Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0313391	01/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Medsouth Medical Center	1720 Woodlawn Avenue Suite 1, Dyersburg, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and staff interviews, the laboratory failed to retain complete PT records for two years (five of six events reviewed) in 2022 and 2023. The findings include: 1. Review of the laboratory's MLE PT records revealed the following documents were not retained: Performance evaluations: 2022 Event one, 2022 Event three, 2023 Event one, 2023 Event two, or 2023 Event three. PT attestation statements: 2023 Event one, 2023 Event two, 2023 Event three. 2. Interview on 01/30/2024 at 11:30 am with testing person six and the clinic manager confirmed the laboratory failed to retain performance evaluations reports and attestation statements for a period of two years.
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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's complete blood count (CBC) quality control (QC) records, lack of documentation, and staff interview, the laboratory failed to retain QC limits used for five of five parent lots/fifteen of fifteen sub-lots reviewed in 2022 and 2023. The findings include: 1. Observation of the laboratory on 01/30/2024 at 9:30 am revealed the Sysmex XN 330 (Serial #13835) instrument used for CBC patient testing. 2. Review of the laboratory's CBC QC records revealed the following: Lot 32931400 used on 12/19/2023 Lot 31251400 used on 06/07/2023 Lot 23221400 used on 01/04/2023 Lot 22381400 used on 09/09/2022 Lot 20701400 used on 05/10/2022 Each "parent" lot contained three sub-lots (low-01, normal-02, and high-03). 3. Documentation of QC ranges was not available on the date of the survey (01/30/2024). 4. Interview with testing person six on 01/30/2024 at 2:15 pm confirmed the laboratory failed to retain records of CBC QC ranges used in 2022 and 2023 for five of five parent lots/fifteen of fifteen sub-lots.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, testing personnel records, and staff interviews, the laboratory failed to follow its' own policy for assessing testing personnel (six of six reviewed) that performed CBC patient testing on the Sysmex XN 330 instrument in 2022 and 2023. The findings include: 1. Observation of the laboratory on 01/30/2024 at 9:30 am revealed the Sysmex XN 330 (Serial #13835) instrument used for CBC patient testing. 2. Review of the laboratory testing personnel competency assessment policy titled "Personnel" revealed "Testing personnel are evaluated initially after training, at 6 months, and then yearly" and "Competencies are completed using the six CLIA Assessment Components." 3. Review of the laboratory's personnel records revealed the following: Six of six testing personnel annual competency assessment did not include the six assessment elements (Direct observation of routine test performance, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, direct observation of instrument maintenance and function checks, assessment of test performance through blind testing, evaluation of problem solving skills) in 2023. Testing person four (hired 05/23/2022) did not have a competency assessment following initial training in 2022. 4. Interview with testing person six and clinic manager on 01/30/2024 at 12:00 pm confirmed the laboratory did not follow the personnel policy for competency assessment in 2022 and 2023 for six of six testing personnel. *Word key CLIA- Clinical Laboratory Improvement Amendments
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) 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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer operator's manual, and staff interview, the laboratory failed to follow the manufacturer requirements for QC following a reagent change. The findings include: 1. Observation of the laboratory on 01/30/2024 at 9:30 am revealed the Sysmex XN 330 (Serial #13835) instrument used for CBC patient testing. Testing person six described control frequency procedures. She stated that controls were not performed following a reagent change. 2. Review of the manufacturer operator's manual section "3.2.2 When QC analysis is performed" revealed QC was required "After replacement/replenishment of reagents." 3. Interview with testing person six on 01/30/2024 at 9:30 am confirmed the laboratory did not follow the manufacturer requirement when the laboratory did not perform QC after a reagent change on the Sysmex XN 330 CBC instrument.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory policy, laboratory QC records, lack of records, and staff interview, the laboratory failed to follow its' own policy for monthly printing and review of statistical CBC QC data in 2022 or 2023. The findings include: 1. Observation of the laboratory on 01/30/2024 at 9:30 am revealed the Sysmex XN 330 (Serial #13835) instrument used for CBC patient testing. 2. Review of the laboratory quality assurance policy titled "Quality Assurance Program Outline" section "Monthly Quality Control Records" revealed monthly "Summary Statistics" QC reports for CBC controls would be generated and reviewed by the laboratory director or technical consultant. 3. Review of the laboratory's CBC QC records revealed the following: Lot 32931400 used on 12/19/2023 Lot 31251400 used on 06/07/2023 Lot 23221400 used on 01/04/2023 Lot 22381400 used on 09/09 /2022 Lot 20701400 used on 05/10/2022 Each "parent" lot contained three sub-lots (low-01, normal-02, and high-03) 4. Monthly CBC QC "Summary Statistics" reports for 2022 or 2023 were not available for review on the date of the survey (01/30/2024). 5. Interview with testing person six on 01/30/2024 at 2:15 pm confirmed the laboratory failed to follow the quality assurance policy when monthly QC reports were not printed or reviewed for the CBC QC on the Sysmex XN 330 in 2022 or 2023.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory policy, lack of records, and staff interview, the laboratory failed to follow its' own policy for post-analytic quality assessment activities in 2022 or 2023. The findings include: 1. Observation of the laboratory on 01/30/2024 at 9:30 am revealed the Sysmex XN 330 (Serial #13835) instrument used for CBC patient testing. 2. Review of the laboratory quality assurance policy titled "Quality Assurance Program Outline" section "Chart Review Protocol" revealed the laboratory would perform quarterly patient chart reviews. 3. No documentation of quarterly patient chart reviews for 2022 or 2023 was available on the date of the survey (01/30/2024). 4. Interview with testing person six on 01/30 /2024 at 2:15 pm confirmed the laboratory failed to follow the postanalytic quality assurance policy when CBC patient chart reviews were not conducted in 2022 or 2023.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the laboratory's MLE PT records and staff interviews, the laboratory director failed to review the performance evaluations for five events (five of six reviewed) in 2022 and 2023 (Refer to D2015). The findings include: 1. Review of the laboratory's MLE PT records revealed no documented review by the laboratory director for 2022 events one and three, and 2023 events one, two, and three. 2. Interview on 01/30/2024 at 11:30 am with testing person six and clinic managers confirmed the laboratory director had not reviewed the performance evaluations for MLE PT events in 2022 and 2023.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, laboratory policy review, personnel record review, and staff interviews, the laboratory director failed to ensure the policy for assessing testing personnel (six of six reviewed) that performed CBC patient testing on the Sysmex XN 330 instrument was followed in 2022 and 2023 (Refer to D5209). The findings include: 1. Observation of the laboratory on 01/30/2024 at 9:30 am revealed the Sysmex XN 330 (Serial #13835) instrument used for CBC patient testing. 2. Review of the laboratory policy titled "Personnel" revealed "Testing personnel are evaluated initially after training, at 6 months, and then yearly" and "Competencies are completed using the six CLIA Assessment Components" by the technical consultant or laboratory director. 3. Review of the laboratory's personnel records revealed the following: Six of six testing personnel annual competency assessment did not include the six assessment elements (Direct observation of routine test performance, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, direct observation of instrument maintenance and function checks, assessment of test performance through blind testing, evaluation of problem solving skills) in 2023. Testing person four (hired 05/23/2022) did not have a competency assessment following initial training in 2022. 4. Interview with testing person six and clinic managers on 01/30/2024 at 12:00 pm confirmed the laboratory director did not ensure the personnel policy was followed in 2022 and 2023 for testing personnel that performed CBC patient testing on the Sysmex XN 330.