

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0029634	(X3) Date Survey Completed 06/22/2023
Name of Provider or Supplier Ummc - Grenada	Street Address, City, State 960 Jk Avent Drive, Grenada, MS	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel records since 12/2/2021 and confirmation with the technical consultant (TC) #2, the laboratory failed to follow written policies to assess general supervisor (GS) and TC competency. The competencies available the day of survey were performed by someone other than the laboratory director. Findings include: 1. Based on review of the personnel records and the CMS-209 personnel form, the laboratory failed to follow written policies and procedures to evaluate the competencies of the following technical consultants (TC) and general supervisors (GS) at least annually since the last survey: a. TC #2/GS #1- No general supervisor or technical consultant competency for 2022 and 2023 b. TC #3/GS #2- No general supervisor or technical consultant competency for 2022 and 2023 by LD c. TC #4/GS #3- No general supervisor or technical consultant competency for 2022 and 2023 2. TC#2/GS#1 confirmed in an interview at 1:00 p.m. on 6/22/2023 that the laboratory failed to follow policies to assess general supervisor and technical consultant competency.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory proficiency testing records, lack of documentation of twice annual verifications on the Procalcitonin assay, and interview with technical consultant (TC) #2 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form on 6/22/2023 at 12:15 P.M., the laboratory failed to verify the accuracy of Procalcitonin testing twice per year for 4 of 4 verifications due since testing began on 8/25/2021. Findings included: 1. Review of proficiency testing records and lack of verification records for Procalcitonin revealed no twice annual test verification was performed for 4 of 4 verifications due between 8/25/2021 and 6/22/2023. The laboratory performs approximately 1,445 Procalcitonin tests each year. 2. During an interview on 6/22/2023 at 12:15 P.M., technical consultant # 2 confirmed no twice annual test verifications for Procalcitonin were performed.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
A. Based on review of the Gem Premier 5000 blood gas analyzer records including quality control, maintenance, and calibration verification records from installation on 8/24/2022 through 6/22/2023 and confirmation with the respiratory testing personnel (TP) #1 and technical consultant (TC) #2 as listed on the Centers for Medicare and Medicaid Services 209 personnel form at 12:00 p.m. on 6/22/2023, the laboratory failed to document as performed calibration verification on the Gem Premier 5000 blood gas analyzer every 6 months for pCO₂, pH, pO₂. One of three calibration verifications was missed during the timeframe reviewed, and one of three calibration verifications exceeded the sixth month timeframe required by the manufacturer. Findings include: 1. Calibration verification is required every 6 months on any assay which is calibrated with less than 3 levels of calibration material. The Gem Premier 5000 blood gas analyzer uses a single calibrator level to perform calibrations. 2. The Gem Premier 5000 blood gas analyzer records revealed calibration verification was performed during installation on 8/24/2022 and again on 6/6/2023. 3. The respiratory

TP #1 and TC #2 confirmed in an interview at 12:00 p.m. on 6/22/2023 that calibration verification on pH, pCO2 and pO2 was not performed at the appropriate timeframe or frequency during the period of time reviewed. One of three verifications required was not performed and exceeded the 6 month timeframe required by the manufacturer. B. Based on review of laboratory chemistry records from 12/2/2021 through 6/22/2023 and interview with the laboratory testing personnel (TP) #2 at 3:00 p.m. on 6/21/2023, the laboratory failed to document as performed calibration verification on the two Cobas 6000--501c and e601--chemistry analyzers every 6 months for 51 chemistry analytes. Two of four verifications due were not performed. One of four verifications exceeded the recommended time frame. Findings include: 1. Review of the Cobas 6000 501c and Cobas e601 calibration verification records revealed that 51 chemistry tests are calibrated with a 2 point calibrator. Assays which are calibrated with two point calibrators include: Hemoglobin A1c, Acetaminophen, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Vitamin B12, BUN, Calcium, Cholesterol, CK, CO2, Creatinine, Direct Bilirubin, ETOH, Ferritin, Folate, free T3, free T4, GGT, Glucose, Hepatitis B Surface Antigen, beta-hCG, HDL Cholesterol, Iron, Lactic Acid, LDH, Lipase, Microalbumin, Magnesium, Ammonia, Prealbumin, Procalcitonin, Phosphorus, Pro-BNP, Rubella IgG, Salicylate, Thyroxine, T4, Total Bilirubin, Troponin, Total Protein, PSA, Triglyceride, TSH, Uric Acid, Vitamin D, Sodium, Potassium, Chloride. 2. Calibration verification is required on any assay which is calibrated with less than 3 calibration materials. 3. Calibration verification was performed and completed on the listed chemistry analytes on 1/5/22 and 4/21 /2023. 4. The technical consultant /TP #2 confirmed in an interview at 3:00 p.m. on 6 /21/2023 that chemistry calibration verifications were not performed every 6 months during the period of time reviewed from 12/2/2021 to 4/21/2023. Two of four verifications required were not performed and and one of the four performed exceeded the 6 month required timeframe.

D5503

BACTERIOLOGY
CFR(s): 493.1261(a)(2)

(a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains.

This STANDARD is not met as evidenced by:
Based on review of microbiology patient and quality control (QC) records, microbiology procedure manual, and interview with general supervisor (GS) # 4 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form on 6 /20/2023 at 2:00 P.M. the laboratory failed to perform QC each day of gram stain testing on 8 of 8 days from 12/2/2021 through 6/20/2023. Findings include: 1. Review of the microbiology patient and QC records indicated the laboratory did not perform a gram negative and gram positive control each day of patient testing from 12/2/2021 through 6/20/2023 for 8 out of 8 patient gram stains reported. 2. During an interview at 2:00 P.M. on 6/20/2023, GS #4 confirmed the laboratory did not perform QC daily with each patient gram stain as required in the microbiology procedure manual.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

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

This STANDARD is not met as evidenced by:
 Based on review of respiratory department testing personnel records since the last survey 12/2/2021, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with technical consultant (TC) #2 at 1:00 p.m. on 6/22/2023, a TC failed to evaluate and document the performance of three of nine respiratory testing personnel TP #4, TP #5 and TP #10 at least semiannually during the first year of moderate complexity (blood gas) testing. Findings include: 1. Review of the laboratory personnel records indicated that there were no 6-month evaluations available for respiratory TP #4, TP#5 and TP#10. TP #4 initial training date 7/19/2022 - 6 month evaluation due January 2023 TP #5 initial training date 7/19/2022 - 6 month evaluation due January 2023 TP #10 initial training date 7/19/2022 - 6 month evaluation due January 2023 2. TC#2 confirmed in an interview at 1:00 p.m. on 6/22/2023 that no 6 month evaluation/competency was performed on respiratory TP #4, #5 or #10 during the first year performing moderate complexity (blood gas) testing. Three of nine new respiratory department testing personnel did not have a 6 month evaluation /competency at the appropriate time.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
 Based on review of respiratory testing personnel (TP) records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with the technical consultant (TC) #2, a TC failed to evaluate annually and document the performance of five of twelve respiratory testing personnel (TP) #1, TP #3, TP #8, TP #9, and TP #11 responsible for performing blood gas testing. Findings include: 1. Based on respiratory personnel records available for review on the day of survey, the evaluation/competencies were not documented as performed or performed by other than a qualified TC on the following respiratory TP since 12/2/2021: TP #1 - No annual evaluation for 2022 TP #3 - 2021 and 2023 evaluations performed by someone other than a qualified TC TP #8 - No annual evaluation for 2022 TP #9 - No annual evaluation for 2022 and 2023 TP #11 - No annual evaluation for 2021 2. Interview with TC #2 confirmed no annual evaluation/competencies for respiratory TP #1, TP #8, TP #9, and TP #11 had been documented as performed by a TC for the year 2021 and TP#3 had a evaluation performed by staff other than a TC. Five of twelve laboratory testing personnel did not have an annual evaluation/competency for the years 2022 and 2023.