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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0643690 | (X3) Date Survey Completed 03/11/2019 |
| Name of Provider or Supplier Lucile Salter Packard Children's | Street Address, City, State 1195 W Fremont Ave, Sunnyvale, CA | |
| 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 |
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| D5439 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the Roche Cobas e411 test system, review of laboratory records and patients test records, the lack of laboratory records, and interview with a laboratory person, the laboratory failed to perform procedures to verify calibrations at least once every 6 months. Findings included: a. The Roche Cobas e411 analyzer was used to test for the following analytes: Estradiol (E2) FSH (Follicle Stimulating Hormone) hCG (Human chorionic gonadotropin) LH (Luteinizing Hormone)</p> |

Progesterone (Prog) Prolactin (PRL) TSH (Thyroid Stimulating Hormone) AMH (Anti Muellierian Hormone) b. Laboratory records revealed procedures verifying calibrations were performed as follows: FSH4/2016* ...5/2017* ...12/2017 ...6/2018* LH4/2016* ...5/2017*12/2017 ...6/2018* PRL4/2016* ...5/2017* ...12/2017 ...6/2018* E24/2016* ...5/2017*1/2018 ...6/2018* Prog4/2016* ...5/2017*1/2018 ...6/2018* hCG 4/2016* ...5/2017*2/2018 ...6/2018* TSH4/2016* ???.12/2017 ...6/2018* AMH6/201712/2017....6/2018* c. (*) The laboratory was unable to provide for review records verifying calibrations within 6 months of this date. d. The laboratory person affirmed (3/11/19 at 3pm) the aforementioned lack of laboratory records; and thus, the laboratory's failure to verify calibrations at least once every 6 months since initial use in 2016. e. The reliability and quality of results reported could not be assured when calibrations had not been verified during the timeframes October 2016 to April 2017, November 2017, and December 2018 to January/February 2019. f. Based on the laboratory's stated annual testing volumes (3/13/19), the laboratory reported approximate monthly volumes of results as follows: E2185 FSH33 hCG268 LH.....40 Prog294 PRL 33 TSH 66 AMH66