Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0313243	04/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dowling Medical Clinic	2569 N Washington Ave, Brownsville, 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
D0000	During a routine recertification survey conducted on 04/14/25, the laboratory was found out of compliance with the following condition: 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on laboratory observation, review of quality control records and staff interview, the laboratory failed maintain to records of quality control ranges used for three of three primary lots (nine of nine sub-lots) reviewed from 2024 and 2025. The findings include: 1. Laboratory observation on 04/14/25 at 10:05 a.m. revealed the Sysmex XP-300 instrument used for performing patient testing for Complete Blood Count with automated white blood cell differential (CBC w/Diff). 2. A review of the laboratory's quality control records revealed the following: The laboratory's CBC w/Diff quality control ranges did not match the manufacturer's package insert ranges for three of three primary lots (4051, 4219, and 4303), nine of nine individual lots (40510710, 40510711, 40510712, 42190710, 42190711, 42190712, 43030710, 43030711, 43030712). Lot 4051 was used from 03/07/24 to 05/29/24, lot 4219 was used from 08 /02/24 to 11/13/24, lot 4303 was used from 11/14/24 to 2/4/25. 3. The lead testing person stated the following during an interview on 04/14/25 at 2:30 p.m.: The laboratory scanned the manufacturer's ranges at the beginning of the lot's use, but no record of scanned ranges was retained. When the laboratory finished with quality control lots, the auto-set button was hit, and quality control targets and ranges were recalculated based on the values obtained during the lot's use. Then, the quality

	control reports were printed for retention and review. She stated the control records did not reflect the quality control ranges that the laboratory entered at the beginning of the lot use. This confirmed the survey findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on direct observation, review of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records, lack of documentation and staff interview, the laboratory failed to retain three of four proficiency testing performance evaluations from 2024 and 2025. The findings include: 1. Laboratory observation on 04/14/25 at 10:05 a.m. revealed the Sysmex XP-300 instrument used for performing patient testing for Complete Blood Count with automated white blood cell differential (CBC w/Diff). 2. A review of the laboratory's WSLH CBC w/Diff proficiency testing records revealed no performance evaluation reports for 2024 events one, two and three. 3. The lead testing person confirmed the survey findings during an interview on 04/14/25 at 11:30 a.m.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of proficiency testing records, lack of documentation and staff interview, the laboratory failed to print and review three of four proficiency testing performance evaluations from 2024 and 2025. This deficiency was cited on the previous recertification survey conducted in February 2024 and compliance was not maintained. The findings include: 1. Laboratory observation on 04 /14/25 at 10:05 a.m. revealed the Sysmex XP-300 instrument used for performing patient testing for Complete Blood Count with automated white blood cell differential (CBC w/Diff). 2. A review of the laboratory's proficiency testing records revealed the laboratory had not printed and reviewed the performance evaluation reports for 2024 events one, two, and three. 3. The lead testing person confirmed the survey findings during an interview on 04/14/25 at 11:30 a.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains,

and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 laboratory observation, a review of the Sysmex XP-300 operator's manual, a review of patient CBC w/Diff results, a review of the laboratory's procedure manual, and staff interview, the laboratory procedure failed to include actions to take for flagged CBC w/Diff results, failed to include the reportable range as determined during validation, failed to include actions to take if results are outside the reportable range, failed to include critical/alert values, and failed to include the procedure for patient test result entry. The findings include: 1. Laboratory observation on 04/14/25 at 10:05 a.m. revealed the Sysmex XP-300 instrument used for performing patient testing for Complete Blood Count with automated three-part white blood cell differential (CBC w/Diff). 2. A Review of the Sysmex XP-300 Operator's manual revealed the following regarding instrument flags and possible causes: "When the histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following: [WL]-Probable cause-Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. [RL]-Probable cause-Presence of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, etc. [PL]- Effects of cryoglobulins, fragmented red blood cells, or cellular fragments of white blood cells, etc. [WU] - Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc. [RU]-Effects of cold agglutinin, inclusion of white blood cells, etc. [PU]-Increase of large platelets, inclusion of fragmented red blood cells, precipitation of cryoglobulins, etc. [DW] (RBC) Significant anisocytosis, etc. [DW] (PLT) Inclusion of fragmented red blood cells, non-uniformity in size of platelets, effects of cryoglobulins. [MP] (RBC) Effects of anemia treatment or blood transfusion causing the presence of cells of multiple sizes. [MP] (PLT) Platelet aggregation, sample with low values for platelets. [T1] Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, etc. [T2]- Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc. [F1], [F2], [F3]-Presence of CML or other immature granulocytes, sample with high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc. [AG] Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Probable cause is platelet agglutination, which does not alter WBC count but may result in decreased platelet count. Suggested manufacturer actions included checking a smear, centrifuging the sample, and replacing plasma with saline, warming the sample, and performing manual cell counts. 3. A review of patient instrument printouts revealed the following: Four of five patients reviewed had instrument flags. Patient number one, performed on 11/01/24, platelet count was flagged with "AG*"; the mixed and

	neutrophil % parameters were flagged with "T2". Patient number three, performed on 04/01/24, platelet count was flagged with "AG*". Patient number four, performed on 04/01/24, platelet count was flagged with "AG*"; the white blood cell count and white blood cell differential were flagged with "WL*". Patient five, performed on 02/03/25, platelet count was flagged with "AG*"; the mixed and neutrophil % parameters were flagged with "T2". All four patient results were reported. None of the patients with flagged results had documented corrective action. 4. A review of the daily patient logs revealed the following: On 11/01/24, four of the 12 patient CBCs performed had instrument flags. Three of the four were not repeated. On 02/03/25, six of the 16 patient CBCs performed had instrument flags. None of the six were repeated. 5. A review of the laboratory's Sysmex XP-300 procedure revealed that it did not include the reportable range for the instrument as determined during instrument validation, actions to take if results were outside the reportable range of the instrument, actions to take when CBC results were flagged, or the procedure for reporting patient CBC w /Diff results. The manual also included instructions for dilution of samples that the laboratory did not perform. 6. The lead testing person confirmed the survey findings during an interview on 04/14/25 at 2:45 p.m. Word Key: %=Percent CML=Chronic Myelogenous Leukemia
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on patient test orders, final patient test results and staff interview, the laboratory failed to report results for Red Blood Cell count (RBC) and Mixed/Mono White Blood Count results and the final patient test report failed to include units of measure for the white blood cell count and hematocrit analytes for five of five patients reviewed from 2024 and 2025. The findings include: 1. A review of patient testing orders revealed that Complete Blood Counts (CBCs) were ordered for patients one, two, three, four, and five. 2. A review of the same five final patient test reports (patients one, two, three, four, and five) revealed that the laboratory did not report the RBC count and Mixed/Mono white blood cell differential. 3. The final patient report for patients one, two, three, four, and five did not include units of measure for white blood cell count and hematocrit analyte. 4. The lead testing person confirmed the survey findings during an interview on 04/14/25 at 2:45 p.m.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on laboratory observation, review of laboratory personnel and quality records, and staff interview, the laboratory director did not qualify to perform technical consultant duties due to a lack of documentation of testing experience in hematology. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on laboratory observation, laboratory records, and staff interview, the laboratory director did not qualify to perform technical consultant duties due to a lack

	of documentation of non-waived testing experience or training in hematology. The findings include: 1. Laboratory observation on 04/14/25 at 10:05 a.m. revealed the Sysmex XP-300 instrument used for performing patient testing for Complete Blood Count with automated three-part white blood cell differential (CBC w/Diff). 2. A review of personnel records, quality control records, and proficiency testing records revealed that the laboratory director performed the technical consultant tasks of competency assessment, review of quality control records, signing attestation statements, and reviewing proficiency testing documents. 3. A review of personnel records revealed no documentation that the laboratory director had the necessary testing experience in hematology to perform technical consultant duties. 4. The lead testing person confirmed the survey findings during an interview on 04/14/25 at 2:45 p.m.