| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 44D1021135 | 11/21/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Cleveland Family Health Care Center | 2020 Westland Drive Sw, Cleveland, TN | |

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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| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of quality control (QC) records, lack of documentation, and staff interviews, the laboratory failed to document corrective actions for unacceptable QC of their hematology analyzer for 7 of 37 patient testing days in November 2023 and January 2024. The findings include: 1. A random review of the laboratory's complete blood count (CBC) QC data for the Horiba Micros analyzer (ID: 206CS91737) revealed the following: - The laboratory performed QC 19 days in November 2023 using three levels (Low, Normal, High) of Horiba ABX Minotrol 16 (Lot: MX444) quality control material. The analyzer recorded unacceptable results on 11/01/2023 at 8:46 a.m. and 9:03 a.m. for the Low-level QC. - The laboratory performed QC 18 days in January 2024 using three levels (Low, Normal, High) of Horiba ABX Minotrol 16 (Lot: MX445) quality control material. The analyzer recorded unacceptable results on 01/04/2024 at 8:07 a.m. for the Low-level QC and 8:07 a.m. for the Normal-level QC; 01/05/2024 at 10:04 a.m. and 10:10 a.m. for the High-level QC; 01/09/2024 at 8:17 a.m. for the Normal-level QC, 8:20 a.m. and 8:22 a.m for the High-level QC; 01/11/2024 at 8:29 a.m. for the Normal-level QC, 8:33 a.m. and 8:34 a.m for the High-level QC; 01/12/2024 at 8:31 a.m., 8:32 a.m., 8:38 a.m., and 8:40 a. m. for the Normal-level QC and 8:42 a.m. for the High-level QC; 01/22/2024 at 8:33 a.m. and 8:35 a.m. for the High-level QC. 2. No documentation of corrective actions |

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| | or troubleshooting for unacceptable QC was available for 11/01/2023, 01/04/2024, 01 /05/2024, 01/09/2024, 01/11/2024, 01/12/2024, or 01/22/2024. 3. The findings were confirmed by an interview with the Lab Coordinator on 11/21/2024 at 12:00 p.m. |
| **D6055** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory observation, review of patient test records, testing personnel records, and staff interviews, the technical consultant failed to reevaluate one of two testing personnel (TP) competencies for the use of the Sysmex XP-300 hematology analyzer before patient testing began in October 2024. The findings include: 1. Observation of the laboratory on 11/21/2024 at 09:00 a.m. revealed that the laboratory used a Sysmex XP-300 (ID: C6323) for complete blood count (CBC) testing. This instrument was new since the last survey date and replaced their Horiba Micros (ID: 206CS91737) CBC analyzer. 2. A review of patient test records revealed the laboratory began patient testing with the Sysmex XP-300 on 10/29/2024 (Patient ID: 0516). Further review revealed that TP-1 and TP-2 performed CBC testing using the new Sysmex XP-300. 3. A review of testing personnel records revealed the technical consultant had not documented training or reassessed the competency of TP-2 for the use of the new Sysmex XP-300 analyzer. 4. The findings were confirmed by an interview with the Lab Coordinator on 11/21/2024 at 12:00 p.m. |