

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0692017	<b>(X3) Date Survey Completed</b>  05/02/2022
<b>Name of Provider or Supplier</b>  Maryland Endocrine Pa	<b>Street Address, City, State</b>  10710 Charter Drive Ste 410, Columbia, MD	
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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the testing person (TP), the TP and laboratory director (LD) or designee failed to sign the statement attesting to the routine integration of PT samples into the patient workload using the laboratory's routine methods in two of six chemistry PT events. Findings: 1. Records for two 2020 PT events, three 2021 PT events and one 2022 PT event were reviewed. 2. Records for the 1st and 2nd 2021 chemistry PT events did not include the attestation statements signed by the TP and LD or designee stating that PT samples were integrated into the routine patient workload using routine methods. 3. During the survey on 05/02/2022 at 3:45 pm, the TP confirmed that the 2021 chemistry 1st and 2nd PT event records did not include the signed attestation statements.</p>
<b>D2094</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p>

This STANDARD is not met as evidenced by:  
Based on review of proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to document the investigation into the root cause of and remedial actions taken for unacceptable results for two chemistry analytes in the 2020 3rd PT event. Findings: 1. The laboratory scored a 60% for total cholesterol and a 20% for low-density lipoprotein (LDL) cholesterol in the 2020 chemistry 3rd PT event. 2. Laboratory PT records for the 2020 chemistry 3rd event failed to include the investigation into the root cause of the unacceptable scores and the remedial actions taken for the test system and patient results that were potentially affected to ensure accurate and reliable test results. 3. During the survey on 05/02/2022 at 3:45 pm, the TP confirmed that the 2020 chemistry 3rd PT event records did not include documentation of the investigation and corrective actions taken for unacceptable total cholesterol and LDL results.

**D5403**

PROCEDURE MANUAL  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on review of the standard operating procedure manual (SOPM) and interview with the testing person (TP), the laboratory failed to have written policies and procedures for all required activities performed by the testing personnel. Findings: 1. According to the TP, the specimens are collected, labeled and entered into the electronic medical records (EMR) by a contracted phlebotomy service. When the specimens are received by the laboratory staff they are required to identify improperly and mislabeled specimens. The SOPM does not define what would constitute an improperly labeled and mislabeled specimen and what corrective actions should be taken. 2. According to the TP, the patient specimens are stored in the refrigerator for seven days prior to disposal. The SOPM states that the specimens collected for testing are stable for seven days at 2-8 degrees Celsius. The SOPM does not define how long patient specimens are stored before they are discarded into the biohazard waste container. 3. According to the TP, complaints are received via email from the physicians at the practice and the investigation is documented on a "Maryland Endocrine Laboratory Complaint Form." The SOPM does not include the approved

"Maryland Endocrine Laboratory Complaint Form", define how complaints are received, investigated, documented and reviewed by the appropriate laboratory staff to ensure the accuracy and reliability of patient test results. 4. During the survey on 05/02/22 at 3:30 PM, the TP confirmed that the laboratory SOPM did not include written procedures for all laboratory activities performed by the laboratory staff.

**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 monthly maintenance logs and interview with the testing person (TP), the laboratory failed to document performance of routine maintenance with at least the frequency specified by the manufacturer. Findings: 1. The laboratory performed testing using a cobas e 411 analyzer and a cobas integra 400 plus analyzer. 2. The laboratory recorded all maintenance activities on monthly logs for each analyzer that were provided by the manufacturer and listed all maintenance activities and the specified frequency to perform each activity. 3. Monthly maintenance logs for both analyzers were reviewed from 08/2020-04/2022 for a total of 21 months. 4. The cobas e 411 analyzer maintenance logs stated to replace the pinch valve tubing monthly when using Sample Reception Mode or every two months when not using Sample Reception Mode. This activity was not documented as performed for 21 of 21 months reviewed. 5. The cobas e 411 analyzer maintenance logs stated to clean rinse stations every two weeks and to perform liquid flow cleaning every two weeks or 2500-3000 cycles, whichever comes first. These activities were documented as performed once a month, not every two weeks, for five of 21 months reviewed (01/2021, 03/2021, 06/2021, 10/2021, and 11/2021). 6. The cobas integra 400 plus analyzer maintenance logs stated to clean the waste box fitting every 30 days or after 2000 ISE tests are run. This activity was not documented as performed for five of 21 months reviewed (09/2021, 10/2021, 11/2021, 12/2021, and 03/2022). 7. The cobas integra 400 plus analyzer maintenance logs stated to clean the ISE tower manually every 30 days. This activity was not documented as performed for three of 21 months reviewed (09/2021, 11/2021, and 12/2021). 8. The cobas integra 400 plus analyzer was replaced in 07/2021 and the monthly maintenance logs began to include quarterly maintenance activities. 9. The cobas integra 400 plus analyzer maintenance logs stated to clean the external water and fluid waste reservoirs, clean and lubricate the rotor, and replace the external water reservoir filter every three months. Since the new analyzer was installed in 07/2021, the external water reservoir filter was documented as replaced for one of 10 months reviewed (12/2021) and all other activities were documented as performed for 0 of 10 months reviewed. 10. The cobas integra 400 plus analyzer maintenance logs stated to replace the ventilation filters quarterly or after 500 hours in Running or Standby. This activity was documented as performed in one of 10 months reviewed (03/2022). 11. During the survey on 05/02/2022 at 3:45 pm, the TP confirmed that maintenance activities were not documented as performed with at least the frequency specified by the manufacturer.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on review of instrument records and interview with the testing person (TP), the laboratory failed to verify the pipet calibration for one of three years reviewed.

Findings: 1. The laboratory sent the pipet to an outside company for calibration verification. 2. Records for pipet number J115088E showed that calibration verification was performed on 12/09/2019 and 12/20/2021. 3. The TP stated that pipet calibration verification should be performed annually. 4. During the survey on 05/02/2022 at 3:45 pm, the TP confirmed that calibration verification for pipet J115088E was not performed in 2020.

**D6012**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(i)

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)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care;

This STANDARD is not met as evidenced by:

Based on review of the standard operating procedure manual (SOPM) and interview with the testing person, the laboratory director failed to ensure that the validation performed on the two new chemistry analyzers had been approved and failures investigated. Findings: 1. The laboratory records show that a validation was performed and completed on July 23, 2022 by the manufacturer of the Cobas e411 and Cobas 400 plus analyzers and were not approved prior to being put into use for patient testing. 2. The linearity validation "Evaluation of Results" for free thyroxine 4 (FT4) shows that "The results are NON-LINEAR." The worksheet summary showed that standard #4 and #5 had failed and there was no documented investigation of the failure. 3. During the survey on 05/02/22 at 3:30 PM, the testing person confirmed that there was no the validation documentation had not been reviewed and approved and the FT4 linearity failure had not been investigated.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
Based on review of the standard operating procedure manual (SOPM) and interview with the testing personnel, the laboratory director failed to ensure that the laboratory had an approved verification procedure to perform the initial validation of the two new chemistry instruments to ensure the laboratory provided accurate and reliable test results. Findings: 1. The SOPM failed to provide written protocols that list specific instructions to be followed when performing the validation of the two new chemistry analyzer in July 2021.for accuracy, precision, reportable range, normal patient values, comparison of methods, linearity and corrective actions when limits were not met. 2. During the survey on 05/02/22 at 3:30 PM, the testing person confirmed that there was no written validation protocol for the two new chemistry analyzers.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the standard operating procedure manual (SOPM) and interview with the testing person (TP), the laboratory director (LD) failed to specify responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results were available and accurate. Findings: 1. The SOPM failed to include written responsibilities and duties of the clinical consultant. 2. The job description on the SOPM for the Medical Laboratory Directors responsibilities states, "Ensure quality control, maintenance, temperature charts, proficiency, etc. are being reviewed weekly, initially, and monthly thereafter. This review is delegated to the Technical Consultant. A report will be forwarded to the Medical Laboratory Director, via e-mail from the Technical Consultant, after each review." 3. According to the "Laboratory Personnel Report (CLIA)" that was signed by the LD, the technical consultant (TC) is also the LD. At this time the "Laboratory Technologist/Technician" performing day to day reviews and the TC is performing quarterly reviews. 4. During the survey on 05/02/22 at 3:45 PM, the TP confirmed that the SOPM failed to clearly delegate the duties and responsibilities of the LD, TC, and "Laboratory Technologist/Technician."

**D6043**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:

Based on review of the Levy-Jennings (L-J) Report and interview with the testing person (TP), the technical consultant (TC) failed to ensure that remedial actions were taken and documented in a timely manner when quality control (QC) results were not within acceptable limits. Findings: 1. Review of the QC results for glycosylated hemoglobin (A1C) for the month of January 2022 showed that the results for the low level, A1C\_GEN3 I, had a mean of 5.13 and the value for plus 3 standard deviations (SD) and minus 3 SD were also 5.13. The L-J graphs did not have the correct reference ranges to properly evaluate the QC results. The L-J graph showed that 16 of 22 results were less than 3 SD and no investigation of the QC failures was documented. The records show that the L-J errors were not addressed and documented until 03/09/22. 2. The January 2022 QC section had a three page report of patient A1C results from January 18, 19, 20, 21, 24, and 25/ 2022. There were handwritten A1C results next to 38 of the 90 patients listed. The TP stated that, via an email, on 01/23 /22 one of the doctors had concerns with "Lower than expected A1C numbers" and on 01/25/22 the TP communicated that the low level A1C QC was running low. The analyzer was due for a preventative maintenance (PM) and A1C results could be rerun after the PM. 3. On 03/09/22 the TP documented the following investigation on the January 2022 L-J printout- \*QC running low. Tech called. PM maintenance performed \*Rerun Pts. -see attached. Baseline 5.13 Accumulation 3.61 adjusted low /high. There was an updated L-J printed on 03/09/22 showing a mean of 5.01, plus 2 SD was 6.41 and minus -2 SD was 3.61. The control, A1C\_GEN3 I, showed 5 consecutive QC values were minus the 2 SD acceptability limit of 3.61 between 01/20 /22 to 01/26/22. The QC result was still minus 2 SD after the PM was performed on 01 /25/22. 4. The "Maryland Endocrine Laboratory Complaint Form" was not used to document the description of the complaint, which doctors wanted the A1C repeated after the PM, were any other patient affected by the unacceptable QC results. 5. The TP failed to document the investigation until 03/09/22. The records failed to include why the specimens were retested, which specimens had been requested to be retested, when they were retested, was the complaint substantiated, were other patients affected and if what was the resolution. 6. The laboratory director initiated the January 2022 L-J printout on 04/26/22 and failed to ensure that the TP used the correct form and documented the investigation in a timely manner. 7. During the survey on 05/02/22 at 3:30 PM, the TP confirmed that the laboratory records did not include documented remedial actions in a timely manner.