

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/04/2021  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>11D2025053</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>11/09/2021</b>
NAME OF PROVIDER OR SUPPLIER  <b>COLUMBUS WOMENS HEALTH ORG</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>3850 ROSEMONT DRIVE COLUMBUS, GA 31904</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
D 000	INITIAL COMMENTS	D 000			
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) supplier documents, and staff interview, the laboratory was not rotating PT sample testing through the entire TP staff.</p> <p>Findings</p> <ol style="list-style-type: none"> <li>Review of the API, PT attestation statements for the year 2020 and 2021, were signed by the same TP for all three events of 2020, and event one and two of 2021.</li> <li>Staff interview with the laboratory manager, on 11/09/2021 at approximately 1 pm in the front office confirmed the above aforementioned statement.</li> </ol>	D2007	<ol style="list-style-type: none"> <li>API samples will be tested in rotation by all regular lab personnel who routinely perform the patient testing in lab to ensure that all personnel remain proficient.</li> <li>All lab personnel have been informed by the Lab Director that sample testing will be done by all personnel for proficiency.</li> <li>No patients have been affected by the practice because each lab personnel were shown to be proficient in testing by the Lab Director before any patient testing was done by the lab personnel.</li> <li>The Lab Director will be notified of which lab personnel will be performing the API samples each quarter prior to the sample results being reported to API in order to ensure that the deficient practice does not recur.</li> </ol>	Dec 18 2021	
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the</p>	D6004			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE



Director

12/18/2021

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D6004	<p>Continued From page 1</p> <p>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.</p> <p>(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively.</p> <p>(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) supplier documents, and staff interview, the Laboratory Director (LD) was not monitoring the PT sample testing was being rotated through the entire TP staff.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the API PT attestation documents for all three events in 2020, and events one and two in 2021 showed that only one TP was performing the PT samples for evaluation.</li> <li>2. Staff interview with the laboratory manager, on 11/09/2021 at approximately 1 pm in the front office confirmed the above aforementioned statement.</li> </ol>	D6004	<ol style="list-style-type: none"> <li>1. API samples will be tested in rotation by all regular lab personnel who routinely perform the patient testing in lab to ensure that all personnel remain proficient.</li> <li>2. All lab personnel have been informed by the Lab Director that sample testing will be done by all personnel for proficiency.</li> <li>3. No patients have been affected by the practice because each lab personnel were shown to be proficient in testing by the Lab Director before any patient testing was done by the lab personnel.</li> <li>4. The Lab Director will be notified of which lab personnel will be performing the API samples each quarter prior to the sample results being reported to API in order to ensure that the deficient practice does not recur.</li> </ol>	Dec 18 2021	