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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2085618 | (X3) Date Survey Completed 08/22/2023 |
| Name of Provider or Supplier Tlc Complete Care | Street Address, City, State 7330 South Staples Street, Corpus Christi, 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. |
| D5429 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's maintenance records from May 2022 to July 2023 for the Piccolo Xpress instrument, and staff interview it was revealed the laboratory failed to have documentation of performing monthly maintenance for 3 of 15 months. The findings include: 1. A review of the laboratory's Piccolo Xpress maintenance records from May 2022 to July 2023 revealed the following monthly maintenance was required to be performed: - Clean Filter 2. Further review of the Piccolo Xpress maintenance records from May 2022 to July 2023 revealed the laboratory failed to have documentation of performing the monthly maintenance for the following 3 of 15 months: June 2022 October 2022 February 2023 3. The laboratory was asked to provide documentation of performing the required maintenance. No documentation was provided. 4. An interview with the technical consultant on 08/22/2023 at 1320 hours in the office - after his review of the records- confirmed the findings.</p> |
| D5469 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p> |

Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, review of the laboratory's hematology quality control records from July 2022 to August 2023, and staff interview, it was revealed the laboratory failed to have documentation of verifying quality control material prior to being placed into service for 5 of 5 lots. The findings include: 1. A review of the laboratory's policy titled "Quantitative Quality Control" (approved by the laboratory director on 11/13/2019) under the section titled "New Lots of QC Material" revealed: "Whenever a new lot number of QC material is received into the laboratory, certain steps must be accomplished in order to ensure the NEW lot is functioning properly and that instrument problems will be identified as soon as any occur. 1. Perform Crossover Studies... a. Before the old lot expires, run each level of new lot of QC material (Low, Normal, and High) a number of times. b. Compare the results of the new lot to those of the current lot in use. c. Compare the results of the new lot to those of the current lot in use. d. Ideally, run the new lot number levels again, at least once daily, for several days. Attempt to gather 10 data points for each level of new lot prior to PIU (putting in use)." 2. A review of the laboratory's quality control records from July 2022 to August 2023 (as of the day of the survey) revealed the laboratory failed to have documentation of performing the crossover studies for 5 of 5 lots of the hematology EightCheck-3WP X-tra controls. The lots identified were: a) Lot: 2194 In use: 7/27/2022 to 10/18/2022 b) Lot: 2278 In use: 10/19/2022 to 01/10/2023 c) Lot: 2362 In use: 01/11/2023 to 04/04/2023 d) Lot: 3081 In use: 04/05/2023 to 06/24/2023 e) Lot: 3165 In use: 06/25/2023 to current 3. The laboratory was asked to provide documentation of performing the crossover studies as required by its policy. No documentation was provided. 4. An interview with the technical consultant on 08/22/2023 at 12:08 hours in the office - after her review of the records- confirmed the findings.