

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D0318207	<b>(X3) Date Survey Completed</b>  11/07/2022
<b>Name of Provider or Supplier</b>  Mea Medical Clinic Pearl	<b>Street Address, City, State</b>  342 Gilchrist Drive, Pearl, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records since the last survey on 4/20/2021 and lack of documentation of signed attestation statements and instrument printouts for testing of PT samples, the laboratory failed to maintain a copy of PT records, including signed attestation statements for three of the five PT events since the last survey and hematology analyzer printouts for one PT event. Findings include: Review of proficiency testing (PT) records since the last survey on 4/20/21 revealed the laboratory failed to maintain a copy of attestation statements, signed by the analyst and the laboratory director, for hematology PT Event 1 of 2021, Event 2 of 2021, and Event 2 of 2022 and failed to maintain a copy of CDS Medonic hematology analyzer printouts for testing of complete blood count (CBC) PT samples for Event 2 of 2021.</p>
<b>D5217</b>	<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</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records since the last survey on 4/20/2021 and lack of documentation of verification of accuracy for wet preparation examinations and microscopic urinalysis, the laboratory failed to verify the accuracy of wet preparation examinations and microscopic urinalysis, when proficiency testing scores were unsatisfactory. Findings include: 1. Review of proficiency testing records since the last survey on 4/20/2021 revealed the laboratory's microscopic urinalysis proficiency testing score for Event 2 of 2021 was 75 percent. Proficiency testing for Event 3 of 2021 and Event 1 of 2022 was not performed. The laboratory failed to verify the accuracy of microscopic urinalysis at least twice annually for 2021 and 2022. 2. Review of proficiency testing records since the last survey on 4/20/2021 revealed the laboratory's wet preparation examination proficiency testing score for Event 2 of 2022 was 50 percent. Proficiency testing for Event 1 of 2022 was not performed. The laboratory failed to verify the accuracy of wet preparation examinations at least twice annually for 2022.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of preventive maintenance logs for the CDS Medonic hematology analyzer from 5/1/2021 through 8/8/2022, when it was taken out of service, and lack of documentation of monthly maintenance for six months during this time frame, the laboratory failed to perform and document maintenance as defined by the manufacturer, with at least the frequency specified by the manufacturer. Findings include: Review of preventive maintenance logs for the CDS Medonic hematology analyzer since the last survey on 4/20/2021 revealed the monthly maintenance procedure "Monthly Cleaning and Clot Prevention" was not documented, as performed, for the months of September, November, and December of 2021 and February, April, and June of 2022.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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.

This STANDARD is not met as evidenced by:

Based on review of personnel records since the last survey on 4/20/2021, 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 #13 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 4/20/2021, and the CMS 209 personnel form revealed the laboratory director failed to ensure that Testing Personnel #13, whose date of hire was 4/5/2022, received appropriate training for performing moderate complexity testing prior to testing patients' specimens. There was no documentation of training available for Testing Personnel #13, listed on the CMS 209 personnel form, on 11/7/2022.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iii)

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 preventive maintenance logs for the CDS Medonic hematology analyzer from 5/1/2021 through 8/8/2022, when it was taken out of service, and lack of documentation of review by the technical consultant, the technical consultant failed to document review of the CDS Medonic preventive maintenance logs for the fifteen months it was in use since the last survey. Findings include: Review of preventive maintenance logs for the CDS Medonic hematology analyzer from 5/1/2021 through 8/8/2022 revealed no documentation of review by the technical consultant for the fifteen months it was in use since the last survey, for the evaluation of the competency of the staff. Refer to D5429 (Failure to document monthly maintenance for six months.)

**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 4/20/2021, 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 #1 through #6, #12, and #14 at least annually. Findings include: Review of personnel records since the last survey on 4/20/2021 and the CMS 209 personnel form revealed the technical consultant failed to evaluate and document the performance of Testing Personnel #1 through #6, #12, and #14, who were responsible for moderate complexity testing, at least annually since 4/20/2021.