Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2140776	10/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Froedtert & Mcw Drexel Town Square Laboratory	7901 South 6th Street, Oak Creek, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) and American Proficiency Institute (API) PT records, and interview with the general supervisor, the laboratory failed to participate successfully in PT for the Digoxin analyte in the Specialty of Chemistry for events 2020-1 and 2020-2. See D2118.
D2118	TOXICOLOGY CFR(s): 493.845(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) and American Proficiency Institute (API) PT records, and interview with the general supervisor, the laboratory failed to participate successfully in PT for the Digoxin analyte in the Specialty of Chemistry for events 2020-1 and 2020-2. Findings include: 1. Review of the CASPER PT report showed unsuccessful scores for events one and two in 2020 for Digoxin. The laboratory received a score of 60% for event one and 20% for event two. 2. Review of the API PT records showed the following unacceptable digoxin results in 2020. Results are in ng/mL (nanograms per milliliter) Event one: Sample / reported result / expected range CH-04 / 1.5 / 1.6 - 2.5 CH-05 / 0.9 / 1.0 - 1.6 Event two: CH-06 / 1.0 / 1.1 - 1.8 CH-07 / 0.7 / 0.8 - 1.4 CH-08 / 1.1 / 1.5 - 2.4 CH-10 / 0.8 / 1.0 - 1.6 3. Interview with the general supervisor on October 7, 2020 at 9:00 AM confirmed the laboratory failed to achieve satisfactory performance for digoxin in two consecutive testing events.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records, patient reports, and interview with the technical consultant, testing personnel reported a patient's prothrombin time result when the results of control material did not meet the laboratory's criteria for acceptability. Findings include: 1. Review of the 'QC Cumulative Report' for the ACL Elite Pro analyzer showed the laboratory tested the abnormal control three times on October 3, 2020. Time tested / results (seconds) / warning 7:25 AM / 39.2 / QC Invalid 1:31 PM / 40.2 / QC Invalid 2:23 PM / 38.0 2. Review of a 'Cumulative Report' from the ACL Elite Pro for Patient 1 showed testing personnel performed a Prothrombin Time test at 1:31 PM. The report shows the result was 12.4 seconds. The report includes a warning "QC out of range" 3. Review of the test report for patient 1 showed the Prothrombin Time as 12.4 seconds on October 3, 2020. 4. Interview with the technical consultant on October 7, 2020 at 1:00 PM confirmed the QC results were not acceptable before the laboratory reported the Prothrombin Time result for patient 1 on October 3, 2020.