

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0388938	<b>(X3) Date Survey Completed</b>  09/17/2020
<b>Name of Provider or Supplier</b>  Watertown Family Practice Associates Sc	<b>Street Address, City, State</b>  127 Hospital Dr, Watertown, WI	
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>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>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) reports, American Association of Bioanalysts (AAB) and American Proficiency Institute (API) PT evaluation reports, the laboratory failed to successfully participate in PT for the Sodium analyte in the Specialty of Chemistry for events 2018-1, 2018-2, 2019-3, and 2020-2. Findings include: 1. Review of PT records in the federal CASPER reporting system shows that the laboratory had unsatisfactory performance for Sodium on events 2018-1, 2018-2, 2019-3, and 2020-2. Event 2018-1, score 40% Event 2018-2, score 60% Event 2019-3, score 60% Event 2020-2, score 0% 2. Surveyor review of the AAB PT evaluation</p>

	<p>reports confirmed the unsatisfactory scores for Sodium for events 2018-1 and 2018-2. Review of the API PT evaluation reports confirmed the unsatisfactory scores for Sodium for events 2019-3 and 2020-2. This results in subsequent unsuccessful participation in PT for Sodium. 3. Surveyor review of the federal CASPER reporting system on September 14, 2020 shows this is a subsequent unsuccessful PT performance and a repeat deficiency which was previously cited November 1, 2018. See D 2096.</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>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.</p> <p>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) reports, American Association of Bioanalysts (AAB) and American Proficiency Institute (API) Proficiency Testing (PT) evaluation reports, the laboratory failed to successfully participate in PT for the Sodium analyte in the Chemistry Specialty for PT events 2018-1, 2018-2, 2019-3, and 2020-2. Findings include: 1. Review of PT records in the federal CASPER reporting system shows that the laboratory had unsatisfactory performance for Sodium testing on events 2018-1, 2018-2, 2019-3, and 2020-2. Event 2018-1, score 40% Event 2018-2, score 60% Event 2019-3, score 60% Event 2020-2, score 0% 2. Surveyor review on September 14, 2020 of the AAB PT evaluation reports from events 2018-1 and 2018-2 confirmed the unsatisfactory scores for Sodium. Review of the API PT evaluation reports from events 2019-3 and 2020-2 confirmed the unsatisfactory scores for Sodium. This results in subsequent unsuccessful participation in PT for Sodium testing. This deficiency was previously cited November 1, 2018.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>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) reports, American Association of Bioanalysts (AAB) and American Proficiency Institute (API) PT evaluation reports, the laboratory failed to successfully participate in PT for the Sodium analyte in the Specialty of Chemistry for events 2018-1, 2018-2, 2019-3, and 2020-2 which resulted in a subsequent unsuccessful PT performance. The laboratory director has not provided overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. The laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. See D 6019.</p>
<p><b>D6019</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b></p>

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

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) reports, American Association of Bioanalysts (AAB) and American Proficiency Institute (API) PT evaluation reports, the laboratory had subsequent unsuccessful performance in PT for the Sodium analyte in the Chemistry specialty for PT events 2018-1, 2018-2, 2019-3, and 2020-2. The laboratory director did not ensure that an approved corrective action plan was followed. Findings include: 1. Surveyor review of the federal CASPER PT reports and AAB and API PT records on September 14, 2020, shows this is a subsequent unsuccessful PT performance. 2. The laboratory director did not ensure that the corrective action plan submitted for the November 1, 2018 allegation of compliance was effective in preventing subsequent unsuccessful PT performance in the Chemistry specialty for Sodium testing.