| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>25D0689771 | (X3) Date Survey Completed<br>10/25/2018 |
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| **Name of Provider or Supplier**<br>North Sunflower Medical Center | **Street Address, City, State**<br>840 N Oak Ave, Ruleville, 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 |
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| **D2010** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(2)<br><br>The laboratory must test samples the same number of times that it routinely tests patient samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of hematology proficiency testing (PT) records since the last survey on 1-26-17 and confirmation by Technical Consultant #2 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory tested all five hematology PT samples of Event 1, Event 2, and Event 3 of 2017 and Event 1 of 2018 twice prior to submitting the results to the PT provider. Technical Consultant #2 confirmed the laboratory routinely tests patient hematology samples only once prior to reporting results. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the patient and Quality Control (QC) logs for the Sure-Vue RF (Rheumatoid Factor) test from 5/10/17 to 9/26/18 and the Sure-Vue RF manufacturer's procedure, the laboratory failed to follow the manufacturer's instructions for the rotator speed when testing patient specimens. Findings include:<br>The manufacturer's instructions for the Sure-Vue RF test system state the rpm's |

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| | (rotations per minute) on the rotator should be between 80-100 rpm (20-25 rpm per 15 seconds) for 2 minutes when testing patients. The laboratory was using the range of 24-27 rpm for 15 seconds to verify the rpm's prior to patient testing. This range includes rpm's that are higher than the manufacturer's requirement . Approximately one hundred and fifty three patients were tested when the rotator speed was verified using the incorrect range from 5/10/17 through 9/26/18. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation of bacteriology microbiological culture media (MacConkey II agar) in use by the laboratory on 10-24-18, the media had exceeded the expiration date as established by the manufacturer when patient microbiological cultures were performed and results reported. Findings include: Surveyor observation of the MacConkey II microbiological culture media in use by the laboratory on 10-24-18 revealed the laboratory performed patient microbiological culture testing procedures using expired MacConkey II agar as follows: MacConkey agar (lot # 8194728) observed under the biological safety hood, in the bacteriology refrigerator and in the bacteriology incubator had expired on 10-12-18. Seven urine cultures on expired media were observed as testing was in progress on 10-24-18. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>1. Based on the Respiratory Department personnel and training documentation available the day of survey, the laboratory director had not ensured that testing personnel listed on the CMS 209 personnel form as testing personnel #20 and #21 had received the appropriate initial training for testing blood gases prior to testing patients. Testing personnel #20 and #21 both began employment in the Respiratory Department in 2018 according to staff (Hire date unavailable on day of survey). 2. Based on the laboratory personnel and training documentation available the day of survey, the laboratory director had not ensured that testing personnel listed on the CMS 209 personnel form as tesing personnel #4, #5 and #7 had received the appropriate initial training for moderate complexity testing (endocrinology, chemistry, hematology, urinalysis, etc.) prior to testing patients. Testing personnel #4 began employment in June 2017, #5 began in May 2017 and #7 began August 2018. |

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| **D6045** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(7)<br><br>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of quality control (QC) records, microbiological media (stored and in use), review of proficiency testing records since the last survey on 1-26-17 through 10-25-18 and interview with staff at 3:00 pm on the day of survey, the technical consultant did not identify training needs for performing quality control, using media prior to expiration, and failure to perform proficiency testing samples in the same manner as patients. Findings include: The technical consultant did not recognize the following testing personnel training needs: 1. Quality control material for Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and D-dimer were tested numerous times without troubleshooting or retraining of testing personnel (repeated until values were in range). 2. MacConkey II media was used beyond its expiration date for patient testing of urine cultures. (Refer to D5417) 3. Proficiency Testing specimens were not tested in the same manner as patient specimens. (Refer to D2010) |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory personnel records from last survey (1/26/17) through the current survey (10/25/18) and the CMS 209 personnel form, the technical supervisor failed to evaluate and document the performance of testing personnel # 8 responsible for performing high complexity testing at least semiannually during the first year of employment. The hire date for testing personnel #8 was 5/17/17. An annual competency evaluation was performed on 5/23/18. A semiannual evaluation must be performed during the first year of employment by the laboratory. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory personnel records since last survey and confirmation with staff, the technical consultant failed to evaluate annually and document the performance of testing personnel/respiratory supervisor (listed on the Centers for |

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| | Medicare & Medicaid 209 form) as testing personnel #22 for the years 2017 and 2018. |
| **D6127** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory personnel records from last survey (1/26/17) through day of survey (10/25/18) and the CMS 209 personnel form, the technical supervisor failed to evaluate and document the performance of testing personnel # 8 responsible for performing moderate and high complexity testing at least semiannually during the first year of employment. The hire date for testing personnel #8 was 5/17/17. An annual competency evaluation was performed on 5/23/18. A semiannual evaluation must be performed during the first year of employment by the laboratory. |