

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2150353	<b>(X3) Date Survey Completed</b>  10/14/2020
<b>Name of Provider or Supplier</b>  Smart Physician Systems Pc	<b>Street Address, City, State</b>  10176 W 400 N, Suite A, Michigan City, IN	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to 1) ensure the laboratory director attested to the routine integration of proficiency testing (PT) samples into the patient workload for three of three PT events reviewed (event 1, 2019; event 2, 2019; and event 1, 2020) (refer to D2009); and 2) refrain from inter-laboratory communication pertaining to the results of proficiency testing (PT) samples for three of three PT events reviewed (event 1, 2019, event 2, 2019, and event 2, 2020) (refer to D2011).</p>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on document review and interview, the laboratory director failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload for three of three PT events reviewed (event 1, 2019; event 2, 2019; and event 1, 2020). Findings included: 1. Review of "Proficiency Testing," policy/procedure, effective 11-30-2018, did not require the attestation statement to be signed by the laboratory director. 2. Review of proficiency testing attestation statements indicate the laboratory director did not sign the attestation statements to attest to the routine integration of samples into the patient workload for the following PT testing events: event 1, 2019; event 2, 2019; and event 1, 2020. 3. In interview on 10-14-2020 at 2:40 PM SP2, testing person, indicated they were unaware the above attestation statements were not signed by the laboratory director, as a former employee was responsible for PT.

**D2011**

**TESTING OF PROFICIENCY TESTING SAMPLES**  
CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory failed to refrain from inter-laboratory communication pertaining to the results of proficiency testing (PT) samples for three of three PT events reviewed (event 1, 2019; event 2, 2019 and event 1, 2020). Findings included: 1. Review of "Proficiency Testing" policy/procedure, effective 11-30-2018, read: "Communication between staff and with outside laboratories regarding PT testing prior to the cut-off date and submission of results is prohibited..." 2. Review of PT documentation indicated the following: a. The laboratory's proficiency provider was American Proficiency Institute (API). b. Laboratory B's proficiency provider was API. c. Event 1, 2019, three PT samples for urine creatinine (UAD-01; UAD-02; and UAD-03) and three PT samples for urine drug screen (UDS-01; UDS-02; and UDS-03) were tested on 4-30-2019. The test reports for the samples were printed on 4-30-2019 between 4:49 PM and 4:52 PM. The attestation statement was signed by SP5 (testing person) and dated 4-30-2019. d. Event 1, 2019, Laboratory B performed three PT samples for urine creatinine (UAD-01; UAD-02; and UAD-03) and three PT samples for urine drug screen (UDS-01; UDS-02; and UDS-03) on 5-1-2019. The test reports for the samples UAD-01, UAD-02, UAD-03, UDS-02, and UDS-03 were printed on 5-2-2019 between 12:00 PM and 3:50 PM. The attestation statement was signed by SP5 and dated 5-1-2019. e. Event 2, 2019, three PT samples for urine creatinine (UAD-04; UAD-05; and UAD-06) and three PT samples for urine drug screen (UDS-04; UDS-05; and UDS-06) were tested on 10-21-2019. The test reports for the samples were printed on 10-23-2019 between 12:03 PM and 12:05 PM. The attestation statement was signed by SP5 and dated 10-21-2019. f. Event 2, 2019, Laboratory B performed three PT samples for urine creatinine (UAD-04; UAD-05; and UAD-06) and three PT samples for urine drug screen (UDS-04; UDS-05; and UDS-06) on 10-23-2020. The test reports for the samples were printed on 10-23-2019 between 3:18 PM and 3:22 PM. The attestation statement was signed by SP5 and dated 10-23-2019. g. Event 1, 2020, three PT

samples for urine creatinine (UAD-01; UAD-02; and UAD-03) and three PT samples for urine drug screen (UDS-01; UDS-02; and UDS-03) were tested on 4-28-2020. The test reports for the samples were printed on 4-28-2020 between 4:45 PM and 4:47 PM. The PT attestation statement, signed by SP5 and dated 5-4-2020, indicated the PT results for event 1, 2020 were "electronically submitted" to API on "May 4 2020 1:41 PM (Eastern US)." h. Event 1, 2020, Laboratory B performed three PT samples for urine creatinine (UAD-01; UAD-02; and UAD-03) and three PT samples for urine drug screen (UDS-01; UDS-02; and UDS-03) on 4-27-2020. The test reports for the samples were printed on 4-30-2020 between 4:39 PM and 4:41 PM. The PT attestation statement for Laboratory B, signed by SP5 and dated 5-4-2020, indicated the PT results for event 1, 2020 for Laboratory B were "electronically submitted" to API on "May 4 2020 1:31 PM (Eastern US)." 3. During interview on 10-14-2020 at 2:40 PM, SP2, testing person, phoned API and confirmed the PT results for event 1, 2019 were submitted to API on 5-10-2019 at 4:31 PM and event 1, 2019 results for Laboratory B were submitted to API on the same date (5-10-2019) at 4:59 PM. Event 2, 2019 PT results were submitted to API on 10-28-2019 at 5:17 PM and event 2, 2019 results for Laboratory B were submitted to API on 10-29-2019 at 1:56 PM. SP2 further indicated event 1, 2020 PT results were submitted to API on 5-4-2020 at 1:41 PM, and event 1, 2020 results for laboratory B were submitted to API on 5-4-2020 at 1:31 PM.