

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1018564	(X3) Date Survey Completed 03/20/2018
Name of Provider or Supplier Mount Carmel New Albany Surgical Hospital Lab	Street Address, City, State 7333 Smith'S Mill Road, New Albany, OH	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, review of the manufacturer's packaging, laboratory inspection, review of the manufacturer's package insert, and an interview with the General Supervisor (GS), the laboratory failed to establish written policies and procedures for specimen storage and preservation that meet manufacturer's requirements. Findings Include: 1. Review of the laboratory's procedure manual titled " Routine Microbiology Set-Up" did not find any instructions for the proper storage of bacterial culture plates. 2. Inspection of the MacConkey manufacturer's package revealed storage conditions at 2-8 Celsius. 3. Inspection of the microbiology laboratory found two unopened packages of MacConkey agar plates and four unopened Chocolate agar plates sitting on a counter at room temperature. 4. Review of the MacConkey II Agar manufacturer's package insert instructions stated the following under storage instructions: " On receipt, store plates in the dark at 2-8 degrees Celsius." 5. Review of the BD Chocolate Agar manufacturer's package insert instructions stated the following under storage and shelf life: " On receipt, store plates in the dark at 2-8 degrees Celsius." 5. GS #2 confirmed that the laboratory did not follow the manufacture's instructions. The interview occurred on 03/20/2018 at 1:30 PM.</p>
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to evaluate and document the performance of Testing Personnel (TP) who was responsible for high complexity testing procedures at least semiannually during the first year the individual tested patient specimens. Findings Include: 1. Review of the laboratory's 2017 training and competency assessment documentation, provided on the date of the inspection, found TP#4 did not have a semi-annual training record. A semi-annual laboratory training record was provided for TP#2 only. 3. The GS#2 stated the laboratory's 2017 competency assessments and documentation of the assessments were lacking and confirmed the laboratory did not conduct and document semiannual competency assessments for TP#4 within the first year of testing. The interviews occurred on 03/20/2018 at 9:40 AM.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to evaluate and document the 2017 competency of a General Supervisor (GS) who was responsible for high complexity testing. Findings Include: 1. Review of the laboratory's annual 2016-2017 competency records found GS#3 had no competency assessment completed in 2016. Further review showed GS#3 had two competency assessments completed in 2017. 2. GS#2 confirmed GS#3 did not have a competency assessment in 2016 due to a late assessment which occurred in 2017 for 2016. The interview occurred on 03/20/2018 at 9:50 AM.