

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0931261	<b>(X3) Date Survey Completed</b>  12/12/2023
<b>Name of Provider or Supplier</b>  Jaars Health Services	<b>Street Address, City, State</b>  6705 Wycliffe Ave, Waxhaw, NC	
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>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based upon the review of a sampling of patient test reports and interview with the LD (Laboratory Director) on 12/12/23, the laboratory failed to disclose its physical address on patient test reports. Findings: Review of two patient test reports generated by the laboratory displayed the laboratory's name and an address which is a PO Box. In interview at approximately 10:15 a.m., the LD stated that patient test reports generated by the laboratory display a mailing address.</p>
<b>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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</p>

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;

This STANDARD is not met as evidenced by:  
Based upon the review of employee records and interview with the Laboratory Director on 12/12/23, the Laboratory Director failed to assess the competency of the Clinical Consultant. Findings: The review of employee records revealed the credentials of the Clinical Consultant. The absence of 2022 and 2023 competency assessments for the Clinical Consultant was observed. In interview at approximately 9:45 a.m., the Laboratory Director stated she was unaware that she was responsible for the assessment of the Clinical Consultant's competency.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based upon the review of employee records and interview with the Laboratory Director on 12/12/23, the Laboratory Director failed to create a job description for the Clinical Consultant. Findings: The review of employee records revealed the credentials of the Clinical Consultant. The absence of a job description for the Clinical Consultant was observed. In interview at approximately 9:45 a.m., the Laboratory Director confirmed the absence of a job description for the Clinical Consultant.