Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0667822	07/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Missouri State Public Health Lab	101 North Chestnut Street, Jefferson City, MO	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Review of the manufacturer's instructions, patient test volumes, observation of one of one opened bottle of internal standard material stored in the refrigerator, and interview with the technical supervisor (TS) #2, the laboratory failed to follow the manufacturer's instructions for storage of control material for X-linked Adrenoleukodystrophy (X-ALD) Newborn Screening. Findings: 1. Review of the Perkin Elmer manufacturer's instructions stated, "to store the Lypo PC internal standard at minus 20 degrees Celsius (C)." 2. Observation of the refrigerator showed one opened bottle of Perkin Elmer Lypo PC (lot #20210222) internal standard being stored at 2-8 degrees C. 3. The laboratory performs approximately 90,000 tests annually for X-ALD. 4. Interview with TS #2 on July 18, 2022, at 10:30 a.m. confirmed the laboratory failed to store the internal standard material per manufacturer's instructions.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of three of three opened bottles of Bio-Rad quality control (QC) for blood lead testing, review of manufacturer's instructions, patient test volumes, and interview with the technical supervisor (TS) #1, the laboratory used QC material once it exceeded the expiration date. Findings: 1. Observation of the refrigerator located in the chemistry laboratory area showed three opened bottles of Bio-Rad Lyphocheck (lot #84910), QC levels 1, 2, and 3, for blood lead testing with no open date. 2. Review of Bio-Rad manufacturer's instructions confirmed, "after reconstituting and storing tightly capped at 2-8 degrees C, this product will be stable for 14 days." 3. The laboratory performs approximately 2251 tests annually. 4. Interview with TS #1 on July 18, 2022, at 9:30 a.m. confirmed the laboratory used the QC for blood lead past the expiration date of 14 days.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance verification procedures for the 17-hydroxyprogesterone (17-OHP) assay on the genetic screening processor (GSP), and interview with the technical supervisor (TS #2), the laboratory failed to ensure that the reportable range of test results for the test system was appropriate prior to reporting patient test results. Findings: 1. The laboratory uses Perkin Elmer genetic screening processors (GSP), GSP-20210150 (Oscar) and GSP-20210545 (Tony) to screen newborns for increased (17-OHP) activity. 2. Review of the verification procedures for the 17-OHP assay on the GSP-20210545 (Tony) determined that no reportable range of test results was performed. 3. The laboratory reports a 17-OHP annual test volume of 90,000. 4. Interview with TS #2 on July 20, 2022 at 9:30 a.m. confirmed that the laboratory failed to ensure that the reportable range of test results for the 17-OHP assay using GSP-20210545 (Tony) was appropriate prior to reporting patient test results.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv)

	Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of Perkin Elmer manufacturer's manual, review of the verification of performance specifications, review of patient test volumes, and interview with the technical supervisor (TS) #2, the laboratory failed to provide documentation of analytical sensitivity, analytical specificity, reportable range, and reference intervals for a non-FDA approved test system for X-linked Adrenoleukodystrophy (X-ALD) Newborn screening. 1. Review of the Perkin Elmer QSight 225 LC-MS/MS analyzer manual for X-ALD testing revealed: "not FDA approved." 2. Review of the laboratory's validation reports for performance specifications of the Perkin Elmer QSight 225 LC-MS/MS analyzer (Butters) revealed the laboratory failed to verify analytical specificity, analytical sensitivity, reoportable range, and reference intervals (normal values). 3. The laboratory performs approximately 90,000 X-ALD patient tests annually. 4. Interview with TS #2 on July 20, 2022, at 11:00 a.m. confirmed the laboratory failed to provide the performance specifications for analytical specificity, analytical sensitivity, reportable range, and reference intervals before using a non-FDA approved test system.