

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0506634	(X3) Date Survey Completed 05/11/2018
Name of Provider or Supplier Hereford Regional Medical Center	Street Address, City, State 540 West 15th Street, Hereford, TX	
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
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1441 Condition: Laboratories Performing High Complexity Testing; laboratory director 493.1250 Condition: Analytic Systems
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratories policies and procedures, quality control records, patient test records, verification records and confirmed in interview, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. (Refer to D 5407, D5421, D5445, D5449, and D5791)</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Review of policies and procedures and interview of facility personnel found that the</p>

laboratory director failed to approve, sign and date seven of seven procedures available to testing personnel for use in testing patient specimens in the cardiopulmonary department. Findings included: 1. Review of Policies and Procedures in the Cardiopulmonary Services policy and procedure manual found no documentation of the approval (including signature and date of approval) by the current laboratory director for seven of seven procedures. Procedures contained in this notebook were documented as approved by DR, CNO, PI, CEO, GB, with revision dates between 01/09/2017 and 10/29/2017. Arterial Blood Gas Analysis had an effective date of 02/25/15 and a reviewed/ revised date of 10/29/17 Arterial Blood Gas Sampling had an effective date of 05/05/09 and a reviewed/ revised date of 10/29/17 Critical Tests and Result Reporting had an effective date of 05/12/09 and a reviewed/ revised date of 10/29/17 Capillary Blood Sampling- Infants had an effective date of 04/29/09 and a reviewed/ revised date of 10/29/17 Critical Points in Arterial Blood Gases had an effective date of 04/29/09 and a reviewed/ revised date of 10/29/17 Blood Gasses-Capillary had an effective date of 01/09/17 and a reviewed/ revised date of 01/09/17 Quality Control (Troubleshooting) Arterial Blood Gas Analysis had an effective date of 04/29/09 and a reviewed/ revised date of 10/29/17 2. Interview of the Technical Consultant of the CMS report 209 Laboratory Personnel Report conducted on May 9, 2018 at 10:38 AM confirmed that the procedures had no documentation of approval by the current laboratory director.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on observations, review of verification records and interview of facility personnel, the laboratory failed to perform a complete verification study for three of three panels tested using the BioFire Film Array prior to patient testing. Findings included: 1. Observations made during the tour of the laboratory found that the laboratory was currently using the BioFire Film Array GI panel, Respiratory Panel and the Blood Culture ID panel for testing patient specimens. 2. Review of of verification studies found that the laboratory completed verification procedures for each of the panels as follows: Respiratory Panel - Verification study approved by the laboratory director on 05/27/2016. The verification study consisted of a 3 day Daily QC study and the 20 day study as defined by the manufacturer, and a comparison of 3 specimens with another facility performing the same method. The laboratory failed to evaluate the data to determine if the results obtained met the manufacturers claims for accuracy and precision. Gastrointestinal Panel - Verification study approved by the laboratory director on 05/27/2016. The verification study consisted of a 3 day Daily QC study and the 20 day study as defined by the manufacturer, and a comparison of 3 specimens with another facility performing the same method. The laboratory failed to evaluate the data to determine if the results obtained met the manufacturers claims for accuracy and precision. Blood Culture ID Panel - Verification study approved by the laboratory director on 07/19/2016. The verification study consisted of a 3 day Daily

AC study and the 20 day study as defined by the manufacturer, and a comparison of 3 specimens with another facility performing the same method. The laboratory failed to evaluate the data to determine if the results obtained met the manufacturers claims for accuracy and precision. 3. Interview of the Technical Consultant conducted on May 9, 2018 at 10:40 AM confirmed that the laboratory did not evaluate the data used to verify the performance of the BioFire FilmArray panels to ensure it met the manufacturer's claims for accuracy.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Review of the laboratory's Quality control plan for IStat G3+ cartridges, quality control records, patient test records and interview of facility personnel found that the laboratory failed to ensure that external quality controls were tested at the frequency defined in their own written procedure. Findings included: 1. Review of the Laboratory's Quality Control Plan for the IStat G3+ Cartridges (signed by the laboratory director on 12/30/15 and 03/26/18) found that the external quality controls will be tested" upon opening a box from a new shipment or a lot number and any time there is a question about the stability of the device and at least once per month." 2. Review of Quality control records between January 10, 2018 and May 7, 2018 found that the laboratory tested iStat G3+ cartridges on the following dates using two levels of quality control material: January 11, 2018 - iStat G3+ cartridges lot 212D172431241 February 12, 2018 - iStat G3+ cartridges lot 212D172861228 March 12, 2018 - iStat G3+ cartridges lot 212D172861228 April 12, 2018 - iStat G3+ cartridges lot 212D172861228 May 7, 2018 - iStat G3+ cartridges lot 212D173200243 3. Review of patient test records found 18 patient specimens tested on iStat G3+ cartridges without documentation of testing 2 levels of external controls at least once each month prior to testing patient specimens. January 10, 2018 - patient 70036101 was tested using iStat G3+ cartridge lot 212D72431241 with no external Quality control documented prior to January 11, 2018 January 11, 2018 - patient 70033729 was tested twice using iStat G3+ cartridge lot 212D72240229 with no external quality control documented in January 2018. February 3, 2018 - Patient 70043201 was tested using iStat G3+ cartridge lot 212D172861228 with no external Quality control documented prior to February 12, 2018 February 4, 2018 - Patient 70043211 was tested twice using iStat G3+ cartridge lot 212D172861228 with no external Quality control documented prior to February 12, 2018 February 5, 2018 - Patient 70042704 was tested twice using iStat G3+ cartridge lot 212D172861228 with no external Quality control documented prior to February 12, 2018 Patient 70043211 was tested using iStat G3+ cartridge lot 212D172861228 with no external Quality control documented prior to February 12, 2018 Patient 70043475 was tested using iStat G3+ cartridge lot 212D172861228 with no external Quality control documented prior to February 12, 2018 February 7, 2018 - Patient 70044310 was tested twice

using iStat G3+ cartridge lot 212D172861228 with no external Quality control documented prior to February 12, 2018 February 8 , 2018 - Patient 70044386 was tested twice using iStat G3+ cartridge lot 212D172861228 with no external Quality control documented prior to February 12, 2018 Patient 70043211 was tested using iStat G3+ cartridge lot 212D172861228 with no external Quality control documented prior to February 12, 2018 May 3, 2018 - Patient 70062159 was tested using iStat G3+ cartridge lot 212D173200243 with no external quality control documented prior to May 7, 2018 May 5, 2018 - Patient 70062881 was tested twice using iStat G3+ cartridge lot 212D173200243 with no external quality control documented prior to May 7, 2018 4. Interview of the Technical Consultant conducted on May 9, 2018 at 11:49 AM confirmed that the laboratory failed to test each lot of iStat 3+ cartridges at least once each month before testing patient specimens.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Review of the laboratory's Quality control plan for the BioFire FilmArray GI Panel, quality control records, patient test records and interview of facility personnel found the laboratory tested 5 patient specimens between April 17 and April 24, 2018 without testing a negative and positive quality control material to ensure the quality of testing. Findings included: 1. Review of the Quality control plan for the BioFire FilmArray GI Panel (signed by the laboratory Director on 05/27/2016 and 03/26/2018)found that the laboratory's policy was to test "external controls upon opening a box from a new shipment, lot number, and any time there is a question about the stability of the system and at least once per month ." 2. Review of Quality control records found that the laboratory tested quality control materials using the BioFire FilmArray GI Panel Lot 838318 on March 15, 2018 and Lot 862218 on April 15, 2018. 3. Review of patient test records found the laboratory tested five patient specimens between April 17 and April 24, 2018 without testing a negative and positive quality control material using panels from Lot 838318 without performing quality control procedures on this lot during the month of April, 2018. Patient 24181070089A was tested on April 17, 2018 using GI Panel lot 838318 Patient 24181100047A was tested on April 20, 2018 using GI Panel lot 838318 Patient 24181100081A was tested on April 20, 2018 using GI Panel lot 838318 Patient 24181140041A was tested on April 24, 2018 using GI Panel lot 838318 Patient 24181140056A was tested on April 24, 2018 using GI Panel lot 838318 4. Interview of the Technical Consultant conducted on May 9, 2018 at 2:10 PM confirmed that the laboratory did not test external quality control materials at least once each month for each lot of the BioFire FilmArray GI Panel used in patient testing.

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 review of the laboratories policies and procedures, quality control records, patient test records, verification records, and confirmed in interview, the quality assessment system used by the laboratory failed to identify and correct problems in the analytic systems. (Refer to D 5407, D5421, D5445, D5449)

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the laboratory's quality control records, quality assessment records, record review and staff interview, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. The findings included: 1. The laboratory director failed to ensure that the verification procedures had been completed for the Bio Fire FilmArray panels used for testing patients prior to testing patient specimens. (See D6013) 2. The Laboratory Director failed to ensure that the quality control program had been established and maintained for the BioFire FilmArray panels and the iSTAT G3+ cartridges used for testing patients arterial blood gasses. (See D6020) The Laboratory Director failed to ensure approved policies and procedures were available to all testing personnel performing Blood Gas Analysis (see D6031)

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

The laboratory director failed to ensure that the verification procedures had been completed for three of three panels tested on the Bio Fire FilmArray instrument used for testing patients prior to testing patient specimens. (See D5421)

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Review of quality control records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that the quality control program for arterial blood gasses and the BioFire Film Array panels had been established and maintained. (See D5445 and D5449)

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manual and interview of facility personnel, the Laboratory Director failed to ensure approved procedures for all aspects of Arterial blood gas testing was available to all testing personnel. (see D5407)

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Review of quality control records and patient test records found that the technical consultant failed to ensure that a negative and positive quality control material were tested at least once each month for each lot of the BioFire FilmArray GI Panel used in patient testing. (see D5449) Review of quality control records and patient test records found that the technical consultant failed to ensure that two levels of quality control materials were tested at least monthly for each lot of iSTAT G3+cartridges used in patient testing. (see D5445)