

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0904608	(X3) Date Survey Completed 09/06/2022
Name of Provider or Supplier Conway Womens Health Center Pa	Street Address, City, State 2519 College Avenue, Conway, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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: . Through a review of proficiency test documentation for 2021 and 2022 (four testing events), it was determined the laboratory failed to maintain a copy of attestation sheets for three of five testing events reviewed. Survey findings include: A. The surveyor reviewed documentation for the First, Second, and Third Microbiology Proficiency Test Events in 2021 and the First and Second Events in 2022. Attestation statements were not available for the First and Third Testing Events of 2021 and the First Testing Event of 2022. B. In an interview, 10:32 a.m. on 9/6/2022, laboratory employee #2 (as listed on the form CMS-209) confirmed the attestation statements were not available for three Proficiency Test Events in 2021 and 2022.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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 files for the seven testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to authorize two of seven testing personnel to perform testing without direct supervision. Survey findings include: A. During a review of personnel files for seven testing personnel listed on form CMS-209 (Personnel #2 - #8) the surveyor determined employees #4 and #5 (as listed on the form CMS-209) failed to have written authorization, from the laboratory director, to perform testing without direct supervision. B. In an interview, at 10:32 a.m. on 9/6 /2022, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of written authorizations to test for employees #4 and #5.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

. Through a review of personnel records for seven testing personnel listed on the form CMS-209 it was determined the technical consultant failed to annually document competency on five of seven employees. Survey findings include: A. The surveyor reviewed personnel files for the seven testing personnel listed on the CMS-209 form as #2 through #8. B. Five of Seven testing personnel (#2, #3, #6, #7, and #8 as listed on the form CMS-209) did not have annual competency assessment documented since 1/28/2021 (19 months). C. In an interview, at 10:32 a.m. on 9/6/2022, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of annual competency assessments for five of seven testing personnel.