

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0377479	(X3) Date Survey Completed 04/15/2021
Name of Provider or Supplier Northside Pediatrics Pc	Street Address, City, State 265 Fremont Street Suite 1, Battle Creek, MI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to evaluate testing personnel performing Complete Blood Count (CBC) testing for 1 (Testing Personnel #1) of 3 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's competency records revealed a lack of a documented competency assessment for Testing Personnel #1 performing CBC testing in 2020. 2. A review of the laboratory's "CBC Training and Competency Policy" revealed a section stating, "Competency evaluations will be performed on new employees at the initial training, semiannually for the first year and then yearly thereafter." 3. An interview on 4/15/21 at 2:43 pm with TC1 confirmed the above findings.</p>
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with Technical Consultant #1, the laboratory failed to ensure the testing personnel met the qualification requirements at 493.1423.</p>

Findings include: 1. The laboratory failed to ensure testing personnel was qualified. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on record review and interview with Technical Supervisor #1 (TC1), the laboratory failed to ensure personnel performing Complete Blood Count (CBC) testing were qualified for 1 (Testing Personnel #2) of 3 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of the laboratory's testing personnel records revealed a lack of qualification documentation for Testing Personnel #2. 2. An interview on 4/15/21 at 12:50 pm with TC1 confirmed qualification documentation was not available for Testing Personnel #2. 3. The laboratory was given an additional 7 days to supply the necessary education documents. The documents were not received.