

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2006205	(X3) Date Survey Completed 08/11/2022
Name of Provider or Supplier Halo Medical Group Pllc	Street Address, City, State 22720 Michigan Avenue Suite 200, Dearborn, MI	
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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the General Supervisor (GS), the laboratory failed to perform and document the function checks as required for the humidity in the laboratory for 10 (February 2021 to August 2022) of 19 months of patient testing. Findings include: 1. A record review on 8/11/2022 at 11:09 am revealed lack of documentation of the humidity readings in the laboratory for 10 of 19 months of patient testing as follows: 2021 a. February - 23-26 b. March - 1-5, 8-12, 15-19, 22-26, and 29-31 c. April - 1-2, 5-9, and 12 d. June - 3-4, 7-11, 14-18, 21-25, and 28-30 e. July - 1-2, 6-9, 12-16, 19, and 21-23 f. September - 13-17, 20-24, and 27-30 g. October - 1, 4-8, 11-15, 18-22, and 25-29 h. December - 22-23, and 28-30 2022 a. January - 3-7, 10-14, 17-21, 24-28, and 31 b. February - 1-4, and 7-11 2. An interview on 8/11/2022 at 11:09 am, the GS confirmed the laboratory failed to perform and document the humidity in the testing room.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)</p>

(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor (GS), the laboratory failed to document corrective action for the out of range humidity readings in the laboratory for 9 (February 2021 to August 2022) of 19 months of documents reviewed. Findings include: 1. A record review of the temperature log revealed for 9 of 19 months the humidity readings were below the stated range of 20-85% and no corrective action was performed and documented as follows: 2021 a. February - 1-5, 8-12, 15, 17-19, and 22 b. April - 14-16, 19-23, and 26-27 c. May - 7 and 10-14 d. November - 15-16, 22-24, and 29-30 e. December - 1-3, 6-10, 11, 13-14, 16-17, and 20-21 2022 a. February - 14-18, 24-25, and 28 b. March - 1-4, 7-8, 14-18, 21, and 31 c. April - 1, 4-7, 13-15, 18-20, 22, and 26-29 d. May - 6, 9-10, and 12 2. An interview on 8/11/2022 at 11:09 am, the GS confirmed no corrective action had been performed and documented to resolve the out of range humidity readings.