

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2219632	(X3) Date Survey Completed 09/01/2023
Name of Provider or Supplier Bonfire Behavioral Health	Street Address, City, State 2957 Main St, Bethlehem, NH	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, laboratory (lab) personnel failed to sign the attestation form for 1 of 1 chemistry proficiency testing (PT) event in 2023. Findings include: 1. Review on 8/29/2023 of PT records from 2023 revealed the lab had enrolled in PT through College of American Pathologists (CAP) and had completed 1 PT event as of the survey date for urine drug screen (UDS) testing (CAP event UDS-B 2023) . Review of the PT attestation form revealed no signatures from the testing personnel or from the laboratory director. 2. Interview on 8/29/2023 at 9:55 a.m. with Testing Personnel confirmed the above finding.</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 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or</p>

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 record review and staff interview, the laboratory's (lab) procedure for chemistry tests failed to include the lab's verified reportable range. Findings include: 1. Review on 8/29/2023 of the lab's verification of performance specifications for creatinine, specific gravity, and general oxidants revealed the following verified reportable ranges: creatinine = 1.3 - 23.0 mg/dL specific gravity = 1.010 - 1.030 g/mL general oxidants = 0 - 300 mg/L 2. Review on 8/29/2023 of the lab's procedures for these 3 analytes revealed the lab referred to the package inserts and did not specify the ranges verified by the lab listed in the above finding. The ranges listed in the package inserts are: creatinine = 0.780 - 420 mg/dL specific gravity = 1.000 - 1.040 g/mL general oxidants = no range included 3. Interview on 8/29/2023 at 10:45 a.m. with the Technical Consultant confirmed the lab's verified reportable ranges were not included in the lab's procedures.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director (LD) failed to provide a dated signature for chemistry and toxicology procedure manuals in 2023. Findings include: 1. Review on 8/29/2023 of the "Laboratory Director Review and Approval" pages for "Procedures for Urine Drug Screen (UDS)" and "quality management polices and procedures, and forms used for collecting quality indicator data at this lab" revealed the signature line failed to include a dated signature from the LD. 2. Interview on 8/29/2023 at 10:00 a.m. with Testing Personnel confirmed the LD had not signed and dated the signature pages for these procedure manuals.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on record review, the laboratory (lab) failed to establish analytic sensitivity and analytic specificity performance specifications for ethyl glucuronide (ETG), a test system not approved or cleared by the FDA. Findings include: 1. Review on 8/29 /2023 of the lab's test list revealed ETG listed as a moderately complex test performed on the Indiko Plus instrument using Thermo Fisher's DRI ETG Assay. 2. On 9/1/2023, a search for ETG on the FDA test complexity database yielded no results. 3. Review on 9/1/2023 of the manufacturer's package insert for DRI ETG Assay states at the top of page 1 the assay is "For Criminal Justice and Forensic Use only". 4. Review on 8/29 /2023 of the lab's verification of performance specifications completed in May 2023 revealed the lab did not establish ETG performance specifications for analytic sensitivity and analytic specificity. 5. Interview on 8/29/2023 at 9:00 a.m. with the General Supervisor (GS) revealed patient testing started 5/12/2023 and as of 8/29 /2023 has performed 824 ETG tests.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory (lab) reported 1 of 2 creatinine test results outside the lab's verified reportable range in August 2023. Findings include: 1. Review on 8/29/2023 of 2 patients' test results reported on 8/15 /2023 revealed 1 of 2 patients' creatinine result was reported as 179.3 mg/dL. 2. Review on 8/29/2023 of the lab's verification of performance specifications for creatinine revealed the lab verified a range of 1.3 - 23.0 mg/dL. 3. Interview on 8/29 /2023 at 10:45 a.m. with the Technical Consultant confirmed the test fell outside the lab's verified reportable range. The testing personnel revealed the lab did not have a system in place, either manual or electronic, to report quantitative values that fall outside the lab's reportable ranges as less than or greater than the reportable limit.

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 record review and staff interview, the Laboratory Director (LD) failed to meet responsibilities for a director overseeing high complexity chemistry testing in

	<p>2023. Findings include: 1. The LD failed to establish analytic sensitivity and analytic specificity performance specifications for ethyl glucuronide (ETG), a test system not approved or cleared by the FDA. Refer to D6086. 2. The LD failed to review and provide a dated signature on 1 of 1 proficiency testing (PT) evaluation form in 2023. Refer to D6091. 3. The LD failed to ensure 3 of 3 Testing Personnel and 1 of 1 General Supervisor met educational qualification requirements for high complexity testing in 2023. Refer to D6101.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to establish analytic sensitivity and analytic specificity performance specifications for ethyl glucuronide (ETG), a test system not approved or cleared by the FDA. Findings include: 1. Review on 8/29/2023 of the laboratory's (lab) test list revealed ETG listed as a moderately complex test performed on the Indiko Plus instrument using Thermo Fisher's DRI ETG Assay with an estimated annual test volume of 1,800. 2. On 9/1/2023, the State Agency conducted a search for ETG on the FDA test complexity database, no results were found. 3. Review on 9/1/2023 of the manufacturer's website revealed the package insert for DRI ETG Assay states at the top of page 1 the assay is "For Criminal Justice and Forensic Use only". 4. Review on 8/29/2023 of the lab's verification of performance specifications completed in May 2023 revealed the lab did not establish ETG performance specifications for analytic sensitivity and analytic specificity. 5. Interview on 8/29/2023 at 8:30 a.m. with the General Supervisor revealed the lab began patient testing on 5/12/2023.</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to sign 1 of 1 proficiency testing (PT) evaluation form in 2023. Findings include: 1. Review on 8/29/2023 of the laboratory's PT records revealed it had completed 1 PT event in 2023. Further review of the evaluation form for College of American Pathologist (CAP) event UDS-B 2023 revealed it had not been signed by the LD and was signed by the Technical Consultant (TC) instead. 2. Interview on 8/29/2023 at 9:55 a.m. with Testing Personnel confirmed the LD did not sign the evaluation form for UDS-B 2023. 3. Interview on 8/29/2023 at 10:45 a.m. with the TC confirmed the LD had not signed a letter designated the TC for reviewing and signed PT forms.</p>
<p>D6101</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11)</p>

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director (LD) failed to ensure 3 of 3 Testing Personnel and 1 of 1 General Supervisor met educational qualification requirements for high complexity testing in 2023. Findings include: 1. Review on 8/29/2023 of the lab's test list revealed ethyl glucuronide (ETG), creatinine, specific gravity, hydrogen concentration (pH), and general oxidants listed as a moderately complex tests performed on the Indiko Plus instrument using Thermo Fisher's DRI reagents. 2. On 9/1/2023, the State Agency conducted a search for ETG, creatinine, specific gravity, pH, and general oxidants for the Thermo Fisher DRI reagents on the FDA test complexity database, no results were found indicating they had not been approved as moderate complexity tests and default to high complexity. 3. Review on 8/29/2023 of 3 of 3 Testing Personnel (TP) records revealed no educational qualifications for 2 of 3 TP (TP1 and TP2) and the third TP (TP3) has a Bachelors in Public Health. This documentation is not adequate to verify qualification requirements for testing personnel performing high complexity testing. found at 493.1489(b). 4. Review on 8/29/2023 of 1 of 1 General Supervisor (GS) personnel records revealed no documentation of educational qualifications. 5. Interview on 8/29/2023 at with the GS confirmed the personnel records were missing documentation of educational qualifications TP1 and TP2, did not have additional documentation for TP3, and no documentation for 1 of 1 GS. The GS revealed patient testing started 5/12/2023 and as of 8/29/2023 has performed 13,184 toxicology and routine chemistry tests.

D6141

GENERAL SUPERVISOR

CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the General Supervisor (GS) failed to meet qualification requirements to provide onsite supervision of high complexity chemistry testing in 2023. Refer to D6143.

D6143

GENERAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the General Supervisor (GS) failed to meet qualification requirements to provide onsite supervision of high complexity chemistry testing in 2023. Findings include: 1. Review on 8/29/2023 of 1 of 1 General Supervisor (GS) personnel records revealed no documentation of educational qualifications. 5. Interview on 8/29/2023 at 9:00 a.m. with the GS confirmed the GS personnel record did not include educational qualifications. The GS revealed patient testing started 5/12/2023 and as of 8/29/2023 has performed 13,184 toxicology and routine chemistry tests.

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 record review and staff interview, 3 of 3 Testing Personnel (TP) failed to meet educational qualifications to perform high complexity Chemistry testing in 2023. 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 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 record review and staff interview, 3 of 3 Testing Personnel (TP) failed to meet educational qualifications to perform high complexity Chemistry testing in 2023. Findings include: 1. Review on 8/29/2023 of 3 of 3 Testing Personnel (TP) records revealed no educational qualifications for 2 of 3 TP (TP1 and TP2) and the third TP (TP3) has a Bachelors in Public Health. This documentation is not adequate to verify qualification requirements for testing personnel performing high complexity testing. 2. Interview on 8/29/2023 at 9:00 a.m. with the GS confirmed the personnel records were missing documentation of educational qualifications for TP1 and TP2, and did not have additional documentation for TP3. The GS revealed patient testing started 5 /12/2023 and as of 8/29/2023 has performed 13,184 toxicology and routine chemistry tests.