| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D2041010 | 03/05/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Baylor College Of Medicine | 333 N Texas Avenue, Webster, 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** | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on the direct observation of the surveyor and confirmed in an interview, the laboratory failed to have QC slides for Hematoxylin and Eosin (H&E) stain to predict stain characteristics prior to patient testing for 5 of 5 days H&E stain was in use in 2023. The findings were: 1. The surveyor's direct observation on 03/05/2024 at 10:35 am in the laboratory revealed no H&E QC slides for 5 of 5 days H&E was in use. 02 /16/2023 08/18/2023 09/15/2023 10/20/2023 12/01/2023 2. In an interview on 03/05 /2024 at 10:39 am in the laboratory, the laboratory director confirmed the above findings. Key: QC=Quality Control |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must 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 |

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| | results.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's CMS 209 form, policy, personnel competency assessment records, and confirmed in an interview, the laboratory director failed to ensure personnel competency assessment was documented prior to working independently. (Refer to D6127 and D6128). |
| **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 the review of the laboratory's CMS 209 form, policy, personnel competency assessment records, and confirmed in an interview, the technical supervisor failed to document 1 of 4 initial competency assessment and 3 of 4 semiannually competency assessment prior to work independently. The findings were: 1. Review of the laboratory's CMS 209 form titled Laboratory Personnel Report (CLIA), signed by the laboratory director on 03/05/2024, revealed 5 testing personnel (TP) and the laboratory director is also the technical supervisor. 2. Review the laboratory's policy titled PROFESSIONAL COMPETENCY under POSSIBLE CRITERIA CATEGORIES FOR THE ASSESSMENT revealed "...5. Grossing competency and /or..." and under ASSESSMENT PROCEDURE revealed "1. Assessment is by the Medical Director is done initially during pathologist's first 6 month then annual thereafter." In addition, under DOCUMENTATION revealed "the Medical Director will document assessment criteria on annual professional competency summary form." 3. Review of the personnel competency records revealed the technical supervisor failed to document 1 of 4 initial competency assessment and 3 of 4 initial and semiannually competency assessment during the first year prior to work independently. Missing initial competency assessment TP#3 Hired Date: 05/28/2023 Missing initial and semiannual competency assessment during the first year TP#1 Hired Date: 02/17/2022 TP#2 Hired Date: 02/29/2008 TP#5 Hired Date: 07/21/2022 4. In an interview on 03/05/2024 at 10:25 am in the laboratory, the laboratory director confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services |
| **D6128** | 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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's CMS 209 form, policy, personnel competency assessment records, and confirmed in an interview, the technical supervisor failed to |

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| | document 2 of 4 annual competency assessment. The findings were: 1. Review of the laboratory's CMS 209 form titled Laboratory Personnel Report (CLIA), signed by the laboratory director on 03/05/2024, revealed 5 testing personnel (TP) and the laboratory director is also the technical supervisor. 2. Review the laboratory's policy titled PROFESSIONAL COMPETENCY under DOCUMENTATION revealed "the Medical Director will document assessment criteria on annual professional competency summary form." 3. Review of the personnel competency records revealed the technical supervisor failed to document 2 of 4 annual competency assessment prior to work independently. TP#1 Hired Date: 02/17/2022 TP#2 Hired Date: 02/29 /2008 4. In an interview on 03/05/2024 at 10:25 am in the laboratory, the laboratory director confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services |