

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0921162	(X3) Date Survey Completed 08/12/2024
Name of Provider or Supplier Contemporary Family Medicine	Street Address, City, State 200 East Boothe Street Suite 100, Cleveland, 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
D0000	An announced survey of the laboratory was conducted on 08/12/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's submitted form "Listing of Laboratory Personnel", proficiency testing (PT) records, policies/procedures and staff interview, the laboratory failed to incorporate PT into regular patient workload for 2 of 3 personnel who routinely performed complete blood count (CBC) testing in the laboratory in 2023, testing person (TP) number 2 and TP number 4. Findings included: 1. Review of laboratory's submitted form "Listing of Laboratory Personnel" revealed there were 3 testing personnel in 2023 (TP1, TP2 and TP4) that routinely performed CBC testing. 2. Review of laboratory's American Proficiency Institute PT records from 2023 revealed all testing events were performed by the same personnel, TP number 1. There was no documentation of PT performance with routine patient testing for TP number 2 or TP number 4 (as indicated on submitted form "Listing of Laboratory Personnel"). 3. Review of laboratory's policies/procedures revealed there were no protocols in place for ensuring that PT is incorporated into regular patient workload with rotation among laboratory's testing personnel. 4. In an interview on 08/12/2024 at 1010 hours in the laboratory, TP number 1 (as indicated on submitted Form CMS 209) confirmed the findings.</p>

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of laboratory's test records, manufacturer instructions, laboratory's policies/procedures and staff interview, the laboratory failed to define and follow protocols for addressing flagged sample results for 1 of 1 hematology testing platforms used by the laboratory in 2023 and 2024, the Sysmex XNL-330. Findings included: 1. Review of laboratory's test records from August 2024 revealed patient instrument reports had the "*" annotation next to the results as follows: Sample tested: 08/08/2024 13:26:52 Results with "*": Neutrophils, Lymphocytes, Monocytes, IG (Immature Granulocytes) Sample judgement: Positive WBC (white blood cells) IP Message: "Blasts/Abn (abnormal) Lympho?" Sample tested: 08/08/2024 10:36:00 Results with "*": Neutrophils, Lymphocytes, Monocytes, IG Sample judgement: Positive WBC (white blood cells) IP Message: "Blasts/Abn Lympho?" Sample tested: 08/06/2024 14:16:31 Results with "*": Neutrophils, Lymphocytes, Monocytes, Eosinophils, IG Sample judgement: Positive WBC (white blood cells) IP Message: "Neutrophilia, Monocytosis, IG Present" Sample tested: 08/06/2024 10:02:17 Results with "*": Neutrophils, Lymphocytes, Monocytes, IG Sample judgement: Positive WBC (white blood cells) IP Message: "Blasts/Abn Lympho?" 2. Review of manufacturer instructions for laboratory's hematology analyzer "Automated Hematology Analyzer XN-L Series... Troubleshooting" (document code: BW212660 en-am, version 3, last revised 04/2020) revealed: "With respect to the following IP messages, when a sample judgement is Positive, the results are regarded as having low reliability due to the abnormality, and "*" is displayed to the right of the data..." 3. Review of manufacturer's "Sysmex XN-L Series Flagging Guide" (document 1399-LSS, revision 3, February 2021) revealed: "Suspect, Blast/Abn Lympho? ... The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting." 4. Review of laboratory's policies/procedures revealed there were no protocols in place for confirming results with "*" annotation. 5. In an interview on 08/12/2024 at 1010 hours in the laboratory, TP (testing person) number 1 (as indicated on submitted Form CMS 209) confirmed the findings.