personnel records of testing personnel, (number 39 on the CMS 209 form), indicated that the employee was hired in January 2024 and authorized by the laboratory director to perform moderately complex testing without direct supervision in January 2024. B) Upon review of personnel records of testing personnel (number 39 on the CMS 209 form) only one instance of competency evaluation was found dated in October 2024. C) In an interview on 5/28 /25 3:30 p.m., the laboratory staff member (# 34 on the CMS 209 form) confirmed that only one competency evaluation was present in the personnel file of the testing personnel (number 39 on the CMS 209 form).

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. Based upon a review of personnel records of twenty-seven testing personnel performing moderately complex laboratory assays, and interviews with laboratory staff, the laboratory director failed to give written authorization for one of twenty-

seven testing personnel reviewed to perform moderately complex procedures without direct supervision. Survey findings follow: A) A review of personnel records of twenty-seven randomly selected testing personnel, who have completed training for performing moderately complex procedures, revealed that one (#38, as listed on the form CMS-209) failed to have the laboratory director's written authorization to perform moderately complex testing without supervision. B) In an interview, at 3:57 p. m. on 5/28/25, laboratory employee (#34 as listed on the form CMS-209) confirmed the lack of written authorizations for the laboratory staff member (# 38 on form CMS 209) and that they performed moderately complex testing for Arterial Blood Gas on 4 /25/25 at 3:43 a.m. .