Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0984059	10/31/2018
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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to test proficiency testing (PT) samples the same number of times as patient samples for 1 of 2 PT events in 2017 for the specialty of hematology. Findings Include: 1. Review of American Association of Bioanalysts (AAB) Sperm Count PT records from event 2 of 2017 found documentation of the PT samples being performed in duplicate by two different testing personnel (TP#2, TP#3) on 11-8-2017. 2. Review of the laboratory procedure, "Proficiency Testing (PT)", stated "All proficiency testing will be conducted as if it were an unknown patient sample." 3. Interview with TP#1 on survey date 10-23-2018, at 2:20 pm, confirmed patient samples are not tested in duplicate by multiple testing personnel routinely and the PT procedure was not followed for AAB PT event 2, 2017, sperm counts.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with testing personnel (TP) #1; the laboratory failed to establish a maintenance protocol for the Gilson Pipetman P100 (Identification # N-1874) and document the calibrations of the pipette to ensure accurate and reliable test performance for hematology testing. Findings Include: 1. Direct observation on 10-23-2018, at 11:45 AM, identified a Gilson Pipetman P100 (Identification # N-1874) pipette. 2. Interview with TP#1 on 10-23-2018, at 11:45 AM, confirmed the pipette is used for is used for semen analysis testing performed in the laboratory. 3. Review of the laboratory's policy and procedure manual failed to identify a maintenance protocol for the Gilson Pipetman P100 (Identification # N-1874) pipette. 4. On survey date 10-23-2018, at 12:25 PM, TP#1 confirmed no maintenance protocol had been established for the Gilson Pipetman P100 (Identification # N-1874) and no calibrations had been documented.
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 review of laboratory records and interview with testing personnel (TP) #1; the laboratory director failed to ensure proficiency testing problems were identified and corrective action was taken for sperm motility testing in event 2 of 2016. Findings Include: 1. Review of American Association of Bioanalyts (AAB) proficiency testing (PT) records for event 2 of 2016 found the laboratory failed to submit data for sperm motility. 2. Review of AAB PT results found the laboratory director (LD) signed off on the review of the PT event on 3-28-2017 but failed to identify and document the failure of the laboratory to submit sperm motility data to AAB. 3. On survey date 10-23-2018, at 2:20 pm, TP#1 confirmed the LD failed to identify the failure of the laboratory to submit data to AAB for sperm motility in the second event of 2016.