

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0271787	(X3) Date Survey Completed 09/04/2024
Name of Provider or Supplier Gainesville Pediatric Associates	Street Address, City, State 6440 W Newberry Rd Ste 402, Gainesville, FL	
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
D0000	At the time of the announced, on-site recertification survey, Gainesville Pediatric Associates was found to be NOT in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure blood agar plates were not expired prior to being used for patient testing on 5/26/23, 7/17/23, 3/6/24, 3/7/24, 3/8/24, 3/9/24, 5/30/24, 5/31/24, and 6/3/24. The findings include: The laboratory uses Hardy Diagnostics Blood Agar Plate for presumptive identification of Streptococcus A. The laboratory document titled "CLIA Individualized Quality Control Plan (IQCP)" dated December 2020 states "daily recording of lot numbers and expiration dates (of blood agar plates) ... to ensure no out of date materials are being used. This prevents use of inadequate testing materials." 1. Review of the documented titled "Media tracking for blood agar plates" showed on 5/17/23 Hardy Diagnostics Blood Agar plate lot #151036 was opened with an expiration date of 5/25/23. Review of the laboratory document titled "Throat Culture" dated 5/26/23, showed no lot number or expiration date for the blood agar was documented with 1 patient tested. The laboratory document titled "Throat Culture" dated 5/27/23 shows a blood agar lot number of 151458 and expiration date of 6/15/23. Review of the "Media tracking for blood agar plates" showed lot number 151458 was opened on 5/27/23. The interview with the Laboratory Director on 9/4/24 at 11:30 am confirmed the lot number and expiration date from 5/26/23 was missing and was unable to determine if the expired plate from 5/25/23 was used. 2. Review of the documented titled "Media</p>

tracking for blood agar plates" showed on 6/13/23 Hardy Diagnostics Blood Agar plate lot #152088 was opened with an expiration date of 7/16/23. The laboratory document titled "Throat Culture" dated 7/17/23 shows blood agar lot number of 152088 and expiration date of 7/16/23. 2 patients were tested. The interview with the Laboratory Director on 9/4/24 at 11:30 am confirmed the lot was expired. 3. Review of the documented titled "Media tracking for blood agar plates" showed on 3/7/24 Hardy Diagnostics Blood Agar plate lot #617442 was opened with an expiration date of 3/5/24. The laboratory document titled "Throat Culture" dated 3/6/24 shows blood agar lot number of 617442 and expiration date of 3/5/24. 4 patients were tested. The laboratory document titled "Throat Culture" dated 3/7/24 shows blood agar lot number of 617442 and expiration date of 3/5/24. 5 patients were tested. The laboratory document titled "Throat Culture" dated 3/8/24 shows blood agar lot number of 617442 and expiration date of 3/5/24. 2 patients were tested. The laboratory document titled "Throat Culture" dated 3/9/24 shows blood agar lot number of 617442 and expiration date of 3/5/24. 3 patients were tested. The interview with the Laboratory Director on 9/4/24 at 11:30 am confirmed the lot was expired. 4. Review of the documented titled "Media tracking for blood agar plates" showed Hardy Diagnostics Blood Agar plate lot #624004 with an expiration date of 5/29/24. Review of the laboratory document titled "Throat Culture" dated 5/30/24, showed no lot number or expiration date for the blood agar was documented with 5 patients tested. The laboratory document titled "Throat Culture" dated 5/31/24, showed no lot number or expiration date for the blood agar was documented with 3 patients tested. The laboratory document titled "Throat Culture" dated 6/3/24 shows blood agar lot number of 624004 and expiration date of 5/29/24. 6 patients were tested. The interview with the Laboratory Director on 9/4/24 at 11:30 am confirmed the lot number and expiration date from 5/30/24, and 5/31/24 was missing and was unable to determine if the expired plate from 5/29/24 was used. It was confirmed the lot number was expired on 6/3/24.