

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0651950	(X3) Date Survey Completed 09/07/2018
Name of Provider or Supplier Perry County General Hospital Lab	Street Address, City, State 206 Bay Avenue, Richton, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for D-Dimer testing on the Alere Triage Meter Pro from 12-22-16 through 8-20-18 and the laboratory's written Individualized Quality Control Plan (IQCP), the laboratory failed to follow its written IQCP for performing two levels of external quality control at least every thirty days and at change of kit lot number. Findings include: The laboratory's IQCP states, "Two levels of Alere Total 5 external controls, an abnormal level and a normal level, will be tested and documented at least every 30 days and at change of kit lot number." Review of QC records for D-Dimer testing on the Alere Triage Meter Pro from 12-22-16 through 8-20-18 revealed: (1) External controls for D-Dimer testing were not documented, as performed, from 9-21-17 until 5-8-18. (2) Two levels of external control were not documented, as performed, on D-Dimer Cartridge Lot #62822, put in use on 2/17/17, and on Cartridge Lot #63029 on 5/20/17.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
 A. Based on review of Beckman Coulter AU480 chemistry system maintenance logs from 10-20-16 through 8-31-18 and lack of documentation of Ion Specific Electrode (ISE) maintenance, the laboratory failed to document, as performed, the daily, weekly, and every-other-week ISE maintenance, as defined by the manufacturer, for twelve months during this time frame and failed to document, as performed, the every-three-month maintenance since April 2017. Findings include: 1. Review of Beckman Coulter AU480 chemistry system maintenance logs from 10-20-16 through 8-31-18 revealed the following ISE maintenance procedures were not documented as performed for the month of August 2017 and for the months of October 2017 through August 2018: Daily Check the buffer syringe for leaks. ISE cleaning. Weekly Enhanced cleaning of electrode line. Every Other Week Manually wash the mix bars, liquid level sensors, sample pot, and sample pot tubes. 2. Review of Beckman Coulter AU480 chemistry system maintenance logs from 10-20-16 through 8-31-18 revealed the following every-three-month ISE maintenance procedures were not documented as performed since 4-30-17: Every Three Months Replace the roller tubes for MID solution dispense and mixture aspiration. Replace the pinch valve tubing. B. Based on review of the ITC IRMA Blood Analysis System User Manual and maintenance records since the last survey on 10-19-16, the laboratory failed to document, as performed, the annual maintenance, as defined by the manufacturer, for the ITC IRMA Blood Analysis System since 10-19-16. Findings include: Review of the ITC IRMA Blood Analysis System User Manual revealed the manufacturer's instructions state, "The IRMA barometer should be calibrated annually to maintain analyzer accuracy." There was no documentation of the barometer calibration since 10-19-16.

D5431

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(2)

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.

This STANDARD is not met as evidenced by:
 Based on review of the ITC IRMA Blood Analysis System User Manual, monthly temperature checks, and quality control records for November 2016 through July 2018, the laboratory failed to perform and document the monthly temperature check, as required by the manufacturer, for twelve months during this time frame when patient blood gas testing was being performed. Findings include: Review of the ITC IRMA Blood Analysis System User Manual revealed the manufacturer's instructions state to run a temperature test monthly to verify that the IRMA temperature control system is operating properly. Review of the instrument printouts for monthly temperature checks and quality control records for the ITC IRMA Blood Analysis System for November 2016 through July 2018 revealed no documentation of a monthly temperature check from August 2017 through July 2018. THIS IS A REPEAT DEFICIENCY.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
 CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the

manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of calibration records for the Beckman Coulter DxH 600 hematology analyzer since the last survey on 10-19-16 and lack of documentation of calibration, the laboratory failed to document, as performed, calibration on the Beckman Coulter DxH 600 hematology analyzer every six months, according to laboratory policy. Findings include: Review of calibration records for the Beckman Coulter DxH 600 hematology analyzer since the last survey on 10-19-16 revealed no documentation of calibration of the DxH 600 hematology analyzer since 5-12-17.

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 calibration records for the Beckman Coulter AU480 chemistry system and lack of documentation of calibration verification, the laboratory failed to document, as performed, calibration verification for routine chemistry tests performed on the Beckman Coulter AU480 chemistry system at least once every six months since the last survey on 10-19-16. Findings include: Review of calibration records for the Beckman Coulter AU480 chemistry system revealed the routine chemistry tests performed on the chemistry system have fewer than three calibrators. There was no documentation of calibration verification performed for the routine chemistry tests on the Beckman Coulter AU480 chemistry system since the last survey on 10-19-16.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(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-- 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.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records for the Beckman Coulter Access 2 immunoassay system from 3-1-18 through 5-31-18, the laboratory failed to include at least two controls for two days of cardiac panel testing during this time frame. Findings include: Review of QC records for the Beckman Coulter Access 2 immunoassay system from 3-1-18 through 5-31-18 revealed the laboratory failed to include one of two levels of control material for the following tests on these days: 5-1-18--Level 1 control not performed for CKMB testing. 5-4-18--Level 3 control not performed for CKMB, Myoglobin, and Troponin I testing.

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:

1. Based on review of quality control (QC) records for the Beckman Coulter Access 2 immunoassay system from 3-1-18 through 5-31-18 and manufacturer's acceptable ranges for MAS CardioImmune Controls, Lot #CXL20011A and Lot #CXL20013A, the laboratory failed to document, as performed, the establishment of statistical parameters for acceptable ranges for the CKMB test with the MAS CardioImmune Controls, in use for quality control testing during this time frame. Findings include: Review of QC records for the Beckman Coulter Access 2 immunoassay system from 3-1-18 through 5-31-18 revealed MAS CardioImmune Controls, Lot #CXL20011A and Lot #CXL20013A, were in use for CKMB testing during this time frame. Review of the manufacturer's acceptable ranges for MAS CardioImmune Controls, Lot #CXL20011A and Lot #CXL20013A, revealed no acceptable range for CKMB testing on the Beckman Coulter Access 2 immunoassay system. On the day of the survey, 9-7-18, there was no documentation of establishment of statistical parameters for CKMB ranges listed on the Access 2 QC records. 2. Based on review of QC records for the Beckman Coulter AU480 chemistry system from 4-1-18 through 5-31-18, observation

of MAS ChemTrak-H Liquid Assayed Chemistry Controls Level 1, Lot #CHA19071A, and Level 2, Lot #CHA19073A, in the laboratory refrigerator on 9-7-18 at 12:15 p.m., and manufacturer's acceptable ranges for Lot #CHA19071A and Lot #CHA19073A, the laboratory failed to document, as performed, the establishment of statistical parameters for acceptable ranges for MAS ChemTrak-H Liquid Assayed Chemistry Controls, Lot #CHA19071A and Lot #CHA19073A, currently in use for quality control testing for routine chemistry tests. Review of the manufacturer's ranges for these lot numbers revealed the manufacturer's ranges were not used for determining acceptability of quality control testing with these lot numbers 3. Based on review of QC records for the IRMA Blood Analysis System from 9-8-17 through 7-13-18, observation of RNA Medical Liquid Controls Lot #502433 in the laboratory on 9-7-18 at 1:30 p.m., and the manufacturer's assay sheet for this lot number of controls, the laboratory failed to document, as performed, the establishment of statistical parameters for acceptable ranges for pH, pO₂, and pCO₂ testing with the RNA Medical Liquid Controls, in use for quality control testing during this time frame. Findings include: Review of the manufacturer's acceptable ranges for RNA Medical Liquid Controls Lot #502433 revealed no acceptable range for pH, pO₂, and pCO₂ testing on the IRMA Blood Analysis System. On the day of the survey, 9-7-18, there was no documentation of establishment of statistical parameters for the ranges listed for pH, pO₂, and pCO₂ testing on the IRMA Blood Analysis System QC records.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
1. Based on review of manufacturer's acceptable ranges for Alere Total 5 controls and quality control (QC) records for D-Dimer testing on the Alere Triage Meter Pro from 12-22-16 through 8-20-18, the laboratory failed to ensure the Level 2 control result met the manufacturer's criteria for acceptability on 3-16-17, 4-20-17, and 7-31-18. Findings include: Review of manufacturer's acceptable ranges for Alere Total 5 controls and QC records for D-Dimer testing on the Alere Triage Meter Pro from 12-22-16 through 8-20-18 revealed Level 2, of two levels of control material performed every 30 days, was outside the manufacturer's acceptable range on 3-16-17, 4-20-17, and 7-31-18. 2. Based on review of instrument QC printouts for the ITC IRMA Blood Analysis System from 9-8-17 through 7-13-18, the laboratory failed to ensure at least 2 of 3 levels of control met the laboratory's criteria for acceptability for two days of testing during this time frame. Findings include: Review of instrument QC and patient printouts for the ITC IRMA Blood Analysis System from 9-8-17 through 7-13-18 revealed the laboratory failed to ensure two of three levels of control material met the laboratory's criteria for acceptability for the following tests on these days: 1-27-18--Level 2 and Level 3 controls outside laboratory's acceptable range for pO₂ testing when one patient result was reported. 7-13-18--Level 1 and Level 3 controls outside laboratory's acceptable range for pH testing when one patient result was reported.

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the

laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of the ITC IRMA Blood Analysis System User Manual, monthly temperature checks, and quality control records for November 2016 through July 2018, testing personnel responsible for moderate complexity testing failed to document, as performed, the monthly temperature check on the ITC IRMA Blood Analysis System, as required by the manufacturer, for twelve months during this time frame when patient blood gas testing was being performed. Refer to D5431 (Failure to perform monthly temperature checks as required by the manufacturer). THIS IS A REPEAT DEFICIENCY.

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 personnel form and personnel records since the last survey on 10-19-16, the laboratory director failed to ensure that Testing Personnel #1, responsible for high complexity and moderate complexity testing, had the appropriate education and training PRIOR to performing patient testing and that Testing Personnel #5, responsible for moderate complexity testing, had the appropriate education PRIOR to performing patient testing. Findings include: 1. Review of the CMS 209 personnel form and personnel records since 10-19-16 revealed no documentation of education or training for Testing Personnel #1, date of hire 8-6-18, responsible for high complexity and moderate complexity testing. 2. Review of the CMS 209 personnel form and personnel records since 10-19-16 revealed no documentation of education for Testing Personnel #5, whose initial evaluation for moderate complexity patient testing was performed on 4-13-17.