Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2161638	03/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital Of Converse County Medical	700 Center Street, Douglas, WY	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure safe practices were followed to ensure protection from biohazardous materials. The findings were: Observation on 3/7/23 at 2:04 PM of the laboratory testing area showed a urine drug test was in progress and two vials of blood were sitting on the counter. In addition, the eyewash station mounted to the wall showed two containers of solution with an expiration date of 1/2023. Next to the blood vials was a personal-use thermos-type water bottle. Interview with the laboratory director at that time revealed it was against policy to have food or drink in the laboratory testing area and immediately removed the water bottle. The laboratory director also confirmed the eyewash fluid had expired and discarded the solution.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files, staff interview, and policy and procedure review, the laboratory failed to perform and document an initial competency assessment for 3

	of 3 (TP #1, TP #2, TP #3) new testing personnel prior to patient testing. The findings were: 1. Review of the personnel files for TP #1, TP #2, and TP #3 showed no evidence an initial competency assessment had been completed prior to independently testing patient samples. 2. Interview with the laboratory director on 3/7/23 at 1 PM confirmed there was no documentation the initial competency assessments had been completed. 3. Review of the Competency Monitoring of Laboratory Personnel, 2200-0003-02 showed "...Laboratory employees will be evaluated after initial training... Training documentation/competency records will be retained in a designated location within the laboratory...Initial training documents/competency records will be retained for at least two (2) years past the life of the instrument for which competency is being assessed."
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to ensure an ongoing system was in place to monitor, assess, and correct problems in the general laboratory system from 10/1/21 through 3/7/23. The findings were: 1. The laboratory was unable to locate any quality assurance documentation from 10/1/21 to 3/7/23. 2. Interview with the laboratory director (LD) on 3/7/23 at 2 PM revealed she was unable to locate the quality assurance (QA) documentation. In addition the LD stated she tried to visit the laboratory once a week and completed the QA review on a monthly basis; however, she had not completed any QA review since July of 2022 due to time constraints.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and the individual quality control plan (IQCP), staff interview, and review of the manufacturer's instructions for use, the laboratory failed to perform QC which included a positive and negative control material for the MedToxScan panel which included 13 drugs of abuse from 10/1/21 to 3/7/23. The laboratory performed approximately 129 drug of abuse panels annually. The findings were: 1. Review of the laboratory's records showed no evidence QC had been performed from 10/1/21 to 3/7/23. 2. Review of the laboratory's IQCP for the

	MedTox Urine Drug Screen procedure, last reviewed on 9/29/21, showed QC should be performed weekly. 3. Review of the MedTox Profile Drugs of Abuse manufacturer's instructions showed external control materials should be performed "routinely or as needed for any of the following reasons: (1) to practice the test with a known control, (2) when you open a new lot of devices, (3) once a week, (4) if you suspect that the reader or test device is not working properly, (5) if you have had a repeated unexpected test result, or (6) if you suspect that the test devices have been stored improperly." 4. Interview with the laboratory director on 3/7/23 at 1 PM revealed she was unable to locate the quality control records from 10/1/21 through 3/7/23.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, manufacturer's instructions for use, the Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) test categorization database, and staff interview, the laboratory failed to perform QC which included a positive and negative control material for the Discover Plus drugs of abuse test method for tramadol and the One Step Fentanyl Test method for fentanyl. The laboratory performed approximately 129 drugs of abuse panels annually. The findings were: 1. Review of the laboratory's records showed no evidence QC had been performed each day of patient testing from 4/11/22 to 3/7/23. 2. Review of the One Step Fentanyl Test Dip Card manufacturer's instructions showed the test was "For forensic use only". The manufacturer stated "It is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance." 3. Review of the Discover Plus Drugs of Abuse (Strip/Card/Device/Cup) manufacturer's instructions for use for the detection of tramadol showed the test was "For forensic use only". The manufacturer stated "It is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance." 4. Review of the FDA CLIA test categorization database showed the Discover Plus and One Step test methods had not been approved by the FDA and therefore were classified as high complexity testing. 5. Interview with the laboratory director on 3/7/23 at 1 PM revealed she was unable to locate the quality control records from 4/11/22 through 3/7/23.
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 test records, the manufacturer's instructions for the One Step Fentanyl Test Dip Card for fentanyl and the Discover Plus Drugs of Abuse (Strip/Card/Device/Cup) for tramadol test methods, the Food and Drug Administration Clinical Laboratory Improvement Amendments test categorization database, personnel records, and staff interview, the laboratory director failed to qualify as a high complexity director for the fentanyl and tramadol test method in use. The laboratory performed approximately 129 patient drugs of abuse screening tests per year. Refer to 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 possess qualifications that are equivalent to those required for such certification; or (b)(2) 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of the laboratory's test records, the manufacturer's instructions for the One Step Fentanyl Test Dip Card for fentanyl and the Discover Plus Drugs of Abuse (Strip/Card/Device/Cup) for tramadol test methods, the Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) test categorization database, personnel records, and staff interview, the laboratory director failed to qualify as a high complexity director for the fentanyl and tramadol test method in use. The laboratory performed approximately 129 patient drugs of abuse

	screening tests per year. The findings were: 1. Review of the laboratory test records showed documentation the laboratory performed patient testing for fentanyl and tramadol from 4/11/22 to 3/7/23. 2. Review of the One Step Fentanyl Test Dip Card manufacturer's instructions showed the test was "For forensic use only". 3. Review of the Discover Plus Drugs of Abuse (Strip/Card/Device/Cup) manufacturer's instructions for use for the detection of tramadol showed the test was "For forensic use only". 4. Review of the FDA CLIA test categorization database showed the Discover Plus and One Step test methods had not been categorized by the FDA. Laboratory tests that have not been categorized by the FDA default to CLIA high complexity tests. 5. Review of the personnel record for the laboratory director showed she did not qualify as a high complexity laboratory director. 6. Interview with the laboratory director on 3/7/23 at 4:35 PM revealed she was unaware the test methods for tramadol and fentanyl were considered high complexity 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 review of personnel records, lack of documentation, review of the CMS 209 Laboratory Personnel Report, and staff interview, the laboratory failed to ensure 3 of 3 testing personnel (TP #1, TP #2, TP #3) qualified to perform high complexity testing. Refer to D6170.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of personnel records, lack of documentation, review of the CMS 209 Laboratory Personnel Report, and staff interview, the laboratory failed to ensure 3 of 3 testing personnel (TP #1, TP #2, TP #3) qualified to perform high complexity testing. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed TP #1, TP #2, and TP #3 were listed as testing personnel. The following concerns were identified: a. Review of the personnel file for TP #1 showed transcripts which indicated TP #1 had been awarded a high school diploma. b. Review of the personnel file for TP #2 showed no evidence of TP #2's educational status. c. Review of the personnel file for TP #3 showed no evidence of TP #3's educational status. 2. Interview with the laboratory director on 3/7/23 at 1:30 PM confirmed no further documentation was available.