

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0219450	(X3) Date Survey Completed 10/30/2023
Name of Provider or Supplier Whole Woman's Health Of Baltimore	Street Address, City, State 7648 Belair Rd, Baltimore, MD	
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
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</p> <p>This STANDARD is not met as evidenced by: Based on review of the patient logbook, proficiency testing (PT) records, interview with the office manager (OM), the laboratory failed to document the PT samples along with the regular patient workload. Findings: 1. The immunohematology PT records from 2023 were reviewed for a total of three events. 2. Review of the patient logbooks from 2023 showed that the PT samples for all three events were not documented in the logbook in the same manner as the patients. The original test results were not documented and maintained in the same manner as the patients. 3. During the survey on 11/13/2023 at 11:45 AM, the OM confirmed that the PT results were not being documented in patient logbook in the same manner as the patients.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

This STANDARD is not met as evidenced by:
 Based on review of the "Laboratory Personnel Report (CLIA)", testing personnel qualifications, and interview with the office manager (OM), the laboratory director (LD) failed to ensure that all the testing personnel (TP) working in the laboratory met the minimum educational requirements. Findings: 1. The "Laboratory Personnel Report (CLIA)" listed fourteen TP. The educational documentation reviewed showed that one TP was not from the United States (U.S.). Individuals who have degrees from foreign institutions must have an evaluation of their credentials to determine the equivalency of their education to an education obtained in the U.S. 2. On 11/30/23, the OM emailed documentation of a medical assistant certification, and a document titled "Certification of Translation Accuracy." The document included this statement: "This is to certify the correctness of the translation only. I do not make any claims or guarantees about the authenticity or content of the original document. Further, RushTranslate assumes no liability for the way in which the translation is used by the customer or any third party, including end-users of the translation." 3. The regional office in Philadelphia reviewed the foreign transcripts and documents and confirmed that the documents only contain evidence of translation, and not an evaluation of credentials to determine equivalency of education to education obtained in the U.S. Personnel records cannot be evaluated without this. 4. The OM was notified via email on 12/06/23 at 1:30 PM, that the credentials submitted on 11/30/23 had not been evaluated by an approved agency to ensure that the credentials were equivalent to an education obtained in the U.S. and were therefore unacceptable. On 12/06/23 at 2:45 PM, the OM confirmed via email that the LD and TP would be notified of the unacceptable credentials.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
 Based on review of competency assessment records, Laboratory Personnel Report (CLIA) (CMS-209), and interview with the office manager (OM), the laboratory director acting as the technical consultant failed to perform a six month competency assessment for new testing personnel (TP). Findings: 1. Competency evaluations for 2022 and 2023 were reviewed. 2. The CMS-209 form listed 15 TP. The OM stated that 4 of the TP had been working for less than two years. 3. The competency assessment documentation showed that one of the four TP had not had their six months evaluation performed. The records for the other three new TP showed that the six month evaluation was identified as "Annual" and not "Six month." 4. During the survey on 11/13/2023 at 11:45 AM, the OM confirmed that one six month competency had not been documented and the records for the other three new TP showed that an "Annual" evaluation had been documented and not a "Six month" evaluation.

D6071

TESTING PERSONNEL RESPONSIBILITIES
 CFR(s): 493.1425(b)(2)

Each individual performing moderate complexity testing must maintain records that

demonstrate that proficiency testing samples are tested in the same manner as patient samples.

This STANDARD is not met as evidenced by:

Based on review of the proficiency testing (PT) records, patient test logs and interview with the office manager, the testing personnel failed to ensure that the PT samples were tested and documented along with the laboratory's regular patient test workload. Cross refer to Tag D2007 for details.