Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0651752	03/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Progressive Medical Mgmt Dba Panola Medical Center	303 Medical Center Drive, Batesville, MS	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(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 surveyor review of the laboratory proficiency testing (PT) records from 8/12/2021 through 3/8/2023 and confirmation by testing personnel (TP) # 1 and # 8 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form at 11:30 a.m. on 3/8/2023, the laboratory failed to retain 7 of 24 PT attestation statements and 2 of 24 PT evaluations for at least 2 years. Findings include: 1. Review of PT records for 2021-3rd event and 2022-1st, 2nd, and 3rd events revealed the laboratory did not retain the following records: a. Signed attestation statements were not kept for 7 of 24 events. This included Microbiology 2021-3rd event, Miscellaneous Chemistry 2022-1st event, Core Chemistry 2022-1st event and Blood Gas 2021-3rd event, 2022-1st, 2nd, and 3rd events. b. Graded PT evaluation reports were not kept for 2 of 24 events. This included Miscellaneous Chemistry 2022-2nd event and Immunohematology/Immunology 2021-3rd event. 2. TP # 1 and # 8 confirmed in an interview at 11:30 a.m. on 3/8/2023 that the proficiency testing records listed above were not retained.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of the Stago STA-Satellite Procedures and Reference Manual, the manufacturer's package insert for Stago activated partial thromboplastin time (APTT) Reagent Lot #260971, coagulation testing quality control (QC) logs from 9/1/2021 through 3/8/2023, and interview with General Supervisor #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 3/8/2023 at 11:45 a. m., the laboratory failed to follow the manufacturer's Lot Conversion Protocol with 1 of 1 lot conversions for APTT Reagent Lot #260971, put in use in August 2022 for patient APTT testing on the Stago STA-Satellite coagulation system. Findings include: 1. Review of the manufacturer's package insert for Stago APTT Reagent Lot #260971 and coagulation testing QC logs from 9/1/2021 through 3/8/2023 revealed Stago APTT Reagent Lot #260971 was put in use for patient testing in August 2022. 2. Review of the Stago STA-Satellite Procedures and Reference Manual revealed the Lot Conversion Protocol states, "Lot conversion studies should be performed prior to starting a new lot number of protime or APTT reagent." 3. On 3/8/2023 there was no documentation available of lot conversion studies performed on 1 of 1 lot conversions (APTT Reagent Lot #260971). 4. In an interview on 3/8/2023 at 11:45 a.m., General Supervisor #2, listed on the CMS 209 personnel form, confirmed the Lot Conversion Protocol was not performed for Stago APTT Reagent Lot #260971 before it was put in use for patient testing in August 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Siemens Rapid Point 500e blood gas analyzer records including quality control, maintenance, operating manual, and a lack of calibration records from 08/10/2021 through 3/7/2023 and confirmation with testing personnel #7 (as listed on the Centers for Medicare and Medicaid Services 209 Personnel form) at 12:00 p.m. on 3/8/2023, the laboratory failed to document as performed calibration verification (CVM) on the Siemens Rapid Point 500e blood gas analyzer every 6

	months for pCO2, pH, pO2. Three of three verifications were missed during the timeframe reviewed. Findings include: 1. Calibration verification is required every 6 months on any assay which is calibrated with less than 3 levels of calibration material. 2. Review of the calibration procedure for the Siemens Rapid Point 500e Blood Gas Analyzer revealed that less than 3 levels of calibration material are used during routine calibration. 3. There were no records to indicate that calibration verification /linearity had been performed on the Siemens Rapid Point 500e for pH, pCO2 and pO2 since installation on 6/30/2021. 4. Testing personnel #7 confirmed in an interview at 12:00 p.m. on 3/8/2023 that the CVM (calibration verification) on pH, pCO2 and pO2 was not performed every 6 months for a total of 3 of 3 six-month periods.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--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 manufacturer's package inserts for Stago STA-COAG controls and Stago STA-LIATEST controls, coagulation testing quality control (QC) logs from 9/1/2021 through 3/8/2023, and interview with General Supervisor #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 3/8/2023 at 11:45 a.m., the laboratory failed to verify the manufacturer's stated values of Stago quality control for 4 of 4 levels put into use during the review period. This included the STA-COAG normal and abnormal controls, Lot #260839, for prothrombin (PT) and activated partial thromboplastin time (APTT) testing in use on 10/20/2022 and Stago STA-LIATEST normal and abnormal controls, Lot #260548, for D-Dimer testing in use in August 2022. Findings include: 1. Review of the manufacturer's package inserts for Stago STA-COAG controls and coagulation testing QC logs from 9/1/2021 through 3/8/2023 revealed the Stago STA-COAG normal and abnormal controls, Lot #260839, currently in use, were put in use for PT and APTT testing on 10/20/2022. 2. Review of the manufacturer's package inserts for Stago STA-LIATEST controls and coagulation testing QC logs from 9/1/2021 through 3/8/2023 revealed Stago STA-LIATEST normal and abnormal controls, Lot #260548, currently in use, were put in use for D-Dimer testing in August 2022. 3. On 3/8/2023 there was no documentation available for review of verification of the manufacturer's stated ranges for 4 of 4 levels of Stago quality control before they were put in use for patient testing. This included 2 levels of STA-COAG controls (Lot #260839) and 2 levels of STA-LIATEST controls (Lot #260548). 4. In an interview on 3/8/2023 at 11:45 a.m.,

	General Supervisor #2, listed on the CMS 209 personnel form, confirmed that the manufacturer's ranges were not verified for these lots of controls before they were put in use.
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 surveyor review of proficiency testing (PT) records from 8/12/2021 through 3/8/2023 and confirmation by testing personnel # 1 listed on the Center for Medicare and Medicaid (CMS) 209 personnel form at 11:30 am on 3/8/2023, the laboratory director failed to ensure 2 of 24 proficiency testing evaluations were reviewed by the appropriate staff. Findings include: 1. Review of PT records on 3/8/2023 for 2021-3rd event and 2022-1st, 2nd, and 3rd events revealed 2 of 24 graded PT provider evaluations were not documented as reviewed by the appropriate staff. This included Miscellaneous Chemistry 2022-2nd event and Immunohematology/Immunology 2021-3rd event. 2. Interview with TP # 1 on 3/8/2023 at 11:30 a.m. confirmed the appropriate laboratory staff did not review PT results to identify problems requiring corrective action.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records, lack of documentation of corrective action, and confirmation by testing personnel # 8 as listed on the Centers for Medicare and Medicaid (CMS) 209 personnel form at 11:45 a.m. on 3/8/2023, the laboratory director failed to ensure an approved corrective action plan was followed when 1 of 4 proficiency testing results for pCO2 Blood Gas were found to be unsatisfactory. Findings include: 1. Review of PT records for 2021-3rd event and 2022-1st, 2nd, & 3rd events revealed 1 of 4 pCO2 Blood Gas events had an unsatisfactory score of 60%. 2. There was no documentation of corrective action available for review. 2. Testing Personnel #8 confirmed in an interview at 11:45 a.m. on 3/8/2023 that no corrective action was performed for unsatisfactory pCO2 Blood Gas results.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and an interview with TP #1, TP #2, and TP #7 at 1:00 p.m. on 3/8/2023, the technical consultant failed to evaluate annually and document the competency of 7 of 11 testing personnel (TP #1, TP #2, TP #4, TP #5, TP #7, TP #8 and TP #10) who are responsible for performing moderate testing. Findings include: 1. The surveyor reviewed personnel records for the main laboratory and the respiratory department for 2021 through 2022. 2. There were no annual evaluations-competencies available for review and performed by the technical consultant on 7 of 11 testing personnel for 2021, including TP #1, TP #2, TP #4, TP #5, TP #7, TP #8 and TP #10. 2. TP #1, TP #2, and TP #7 confirmed in an interview at 1:00 p.m. on 3/8/2023 that no annual evaluation-competencies for TP #1, TP #2, TP #4, TP #5, TP #5, TP #7, TP #8 and TP #10 had been documented as performed by the technical consultant for 2021.