

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0405516	<b>(X3) Date Survey Completed</b>  04/11/2024
<b>Name of Provider or Supplier</b>  Madison Healthcare Services	<b>Street Address, City, State</b>  900 2nd Ave, Madison, MN	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to follow the established quality control (QC) requirements in the Profile-V MEDTOXScan procedure in 2022, 2023, and 2024. Findings are as follows:                      1. The laboratory performed moderate complexity Urine Drugs of Abuse testing which falls under the sub-specialty of Toxicology under the specialty of Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 11:55 a.m. on April 10, 2024. 2. A MEDTOXScan Profile-V Drugs of Abuse test system was observed as present and available for use during the tour. 3. The Profile V MEDTOXScan Positive or High Positive and MEDTOXScan Negative Control Solutions were listed as materials required but not provided by the test system in the laboratories established Profile V MEDTOXScan procedure found in PolicyStat electronic procedure manual. Section 9 of the established procedure, goes on to indicate the QC material to be used are urine-based control materials. 4. QC performance records were reviewed for the third quarter of 2022, July, August and September 2022. These records indicated the QC material used for the negative control by the laboratory was DI (distilled) water. 5. The PV MEDTOXScan 2X Pos control (lot # CC01651, Expiration Date 10-31-2021) was observed in the laboratory at 9:15 a.m. on April 11, 2024 as the positive QC material used for the MEDTOXScan Profile-V test system. A urine-based negative MEDTOXScan control was not observed. 6. During an interview at 9:15 a.m. on April 11, 2024, the GS confirmed the laboratory has used distilled water as the negative control for the previous two years. .</p>

## 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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform minimum quality control activities as established by the manufacturer of a Chemistry test for 13 of 22 months reviewed in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed moderate complexity Urine Drugs of Abuse testing which falls under the sub-specialty of Toxicology under the specialty of Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 11:55 a.m. on April 10, 2024. 2. A MEDTOXScan Profile-V Drugs of Abuse test system was observed as present and available for use during the tour. 3. MEDTOXScan quality control (QC) performance was required weekly as established in the manufacturer's Profile-V MEDTOXScan Reader System Quick Reference Instructions, Revision 06/21, found in the current Test Kit used by the laboratory. 4. The laboratory's Individualized Quality Control Plan (IQCP) for the MEDTOXScan Profile -V test system established two levels of external liquid QC must be analyzer prior to using a new lot number or new shipment of cassette devices, as well as once per month. The IQCP did not include weekly QC performance, as required by the manufacturer. This IQCP had been revised in April 2023 to reduce external QC frequency from the manufacturers required weekly QC performance to monthly QC performance. 5. QC performance records indicated QC was performed weekly until May 2023, at which time the laboratory began performing two levels of external QC monthly. See below for QC dates beginning May 2023: QC date 05/01/2023 06/01/2023 07/03/2023 08/01/2023 09/01/2023 10/01/2023 11/01/2023 12/01/2023 01/01/2024 02/05/2024 03/01/2024 04/01/2024 6. Patient testing records indicated 152 patients had been tested on the MEDTOXScan Profile test system since the laboratory had reduced the QC frequency to once per month. 7. During an interview at 9:20 a.m. on April 11, 2024, the GS confirmed the above findings.