Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2114870	09/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Partners In Care Pllc	5616 Brainerd Road, Suite 108, Chattanooga, TN	

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
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: The laboratory failed to follow the manufacturer's instructions (Refer to D5411); the laboratory failed to follow the Centers for Medicare and Medicaid Services (CMS) Individualized Quality Control Plan (IQCP) Procedure (Refer to D5445); the laboratory failed to run two external controls for the Alere Oratect Oral Fluid Drug Screen for moderate complexity testing (Refer to D5449); the laboratory failed to have an effective plan for correction and resolution of analytical problems and procedures in place to prevent recurrence (Refer to D5793) resulting in Immediate Jeopardy.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by:

	BASED ON STATEMENT NUMBER ONE: Based on review of the manufacturer's instructions for the Qualigen FastPack instrument, calibration logs, Quality Control (QC) logs, and interview with the Laboratory Director determined the laboratory failed to follow the manufacturer's instructions for performing QC with each calibration in 2018, resulting in Immediate Jeopardy. The findings include: 1. Review of the Qualigen FastPack manufacturer's instructions revealed under Individualized Quality Control Plan (IQCP): "QC testing frequency may be decreased from daily to weekly* if: a. If the IQCP Risk Assessment determined that the lab's risk level are manageable b. All QC testing performed over the initial 10 day period is satisfactory c. There are no other quality problems noted on the monthly QA Assessment *Even if you adopt a weekly QC frequency, performing QC should still be performed ... after calibration ..." 2. Review of the calibration and QC logs for the Qualigen instrument revealed: a. Thyroid Stimulating Hormone (TSH) with QC not performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 138 patients. b. Vitamin D with QC not performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 153 patients. c. Prostatic Specific Antigen (PSA) with QC not performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 36 patients. d. Testosterone (Testo) with QC not performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 53 patients. 3. Interview with the Laboratory Director on September 7, 2018, at approximately 1:30 PM confirmed the laboratory failed to perform QC after each calibration for the TSH, Vitamin D, PSA, and Testosterone analytes according the manufacturer's instructions for 2018.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Qualigen manufacturer's instructions for performance of IQCP, laboratory IQCP documentation, and interview with the Laboratory Director determined the laboratory failed to follow the CMS IQCP procedure guidelines before decreasing the frequency of QC performed in 2018, resulting in Immediate Jeopardy. The findings include: 1. Review of the Qualigen manufacturer's instructions revealed under Individualized Quality Control Plan (IQCP): a. Perform QC daily for 10 business days during the initial period. Record the QC results from the 10 day period in the Quality Assurance Log. b. Complete the 30-day Risk Assessment Checklist. c. Go to www.qualigeninc.com/IQCP to complete the IQCP Risk Assessment (RA) and QC Plan (QCP). d. Complete a Monthly QA Assessment. 2. Review of CMS IQCP procedure guidelines revealed the requirement to completely document the three components of IQCP to include RA, QCP, and QA assessments with the laboratory director's approval/signature. 3. Review of the laboratory IQCP documentation revealed: a. Thyroid Stimulating Hormone (TSH) with QC evaluations only for 1/29

	/18, 1/30/18, 1/31/18, 2/1/18 and 2/9/18 and then no QC performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 138 patients. b. Vitamin D with QC evaluations only for 1/30/18, 1/31/18, 2/1/18 and 2/6 /18 and then no QC performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 153 patients. c. Prostatic Specific Antigen (PSA) with QC evaluations only for 1/30/18, 1/31/18, 2/1/18, and 2/7/18 and then no QC performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 36 patients. d. Testosterone (Testo) with QC evaluations only for 1/31/18, 2/1/18, and 2/16/18 and then no QC performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 53 patients. 4. Interview with the Laboratory Director on September 7, 2018, at approximately 1:30 PM confirmed the laboratory failed to follow the Qualigen manufacturer's instructions for performance of IQCP, CMS CMS IQCP procedure guidelines before decreasing the frequency of QC performed and after each calibration for the TSH, Vitamin D, PSA, and Testosterone analytes according the manufacturer's instructions for 2018.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer's instructions for the Alere Oratect Oral Fluid Drug Screen, lack of Quality Control (QC) records, review of patient records, and interview with Laboratory Director, the laboratory failed to perform external positive and negative controls at least once per day with three patients in 2018, resulting in Immediate Jeopardy. The findings include: 1. Observation of the laboratory on September 7, 2018, at 10:00 AM revealed the the Alere Oratect Oral Fluid Drug Screen for moderate complexity testing. 2. Review of the Alere Oratect Oral Fluid Drug Screen manufacturer's instructions revealed " that negative and positive saliva controls be used to initially test each new lot of product to ensure proper kit performance. 3. The laboratory was lacking any QC records for the patient testing on the Alere Oratect Oral Fluid Drug Screen for July 5 and 19, 2018. 4. Review of 3 of 3 patient records revealed testing results for the Alere Oratect Oral Fluid Drug Screen for July 5 and 19, 2018. 5. Interview with the Laboratory Director on September 7, 2018, at approximately 1:30 PM confirmed the laboratory failed to perform external positive and negative controls at least once per day with three patients in 2018.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the CMS IQCP procedure guidelines, incomplete Risk Assessment (RA), lack of Quality Control Plan (QCP), QA record review, QC record review of IQCP documentation and interview with the Laboratory Director determined the laboratory failed to have an effective plan for correction and resolution of analytical problems and procedures necessary to prevent the recurrence of QC and Calibration errors in 2018, resulting in Immediate Jeopardy. The findings include: 1. Review of the CMS IQCP procedure guidelines revealed the requirements for Risk Assessment (RA), QCP, and QA assessments for the laboratory to decrease the frequency of QC performed for patient testing. 2. The laboratory IQCP documentation revealed the laboratory failed to follow the CMS IQCP procedure guidelines for the Qualigen FastPack instrument. Risk Assessment (RA) was incomplete because the lab failed to perform QC for 10 consecutive days per the manufacturer's instructions. 3. No QC Plan was available for review as required by the manufacturer's instructions and the CMS IQCP procedure guidelines. 4. Monthly QA assessments revealed the laboratory failed to have an effective plan for correction and resolution of analytical problems and procedures necessary to prevent the recurrence of QC and Calibration errors in 2018. 5. Review of the laboratory IQCP documentation revealed: a. Thyroid Stimulating Hormone (TSH) with QC evaluations only for 1/29/18, 1/30/18, 1/31/18, 2 /1/18 and 2/9/18 and then no QC performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 138 patients. b. Vitamin D with QC evaluations only for 1/30/18, 1/31/18, 2/1/18 and 2/6/18 and then no QC performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 153 patients. c. Prostatic Specific Antigen (PSA) with QC evaluations only for 1/30/18, 1/31/18, 2/1/18, and 2/7/18 and then no QC performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 36 patients. d. Testosterone (Testo) with QC evaluations only for 1/31/18, 2 /1/18, and 2/16/18 and then no QC performed after calibrations from January 26 through the date of initial survey on September 7, 2018, for 53 patients. 6. Interview with the Laboratory Director on September 7, 2018, at approximately 1:30 PM confirmed that QA assessments were being performed and the QC logs were signed when reviewed by the Laboratory Director. The laboratory failed to perform QC after each calibration for the TSH, Vitamin D, PSA, and Testosterone analytes according the manufacturer's instructions for 2018.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory director (LD) serving as the technical consultant's (TC) lack of experience and training of at least one year in non-waived testing in chemistry and endocrinology and interviews with LD and Operations Manager, the LD is not qualified to be the TC for the laboratory in 2018, resulting in Immediate Jeopardy (Refer to D6034).
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411

	The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, review of quality assessment records, and interviews with the Laboratory Director and Operations Manager, the laboratory failed to employ a technical consultant for the specialties of routine chemistry and endocrinology in 2018. The findings include: 1. Review of the laboratory procedure manual revealed the manufacturer's instructions for Thyroid Stimulating Hormone (TSH), Vitamin D, Prostatic Specific Antigen (PSA), and Testosterone (Testo) manufacturer's instructions for patient testing in 2018. 2. Review of quality assessment records revealed no documentation of technical consultant visits for the specialties of routine chemistry and endocrinology for 2018. 3. Interview with the Laboratory Director and Operations Director on September 7, 2018 @ 1:30pm confirmed the laboratory failed to employ a qualified technical consultant in 2018.