

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0919172	(X3) Date Survey Completed 09/11/2023
Name of Provider or Supplier Women's Care Of Alaska	Street Address, City, State 2741 Debarr Road Suite C205, Anchorage, AK	
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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on a review of competency assessment records and an interview with Testing Person 1 (TP1), the laboratory failed to assess the competency of eight of eight testing persons who perform wet mounts in 2021 and 2022. Findings include: 1. A request was made to review documentation of wet mount competency assessments and documentation could not be provided. 2. An interview conducted on September 11, 2023 at 11:30 AM with TP1, confirmed that the laboratory did not have written documentation of wet mount competency assessments. 3. The laboratory reports performing approximately fifty wet mounts annually.</p>