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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 25D0317717 | (X3) Date Survey Completed 12/14/2022 |
| Name of Provider or Supplier Mea Medical Clinic Madison | Street Address, City, State 935 Hwy 51 N, Madison, 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 |
|---------------------------|---|
| D6029 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records since the last survey on 4/14/2021, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and lack of documentation of training, the Laboratory Director failed to ensure that prior to testing patients' specimens, Testing Personnel #1 and #7 received the appropriate training for moderate complexity testing and demonstrated performance of all testing operations reliably to provide and report accurate results. Findings include: Review of personnel records since the last survey on 4/14/2021, and the CMS 209 personnel form revealed the Laboratory Director failed to ensure that Testing Personnel #1 and #7 received appropriate training for performing moderate complexity testing prior to testing patients' specimens. There was no documentation of training available for Testing Personnel #1 and #7 listed on the CMS 209 personnel form on the day of the survey, 12/14/2022. Testing Personnel #1 (date of hire 9/20/2021) Testing Personnel #7 (date of hire 9/1/2021)</p> |
| D6049 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> |

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of laboratory records (including preventive maintenance, temperature logs, quality control, calibration, quality assurance) and interview with the current laboratory Technical Consultant (TC) listed on the CMS-209 form during the survey on 12/14/2022, there was no documented review of records by the previous TC for a period of 11 months. Findings include: 1) There was no review of records documented by the previous Technical Consultant (TC) after 2/1/2021. The new TC first documented review of records in November 2022. 2) All records from January 2022 through November 2022 were signed by the new TC. 3) The current TC confirmed in an interview on 12/14/2022 that there was no documented review of preventative maintenance, temperature logs, quality control, calibration and quality assurance for a period of 11 months from 2/1/2021 through 12/31/2021.

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 the CMS 209 personnel form and personnel records since the last survey on 4/14/2021, the Technical Consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year these individuals tested patient specimens. Findings include: Review of the CMS 209 personnel form and personnel records since the last survey on 4/14/2021 revealed the Technical Consultant failed to evaluate and document the performance of the following testing personnel listed on the CMS 209 personnel form, at least semiannually during the first year these individuals tested patient specimens: Testing Personnel #1 (date of hire 9/20/2021) Testing Personnel #7 (date of hire 9/1/2021)

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 personnel records since the last survey on 4/14/2021, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and lack of documentation of competency assessments, the Technical Consultant failed to evaluate and document the performance of Testing Personnel #2, #3, #4, #5, #6, #7, #8, and #9 at least annually. Findings include: Review of personnel records since the last survey on 4/14/2021 and the CMS 209 personnel form revealed the Technical

Consultant failed to evaluate and document the performance of Testing Personnel #2, #3, #4, #5, #6, #7, #8, and #9 who were responsible for moderate complexity testing, at least annually since 4/14/2021.