Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2181359	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Thedacare Family Medicine Gateway	3925 N Gateway Drive, Appleton, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a technical consultant, staff A, testing personnel used expired potassium hydroxide (KOH) reagent for quality control (QC) and patient testing on November 1, 2021. Findings include: 1. Review of the "KOH QC LOG" revealed testing personnel performed QC on the KOH on November 1, 2021 with KOH lot number 9301 and expiration date of October 28, 2021. 2. Review of the KOH patient log revealed testing personnel performed KOH testing on patient 1 on November 1, 2021. 3. Interview with staff A on December 16, 2021 at 11:25 AM confirmed testing personnel used expired KOH reagent for QC and patient testing on November 1, 2021.
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 surveyor review of laboratory record control, and interview with a technical consultant, staff A, the laboratory did not meet their stated Potassium Hydroxide (KOH) Quality Control (QC) requirements for testing external controls daily with patient testing for one of three days in November 2021. Findings include: 1. Review of the KOH patient test log revealed testing personnel performed KOH testing on patient 2 on November 21, 2021. 2. Review of "KOH QC LOG" showed no documentation the laboratory performed QC testing for KOH on November 21, 2021. 3. Interview with staff A on December 16, 2021 at 11:25 AM confirmed the laboratory did not meet their QC requirements for KOH testing on one of three days in November 2021.