

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0651752	(X3) Date Survey Completed 07/11/2019
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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CytoTherm-4S Plasma Thawing Water Bath Owner's Manual and interview on 7-10-19 at 10:00 a.m. with Laboratory Testing Personnel #19, listed on the Center for Medicare and Medicaid Services (CMS) 209 Laboratory personnel form, the laboratory failed to perform and document the Overtemperature Alarm Test every three months, as specified by the manufacturer, since 9-2-18. Findings include: The CytoTherm-4S Plasma Thawing Water Bath Owner's Manual states that the Overtemperature Alarm Test should be performed every three months. There was no documentation available on the day of the survey of the performance of the Overtemperature Alarm Test since 9-2-18. Laboratory Testing Personnel #19 confirmed in an interview on 7-10-19 at 10:00 a.m. there was no documentation of the performance of the Overtemperature Alarm Test since 9-2-18.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
 Based on review of Pro-Lab Amnio Test Nitrazine/phenaphthazin quality control (QC) records from 9/18 and interview with testing personal on 7/11/19 at 9:00 am, the OB/GYN nursing services failed to perform two levels of QC each day of patient testing when using the Pro-Lab Amnio Nitrazine/phenaphthazin swab test. Findings include: 1. Two levels of external control material must be tested and documented each day of patient testing unless the laboratory chooses to establish an Individualized Quality Control Plan (IQCP). 2. The 2 levels of QC required by the manufacturer for the Amnio Nitrazine/phenaphthazin swab test are Pro Lab Buffer Solutions: QC 1 acid (5.0) and QC 2 base (pH 7.5). 3. Based on interview with the OB/GYN nursing supervisor and review of the hospital LIS, 83 Pro-Lab Amnio Nitrazine /Phenaphthazin swab tests were performed and reported on OB/GYN patients without 2 levels of QC performed on the day of testing. 4. There was no documentation of an IQCP. On the bottom of the QC/patient Amnio Nitrazine/phenaphthazin test log was a statement: "Perform QC with each lot/shipment and each day of patient testing."

D5477

CONTROL PROCEDURES
 CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on surveyor review of the bioMerieux BacT ALERT 3D Microbial Detection System procedure, lack of documentation of microbiological culture media quality control (QC) records, lack of an Individualized Quality Control Plan (IQCP), and confirmation with testing personnel #16 on 7/10/19 at 10:00 am, the laboratory failed to check each new lot number or shipment of blood culture media for sterility, ability to support growth, and to document physical characteristics of the media. Findings include: According to blood culture QC records from 9/2/18 through the day of survey, 7/10/19, and interview with testing personnel #16, the laboratory was retaining the manufacturer's Certificate of Conformance which states that each lot number of bioMerieux BacT ALERT 3D blood culture bottles exhibited the established requirements for pH, sterility and growth performance. The laboratory did not check each new lot number or shipment of media for sterility, ability to support growth and document physical characteristics of the media or develop an IQCP. The laboratory performed 1,161 blood cultures from 9/2/18 through 7/10/19.

D5555

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

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the

alarm system must be documented. (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 blood bank procedure manual, documentation of blood bank alarm checks since 9-2-18, and interview with Laboratory Testing Personnel #19, listed on the CMS 209 Laboratory personnel form, the laboratory failed to document, as performed, quarterly plasma freezer temperature alarm checks, according to the laboratory's written policy. Findings include: Review of the blood bank procedure manual revealed the laboratory's written Blood Bank Refrigerator/Freezer Alarm Check policy states, "These alarms must be checked quarterly for proper functioning." Documentation of blood bank alarm checks since 9-2-18 and interview with Laboratory Testing Personnel #19 on 7-10-19 at 10:00 a.m. revealed the laboratory failed to document, as performed, plasma freezer temperature alarm checks since 9-2-18.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

1. Based on review of the CMS 209 Personnel form and Respiratory personnel records since 9/2/18, the technical consultant failed to evaluate and document the performance of Respiratory Testing Personnel #3 and #6 semiannually during the first year they performed moderate complexity testing. Findings Include: Review of the CMS 209 Personnel form and Respiratory personnel records since 9/2/18 revealed no semiannual evaluations were performed by the technical consultant documenting the performance of Respiratory Personnel #3 (date of hire 7/20/17) and Respiratory Personnel #6 (date of hire 2/17/18). 22079 2. Based on review of the CMS 209 Laboratory personnel form and personnel records since 9-2-18, the technical consultant failed to evaluate and document the performance of Laboratory Testing Personnel #12 and #19 semiannually during the first year these individuals performed moderate complexity testing. Findings include: Review of the CMS 209 Laboratory personnel form and personnel records since 9-2-18 revealed no semiannual evaluations by the technical consultant documenting the performance of Laboratory Testing Personnel #12, date of hire 8-15-18, and Laboratory Testing Personnel #19, date of hire 8-24-18. The only evaluations by the technical consultant documenting the performance of these two individuals for moderate complexity testing were dated 7-8-19. 3. Based on review of the CMS 209 OB Department personnel form and personnel records since 9-2-18, the technical consultant failed to evaluate and document the performance of OB Department Testing Personnel #1, #4, #6, and #12 semiannually during the first year these individuals performed moderate complexity testing. Findings include: Review of the CMS 209 OB Department personnel form and personnel records since 9-2-18 revealed no semiannual evaluations by the technical consultant documenting the performance of OB Department Testing Personnel #1, date of hire 6-28-18, Testing Personnel #4, date of hire 5-22-18, Testing Personnel #6, date of hire 2-28-18, and Testing Personnel #12, date of hire 5-6-18, for performing Pro-Lab Diagnostics Amniotest Nitrazine testing.

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:

1) Based on review of the CMS 209 Respiratory personnel form and personnel records since 9/2/18, the technical consultant failed to evaluate and document the performance of the Respiratory Department Testing Personnel #1, #2, #7, #8, and #9, responsible for moderate complexity testing at least annually for 2018. Findings include: Review of the CMS 209 Respiratory personnel form and personnel records since 9/2/18 revealed no annual evaluations were performed and documented by the technical consultant of Respiratory Testing Personnel #1, #2, #7 #8 and #9 performing blood gas testing. 22079 2) Based on review of the CMS 209 OB Department personnel form and personnel records since 9-2-18, the technical consultant failed to evaluate and document the performance of OB Department Testing Personnel #1 through #7 and #10 through #17, responsible for moderate complexity testing, at least annually. Findings include: Review of the CMS 209 OB Department personnel form and personnel records since 9-2-18 revealed no annual evaluations by the technical consultant documenting the performance of OB Department Testing Personnel #1 through #7 and #10 through #17 for performing Pro-Lab Diagnostics AmnioTest Nitrazine testing.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the CMS 209 OB Department personnel form and personnel records since 9-2-18, the laboratory director failed to ensure that OB Department Testing Personnel #8 and #9, responsible for moderate complexity testing, had the appropriate training prior to performing patient testing. Findings include: Review of the CMS 209 OB Department personnel form and personnel records since 9-2-18 revealed no documentation of training for OB Department Testing Personnel #8, date of hire 4-1-19, and OB Department Testing Personnel #9, date of hire 2-21-19, for performing Pro-Lab Diagnostics AmnioTest Nitrazine testing prior to performing patient testing.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for 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 the CMS 209 Laboratory personnel form and personnel records since 9-2-18, the technical supervisor failed to evaluate and document the performance of Laboratory Testing Personnel #12 and #19 semiannually during the first year these individuals performed high complexity testing. Findings include: Review of the CMS 209 Laboratory personnel form and personnel records since 9-2-18 revealed no semiannual evaluations by the technical supervisor documenting the performance of Laboratory Testing Personnel #12, date of hire 8-15-18, and Laboratory Testing Personnel #19, date of hire 8-24-18, for high complexity testing.