

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1091809	<b>(X3) Date Survey Completed</b>  02/23/2023
<b>Name of Provider or Supplier</b>  Nuestros Ninos Our Kids Pediatrics	<b>Street Address, City, State</b>  777 Franklin Road, Marietta, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 23, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</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)(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. During an interview with Testing Personnel#2(CMS-209) in the basement of the breakroom on February 23, 2023 11:40 AM, confirmed the laboratory SOP did not contain a duties and responsibilities policy and procedure.</p>

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of Testing Personnel(TP) documents and staff interview, the Technical Consultant(TC) failed to perform annual competency on all testing personnel. The Findings include: 1. Competency record review revealed that the Technical Consultant(TC) failed to perform an annual competency for all Testing Personnel (TP) for 2022 (January-December). 2. During an interview with Testing Personnel#1(CMS-209) on February 23, 2023 at approximately 11:00 AM, in the basement of the breakroom, confirmed that the Technical Consultant (TC) did not perform competency for the Testing Personnel for 2022.