

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0892367	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Lebonheur Pediatrics, Llc	Street Address, City, State 3876 New Covington Pike, Memphis, TN	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the proficiency testing (PT) records, and interview with testing personnel number five, the laboratory failed to include all testing personnel in the proficiency testing process, in 2016, 2017 and 2018. The findings include: 1) Observation of the laboratory on August 16, 2018 at 1:20 p.m. revealed the Beckman Coulter Act diff instrument for complete blood count, the incubator for throat culture, the microscope for urine microscopic and pin worm in use for patient testing. 2) Review of the 2016, 2017 and 2018 PT records revealed the following: testing personnel number one didn't participate in microscopic events, testing personnel number two didn't participate in CBC and microscopic events, and, testing personnel number four didn't participate in CBC, throat culture and microscopic events. 3) Interview on August 16, 2017 at 4:45 p.m. with testing personnel number five confirmed testing personnel numbers one, two and four perform patient and quality control testing but did not participate, on a rotating basis, during the last three years for tests they perform on patients.</p>
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p>

This CONDITION is not met as evidenced by:
The laboratory failed to follow the throat culture Strep Select Agar (SSA) manufacturer instructions for incubation time (Refer to D5411 Citation number one); failed to follow the manufacturer instructions for incoming media visual inspection procedures (Refer to D5411 Citation number two); failed to ensure the SSA media was not in use past the expiration dates (Refer to D5417); and, failed to perform at least one organism on the SSA media to confirm it's inhibitory characteristic, (Refer to D5477), resulting in an immediate jeopardy.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
CITATION NUMBER ONE: Based on observation of the laboratory, review of the Strep Select Agar (SSA) manufacturer instructions, the patient log records, patient number one and two final reports, and interview with testing personnel number five, the laboratory failed to follow the throat culture SSA manufacturer instructions for incubation time of 18-48 hours, in 2016, 2017 and 2018, resulting in an immediate jeopardy. The findings include: 1) Observation of the laboratory on August 16, 2018 at 1:20 p.m. revealed an incubator, Strep select agar and bacitracin disk (A disk) in use for patient testing throat culture presumptive Strep A. 2) Review of the SSA manufacturer instructions revealed, "5. Incubate the plates in ambient air (or in an atmosphere enriched with 5 to 10% CO₂) at 35-37°C for 18-48 hours. Note: Pathogens may be detected as early as 18 hours however, it is recommended that inoculated plates be incubated for a total of 48 hours before reporting a culture as 'normal flora' ". 3) Review of the patient log records and patient number one and two final reports revealed patient number one throat culture was collected on 07-13-18 at 11:40 a.m. and reported 23 hours later on 07-14-18 at 11:07 a.m. as presumptive Negative. Patient number two throat culture was collected on 07-23-18 at 3:44 p.m. and reported 17 hours later on 07-24-18 at 8:54 a.m. as presumptive Negative. 4) Interview on August 16, 2018 at 1:30 p.m. with testing personnel number five confirmed patient throat cultures are reported after 18 hours of incubation, but never incubated for 48 hours. CITATION NUMBER TWO: Based on review of the Strep Select Agar (SSA) manufacturer instructions, the "TC Visual inspection of agar plates /Taxo A disc by each lot number change or new shipment" records, the "throat culture control book" records, and interview with testing personal number five, the laboratory failed to follow the manufacturer instructions for incoming media visual inspection procedures, in 2016, 2017, and 2018, resulting in immediate jeopardy. The findings include: 1) Review of the SSA manufacturer instructions revealed, "II Quality Control. The following incoming inspection procedures must be performed for each batch (batch = same lot, same shipment) of culture media received in the laboratory: 1. Inspect plates according to instructions contained on the 'Quality Control Log Sheet'. 2. Peel off the lower portion of a product bag label (Quality Control Certificate) for the lot being acceptable into the laboratory and affix it to the Quality Control Log Sheet. 3. Initial and date the Quality Control Log Sheet." 2) Review of the "TC Visual inspection of agar plates/Taxo A disc by each lot number change or

new shipment" records and the "throat culture control book" records revealed the following Strep Select Agar (SSA) media in use with no documentation of visual inspection: September 21, 2016 lot number 1619304 exp 10-17-16; December 27, 2016 lot number 1629841 exp 1-30-17; April 4, 2017 lot number 1705902 expiration (exp) 5-17-17; May , 2017 lot number 1706611 exp 6-15-17; August 15, 2017 lot number 1716304 exp 9-18-17; and, July 5, 2018 lot number 1807807 exp 7-9-18 3) Interview on August 16, 2018 at 3:20 p.m. with testing personnel number five confirmed the manufacturer instructions were not followed regarding the performance of the visual inspections on SSA media, in 2016, 2017 and 2018.

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 review of the Strep Select Agar (SSA) manufacturer instruction, the "Throat Culture Control Book" records and interview with testing personnel number five, the laboratory failed to ensure the SSA media was not in use past the expiration dates in 2018, resulting in an immediate jeopardy. The findings include: 1) Review of the SSA manufacturer instructions revealed, "Storage/Shelf life. Product which has exceeded the assigned expiration date noted on the label should not be used." 2) Review of the "Throat Culture Control Book" records revealed SSA lot number in use after expiration date: June 19, 2018 lot number 1806006 expired 6-21-18 in use until the entry date of July 5, 2018; July 5, 2018 lot number 1807807 expiration date 7-9-18 in use until the entry date of July 12, 2018. 3) Interview on August 16, 2018 at 4:15 pm with testing personnel number five confirmed the expired SSA lot numbers were in use for patient testing.

D5477

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

(e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the "TC visual inspection of agar plates/Taxo A disc by each lot number change or new shipment" records, the "throat culture control book" records, and interview with testing personnel number five, the laboratory failed to perform at least one organism to confirm it's inhibitory characteristic, in 2016, 2017 and 2018, resulting in immediate jeopardy. The findings include: 1) Observation of the laboratory on August 16, 2018 at 1:20 p.m. revealed an incubator, Strep select agar and bactricin disk (A disk) in use for patient testing throat culture presumptive Strep A. 2) Review of the "TC visual inspection of agar plates

/Taxo A disc by each lot number change or new shipment" records, the "throat culture control book" records revealed no quality control organism in use for inhibitory characteristic (no growth on the SSA). 3) Interview on August 21, 2018 at 1:30 p.m. with testing personnel number five via telephone confirmed the only organisms in use for quality control are *Streptococcus agalactiae* (Strep B) and *Streptococcus pyogenes* (Strep A).