Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 15D2105460	**(X3) Date Survey Completed** 10/09/2019
Name of Provider or Supplier Klarity Medical Laboratory	**Street Address, City, State** 7330 E 82nd St, Ste C, Indianapolis, 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
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 record review and interview, the laboratory failed to ensure two levels of quality control material everyday of patient testing were within acceptable range for seven of seven patients (PTs #1, 3-8) reviewed for three of three analytes (Testosterone, Progesterone, and Estradiol). Findings include: 1) Medical record review indicated the following patients had laboratory testing performed without two levels of quality control being within acceptable range on the Tosoh AIA 360 analyzer: a) PT#1=8/26/19: Testosterone=2.72 ng/dL, Progesterone=0.28 ng/mL, and Estradiol=35.1 pg/mL b) PT#3=9/18/19: Testosterone=397.0 ng/dL, Progesterone=3.37 ng/mL, and Estradiol=195 pg/mL c) PT#4=9/24/19: Testosterone=152.39 ng/dL, Progesterone=3.07 ng/mL, and Estradiol=75.7 pg/mL d) PT#5=10/3/19: Testosterone=640.84 ng/dL and Estradiol=51.3 pg/mL e) PT#6=10/3/19: Testosterone=116.25 ng/dL, Progesterone=13.6 ng/mL, and Estradiol=67.2 pg/mL f) PT#7=10/3/19: Testosterone=206.37 ng/dL, Progesterone=8.74 ng/mL, and Estradiol=139.7 pg/mL g) PT#8=10/3/19: Testosterone=13.48 ng/dL, Progesterone=0.22 ng/mL, and Estradiol=54.6 pg/mL 2) Review of quality control records indicated

	the following acceptable ranges established by the laboratory director for testing on the Tosoh AIA-360 analyzer (serial number=16115308): (ng/mL=nanograms per milliter, ng/dL=nanograms per deciliter, pg/mL=picograms per milliter) a) Testosterone=Level 1 (22-55 ng/dL), Level 2 (327-633 ng/dL), and Level 3 (640-1800 ng/dL) b) Progesterone=Level 1 (0.18-1.9 ng/mL), Level 2 (8.08-14.53 ng/mL), and Level 3 (14-41 ng/mL) c) Estradiol=Level 1 (179-219 pg/mL), Level 2 (450-703 pg /mL), and Level 3 (983-1331 pg/mL) 3) Further review of quality control data indicated the following levels were out of acceptable range for one or more of the assays tested above. The dates below correspond with patient testing dates listed above: Date Analytes Level Value Acceptable 8/26/19 Testosterone 2 200 pg/dL No 8 /26/19 Testosterone 3 1914 ng/dL No 8/26/19 Estradiol 2 262.8 pg/mL No 9/18/19 Testosterone 2 1590.32 ng/dL No 9/18/19 Progesterone 2 16.47 ng/mL No 9/24/19 Estradiol 2 439.0 pg/mL No 9/24/19 Testosterone 2 1739.54 ng/dL No 9/24/19 Testosterone 3 1869.73 ng/dL No 9/24/19 Progesterone 2 17.57 ng/mL No 10/3/19 Estradiol 2 435.3 pg/mL No 10/3/19 Estradiol 3 881.5 pg/mL No 10/3/19 Testosterone 2 1983.84 ng/dL No 10/3/19 Testosterone 3 1978.82 ng/dL No 10/3/19 Progesterone 2 16.87 ng/mL No 10/3/19 Progesterone 3 >H (undetectable)No 10/7/19 Estradiol 3 1139.0 pg/mL No 10/7/19 Testosterone 2 2191.51 ng/dL No 10/7/19 Testosterone 3 2033.42 ng/dL No 10/7/19 Progesterone 2 18.08 ng/mL No 4) In interview on 10/9/19 at 11:14 pm, SP-1 confirmed the above patients were tested without two levels of quality control within acceptable range for one or more analytes, every day of patient testing. 5) Annual testing volume for all four analytes = 3200.