

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2003984	<b>(X3) Date Survey Completed</b>  04/27/2023
<b>Name of Provider or Supplier</b>  Masonboro Urgent Care, Pc	<b>Street Address, City, State</b>  6132 Carolina Beach Rd, Suite 8, Wilmington, NC	
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>D2006</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2021, 2022 and 2023 personnel records, review of 2021 and 2022 AAFP (American Academy of Family Physicians) PT (proficiency testing) records, review of 2023 WSLH (Wisconsin State Laboratory of Hygiene) PT records and interview with TP (testing personnel) #1, 4/27/23, the laboratory failed to ensure all TP participated in PT each year of testing. Findings: Review of laboratory procedure "PROFICIENCY TESTING" revealed "...When a laboratory enrolls in PT, it will receive five "unknown" samples three times a year for the tests ordered. PT samples are tested in the same way as patient samples.". Review of 2021 AAFP PT records for Complete Blood Count (CBC) and iSTAT Chemistry testing revealed TP #1 performed PT events, A and B. Event C was performed by a TP whom is no longer employed. Review of 2021 personnel records revealed 4 TP were employed in 2021, TP #4 began testing in July of 2021. TP #3 did not participate in the 2021 PT events. Review of 2022 AAFP PT records for Complete Blood Count (CBC) and iSTAT Chemistry testing revealed TP #2 performed PT events A and C. Event B was performed by a TP whom is no longer employed. Review of 2022 personnel records revealed 6 TP were employed in 2022, TP #5 and TP #6 began testing in October of 2022. TP #3 and TP #4 did not participate in the 2022 PT events.</p>

Review of 2023 WSLH (Wisconsin State Laboratory of Hygiene) PT records for CBC and iSTAT Chemistry testing revealed TP #2 performed the first event for the CBC and iSTAT testing. Review of 2023 personnel records revealed 6 TP were employed at time of survey. Interview with TP #1 at approximately 1:30 p.m. confirmed all testing personnel had not participated in PT for 2021, 2022 and 2023. She stated she had hired a new laboratory supervisor and wanted to use the PT samples to aid in her training. She also stated she was unaware that more than 1 TP could participate in a PT event if each TP was assigned different sample to test.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
Based on review of manufacturer's instructions, review of laboratory procedure, review of 2021, 2022, and 2023 iSTAT chemistry analyzer records and interview with TP #1, 4/27/23, the laboratory failed to perform and document the recording of the temperature when receiving new cartridges or control shipments for the iSTAT chemistry analyzer for approximately 28 months. Findings: Review of manufacturer's instructions revealed "Required procedure for handling new cartridge or control shipments: 1. Open box marked "Refrigerate Upon Arrival". Find card with temperature strip attached. Read strip immediately...2. Record temperature reading on "Receipt of New Cartridges" log...". Review of laboratory procedure for the iSTAT analyzer revealed "Receipt of New Cartridge...For acceptance of newly received cartridge lots, perform the following: 1. Check Temperature Monitor...Action: Fill out the record of receipt and forward materials to refrigerator. If all windows are white or if only the "A" window is blue transit temperatures were satisfactory. Record this on the Receipt of New Cartridges Log.". Review of 2021, 2022, and 2023 iSTAT chemistry analyzer records revealed no documentation of a "record of receipt" for new cartridge or control shipments. The records also failed to include documentation of temperature recordings for new cartridge or control shipments. Interview with TP #1 at approximately 12:15 p.m. confirmed the laboratory had not recorded temperature readings for receipt of new cartridge or control shipments. She stated they had done it in the past but were informed by an offsite technical consultant that it was not required.