

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D2009775	<b>(X3) Date Survey Completed</b> 06/10/2021
<b>Name of Provider or Supplier</b> Health Foundations Birth Center Women's	<b>Street Address, City, State</b> 968 Grand Avenue, Saint Paul, MN	
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>D5980</b>	<p>PPM LABORATORY DIRECTOR CFR(s): 493.1355</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359.</p> <p>This CONDITION is not met as evidenced by: . Based on review of Centers for Medicare &amp; Medicaid Services (CMS) records, personnel credentials, and interview with site staff, the laboratory failed to ensure the laboratory director met the qualification requirements of 493.1357 to perform the functions specified in 493.1359. Findings are as follows: The laboratory failed to ensure the laboratory director met the qualification requirements of 493.1357 . See D5981. .</p>
<b>D5981</b>	<p>PPM LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1357</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in 493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required. (b) The laboratory director must meet one of the following requirements: (b) (1) Be a physician, as defined in 493.2. (b)(2) Be a midlevel practitioner, as defined in 493.2, authorized by a State to practice independently in the State in which the laboratory is located. (b)(3) Be a dentist, as defined in 493.2.</p> <p>This STANDARD is not met as evidenced by: . Based on review of Centers for Medicare &amp; Medicaid Services (CMS) records,</p>

personnel credentials, and interview with site staff, the laboratory failed to ensure the laboratory director was qualified to hold the position. Findings are as follows: 1. The laboratory performed Fern Testing microscopic examinations as confirmed by Registered Nurse 1 (RN1) during the entrance interview 2:20 p.m. on 06/10/21. 2. CMS records indicated the laboratory's CLIA Certificate for Provider Performed Microscopy Procedures has been active from 7/13/10 through date of investigation, 06/10/21, with the same individual holding the laboratory director (LD) role over this timeframe. 3. RN1 verbally indicated the LD held Naturopathic Doctor, Licensed Midwife, and Certified Professional Midwife credentials. 4. Credentials reviewed on-site confirmed the LD's Naturopathic Doctor degree. A Traditional Midwife license was confirmed by review of the MN Board of Medical Practice professional profile which completed on 06/10/21 after the on-site investigation had concluded. 5. The LD's credentials do not meet the qualification requirements of 493.1357 to perform the functions specified in 493.1359 for the laboratory's CLIA Certificate for Provider Performed Microscopy Procedures. 6. During an interview at 2:25 p.m. on 06/10/21, RN1 confirmed the above finding. .

**D5990**

**PPM TESTING PERSONNEL**  
CFR(s): 493.1361

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1363 to perform the functions specified in 493.1365 for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
. Based on review of personnel credentials and interview with site staff, the laboratory failed to ensure 4 of 6 testing personnel performing microscopic examinations met the qualification requirements of 493.1363 to perform the functions specified in 493.1365. Findings are as follows: The laboratory failed to ensure all staff met the qualification requirements of 493.1363. See D5991. .

**D5991**

**PPM TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1363

Each individual performing PPM procedures must-- (a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and (b) Meet one of the following requirements: (b)(1) Be a physician, as defined in 493.2. (b)(2) Be a midlevel practitioner, as defined in 493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located. (b)(3) Be a dentist as defined in 493.2 of this part.

This STANDARD is not met as evidenced by:  
. Based on review of personnel credentials and interview with site staff, the laboratory failed to ensure 4 of 6 testing personnel (TP) performing microscopic examinations were qualified to do so. Findings are as follows: 1. The laboratory performed Fern Testing microscopic examinations as confirmed by Registered Nurse 1 (RN1) during the entrance interview 2:20 p.m. on 06/10/21. 2. RN1 verbally indicated the following TP performed Fern Testing and indicated their credentials as listed below. Credential abbreviations: Naturopathic Doctor (ND), Licensed Midwife (LM), and Certified Professional Midwife ( CPM), Registered Nurse (RN), Certified Nurse Midwife (CNM). Laboratory Director (LD) - ND, LM, CPM TP1 - LM, CPM TP2 - RN, CNM

TP3 - LM, CPM TP4 - RN, CNM TP5 - LM, CPM 4. Documents reviewed on-site and review of Minnesota Board of Medical Practice and Minnesota Board of Nursing professional profiles, completed 06/10/21 after the on-site investigation had concluded, verified the licenses currently held in the State of Minnesota by the TP. Credential abbreviations: Naturopathic Doctor (ND), Traditional Midwife (TM), Registered Nurse (RN), Public Health Nurse (PHN), Certified Nurse Midwife (CNM). Minnesota Board of Medical Practice LD - ND, TM TP1 - TM TP2 - none found TP3 - TM TP4 - none found TP5 - TM Minnesota Board of Nursing LD - none found TP1 - RN TP2 - RN, PHN, CNM TP3 - none found TP4 - RN, PHN, CNM TP5 - none found 5. The LD, TP1, TP3, and TP5 do not meet the qualification requirements of 493.1363 to perform Fern Testing under the laboratory's CLIA Certificate for Provider Performed Microscopy Procedures. 6. During an interview at 2:30 p.m. on 06/10/21, RN1 confirmed the above finding.