

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2070331	(X3) Date Survey Completed 07/09/2019
Name of Provider or Supplier Northwest Arkansas Internal Medicine	Street Address, City, State 5212 Village Parkway, Suite 2, Rogers, AR	
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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Through review of the findings of the initial certification survey conducted on 4/5/18, observation and interview it was determined that the laboratory director failed to ensure the laboratory was operating under the appropriate CLIA certificate. Findings follow: A) Review of the findings of the initial certification survey conducted on 4/5/18 revealed that the laboratory was not performing any testing of moderately complex or highly complex categorization and the laboratory was to submit a CMS 116 form for a change of certificate type to waived category. B) In a tour of the laboratory conducted on 7/9/19 at approximately 01:30 PM, there was no instrument, microscope, or test kit or reagents present in the laboratory which were capable of performing laboratory assays considered to be moderately complex or highly complex. C) In an interview on 7/9/19 at approximately 01:15 PM, the laboratory personnel, identified as number 3 on the CMS 209 form, stated that the laboratory had not performed any moderately complex or highly complex testing at any time since the initial certification survey, had no plans to begin testing categorized as moderately complex or highly complex and failed to submit a CMS 116 form to change the certificate category to waived status. D) The deficiency was corrected while surveyor</p>

was on-site by submitting a CMS 116 form, signed by the laboratory director, requesting a change in certificate type to waived category.