

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>42D2258952</p>	<p>(X3) Date Survey Completed</p> <p>06/21/2022</p>
<p>Name of Provider or Supplier</p> <p>Diagnostics Centers For Health Initiatives</p>	<p>Street Address, City, State</p> <p>355 South Main Street, 1st And 2nd Floors, Greenville, SC</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D8201</p>	<p>INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b)</p> <p>(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.</p> <p>This STANDARD is not met as evidenced by: Based on observations and testing personnel interview, the laboratory failed to ensure that a CMS or a CMS agent was able to conduct an inspection of a laboratory issued a certificate of waiver during the laboratory's hours of operation. Findings include: 1. Facility observations revealed during an onsite complaint investigation on 06/21/2022, that the facility was unable to be inspected due to not having an accurate location, test information, or director information as reported on the CMS 116 application. CLIA surveyors were unable to locate the laboratory at the address reported or verify the following information: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. 2. Testing personnel confirmed during phone conversation on 06/16/2022 that she is not testing at the location provided.</p>

D8307

COMPLIANCE WITH BASIC INSPECTION REQUIREMENTS

CFR(s): 493.1777(d)

The laboratory must comply with the basic inspection requirements of Sec. 493.1773.

This STANDARD is not met as evidenced by: