Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1096369	09/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
George S Sidhom Md Pa D/B/A Brandon Pain Clinic	722 Bowing Oak Dr, Brandon, FL	

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
D0000	An announced recertification survey was conducted on 09/17/19 thru 09/19/19 at George S Sidmon MD DBA Brandon Pain Clinic. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified at 3:59 PM on 09/18/19. The laboratory reported patient test results without two levels of acceptable quality control (D5400). The following Conditions were not met: D5200 - 493.1230 General laboratory systems D5400 - 493.1250 Analytic systems D6076 - 493.1441 Laboratories performing high complexity testing: laboratory director D6141 - 493.1459 Laboratories performing high complexity testing: general supervisor
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 review of American Proficiency Institute (API) proficiency testing attestation statements and interview with the General Supervisor the Laboratory Director failed to sign 4 (1st testing event 2019, 1st, 2nd testing event 2018, and 2nd testing event 2017) out of 4 testing event attestation statements. Findings Included: API proficiency testing was reviewed for the 1st testing event 2019, 1st, 2nd testing event 2018, and 2nd testing event 2017. Review of API proficiency testing attestation statements revealed no signature of the Laboratory Director on the 1st testing event in 2019, 1st, 2nd testing event in 2018, and the 2nd testing event in 2017. Interview on 09/17/19 at 11:35 AM with the General Supervisor confirmed the lack of Laboratory Director signature on the attestation statements.

D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the General Supervisor the laboratory failed to have documentation of competency and training for 2 out of 2 years (2017-2019) reviewed (See D5209).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor the laboratory failed to have documentation of competency and training for 2 out of 2 years reviewed (2017-2019). This is a repeat deficiency from the 10/24/17 recertification survey. Findings Included: Review of the CMS 209 signed by the Laboratory Director on 09/17/19 revealed two Testing Personnel: Testing Person #A (who is also the General Supervisor) and Testing Person #B. Review of Testing Person/General Supervisor #A's personnel file revealed she worked with the laboratory since it opened on 06/12/14. There were no competency evaluations for being a Testing Person or General Supervisor in the file. Review of Testing Person #B's personnel file revealed that the first day of work was 07/15/19. There was no documentation of training or competency signed off prior to performing patient testing. Review of the undated Policy and Procedure titled Laboratory Requirements (not signed by the Laboratory Director) revealed that "Only trained personnel, as defined by laboratory regulating bodies, are to perform tests in the laboratory." There were no competency polices. Interview on 09/17/19 at 11:21 AM with the General Supervisor confirmed that there were no competencies or training in the personnel binder. Review of the CMS 2567 from the 10/24/17 recertification survey revealed that this was a repeat deficiency. The plan of correction (signed by the Owner on 11/15/17) stated "The lab supervisor/testing person took the personnel binder home to update and forget to bring it the day of the survey. This will not occur again." It also states "The personnel binder will remain in the laboratory and any updates required will be prepared and brought in to be added to the binder. The director and supervisor will insure that this issue does not occur again." The completion date was 11/08/17 and the owner was the current Laboratory Director (as of 06/2018) and the lab supervisor/testing person was the current Testing Person/General Supervisor #A.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing, review of Patient results, and interview with the General Supervisor the laboratory failed to verify the accuracy of the Chemistry testing performed since 10/18/17. Findings Included: Review of the testing menu revealed that the laboratory performed Methamphetamine, urine pH, Urine Creatinine, Oxycodone, Tetrahydrocannabinol (THC), Benzodiazepine, Methadone, Opiates, and Cocaine. The laboratory also performed Ecstasy, Alcohol, and Barbiturates from 11/28/17-12/27/17. Review of API proficiency testing revealed the results were qualitative (Positive and Negative results). Review of the Patient test results from 11/28/17 thru 09/07/19 revealed that the laboratory was reporting out semi-quantitative results (Numerical). Interview on 09 /17/19 at 11:45 AM with the General Supervisor confirmed that the patient results are not reported the same as preficiency testing results.
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 record review and interview with the General Supervisor, the laboratory failed to follow manufacturers instructions of running 5 levels of calibrators for Tetrahydrocannabinol (See D5437) and failed to have 2 acceptable levels of controls prior to reporting patients for 13 (09/07/19, 08/13/19, 08/12/19, 12/04/18, 08/09/18, 06 /19/18, 04/12/18, 04/10/18, 02/05/18, 01/02/18, 12/27/17, 11/30/17, and 11/28/19 out of 15 days (09/07/19, 09/14/19, 08/26/19. 08/13/19, 08/12/19, 12/04/18, 08/09/18, 06 /19/18, 04/12/18, 04/10/18, 02/05/18, 01/02/18, 12/27/17, 11/30/17, and 11/28/19) days reviewed (See D5481). This condition and 2 standards are repeat deficiencies from the 10/24/17 recertification survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual and interview with the General Supervisor the Laboratory Director failed to sign the Policy and Procedure manual since 10/24/17. Findings Included: Interview on 09/17/19 at 9:00 AM with the General Supervisor revealed a change in Laboratory Director occurred in June of

	2018. Electronic correspondence with the Laboratory Unit verified this change on 09 /17/19 at 11:07 a.m. Review of the policy and procedure manual revealed that there were no Laboratory Director signatures to indicate it was reviewed by either the new or previous Laboratory Director. During an interview on 09/17/19 at 11:18 AM, the General Supervisor confirmed that there were no Laboratory Director signatures in the policy and procedure manual to indicate it was reviewed.
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 observations and interview with the General Supervisor the laboratory used calibrators and controls past their expiration date. Findings Included: During the tour of the laboratory on 09/17/19 at 10:00 AM the following calibrators and controls were found expired: Opiate DAU Calibrator 150 ng/mL- expired 05/26/19, Opiate DAU Calibrator 300 ng/mL- expired 01/18/18, Opiate DAU Calibrator 600 ng/mL-expired 05/26/19, Opiate DAU Calibrator 1000 ng/mL- expired 05/26/19, Oxycodone DAU Calibrator 800 ng/mL- expired 12/09/18, Oxycodone 300 Level 1 Control- expired 08 /15/16, and Oxycodone 300 Level 2 control- expired 09/24/15. Photographic evidence was obtained. During an interview on 09/17/19 at 10:16 AM, the General Supervisor confirmed that the calibrators and controls were expired and have been in use.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor the laboratory failed to follow manufacturers instructions (MI) by only running a 4 point calibration for THC (Tetrahydrocannabinol) for an undetermined amount of time. This was a repeat deficiency from the 10/24/17 recertification survey. Findings Included: Review of the MI for THC revealed that for semi-quantitative testing a 5 point calibration was required. The concentrations required were 0, 25 ng/mL, 50 ng/mL, 75 ng/mL, and 100 ng/mL. Review of calibrations revealed only the current calibration was able to be printed. All other calibrations since 10/24/17 only revealed absorbance level. Review of the 09/14/19 calibration revealed only 4 concentrations of calibrators were ran (0, 25 ng/mL, 50 ng/mL, and 100 ng/mL). Interview on 09/17/19 at 4:00 PM with the

	General Supervisor confirmed that only 4 calibrators were used for THC and that only the current calibration showed the concentrations used. Review of the CMS 2567 revealed that this was a repeat deficiency. Review of the plan of correction (signed by the owner on 11/15/17) revealed that "In order to insure accurate patient testing and compliance with regulatory requirements we will convert our assays to multi point calibration as described in the manufacturers package insert." It also stated that "The supervisor/testing person will insure that this change occurs immediately upon receipt of calibrator materials and prior to our next patient testing."
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 record review and interview with the General Supervisor, the laboratory failed to have 2 acceptable levels of controls prior to reporting patients for 13 (09/07 /19, 08/13/19, 08/12/19, 12/04/18, 08/09/18, 06/19/18, 04/12/18, 04/10/18, 02/05/18, 01/02/18, 12/27/17, 11/30/17, and 11/28/19) out of 15 days (09/07/19, 09/14/19, 08/26 /19. 08/13/19, 08/12/19, 12/04/18, 08/09/18, 06/19/18, 04/12/18, 04/10/18, 02/05/18, 01/02/18, 12/27/17, 11/30/17, and 11/28/19) days reviewed. This was a repeat deficiency from the 10/24/17 recertification survey. Findings Included: Observation during the tour on 09/17/19 at 10:00 a.m. revealed drug testing was being performed on a Carolina Liquid Chemistry CLC480 chemistry analyzer. The acceptable ranges for level 1 quality control (QC) were: Methamphetamine - 301-449, pH- 2.6-4.6, Urine Creatinine- 21.5-33.5, Cocaine-175-275, Methadone-175-275, Opiate- 175-275, Barbiturates- 90-170, Benzodiazepine-65-165, Alcohol-24-56, Tetrahydrocannabinol (THC)-15-35, and Oxycodone-175-275. The acceptable ranges for level 2 QC are : Methamphetamine - 501-749, pH- 8-12, Urine Creatinine- 185-273, Cocaine-299-451, Methadone-299-451, Opiate- 299-451, Barbiturates- 170-270, Benzodiazepine-155-255, Alcohol-42-98, THC-34-82, and Oxycodone-264-416. The following tests were not acceptable: on 09/07/19 Benzodiazepine-level 1 (270) and 2 (584) unacceptable, Methadone-level 1 (454) unacceptable-level 2 not ran, Opiates-level 1 not ran, and Cocaine-level 1 not ran; on 08/13/19 Creatinine-level 1 (43.6) and 2(318.5) unacceptable, and Benzodiazepine-level 2 (263) unacceptable; on 08/12/19 Creatinine-level 1 (35.6) and 2 (274.1) unacceptable, THC-level 1 (5) and 2 (16) unacceptable, Benzodiazepine-level 1 (371) and 2 (872) unacceptable, Methadone-level 1 (376) and 2 (929) unacceptable, Opiates-level 1 (151) and 2 (236) unacceptable, and Cocaine-level 1 (288) unacceptable; on 12/04/18 Methamphetamine-level 1 (458) unacceptable, Creatinine-level 1 (55.5) unacceptable, THC-level 1 (37) unacceptable, and Cocaine-level 2 (464) unacceptable; on 08/09/18 Creatinine-level 1 (73.3) unacceptable; on 06/19/18 Creatinine-level 1 (97.4) and 2 (312.6) unacceptable, Oxycodone-level 1 (63) and 2 (118) unacceptable, and THC-level 1 (39) unacceptable; on 04/12/18 Creatinine-level 1 (46.2) and 2 (311.5) unacceptable and THC-level 1 (37) unacceptable; on 04/10/18 Creatinine-level 1 (74.6) unacceptable, Oxycodone-level 1 (281) and 2 (532) unacceptable, THC-level 1 (37) unacceptable, and Opiates-level 2 (284) unacceptable; on 02/05/18 Creatinine-level 1 (52) unacceptable and Cocaine-level 1 (167) and 2 (284) unacceptable; on 01/02/18 Creatinine-level 1 (41.7) and 2 (301.7) unacceptable, Oxycodone-level 2 (439) unacceptable, THC-level 1 (38) unacceptable, Methadone-level 1 (152) and 2 (289)

	unacceptable, Opiates-level 2 (274) unacceptable, and Cocaine-level 2 (290) unacceptable; on 12/27/17 Creatinine-level 1 (59.7) unacceptable, THC-level 1 (36) unacceptable, Benzodiazepine-level 2 (136) unacceptable, Methadone-level 2 (279) unacceptable, Ecstasy-level 2 (500) unacceptable, and Barbiturates-level 2 (158) unacceptable; on 11/30/17 Methamphetamines-level 1 (277) and 2 (420) unacceptable, Creatinine-level 1 (47.3) and 2 (310.8) unacceptable, Oxycodone-level 2 (488) unacceptable, THC-level 1 (56) and 2 (195) unacceptable, Methadone-level 1 (168) unacceptable, Opiates-level 1 (159) and 2 (253) unacceptable, Ecstasy-level 2 (486) unacceptable, and Barbiturates-level 2 (325) unacceptable; and on 11/28/17 Methamphetamines-level 1 (266) and 2 (408) unacceptable, Creatinine-level 1 (43.7) and 2 (313.4) unacceptable, Oxycodone-level 2 (488) unacceptable, THC-level 1 (36) unacceptable, Opiates-level 2 (282) unacceptable, and Barbiturates-level 2 (271) unacceptable. There were 826 patients reported. During an interview on 09/17/19 at 3: 30 PM the General Supervisor confirmed that the QC was not in the acceptable ranges and that patients were reported. Review of the CMS 2567 from the 10/24/17 recertification survey revealed that this was a repeat deficiency. Review of the plan of correction (signed by the Owner 11/15/17) stated that "The testing person will insure that both levels of control results print on the daily log or the current QC log will be printed as well. The supervisor/testing person will insure that this review of printed data occurs along with the current review of daily QC in the instrument."
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 record review and interview with the General Supervisor the Laboratory Director failed to have oversight of the laboratory for 2 out of 2 (2017-2019) years reviewed (See D6079).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor the Laboratory Director failed to have oversight of the laboratory for 2 out of 2 (2017-2019) years reviewed. Findings Included: The Laboratory Director failed to sign attestation

	statements for proficiency testing (See D2009). The Laboratory Director failed to ensure staff competency and training was documented (See D5209). The Laboratory Director did not ensure the laboratory was using Proficiency testing that was reported like patients (See D5217). The Laboratory Director failed to ensure controls and calibrators were discarded after their expiration date (See D5417). The Laboratory Director failed to ensure calibrations were performed per manufacturer's instructions (See D5437). The Laboratory Director failed to ensure 2 levels of controls were acceptable prior to reporting patients (See D5481).
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the General Supervisor, the General Supervisor failed to have oversight of the laboratory for 2 out of 2 (2017-2019) years reviewed (See D6144).
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor, the General Supervisor failed to have oversight of the laboratory for 2 out of 2 (2017-2019) years reviewed. Findings Included: The General Supervisor failed to have the Laboratory Director sign attestation statements for proficiency testing (See D2009). The General Supervisor did not ensure the laboratory was using Proficiency testing that was reported like patients (See D5217). The General Supervisor failed to ensure controls and calibrators were discarded after their expiration date (See D5417). The General Supervisor failed to ensure staff competency and training was documented (See D5209). The General Supervisor failed to ensure calibrations were performed per manufacturer's instructions (See D5437). The General Supervisor failed to ensure 2 levels of controls were acceptable prior to reporting patients (See D5481).