

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0705526	<b>(X3) Date Survey Completed</b>  04/16/2026
<b>Name of Provider or Supplier</b>  Cornerstone Pediatrics Pc	<b>Street Address, City, State</b>  701 Will Halsey Way, Madison, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the temperature charts, Selective Strep Agar (SSA) plate package insert, and an interview with the Laboratory Director (LD), the laboratory failed to document the corrective action when the refrigerator temperature was outside the manufacturer's specified range. The surveyor noted refrigerator temperatures were out of range for 69 days out of 12 months reviewed in 2025 and 2026. The findings include: 1. A review of the temperature charts revealed the following refrigerator temperatures were recorded out of range with no corrective action documented: A) 2025 Laboratory fridge: July (1), August (2), September (1), October (4), November (2), and December (6), B) 2025 Sick Nurses Station fridge: August (1), September (6), October (1), November (2), and December (6), C) 2026 Laboratory fridge: February (1), March (3), April (3), D) 2026 Sick Nurses Station fridge: January (9), February (5), March (13), April (3). 2. A review of the package inserts for the temperature requirements for the materials stored in the fridge revealed SSA plates, "Storage: Upon receipt store at 2-8 degrees Celsius." 3. The LD confirmed the above findings during the exit conference on 4-16-26 at 11:55 AM.</p>
<b>D5477</b>	CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(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.

This STANDARD is not met as evidenced by:

Based on a review of the Selective Strep Agar (SSA) plate QC (Quality Control) log, and an interview with the Laboratory Director (LD), the laboratory failed to document media QC performance and results, media lot numbers, and expiration dates for each lot number prior to use for patient testing. This was noted for 30 days of 2 months reviewed in 2024. The findings include: 1. A review of the SSA QC log revealed no documentation of media from when the last lot expired to when the new lot was put into use. Lot# 621579 was put into use 4-23-24 and expired 5-5-24; 30 days later lot# 626998 was put into use 6-4-24. 2. During an interview on 4-16-26 at 11:06 AM, the LD confirmed media documentation was missed.