Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0035890	(X3) Date Survey Completed 03/15/2021
Name of Provider or Supplier Oakland County Health Division Laboratory	**Street Address, City, State** 1200 N Telegraph Road Bldg 32, Pontiac, MI	

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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review, lack of documentation, and interview with the Technical Supervisor (TS), the laboratory failed to include the 5 (specimen, test system, reagent, environment, and testing personnel) of 5 required components, the 3 (pre-analytic, analytic, and post-analytic) of 3 phases of testing which includes potential failures, the risk criteria, and the quality assessment (QA) plan for the Mycoplasma genitalium (M gen) when implementing the Individualized Quality Control Plan (IQCP). Findings include: 1. On 3/15/2021 at 12:36 pm, review of the IQCP documentation for the Hologic Panther instrument revealed the IQCP plan for the Mycoplasma genitalium (M gen) testing lacked documentation for the 5 (specimen, test system, reagent, environment, and testing personnel) of 5 required components, the 3 (pre-analytic, analytic, and post-analytic) of 3 phases of testing which includes potential failures, the risk criteria, and the quality assessment (QA) plan. 2. The IQCP was put into place and reviewed by the Laboratory Director on 7/30/2019. 3. A interview on 3/15/2021 at 12:36 pm with the TS confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to document corrective action for the out of range humidity readings for 12 days (February 7, 12, 14, 19-21, 28 and December 3, 8-9, 11, and 14 in 2020) of 2 years of documents reviewed. Findings include: 1. A record review of the "Panther Monthly QC Log" showed the range for acceptable humidity is 15 - 85%. The logs revealed for 12 days (February 7, 12, 14, 19-21, 28 and December 3, 8-9, 11, and 14 in 2020) of 2 years the following dates had humidity readings outside the stated range: a. 2/7/2020 - 14.9 b. 2/12/2020 - 13.9 c. 2/14/2020 - 14.7 d. 2/19/2020 - 14.7 e. 2/20/2020 - 14.7 f. 2/21/2020 - 14.7 g 2/28/2020 - 14.7 h. 12/3/2020 - 14.7 i. 12/8/2020 - 14.7 j. 12/9/2020 - 14.7 k. 12/11/2020 - 14.7 l. 12/14/2020 - 14.7 2. An interview on 3/15/2021 at 1:50 pm, the TS confirmed no corrective action had been performed and documented to resolve the out of range humidity readings.