| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D2279979 | 08/22/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Whmh I Llc | 13782 Plantation Road Suite #101, Fort Myers, FL | |

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 announced CLIA recertification, survey was conducted at WHMH I LLC on 8/20-8/22/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows: |
| **D6005** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(c)<br><br>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the Laboratory Director failed to establish a policy to be onsite once every six months and document the onsite visits from 1/1/2025 to 8/20/2025. Findings included: 1. The Laboratory Policy Manual was approved by the Laboratory Director on 3/17/2025, there was no policy to reflect the Laboratory Director would be onsite at least once every six months or how an onsite visit would be documented. 2. The Laboratory Director confirmed the above via email on 8/22/2025 at 5:42 p.m. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>(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; |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview, the Laboratory Director failed to ensure that prior to testing patient specimens, all personnel had demonstrated that they could perform all testing operations reliably to provide and report accurate results for three of three Testing Personnel (TP#A, TP#B, and TP#C). Findings included: 1. The CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 8/11/25 listed three Testing Personnel TP#A, TP#B, and TP#C. TP #A, who provided documents and answered questions during the onsite survey, stated on 8/20/25 at 11:40 a.m. TP#A's date of hire (DOH) in the laboratory was 11/11/2024, TP#B's DOH in the laboratory was 4/1/2024, and TP#C's DOH in the laboratory was 2/1/2025 and that each testing personnel began testing patients as soon as training was completed. Training documents showed the dates for each of the three testing personnel was the date of hire in the laboratory. 2. The Laboratory Policy Manual approved by the Laboratory Director on 3/17/2025, showed the Laboratory Director was to confirm personnel were checked to assure their competency prior to reporting results. 3. TP#A's, TP#B's, and TP#C's personnel records failed to include initial competency prior to performing patient testing as required. There was no evidence the Laboratory Director had ensured the procedure for personnel competencies had been followed. 4. The Laboratory Director confirmed via email on 8/22/25 at 5:42 p.m. there was no record of initial competency prior to performing patient testing as required. |