Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0984059	01/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Androlab Inc	16345 S Harlem - Ste 100, Tinley Park, IL	

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
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 review of Quality Control (QC) procedures; (QC) records; patients' test records; patient test reports; and interview with testing personnel #3 as listed on Laboratory Personnel Report (Form 209), the laboratory failed to perform QC at least once a day patient specimen is examined. Findings: 1. QC procedures reads as follows: "On the day of semen analysis thaw both QC vials and determine sperm concentration using a makler." 2. Review of QC records revealed that there was no QC performance of semen analysis on 05/05/2020. 3. On January 13, 2021 at 11:00 AM, the surveyor reviewed 6 patient test records along the corresponding QC records for the dates of patient testing. There was no documentation to show QC performance on 05/05/2020 for 1 of 6 patients whose test results were recorded and reported on 05 /05/2020. 4. On January 13, 2021 at 11:30 AM, testing personnel #3 (as listed on Form 209) confirmed the surveyor's findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of the lab's test volume; procedures manual; patient testing logs; patient work sheets; quality control (QC) records; patient test reports; and interview with testing personnel #3 as listed on Laboratory Personnel Report (Form 209), the laboratory failed to assess and correct problems identified in the post analytic systems specified in 493.1291. Findings include: 1. The laboratory listed an annual test volume of 46 on its application for CLIA Certification. 2. In a procedure titled, "QUALTIY ASSURANCE PLAN," it reads as follows: "Perform a random audit of patient record and review work sheet with the final report for pre-analytical, analytical and post-analytical documentation." 3. On January 13, 2021, the surveyor selected 6 random patients names from the patient testing logs. 4. The following information is documented on the patients work sheets for Macroscopic Analysis: a. Complete Liquification (Yes/No) b. Color: Pearl White, Yellow, Reddish c. Viscosity: Normal, Slight, Marked d. Volume 5. Review of corresponding work sheets for the 6 patients names selected by the surveyor revealed, an incorrect date of 05/05/2020 was entered on the worksheet of 1 of 6 patients work sheets reviewed. According to the patient testing log, the date should have been entered as 05/06/2020. 6. Review of 6 patients test reports revealed, there is no documentation to show that the laboratory recorded the results of "Complete Liquification" for 4 of 6 patients test reports reviewed. 7. On January 13, 2021 at 12:30 PM, testing personnel #3 confirmed the surveyor's findings.