Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2065964	10/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Chronic Pain Clinics Of America, Llc	1395 South Marietta Parkway, Bldg 100, Ste 101, Marietta, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 8, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 proficiency test (PT) document review and staff interview, the testing personnel (TP) examining the PT samples and the laboratory director (LD) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed there were no TP or LD signatures on the PT attestation statements for the following Miscellaneous Chemistry events: 2017 -- Event 2, 2018 -- Event One; 2019 -- Event One. 2. An interview with the laboratory supervisor in a medical office on 10/08/2019 at approximately 12:00 p.m. confirmed the aforementioned lack of signatures on the PT attestation statements.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the

	proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) documents and staff interview, the laboratory failed to maintain a copy of all records pertaining to each PT event as required. Findings include: 1. American Proficiency Institute (API) document review revealed the following required PT documents for Miscellaneous Chemistry were not available at the time of survey: 2018 -- Event Two: No attestation statement and no laboratory worksheets pertaining to PT event; 2019 -- Event One: No PT report. 2. An interview in a medical office with the laboratory supervisor on 10/08/2019 at approximately 11:45 a.m. confirmed the lack of the aforementioned PT documents.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. Absciex 4500 Mass Spectrophotometer (Chemistry analyzer) QC document review revealed there were no Levey-Jennings charts available at the time of survey for 2019 (January through October). 2. An interview with the laboratory supervisor in a medical office on 10/08/2019 at approximately 2:00 p.m. confirmed there were no Levey-Jennings charts available at the time of survey for the aforementioned time period.
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 review of testing personnel (TP) competency documents and staff interview, the laboratory director (LD) failed to provide overall management and direction of the laboratory as required. Findings include: For details refer to 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 testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure employment of TP competent to perform test procedures as required. Findings include: 1. TP competency document review revealed Staff #2 (CMS 209) did not have an initial training competency for the Biolis 24i Chemistry analyzer performed in 2019 prior to performing patient testing. 2. An interview with the laboratory supervisor in a medical office on 10/08/2019 at approximately 10:30 a.m. confirmed the lack of initial training competency for Staff #2 (CMS 209) in 2019 for the aforementioned analyzer.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure all PT reports received are reviewed by the appropriate staff as required. Findings include: 1. American Proficiency Institute (API) PT report review revealed the LD failed to review the Miscellaneous Chemistry 2019 Event One PT report. 2. An interview with the laboratory supervisor in a medical office on 10/8 /2019 at approximately 11:00 a.m. confirmed the aforementioned lack of PT review by the LD.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to ensure the quality assessment (QA) programs were followed as required. Findings include: 1. SOP review revealed the LD failed to perform a review of the SOP annually as established in the the SOP policies and procedures. 2. SOP review revealed the LD did not perform an SOP review in 2018. 3. An interview with the laboratory supervisor in a medical office on 10/08 /2019 at approximately 12:30 p.m. confirmed the lack of required SOP annual review by the LD in 2018.
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: Testing personnel (TP) document review revealed the laboratory director (LD) failed to ensure all TP have the appropriate training and have demonstrated competency to perform all test operations reliably prior to testing patient specimens. Findings include: 1. TP competency document review revealed Staff #2 (CMS 209) did not have an initial training competency for the Biolis 24i Chemistry analyzer performed in 2019 prior to performing patient testing. 2. An interview with the laboratory supervisor in a medical office on 10/08/2019 at approximately 10:30 a.m. confirmed the lack of initial training competency for Staff #2 (CMS 209) in 2019 for the aforementioned analyzer.