

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2087651	(X3) Date Survey Completed 06/02/2021
Name of Provider or Supplier Quest Diagnostics Inc Shenandoah Community Health	Street Address, City, State 99 Tavern Road, Martinsburg, WV	
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
D0000	An announced, on site, recertification survey was conducted at Quest Diagnostics Incorporated on June 2, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D6056	<p>CLINICAL CONSULTANT CFR(s): 493.1415</p> <p>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview the laboratory has no qualified clinical consultant under CFR 493.1417. Findings: 1. Review of laboratory personnel files, documented education, and the CMS-209 form identified no qualified clinical consultant. See D6057 2. An interview with the lab director, 6/3/2021 at approximately 1:00 pm, confirmed the findings.</p>
D6057	<p>CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417</p> <p>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview the laboratory has no qualified clinical consultant under sections (a) or (b) of CFR 493.1417. Findings: 1. Review of personnel files, documented education, and CMS-209 form identified the following laboratory personnel: Laboratory director qualifies under CFR 493.1405(a)(b)5 Technical consultant qualifies under CFR 493.1411(a)(b)4 2. Review of personnel files and documented education identified no qualified personnel for the position of clinical consultant. 3. An interview with the laboratory director, on 6/3/2021 at approximately 1:00 PM, confirmed the findings.