Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2066048	05/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Summit Pain Management	1721 Magnavox Way Suite B, Fort Wayne, IN	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to ensure proficiency testing (PT) attestation statements were signed by the individual performing the testing during four of four PT events reviewed (event 1, 2018; event 2, 2018; event 3, 2018; and event 1, 2019). Findings included: 1. Review of policy/procedure titled: "Proficiency Testing," last revised 7-8-2016, did not require PT attestation statements to be signed by the individual performing the testing. 2. Review of PT records indicated the following: a. Attestation statements were not signed by the individual performing PT in the speciality of hematology for testing event 2, 2018; event 3, 2018; and event 1, 2019. b. Attestation statements were not signed by the individual performing PT in the subspecialty of routine chemistry for testing event 1, 2018; event 2, 2018; and event 3, 2018. 3. In interview on 5-16-2019 at 2:15 PM, SP1 acknowledged PT attestation statements had not been signed for the hematology testing event 2, 2018; event 3, 2018; and event 1, 2019. SP1 further acknowledged PT attestation statements had not been signed for the routine chemistry testing event 2, 2018; event 2, 2018; and event 3, 2018.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to: 1) perform calibration verification at least once every 6 months, and when a critical part was replaced for one of three analyzers reviewed (refer to D5439); and 2) take corrective action when results of control materials failed to meet the laboratory's established criteria for 8 of 9 analytes reviewed (refer to D5783).
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to perform calibration verification at least once every 6 months, and when a critical part was replaced for one of two analyzers reviewed (Beckman-Counter UniCel DXi), in the specialty of chemistry. Findings included: 1. Review of policy/procedure titled: "Calibration Verification," last revised 1-11-2017, did not require calibration verification at least once every 6 months nor did it require calibration verification when a critical part was replaced. 2. Review of preventative maintenance documentation indicated Beckman-Coulter performed the last calibration verification for the Beckman-Coulter UniCel DXi analyzer on 2-5-2018. Preventative maintenance documentation from Beckman-Coulter, dated 8-15-2018 and 2-13-2019 indicated the aspiration probe was replaced and read: "Customer waived cal./QC verification." 3. Review of "Enclosure I Test Methodology and Annual Test Volume Log," signed by the laboratory director on 5-16-2019, indicated the following analyte testing was performed on the Beckman-Coulter UniCel DXi: estradiol; follicle-stimulating hormone (FSH); luteinizing hormone (LH); prostate specific antigen (PSA); progesterone; testosterone; free T4; thyroid stimulating hormone (TSH); and vitamin D (VITD). 4. Review of patient test

	reports indicated the following: a. Patient #1 had free T4, TSH, and VITD testing performed on 3-26-2019. b. Patient #2 had free T4, TSH, testosterone, and VITD testing performed on 3-26-20109. c. Patient #3 had free T4, TSH, testosterone, VITD, and PSA testing performed on 3-28-2019. d. Patient #4 had free T4, TSH, testosterone, and VITD testing performed on 5-14-2019. e. Patient #5 had free T4, TSH, testosterone, VITD, and PSA testing performed on 5-14-2019. f. Patient #6 had free T4, TSH, and VITD testing performed on 3-28-2019. g. Patient #7 had free T4, TSH, and VITD testing performed on 2-27-2019. h. Patient #8 had free T4, TSH, testosterone, and VITD testing performed on 2-28-2019. i. Patient #9 had testosterone, VITD, and PSA testing performed on 4-18-2019. j. Patient #10 had free T4, TSH, estradiol, FSH, LH, progesterone, and VITD testing performed on 4-2-2019. k. Patient #11 had testosterone and VITD testing performed on 5-15-2019. l. Patient #12 had free T4, TSH, estradiol, FSH, LH, progesterone, and VITD testing performed on 5-7-2019. 5. In interview on 5-16-2019 at 10:20 AM, SP1, general supervisor, acknowledged the last calibration verification performed on the Beckman-Coulter DXi analyzer was on 2-5-2018. SP1 further acknowledged the aspiration probe had been replaced on 8-15-2018 and on 2-13-2018 without performing calibration verification. SP1 stated the laboratory no longer performs calibration verification on the Beckman-Coulter DXi analyzer. 6. Review of "Enclosure I Test Methodology and Annual Test Volume Log," signed by the laboratory director on 5-16-2019 indicated the laboratory performed 1,148 estradiol tests, 1,144 FSH tests, 2,400 LH tests, 458 PSA tests, 1.149 progesterone tests, 1,436 testosterone tests, 3.226 free T4 tests, 3,230 TSH tests, and 3,837 VITD tests on the Beckman-Coulter DXi analyzer annually.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to take corrective action when results of control materials failed to meet the laboratory's established criteria for 8 of 9 analytes reviewed (Albumin, Urine Creatinine, Chloride, Glucose, Vitamin D, Red Blood Cell Count, White Blood Cell Count, and Platelet Count). Findings included: 1. Review of policy/procedure titled: "Application of Westgard Rules," last revised 9-29-2016, read: "Shift: Occurs when 10 consecutive values occur on one side of the mean in a random pattern...Check controls, reagents, and equipment. New lots and controls may explain a shift. Certain Preventative Maintenance (sic) procedures may also cause a shift in the QC results...Run assayed control material, if applicable. Compare interlaboratory comparison reports to see how other labs are comparing. Perform linearity checks to establish accuracy of the procedure. If no discernable problem is detected, or in cases involving new reagent lots for certain tests, recalculate the mean and standard deviation of the affected test..." 2. Review of quality control (QC) records indicated the following: a. QC results for albumin (ALB) control level 1, control lot number 45791, were below the mean for 35 consecutive values (from 3-12-2019 to 5-6-2019), creating a shift. b. QC

	results for urine creatinine (UCREAT) control level 1, control lot number 68541, were below the mean for 24 consecutive values (from 4-10-2019 to 5-15-2019), creating a shift. c. QC results for UCREAT control level 2, control lot number 68542, were below the mean for 36 consecutive values (from 3-26-2019 to 5-16-2019), creating a shift. d. QC results for chloride (Cl) control level 1, control lot number 45791, were above the mean for 32 consecutive values (from 2-20-2019 to 4-8-2019), creating a shift. e. QC results for glucose (GLU) control level control level 1, control lot number 45791, were below the mean on two separate occasions; once for 21 consecutive values (from 3-13-2019 to 4-12-2019), and a second time for 19 consecutive values (from 4-17-2019 to 5-15-2019), creating shifts. f. QC results for vitamin D (VITD) control level 1, control lot number 60251, were below the mean for 16 consecutive values (from 3-7-2019 to 5-2-2019), creating a shift. g. QC results for red blood cell count (RBC) control level 1, control lot number 90430804, were below the mean for 38 consecutive values (from 3-11-2019 to 5-3-2019), creating a shift. h. QC results for RBC control level 1, control lot number 90990804, were below the mean for 19 consecutive values (from 4-22-2019 to 5-16-2019), creating a shift. i. QC results for RBC control level 2, control lot number 90430805, were below the mean on two occasions; once for 14 consecutive values (from 3-11-2019 to 4-1-2019), and a second occasion for 23 consecutive values (from 4-3-2019 to 5-3-2019), creating a shift. j. QC results for RBC control level 2, control lot number 90990805, were below the mean for 19 consecutive values (from 4-22-2019 to 5-16-2019), creating a shift. k. QC results for white blood cell count (WBC) control level 2, control lot number 90430805, were above the mean for 11 consecutive values (from 3-13-2019 to 3-29-2019), creating a shift. l. QC results for WBC control level 3, control lot number 90430806, were above the mean for 38 consecutive values (from 3-11-2019 to 5-3-2019), creating a shift. m. QC results for WBC control level 3, control lot number 90990806, were above the mean for 15 consecutive values (from 4-22-2019 to 5-10-2019), creating a shift. n. QC results for platelet count (PLT) control level 3, control lot number 90430806, were below the mean for 38 consecutive values (from 3-11-2019 to 5-3-2019), creating a shift. o. QC results for PLT control level 3, control lot number 90990806, were below the mean for 19 consecutive values (from 4-22-2019 to 5-16-2019), creating a shift. 3. Review of patient test reports indicated the following patients had testing performed when controls had shifted above or below the mean: a. Patient #1 had ALB, Cl, GLU, VITD, RBC, WBC, and PLT testing performed on 3-26-2019. b. Patient #2 had ALB, Cl, GLU, VITD, RBC, WBC, and PLT testing performed on 3-26-2019. c. Patient #3 had ALB, UCREAT, Cl, VITD, RBC, WBC, and PLT testing performed on 3-28-2019. d. Patient #4 had GLU, RBC, and PLT testing performed on 5-14-2019. e. Patient #5 had GLU, RBC, and PLT testing performed on 5-14-2019. f. Patient #6 had ALB, Cl, GLU, VITD, RBC, WBC, and PLT testing performed on 3-28-2019. g. Patient #7 had Cl testing performed on 2-27-2019. h. Patient #8 had Cl testing performed on 2-28-2019. i. Patient #9 had ALB, GLU, VITD, RBC, WBC, and PLT testing performed on 4-18-2019. j. Patient #10 had ALB,Cl, GLU, VITD, RBC, BC, and PLT testing performed on 4-2-2019. k. Patient #11 had GLU, RBC, and PLT testing performed on 5-15-2019. l. Patient #12 had GLU, RBC, WBC, and PLT testing performed on 5-7-2019. 4. In interview on 5-16-2019 at 3:20 PM, SP1, general supervisor, acknowledged the above shifts in QC for ALB, UCREAT, Cl, GLU, VITD, RBC, WBC, and PLT and indicated the laboratory did not perform remedial action. 5. Review of "Enclosure 1 Test Methodology and Annual Test Volume Log," signed by the laboratory director on 5-16-2019, indicated the laboratory performed 3,909 ALB tests, 9,789 UCREAT tests, 3,914 GLU tests, 3,837 VITD tests, 3,908 RBC tests, 3,908 WBC tests, and 3,908 PLT tests annually.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory director failed to: 1) employ a sufficient number of laboratory personnel from March, 2019 to date of survey (refer to D6101); 2) ensure one of three testing personnel received training prior to testing patients' specimens, and two of three testing personnel demonstrated they could accurately and reliably perform manual differential and slide review testing prior to testing patients' specimens (refer to D6102); 3) ensure competency policies and procedures were followed for three of three testing personnel reviewed (refer to D6103).
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to employ a sufficient number of laboratory personnel from March, 2019 to date of survey. Findings included: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 5-7-2019, indicated SP2 (part-time), and SP3 (full-time) were testing personnel. The CMS-209 further indicated SP1 (full-time) was a testing person and a general supervisor. 2. Review of "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" form (CMS-116) indicated the laboratory performed 235,795 tests annually, as follows: a. In the speciality of chemistry: 1) Routine chemistry - 46,914 tests per year 2) Urinalysis - 4,438 tests per year 3) Endocrinology - 18,568 tests per year 4) Toxicology - 146,835 tests per year b. In the speciality of hematology: 19,540 tests per year 3. Review of personnel records indicated the following: a. The laboratory did not have documentation of training for SP3, hire date March, 2019. b. The laboratory did not have manual differential competency documentation for SP1, hire date 6-15-2015, and SP3, prior to performing patient testing. 4. Quality assurance (QA) documentation for quarter 4, 2018 was reviewed on 3-12-2019 and QA documentation for quarter 1, 2019 was unavailable for review during survey. 5. In interview on 5-16-2019 at 1:20 PM, SP1 indicated training documentation was not provided to SP3 because SP1 did not have time to complete the paperwork. SP1 further indicated they were too busy testing patient samples to perform general supervisor duties. On the same date, at 2:15 PM, SP1 indicated SP2 worked one day a week and SP3 was a full-time employee. At 3:23 PM, on the same date, SP1 indicated the quarter 1, 2019 QA report was in process because SP1 hadn't had time to complete the report. On the same date, at 4:30

	PM, SP1 acknowledged the laboratory needed additional testing personnel to maintain testing in a timely manner and allow the general supervisor to perform training, competency, and quality assurance duties.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure: 1) one of three testing personnel (SP3) received training prior to testing patients' specimens for the Sysmex XS1000i analyzer ,the Beckman-Coulter AU480 analyzer, manual differential testing, and slide reviews; and 2) two of three testing personnel (SP1 and SP3) demonstrated they could accurately and reliably perform manual differential and slide review testing prior to testing patients' specimens. Findings included: 1. Review of document titled: "Staff Orientation, Training, and Competency Assessment," last revised on 1-11-2017 read: "The employee is given department checklists to be completed while during their 90 days of training..." 2. Review of document titled: "Annual and Semiannual Competencies," last revised on 9-29-2016, read: "All personnel prior to testing patient samples must...have demonstrated that they can perform all testing operations reliably to provide and report accurate results." 3. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209) indicated SP1 and SP3 were testing personnel. 4. Review of personnel records indicated the following: a. Documentation for SP1, hire date 6-15-2015, and SP3, hire date March of 2019, did not include documentation that they each demonstrated the ability to perform manual differentials and slide reviews before testing patients' samples. b. SP3 did not have documentation of training for microscopic urinalysis testing, or training on the Sysmex XS1000i and Beckman-Coulter AU480 analyzers before testing patients' samples. 5. Review of patient test records indicated the following: a. SP1 performed a manual differential for Patient #6 (3-28-2019) and a slide review for Patient #7 (2-27-2019). b. SP3 performed a manual differential for Patent #6 (3-28-2019), Patient #11 (5-15-2019), and Patient #12 (5-7-2019) and a slide review for Patient #9 (4-18-2019), Patient #10 (4-2-2019), and Patient #12 (5-7-2019). c. SP3 performed microscopic urine test for Patient #1 (3-26-2019). d. SP3 performed patient testing on the Sysmex XS1000i analyzer for Patient #1 (3-26-2019), Patient #2 (3-26-2019), Patient #3 (3-28-2019), Patient #6 (3-28-2019), Patient #9 (4-18-2019), Patient #12 (5-7-2019). e. SP3 performed patient testing on the Beckman-Coulter AU480 analyzer for Patient #3 (3-28-2019), Patient #4 (5-14-2019), Patient #5 (5-14-2019), Patient #6 (3-28-2019), Patient #9 (4-18-2019), Patient #10 (4-2-2019), Patient #11 (5-15-2019), and Patient #12 (5-7-2019). 6. In interview on 5-16-2019 at 9:30 AM, SP1 stated a slide review was a manual cell morphology review performed, if indicated by the Sysmex XS1000i analyzer. SP1 further stated a manual differential included a white blood cell differential and a cell morphology review, if indicated by the Sysmex XS1000i analyzer. SP1 indicated the laboratory performed approximately 144 slide reviews and approximately 14 manual differentials per year. 7. In interview on 5-16-

	2019 at 10:56 AM, SP1 acknowledged there was no documented training on manual differentials and slide reviews. SP1 stated SP3 was not given departmental checklists for training and acknowledged there was no documentation of training for SP3.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure competency policies and procedures were followed for three of three testing personnel (SP1, SP2, and SP3) reviewed. Findings included: 1. Review of policy/procedure titled: "Annual and Semiannual Competencies," last revised on 9-29-2016, read: "Elements of competency assessment may include but are not limited to the following: Direct observations of routine patient test performance...monitoring the recording and reporting of test results...direct observation of performance of instrument maintenance and function checks...assessment of test performance through testing previously analyzed specimens..." 2. Review of policy/procedure titled: "Staff Orientation, Training, and Competency Assessment," last revised 1-11-2017, read: "Evaluation of Staff (sic)must include but are not limited to: Direct observations of routine patient test performance...monitoring the recording and reporting of test results...review of intermediate test results or worksheets, quality control (QC) records, proficiency testing (PT) results and preventive maintenance records...direct observation of performance of instrument maintenance and function checks... assessment of test performance through testing previously analyzed specimens..." 3. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209) indicated SP1, SP2, and SP3 were testing personnel. 4. Review of personnel records indicated the following: a) SP1, hire date 6/15/15, last competency was performed on 11/14/18. b) SP2, hire date 9/12/18, last competency was performed on 11/14/18. c) SP3, hire date March 2019, last competency was performed on 5/7/19. d) The compliance review did not include: 1) direct observation of routine patient test performance, instrument maintenance and function checks; 2) monitoring the recording and reporting of test results; 3) review of intermediate test results, worksheets, QC records, PT results, and preventative maintenance records; or 4) an assessment of test performance through testing previously analyzed specimens. 5. Review of patient test records indicated the following: a. SP1 performed patient testing for Patient #1 (3-26-2019), Patient #2 (3-26-2019), Patient #6 (3-28-2019), Patient #7 (2-27-2019), Patient #8 (2-28-2019), Patient #9 (4-18-2019), Patient #10 (4-2-2019), and Patient #11 (5-15-2019). b. SP2 performed patient testing for Patient #2 (3-26-2019), Patient #4 (5-14-2019), and Patient #5 (5-14-2019). c. SP3 performed patient testing for Patient #1 (3-26-2019), Patient #2 (3-26-2019), Patient #3 (3-28-2019), Patient #4 (5-14-2019), Patient #5 (5-14-2019), Patient #6 (3-28-2019), Patient #9 (4-18-2019), Patient #10 (4-2-2019), Patient #11 (5-15-2019), and Patient #12 (5-7-2019). 6. In interview on 5-16-2019 at 11:28 AM, SP1 acknowledged competency assessments did not include: 1) direct observation of patient test performance, instrument maintenance and function checks; 2) monitoring the recording and reporting of test results; 3) review of intermediate test

	results, worksheets, QC records, PT results, and preventative maintenance records; or 4) an assessment of test performance through testing previously analyzed specimens for SP1, SP2, and SP3.