Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2060212	06/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ip Eugene 1	10 Coburg Rd, Ste 200, Eugene, OR	

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**
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of reecords and discussion with the Technical Consultant (TC) and testing personnel (TP), the laboratory failed to ensure calibration and calibration verification were performed on the requisite instruments in Hematology and Chemistry every six (6) months. Findings include: 1. The Hematology analyzer Coulter DXH 600 was last calibrated 06/06/2019. The calibration prior was done eight months before this 10/09/2018, two months late. 2. The Endocrinolgy analyzer Cobas

	e411 serial # 115422 was last calibrated for Estradiol, Follicle Stimulating Hormone (FSH), Leutinizing Hormone (LH), Progesterone, Thyroid Stimulating Hormone (TSH), and Testosterone between 10/11/2018 and 10/19/2018. 3. The TC and the TP present during interview 6/24/2019 at approximately 1230 confirmed this was the last time of calibration for both instruments.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records for Microbiological media and discussion with the Laboratory Director (LD), the laboratory failed to perform end user QC on the media used to plate urine cultures. Findings include: 1. The culture media used by the laboratory to plate urine cultures contains two types of media classified as differential (Blood Agar) and inhibitory (MacConkey Agar). No written documentation of QC for either media type could be produced during the survey 06/24/2019. 2. The LD confirmed during interview 06/24/2019 at approximately 1330 that they were not currently performing QC on the media in this lab.