| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D2013404 | 08/03/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Methodist Hospital For Surgery | 17101 Dallas Parkway, Addison, TX | |

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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| **D0000** | An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) 2021 records (1st and 2nd events) and staff interview, the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 2 Chemistry events in 2021. Findings included: 1. Review of laboratory records revealed the laboratory tested the following analytes for blood oximetry on the Gem 4000 blood gas analyzer (Serial Number:19102468): a. Hemoglobin b. Hematocrit 2. Review of API test records revealed the following |

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| | statement: "Attestation Statement SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of API PT records from 2021 revealed the laboratory director failed to sign the attestation form for the following event: 2021 Chemistry 1st Event 4. During an interview on 08/03/2021 at 3:05 PM in a facility conference room, the laboratory director confirmed the above findings. |
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) records for 2020 (Hematology 1st, 2nd and 3rd events) and 2021 (Hematology 1st event) and confirmed in interview, the laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program for 3 of 4 events in 2020 and 2021. Findings Included: 1. Review of laboratory records revealed the laboratory performed manual blood cell identification on hematology specimens if criteria were met for manual blood cell identification. 2. Review of API PT records from 2020 and 2021 revealed the following events with ungraded performance: a. Hematology 1st Event 2020 Blood Cell ID (Educational): Sample ECl-01 Reported Result: Hypochromic Red Blood Cell Expected Result: See commentary. Performance: Not Graded Sample ECl-02 Reported Result: Eosinophil, all stages Expected Result: Eosinophil, all stages Performance: Not Graded Sample ECl-03 Reported Result: Lymphocyte, normal Expected Result: Lymphocyte, normal Performance: Not Graded Sample ECl-04 Reported Result: Microcytic Red Blood Cell Expected Result: Microcytic Red Blood Cell Performance: Not Graded Sample ECl-05 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed the following statement for corrective action taken: "All analytes reported were 100%. No problems noted." b. Hematology 3rd Event 2020 Blood Cell ID (Educational): Sample ECl-11 Reported Result: Nucleated Red Blood Cell Expected Result: Nucleated Red Blood Cell Performance: Not Graded Sample ECl-12 Reported Result: Lymphocyte, normal Expected Result: Lymphocyte, normal Performance: Not Graded Sample ECl-13 Reported Result: Platelets, giant Expected Result: See commentary. Performance: Not Graded Sample ECl-14 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded Sample ECl-15 Reported Result: Platelets, clumped Expected Result: Platelets, clumped Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed the following statement for corrective action taken: "All analytes reported were 100%. No problems noted." c. Hematology 1st Event 2021 Blood Cell ID (Educational): Sample ECl-01 Reported Result: Dacrocyte, tear drop cell Expected Result: Dacrocyte, tear drop cell Performance: Not Graded Sample ECl-02 Reported Result: Lymphocyte, normal Expected Result: Lymphocyte, normal Performance: Not Graded Sample ECl-03 Reported Result: Platelets, large. Expected Result: See commentary. Performance: Not Graded Sample ECl-04 Reported Result: Neutrophil, |

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| | band Expected Result: Neutrophil, band Performance: Not Graded Sample ECl-05 Reported Result: Neutrophil with toxic granulation Expected Result: Basophil, all stages Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed the following statement for corrective action taken: "No problems noted. Reviewed and accepted." The laboratory failed to provide documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program. 3. During an interview on 08/03/2021 at 3:05 PM in a facility conference room, the laboratory director confirmed the above findings. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records for 2020 (Hematology 1st, 2nd and 3rd events) and 2021 ( Hematology 1st event) and staff interview, the laboratory failed to follow its own policy for evaluating the accuracy of analytes that were not graded by the proficiency testing program for 3 of 4 events in 2020 and 2021. Findings Included: 1. Review of laboratory's policy, "Proficiency Testing" (reviewed by the laboratory director on 11/20/2020) stated the following: "PT Performance Results: Review PT result scores on the CMS summary page to determine is all regulated analytes were scored for CLIA regulatory purposes. Evaluate PT results with the PT investigation Checklist as a guide to assist in investigating and documenting. Review PT results: did any analytes receive an automatic 100% because they could not be graded? If yes, then perform a self-evaluation, since the score does not reflect actual laboratory performance." 2. Review of API PT records from 2020 and 2021 revealed the following events with ungraded performance: a. Hematology 1st Event 2020 Blood Cell ID (Educational): Sample ECl-01 Reported Result: Hypochromic Red Blood Cell Expected Result: See commentary. Performance: Not Graded Sample ECl-02 Reported Result: Eosinophil, all stages Expected Result: Eosinophil, all stages Performance: Not Graded Sample ECl-03 Reported Result: Lymphocyte, normal Expected Result: Lymphocyte, normal Performance: Not Graded Sample ECl-04 Reported Result: Microcytic Red Blood Cell Expected Result: Microcytic Red Blood Cell Performance: Not Graded Sample ECl-05 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed the following statement for corrective action taken: "All analytes reported were 100%. No problems noted." b. Hematology 3rd Event 2020 Blood Cell ID (Educational): Sample ECl-11 Reported Result: Nucleated Red Blood Cell Expected Result: Nucleated Red Blood Cell Performance: Not Graded Sample ECl-12 Reported Result: Lymphocyte, normal Expected Result: Lymphocyte, normal Performance: Not Graded Sample ECl-13 Reported Result: Platelets, giant Expected Result: See commentary. Performance: Not Graded Sample ECl-14 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded Sample ECl-15 Reported Result: Platelets, clumped Expected Result: Platelets, clumped Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed the following statement for corrective action taken: "All analytes reported |

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