Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D1065860	**(X3) Date Survey Completed** 05/11/2022
Name of Provider or Supplier Acton Road Pediatrics Llc	**Street Address, City, State** 2409 Acton Road Suite 171, Birmingham, AL	
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**
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 a review of Throat Culture Quality Control (QC) records, the manufacturer's insert "Product Information and Quality Control Sheet Strep Select Agar", patient logs, and an interview with Testing Personnel #1, the laboratory failed to ensure testing personnel did not utilize Strep Select Agar (SSA) beyond the manufacturer's expiration date. This was noted in eight out of twenty-seven months reviewed by the surveyor. The findings include: 1. A review of Throat Culture QC records revealed the following: a) May 2020 -August 2020 - Lot number 9358539 Expiration 5/2/2020 in use. b) September 2020 - Lot number 9358539 Expiration 5/2/2020 in use until 9/03 /2020. c) November 2020 - Lot number 131429 Expiration 11/05/2020 in use until 11 /23/2020. d) January 2022 - Lot number 140541 Expiration 1/19/2022 in use until 02 /01/2022. e) March 2022 - Lot number 141518 Expiration 3/9/2022 in until 3/15/2022. 2. A review of manufacturer's insert "Product Information and Quality Control Sheet Strep Select Agar" under, VI. Storage/Shelf Life "...Product which has exceeded the assigned expiration date noted on the label should not be used..." 3. A review of patient logs revealed the following: a) From 05/11/2020 to 08/31/2020 a total of 82 patients were performed using Lot number 9358539 Expiration 5/2/2020 SSA. b) From 9/01/2020 to 09/02/2020 a total of 8 patients were performed using Lot number 9358539 Expiration 5/2/2020 SSA. c) From 11/06/2020 to 11/20/2020 a total of 45 patients were performed using Lot number 131429 Expiration 11/05/2020 SSA. d) From 1/20/2022 to 01/31/2022 a total of 53 patients were performed using Lot number 140541 Expiration 1/19/2022 SSA. e) From 3/10/2022 to 3/14/2022 a total of 18 patients were performed using Lot number 141518 Expiration 3/09/2022 SSA. 4.

	During an interview on 5/11/2022 at 12:17 PM, Testing Personnel #1 confirmed the above findings.