

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D2195540	<b>(X3) Date Survey Completed</b> 02/25/2025
<b>Name of Provider or Supplier</b> Wasatch Behavioral Health	<b>Street Address, City, State</b> 151 South University Ave Suite 1200, Provo, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5423</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Federal Food and Drug Administration (FDA) test categorization list review and email correspondence with the Laboratory Director, the laboratory failed to verify the analytical sensitivity and specificity of Ethyl Glucuronide (ETG) testing on the AU-180 Instrument The laboratory tested approximately 14,789 patient samples annually. Findings include: 1. Review of the FDA test categorization website revealed lack of FDA approval for EtG testing for the AU-480 instrument. 2. Review of ARK Ethyl Glucuronide Assay package insert states "This product is intended for Criminal Justice and Forensic Use Only". 2. The laboratory verification for non-FDA approved analyte failed to include test's analytical sensitivity or specificity for EtG testing. 3. Email correspondence with the Laboratory Director on 3/11/2025 at approximately 11:05 a.m. revealed lack of documentation for analytical sensitivity or specificity for EtG testing.</p>
<b>D6076</b>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p>

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:

The director failed to meet the qualification requirements necessary to direct a high complexity laboratory (Ref. D6078).

**D6078**

**LABORATORY DIRECTOR QUALIFICATIONS**

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

This STANDARD is not met as evidenced by:

Based on laboratory record review, FDA test complexity database review, laboratory director education records review, and interview with the director, the director failed to meet the qualifications of a high complexity laboratory director. The laboratory

performs approximately 14,789 high complexity tests annually. Findings include: 1. The laboratory test menu list, patient reports, and method verification studies document Ethyl Glucuronide (ETG) testing. 2. The FDA test complexity database lacks classification of ETG testing. 3. Any test not classified by the FDA defaults to a high complexity laboratory developed test. 4. The director lacked the educational requirements to qualify as the director of a high complexity laboratory. 5. Interview with Laboratory Director on 2/25/2025 at approximately 1:00 p.m. confirmed the Laboratory Director's highest level of education is a Bachelors degree which lacks the educational requirements for Laboratory Director position.

**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 personnel record review and interview with the laboratory director, the laboratory failed to employ qualified testing personnel that meet the educational requirements for high complexity toxicology testing. (refer to D6171)

**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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December

28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of education records and e-mail correspondence with the laboratory director, the laboratory failed to employ qualified personnel to perform high complexity testing for toxicology since the previous survey was conducted on 02/13/2023. The laboratory performed approximately 14,789 toxicology tests per year. Findings include: 1. Review of education records for 8 out of 10 testing personnel revealed educational requirements were not met for high complexity toxicology testing for Ethyl Glucoronide (EtG) on the AU-480 Instrument. 2. During email correspondence with the Laboratory Director on 3/11/2025 at approximately 1:42 p.m. it was confirmed 8 out of 10 personnel did not meet the high complexity educational requirements for toxicology testing for Ethyl Glucoronide (EtG) on the AU-480 Instrument.