

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2227527	<b>(X3) Date Survey Completed</b>  11/21/2023
<b>Name of Provider or Supplier</b>  Freshly Renewed Transitional Treatment	<b>Street Address, City, State</b>  8404 Baseline Road, Little Rock, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test documentation and interviews with laboratory staff, the laboratory director and testing personnel failed to sign proficiency testing attestation statements for three of three testing events in 2023. Survey findings include: A. A review of proficiency testing documentation from 2023 showed the laboratory director and testing personnel failed to sign the attestation statement on the First, Second, and Third Testing Event of 2023. B. In an interview, on 11/21/23 at 11:19 am, laboratory staff (#1 as listed on the form CMS-209) confirmed the attestation statements listed above had not been signed by the laboratory director and testing personnel.</p>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)</p>

Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:  
Through review of laboratory policy and procedure, observation and interview it was determined that the laboratory failed to label three of three specimen collection containers with patient name or unique patient identifier. Findings follow: A) During a tour of the laboratory on 11/21/23 at 11:05 am, three urine specimen containers were observed in the laboratory specimen storage refrigerator; three of three labeled on the specimen lid only. B) Review of the laboratory policy and procedure revealed that "patient specimen containers must be labeled with appropriate identifiers." C) In an interview on 11/21/23 at 11:19 am, the laboratory staff member (#1 on the CMS 209 form) confirmed that the specimens identified above lacked proper patient identification on the containers as required by policy and procedure.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(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:  
Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 11/21/23 at 11:15 am. one (of one) Siemens Creatinine Calibrator (Lot 3T138UL - R5, expiration date 7/7/23) was observed in the laboratory. B) During a tour of the laboratory on 11/21/23 at 11:15 am one (of one) Ark Tramadol Calibrator (Lot WO15307, expiration date 4/30/23) was observed in the laboratory. C) In an interview on 11/21/23 at 11:19 am laboratory staff member (listed as #1 on the CMS 209 form) confirmed that the items, identified above, had exceeded their expiration date and were available for use.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Through a review of Personnel Records for two of two testing personnel listed on the form CMS-209, lack of documentation and through interviews with hospital staff, it was determined the laboratory director failed to give written authorization to two of two testing personnel who perform moderately complex procedures. Survey findings include: A) The surveyor reviewed personnel records for two testing personnel (listed as #3 and #4 on the form CMS-209) who perform moderately complex procedures and no authorization to perform testing was present. B) Upon request, the laboratory was unable to provide authorization to perform moderately complex testing for employee #3 and #4 on the CMS 209 form. C) In an interview, on 11/21/23 at 11:19am, laboratory staff member (#1 on a separate employee identification list) confirmed that employee # 3 and 4 perform testing and that there is no authorization to perform testing signed by the laboratory director.