Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2105460	08/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Klarity Medical Laboratory	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
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to: 1) conduct performance verification for 4 of 4 analytes reviewed (Testosterone, Progesterone, Follicle Stimulating Hormone, and Estradiol), refer to D-5421; 2) use non expired reagents for 4 of 4 analytes reviewed (Testosterone, Progesterone, Follicle Stimulating Hormone, and Estradiol), refer to D-5417; 3) run two levels of external quality control and/or have an IQCP in place for 9 of 9 test reports reviewed, refer to D-5447; and 4) perform twice annual verification of 4 of 4 analytes reviewed (Testosterone, Progesterone, Follicle Stimulating Hormone, and Estradiol) in 2018 and up to the date of survey, refer to D-5217. (Annual test volume for all four analytes = 3200.)
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 document review and interview, the laboratory failed to verify the accuracy of 4 of 4 non-regulated analytes (Testosterone, Estradiol, Follicle Stimulating Hormone, and Progesterone) reviewed in 2018 and up to the date of survey in 2019 (8

	/20/19) for 9 of 9 patients (PT=patients) (PT#s 1-9) reviewed. Findings include: 1) Upon request for review of twice annual verification for 2018 and up to the date of survey in 2019, SP-1 (Laboratory Directory) indicated none was available. 2) Medical record review indicated the following patients had laboratory testing performed: a) PT#1=7/25/19: Progesterone=5.14 ng/mL (ng/mL=nanograms per milliter) b) PT#2=7/29/19: Progesterone=8.56 ng/mL c) PT#3=8/16/19: Progesterone=8.55 ng/mL d) PT#4=1/5/19: Testosterone=79.8 ng/dL (ng/dL=nanograms per deciliter) e) PT#5=3/13/19: Testosterone=102 ng/dL f) PT#6=5/20/19: Estradiol=57 pg/mL (pg/mL=picograms per milliter) g) PT#7=6/26/19: Estradiol=83 pg/mL h) PT#8=7/22/19: Testosterone=67/dL i) PT#9=8/7/19: Follicle Stimulating Hormone=10mIU/mL (mIU/mL=milli-international units per milliliter) 3) In interview on 8/20/19 at 2:50 pm, SP-1 indicated the laboratory had not performed twice annual verification of accuracy for the above analytes (Testosterone, Estradiol, Follicle Stimulating Hormone, and Progesterone) in 2018 and up to the date of the survey. 4) Annual test volume for all four analytes=3200.
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 observation, record review, and interview, the laboratory failed to use non expired reagents for 1 of 4 analyte reagent packs observed (Progesterone) and 3 of 3 patients (PT #1, PT #2, and PT #3) reviewed. Findings include: 1) During tour of the laboratory on 8/20/19 at 10:21 am with SP-1, 4 reagents packs of Progesterone containing 20 cupules per pack and 1 opened pack containing 3 cupules (17 missing), were observed to have an expiration date of 6/31/19. The lot number for the Progesterone reagent packs was I71C360. 2) Medical record review indicated the following patients had Progesterone testing performed after the reagent expiration date of 6/31/19: a) PT#1=7/25/19: Progesterone=5.14 ng/mL (ng/mL=nanograms per milliter) b) PT#2=7/29/19: Progesterone=8.56 ng/mL c) PT#3=8/16/19: Progesterone=8.55 ng/mL 3) In interview on 8/20/19 at 10:30 am, SP-1 confirmed the above reagent packs observed for Progesterone had exceeded their expiration date (6/31/19) and were in use on the date of survey. 4) Annual testing volume for Progesterone=800.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on observation, record review, and interview, the laboratory failed to obtain performance specifications for 4 of 4 analytes (Testosterone, Estradiol, Follicle Stimulating Hormone, and Progesterone) and 9 of 9 patients (PT#s 1-9) reviewed. 1) During tour of the laboratory on 8/20/19 at 10:21 am with SP-1, an Endocrinology analyzer was observed to be in use for Testosterone, Estradiol, Follicle Stimulating Hormone, and Progesterone. The analyzer was a Tosoh, model=AIA-360, and serial number=16115306. 2) Upon request for performance specification documentation for the above 4 analytes being operated on the Tosoh, SP-1 indicated none was available for review. 3) Medical record review indicated the following patients had laboratory testing performed on the Tosoh (serial number=16115306): a) PT#1=7/25/19: Progesterone=5.14 ng/mL (ng/mL=nanograms per milliter) b) PT#2=7/29/19: Progesterone=8.56 ng/mL c) PT#3=8/16/19: Progesterone=8.55 ng/mL d) PT#4=1/5/19: Testosterone=79.8 ng/dL (ng/dL=nanograms per deciliter) e) PT#5=3/13/19: Testosterone=102 ng/dL f) PT#6=5/20/19: Estradiol=57 pg/mL (pg/mL=picograms per milliter) g) PT#7=6/26/19: Estradiol=83 pg/mL h) PT#8=7/22/19: Testosterone=67/dL i) PT#9=8/7/19: Follicle Stimulating Hormone=10mIU/mL (mIU/mL=milli-international units per milliliter) 4) In interview on 8/20/19 at 10:24 am, SP-1 indicated the four above analytes were being run on the Tosoh (serial number=16115306). SP-1 confirmed they moved laboratory testing to a new address located at 7330 E. 82nd St, Indianapolis, IN 46256 and began testing patient samples for Progesterone, Testosterone, Follicle Stimulating Hormone, and Estradiol on January 10, 2019, but did not perform accuracy verification studies prior to testing. 5) Annual testing volume for all 4 assays=3200.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (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 include two levels of quality control material everyday of patient testing and did not have an IQCP (Individualized Quality Control Plan) in place for 9 of 9 patients (PTs #1-9) reviewed. Findings include: 1) Review of the laboratory's policy titled, "Klarity Medical Laboratory," review date of 8/10/19, signed by the laboratory director, read on page 1 of 1, "...Every 10 specimens will have QC (quality control) run..." 2) Medical record review indicated the following patients had laboratory testing performed without two levels of quality control being run or an IQCP in place: a) PT#1=7/25/19: Progesterone=5.14 ng/mL (ng/mL=nanograms per milliter) b) PT#2=7/29/19: Progesterone=8.56 ng/mL c) PT#3=8/16/19: Progesterone=8.55 ng/mL d) PT#4=1/5/19: Testosterone=79.8 ng/dL (ng/dL=nanograms per deciliter) e) PT#5=3/13/19: Testosterone=102 ng/dL f) PT#6=5/20/19: Estradiol=57 pg/mL (pg/mL=picograms per milliter) g) PT#7=6/26/19: Estradiol=83 pg/mL h) PT#8=7/22/19: Testosterone=67/dL i) PT#9=8/7/19: Follicle Stimulating Hormone=10mIU/mL (mIU/mL=milli-international units per milliliter) 3) In interview on 8/20/19 at 1:43 pm, SP-1 confirmed the above patients were tested without two levels of quality control (every day of patient testing) being run prior to testing and had no IQCP in place. 4) Annual testing volume for all 4 assays=3200.