Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1017202	11/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Uw Health Arbor Gate Laboratory	2601 W Beltline Hwy, Ste 200, Madison, WI	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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 surveyor review of the chemistry procedures and interview with the technical consultant, the chemistry procedures did not include reference intervals for testing performed on the Cobas 311 chemistry analyzer. Findings include: 1. Review of the chemistry procedures showed no evidence the laboratory included patient reference intervals in their procedures for testing performed on the Cobas 311 chemistry analyzer. 2. Interview with the technical consultant on November 22, 2019 at 11:30 AM, confirmed that patient reference intervals were not included in the chemistry procedures.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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)(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 surveyor review of temperature logs from December 2018, March 2019, April 2019, October 2019, and November 2019, and interview with the technical consultant, the laboratory did not document corrective action when the relative humidity was outside of the acceptable range. Findings include: 1. Review of the "Daily Temperature Check" logs showed that corrective action was not documented on relative humidity readings when laboratory humidity was outside of the acceptable range of 30-85 percent. Laboratory humidity was below 30-85 percent on both the daily minimum and maximum readings on 70 out of 101 days the lab performed patient testing during review of temperature logs from December 2018, March 2019, April 2019, October 2019, and November 2019. The following dates had humidity readings below the laboratory acceptable range in which no corrective action was documented: December 2018: December 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 17, 18, 19, 20, 21, 26, 27, 28, 31 March 2019: March 1, 4, 5, 6, 7, 8, 11, 12, 13, 19, 20, 21, 22, 25, 26, 27, 28, 29 April 2019: April 1, 2, 3, 4, 5, 10, 11, 12, 15, 16, 25 October 2019: October 24, 25, 28, 29, 30, 31 November 2019: November 1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 22. 2. Interview with the technical consultant on November 22, 2019 at 12:15 PM confirmed that no corrective action was documented when laboratory humidity was outside of the acceptable range.