

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2182994	(X3) Date Survey Completed 02/22/2021
Name of Provider or Supplier Childserve Clinics Lab	Street Address, City, State 5406 Merle Hay Road, Johnston, IA	
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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Procedure Manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:45 am on 2/22/2021, the laboratory director failed to ensure the laboratory established and maintained a quality assessment program which covered the four quality systems: general, pre-analytic, analytic, and post-analytic. At the time of the survey the laboratory did not have a quality assessment procedure, and the laboratory did not have documented quality assessment activities.</p>