

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0651752	(X3) Date Survey Completed 04/23/2025
Name of Provider or Supplier Progressive Medical Mgmt Db a Panola Medical Center	Street Address, City, State 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Stago STA Satellite coagulation system, the manufacturer's package insert for STA-Neoplastine C1 Plus prothrombin time (PT) reagent Lot #267015, patient test count from 12/1/2024 through 4/23/2025, and observation of the ISI (International Sensitivity Index) value in the STA Satellite coagulation system on 4-23-2025 at 3:00 p.m., the laboratory failed to follow manufacturer's instructions for setting up the STA Satellite coagulation system to calculate the INR (International Normalized Ratio) for patient PT testing when PT reagent Lot #267015 was put in use for patient testing on 12/1/2024. Findings include: 1. Manufacturer's instructions for the Stago STA Satellite coagulation system state to enter the ISI value from the package insert with each new lot of PT reagent for correct calculation of the INR. 2. Review of the package insert for the current STA-Neoplastine C1 Plus PT reagent, Lot #267015, put in use on 12/1/2024, revealed the ISI value for this lot of PT reagent was 1.32. 3. The ISI value observed in the STA Satellite coagulation system on 4/23/2025 at 3:00 p.m. was 1.30. 4. Review of patient PT test counts from 12/1/2024 through 4/23/2025 revealed 136 patient PT tests were performed and results were reported during this time frame, when the incorrect ISI value was used to calculate patient INR results.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on review of patient test logs, quality control (QC) records for the Siemens Dimension EXL with LM chemistry analyzer from 5/23/2023 through 4/23/2025, manufacturer's package inserts for Bio-Rad Liquichek Immunoassay Plus controls, Bio-Rad Liquichek Cardiac controls, Bio-Rad Liquichek Plus LT and Bio-Rad Liquichek Qualitative Urine Toxicology controls and interviews with the General Supervisor (GS) and Testing Personnel (TP) #2 listed on the CMS 209 personnel form, it was determined the laboratory used those Bio-Rad quality control material for quality control testing after they had exceeded their expiration dates. Findings include: 1. Review of the manufacturer's package inserts for Bio-Rad Liquichek Immunoassay Plus Controls Level 1 (Lot #85351) and Level 3 (Lot #85353) revealed these two levels of controls had an expiration date of 2/28/2025. These controls were used as quality control testing for Vancomycin and Quantitative Beta HCG patient testing from 3/5/2025 through 4/21/2025. A total of eleven Beta HCG and five Vancomycin patients' results were reported during this time frame. 2. Review of the manufacturer's package inserts for Bio-Rad Liquichek Cardiac Level 1B (Lot# 67685) and Level 3 (Lot# 67683) revealed these two levels of controls had an expiration date of 2/28/2025. These controls were used as quality control testing for Troponin and BNP (LNTP) testing from 3/6/2025 through 4/23/2025. A total of thirty-one BNP (LNTP) and two Troponin patients' results were reported during this time frame. 3. Review of the manufacturer's package inserts for Bio-Rad Liquichek Qualitative Urine Positive Control (Lot # 74712) revealed an expiration date of 1/31/2025 and Negative Control (Lot# 68150) revealed an expiration date of 2/28/2025. These controls were used as quality control testing for Amphetamines, Barbiturates, Benzodiazapine, Cocaine, Ecstasy, Methamphetamine, Opiates, PCP (Phencyclidine) and THC (Tetrahydrocannabinol) testing from 2/28/2025 through 4/23/2025. A total of twenty-two urine drug screens were performed and reported during this time frame. 4. An interview with the GS and TP #2 on 4/23/2025 at 10:00 a.m., confirmed the laboratory used Bio Rad controls that had exceeded their expiration dates for Troponin, BNP (LNTP), Vancomycin, Quantitative Beta HCG and urine drug screen testing and a total of seventy-one patient tests were reported.

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:

Based on review of Ortho Clinical Diagnostics MicroTyping System (MTS) Dispenser Operating Instructions, Transfusion Service Testing Record and Blood Bank Daily/Weekly maintenance records from 3/10/2023 through 3/28/2025, and lack

of calibration checks for the two MTS dispensers, in use for ABO/Rh and compatibility testing, the laboratory failed to follow manufacturer's instructions for performing calibration checks for the MTS 2 diluent dispenser and MTS 2 Plus diluent dispenser for 18 of 24 months reviewed. Findings include: 1. The Ortho Clinical Diagnostics MTS Dispenser Operating Instructions state, "A calibration check should be done as part of a routine laboratory quality control schedule and after each repair." 2. Review of Blood Bank Daily/Weekly maintenance records from 3/10/2023 through 3/28/2025 revealed the laboratory's maintenance policy included monthly calibration checks for the MTS 2 diluent dispenser and MTS 2 Plus diluent dispenser, but there was no documentation of calibration checks for the two MTS dispensers from 9/4/2023 through 3/28/2025 (18 of 24 months reviewed). 3. Review of the Transfusion Service Testing Record from 3/10/2023 through 3/28/2025 revealed ABO/Rh and compatibility testing were performed each month during this time frame.

D5559

IMMUNOHEMATOLOGY
CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the Transfusion Service Testing Record and blood bank reagent quality control (QC) records from 3/10/2023 through 3/28/2025, the laboratory failed to document performance of quality control for the reagent gel cards used for ABO grouping, Rh typing, antibody detection, and compatibility testing for three, of eighteen, days in April 2023 and three, of eighteen, days in May 2023 when testing was performed on ten patients, with eight units of packed red blood cells (PRBC) issued for transfusion to five of these patients. Findings include: Review of the Transfusion Service Testing Record and blood bank reagent QC records from 3/10/2023 through 3/28/2025 revealed that quality control for the blood bank reagent gel cards was not documented, as performed, on the following days when ABO grouping, Rh typing, antibody detection (Ab screen), and compatibility testing were performed on ten patients: 4/24/2023--ABO/Rh and Ab screen performed on Patient #3161119 and #3161233. 4/26/2023--ABO/Rh, Ab screen, and compatibility testing performed on Patient #3161296 for one unit of PRBC transfused on 4/26/2023. ABO/Rh and Ab screen performed on Patient #3160886. 4/27/2023--ABO/Rh, Ab screen, and compatibility testing performed on Patient #3161616 for two units of PRBC transfused on 4/27/2023. ABO/Rh and Ab screen performed on Patient #3160159. 5/2/2023--ABO/Rh, Ab screen, and compatibility testing performed on Patient #3162041 for two units of PRBC transfused on 5/3/2023. ABO/Rh and Ab screen performed on Patient #3162189. 5/20/2023--ABO/Rh, Ab screen, and compatibility testing

performed on Patient #3163938 for one unit of PRBC transfused on 5/20/2023. 5/23/2023--ABO/Rh, Ab screen, and compatibility testing performed on Patient #3164207 for two units of PRBC transfused on 5/23/2023.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of laboratory personnel records including competencies, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to evaluate and document the performance of four of five new testing personnel (TP) responsible for performing moderate and high complexity laboratory testing at least semiannually during the first year of employment. Findings Include: 1. Review of the laboratory personnel records since the last survey on 3/8/2023, revealed the semiannual competency evaluations available the day of survey were performed by the GS for the performance of four of five new laboratory testing personnel (TP #5, TP #6, TP #7 and TP #8). 2. The General Supervisor confirmed in an interview on 4/23/2025 at 2:30 p.m., the six-month competencies available the day of survey were performed by her and not the TS listed on the CMS 209 form.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of laboratory testing personnel competency records for testing personnel (TP) as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with the General Supervisor (GS), the annual evaluations for moderate and high complexity testing personnel (TP) were performed by staff other than the Technical Supervisor (TS) for six of nine testing personnel. Findings include: 1. Review of the laboratory personnel records available on 4/23/2025 revealed annual evaluations/competencies for moderate and high complexity testing personnel were performed by the GS. TP #3- for the years 2023 and 2024 TP #4- for the year 2024 TP #5- for the years 2023 and 2024 TP #6- for the years 2023 and 2024 TP #7- for the years 2023 and 2024 TP #8- for the years 2023 and 2024 2. Interview with the General Supervisor/TP #1 on 4/23/2025 at 2:30 p.m., confirmed the annual evaluation/competencies for moderate and high complexity testing had not been documented as performed by the Technical Supervisor listed on the CMS 209 form. Six of nine laboratory testing personnel did not have annual evaluations /competencies performed by the TS.