

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0725975       | <b>(X3) Date Survey Completed</b><br><br>10/05/2020 |
| <b>Name of Provider or Supplier</b><br><br>Women & Teens Healthcare Inc  | <b>Street Address, City, State</b><br><br>16876 Ne 19 Ave, North Miami Beach, FL |   |
| 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>D0000</b>              | A recertification survey conducted on 10/05/2020 found that the Women & Teens Healthcare Inc clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. Cited the following Condition: -D6063  |
| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and staff interview, the laboratory failed to document the initial competency assessment for 2 out of 2 new Testing Personnel (TP) who started on year 2020. Findings include: 1)Review of CMS 209 Laboratory Personnel Report, which was dated and signed by the Laboratory Director (LD) on 08/24/2020 revealed the following: -The laboratory had 5 TP (A, B, C, D, E) 2) Review of employee folders revealed that TP C started on 5/28/2020, TP E started on 3/20/2020. There was no documentation of the initial evaluation performed by the Technical Consultant before the TP started testing. During an interview on 10/05/2020 at 11:30 AM, with office manager, she confirmed that the laboratory failed to document the initial competency assessment for the TP listed above.</p> |
| <b>D6063</b>              | <p><b>LABORATORY TESTING PERSONNEL</b><br/>CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p>   |

This CONDITION is not met as evidenced by:  
Based on record review and interview with the Office Manager, the laboratory failed to verify the education of 2 (A, C) out of 5 (A-E) Testing Personnel. See D6065

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to verify the education of 2 (A and C) out of 5 (A-E) testing personnel (TP). Findings include: - Review of CMS 209 Laboratory Personnel Report, which was dated and signed by the Laboratory Director on 08/24/2020 included 5 TP (TP A-E). -Review of employee files revealed that for TP A there was no High School Diploma, and for TP C a Nursing Assistant; the Certificate and a Foreign High School Diploma did not show a valid equivalence evaluation in the United States. During an interview on 10/05/2020 at 11:30 am with office manager, she confirmed that the laboratory failed to have documentation that meet the criteria of the education requirement for the TP listed above.