

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2143238	(X3) Date Survey Completed 04/19/2019
Name of Provider or Supplier Holistic, Inc Medical Services And Counseling	Street Address, City, State 4815 Maccorkle Ave, Se, Charleston, 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with the technical consultant, the laboratory failed to establish and publish guidelines for specimen rejection. Findings: 1. Review of the binder titled "SLPs" found that no guidelines for specimen rejection were available. 2. Interview with the technical consultant (TC) on 4/19/2019 at approximately 12:15PM confirmed that specimen rejection guidelines were not included in any procedure.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in</p>

493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manuals and interview with the technical consultant, the laboratory failed to include specimen rejection guidelines in the procedure manual. Findings: 1. Review of the binder titled "SLPs" found that no guidelines for specimen rejection were available. 2. Interview with the technical consultant (TC) on 4/19/2019 at approximately 12:15PM confirmed that specimen rejection guidelines were not included in any procedure.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's personnel records, West Virginia laboratory licensure records, West Virginia administrative rule 64 CSR 57, and interview with the testing person, the laboratory director failed to provide overall management and direction by not ensuring the eligibility of the testing person to perform high complexity testing on the Agilent 6420 LC/MS. Findings: 1. Review of the "Employee Training" binder demonstrated a laboratory technologist job description, signed 1/1/2019 by the director, that states the minimum education for the position is an Associate of Science in laboratory technology. 2. Review of the testing person's qualifications in the "Employee Training" binder demonstrated only a diploma in Medical Assisting. 3. Interview with the testing person on 4/19/2019 at approximately 12:45PM confirmed that no college coursework was completed in laboratory technology or in a chemical, physical, or biological science. 4. Review of the testing person's WV laboratory license found that she is licensed as a Point of Care Technician (POCT). 5. Review of the WV Clinical Laboratory Technician and Technologist Licensure and Certification rule, 64 CSR 57, section 2.16, found that licensed POCTs are only qualified to perform moderate complexity testing.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's personnel records, West Virginia laboratory licensure records, West Virginia administrative rule 64 CSR 57, and interview with the testing person, the laboratory director failed to ensure the eligibility of the testing person to perform high complexity testing on the Agilent 6420 LC/MS. Findings: 1. Review of the "Employee Training" binder demonstrated a laboratory technologist job description, signed 1/1/2019 by the director, that states the minimum education for the position is an Associate of Science in laboratory technology. 2. Review of the testing person's qualifications in the "Employee Training" binder demonstrated only a diploma in Medical Assisting. 3. Interview with the testing person on 4/19/2019 at approximately 12:45PM confirmed that no college coursework was completed in laboratory technology or in a chemical, physical, or biological science. 4. Review of the testing person's WV laboratory license found that she is licensed as a Point of Care Technician (POCT). 5. Review of the WV Clinical Laboratory Technician and Technologist Licensure and Certification rule, 64 CSR 57, section 2.16, found that licensed POCTs are only qualified to perform moderate complexity testing.

D6168

TESTING PERSONNEL
 CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
 Based on review of the laboratory's personnel records and interview with the testing person, the laboratory failed to employ an eligible testing person to perform high complexity testing on the Agilent 6420 LC/MS in accordance with 493.1489. Findings: 1. Review of the testing person's qualifications in the "Employee Training" binder demonstrated only a diploma in Medical Assisting. 2. Interview with the testing person on 4/19/2019 at approximately 12:45PM confirmed that no college coursework was completed in laboratory technology or a physical, chemical, or biological science.

D6171

TESTING PERSONNEL QUALIFICATIONS
 CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory

training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records and interview with the testing person, the laboratory director failed to employ an eligible testing person to perform high complexity testing on the Agilent 6420 LC/MS in accordance with 493.1489. Findings: 1. Review of the testing person's qualifications in the "Employee Training" binder demonstrated only a diploma in Medical Assisting. 2. Interview with the testing person on 4/19/2019 at approximately 12:45PM confirmed that no college coursework was completed in laboratory technology or in a chemical, physical, or biological science.