Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2104181	09/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Benton Medical	188 Burt Boulevard, Benton, LA	

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	A CERTIFICATION SURVEY was performed at Benton Medical - 19D2104181 on September 17, 2018. Benton Medical was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to follow the laboratory's instructions for flags appearing on Complete Blood Counts (CBC) for four (4) of ten (10) patients reviewed. Refer to D5411. 2. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417. 3. The laboratory failed to take corrective action when quality control samples were unacceptable for Hematology testing. Refer to D5783. 4. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Refer to D5791.
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 observation, record review, and interview with personnel, the laboratory failed to follow the laboratory's instructions for flags appearing on Complete Blood Counts (CBC) for four (4) of ten (10) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2018 revealed the laboratory utlilizes the Beckman Coulter ACT Diff 2 Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's policy for "Patient Testing" revealed to review any codes or flags with the following suggested action for each: a) Flag/Code (- - - - - -): Mix and rerun sample; If repeates - zap apertures; If repeats - clean baths; If repeats, call Beckman Coulter technical support. b) Flag/Code (++++++): Verify reagent levels and delivery. If ok, send sample to reference lab for testing. c) Flag/Code (XXXXXX): Check sample for clots; If found recollect sample; If no clot remix and rerun; If alert repeats run a previous specimen; If repeats clean baths; If repeats send to reference lab for testing; ONLY IF SPECIMEN NOT CLOTTED. d) Flag/Code (.....): See instructions for voteout. e) Flag/Code (+): Send to reference lab for testing. f) Flag/Code (1,2,3,4,M): Results reported unless provider request specimen sent for further review by reference lab. g) Flag/Code (X): Mix and rerun; If flag does not repeat, report results; If repeats zap the aperture; If still persists contact Coulter technical support. h) Flag/Code (*): See instructions for ++++++, +, or - - - - - - . 3. Review of the Beckman Coulter's manufacturer instructions under "Parameter Codes And Flags" revealed "If any flag appears, review the results according to your laboratory's protocol". 4. In interview on September 17, 2018 at 4: 22 pm, Personnel 3 stated the laboratory staff reruns any patient samples with flags and that a copy of the rerun sample is kept with the original sample run in patient's chart. Personnel 3 further stated if the sample is not repeated then the staff is to document the reason on the original report. 5. Review of a random selection of patients from April 2018 through September 2018 revealed flags on patient reports for the following four (4) of ten (10) patients reviewed: a) On May 15, 2018 at 11:41 am Patient 1 reported with (*) Flag/Code on Red Cell Distribution Width (RDW) -- no documentation of rerunning sample or reason for not repeating. b) On May 21, 2018 at 11:15 am Patient 8 reported with (*) Flag/Code on Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), Platelets (PLT), and Mean Platelet Volume (MPV) -- no documentation of rerunning sample or reason for not repeating. c) On June 18, 2018 at 16:23 pm Patient 7 reported with Flag/Code on White Blood Cell (WBC), Lymphocyte # (LY #), Monocyte # (MO #), and Granulocyte # (GR #) -- no documentation of rerunning sample or reason for not repeating. d) On July 25, 2018 at 08:36 am Patient 6 reported with Flag/Code on Monocyte % (MO %), and Monocyte # (MO #) -- no documentation of rerunning sample or reason for not repeating. 6. In interview on September 17, 2018 at 4:40 pm, Personnel 2 stated the laboratory is to rerun all flags on patient reports. Personnel 2 confirmed the above patient flags were not repeated according to laboratory policy. 7. Review of the Task 1 & 3 form given to surveyor on site revealed the laboratory performs six hundred (600) CBC's annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(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 observation and interview with personnel, the laboratory failed to ensure supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on September 17, 2018 revealed the following expired items: a) Cabinet located in laboratory: * one (1) 10% Neutral Buffered Formalin v/v Lot 284747 Exp 03/2018 b) Cabinet located in laboratory: * four (4) BioMed Diagnostics In Pouch TV Trichomonas Vaginalis Test Lot 7HA123A Exp 07/14/18 2. In interview on September 17, 2018 at 1:40 pm, Personnel 2 stated he was unaware of expired supplies. Personnel 2 confirmed the supplies were expired.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to take corrective action when quality control samples were unacceptable for Hematology testing. Findings: 1. Observation by surveyor during the tour of the laboratory on September 17, 2018 revealed the laboratory maintained a Beckman Coulter ACT Diff 2 analyzer for Complete Blood Count (CBC) testing which includes: White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), Platelets (PLT), Mean Platelet Volume (MPV), Lymphocyte % (LY %), Lymphocyte # (LY#), Monocyte % (MO %), Monocyte # (MO #), Granulocyte % (GR %), and Granulocyte # (GR #). 2. Review of the laboratory's policy and procedure revealed under Quality Control: "QC must be acceptable before testing and/or reporting of results is permitted. Any results obtained when QC is unacceptable or not performed are invalid and must be repeated." 3. Further review of the laboratory's policy and procedure revealed the laboratory is to review any codes or flags that appear for the following Flag/Code: a) Flag/Code (- - - - - -): Mix and rerun sample; If repeats - zap apertures; If repeats - clean baths; If repeats call Beckman Coulter technical support b) Flag/Code (++++++): Verify reagent levels and delivery. If ok, send sample to reference lab for testing. c) Flag /Code (+): See instructions for ++++++, +, or - - - - - -. 4. In interview on September 17, 2018 at 3:21 pm, Personnel 2 stated the laboratory personnel are to rerun samples if any flags appear on Quality Control (QC) or patient samples. 5. In further interview on September 17, 2018, Personnel 2 stated the laboratory started patient testing in

April 2018. 6. Review of QC records from March 5, 2018 through September 4, 2018 revealed the laboratory did not rerun QC samples according to the laboratory policy for the following: Lot 089200 Exp 6/5/18 a) March 5, 2018 at 12:54: (*) flag on MO % and MO # March 5, 2018 at 12:59: (*) flag on MO % and MO # March 5, 2018 at 13:04: (*) flag on MO % and MO # March 5, 2018 at 13:09: (*) flag on MO % and MO # March 5, 2018 at 13:14: (*) flag on MO % and MO # March 5, 2018 at 16:15: (*) flag on MO % and MO # March 5, 2018 at 16:20: (*) flag on MO % and MO # March 5, 2018 at 16:30: (*) flag on MO % and MO # March 5, 2018 at 16:42: (*) flag on MO % and MO # March 5, 2018 at 16:48: (*) flag on MO % and MO # b) March 6, 2018 at 09:08: (*) flag on MO % and MO # March 6, 2018 at 09:15: (*) flag on MO % and MO # March 6, 2018 at 15:35: (*) flag on MO % and MO # March 6, 2018 at 15:39: (*) flag on MO % and MO # March 6, 2018 at 15:45: (*) flag on MO % and MO # c) March 7, 2018 at 08:37: (*) flag on MO % and MO # March 7, 2018 at 08:46: (*) flag on MO % and MO # March 7, 2018 at 08:47: (*) flag on MO % and MO # March 7, 2018 at 08:54: (*) flag on MO % and MO # March 7, 2018 at 09:00: (*) flag on MO % and MO # March 7, 2018 at 09:05: (*) flag on MO % and MO # d) March 8, 2018 at 09:13: (*) flag on MO % and MO # March 8, 2018 at 09:16: (*) flag on MO % and MO # March 8, 2018 at 09:20: (*) flag on MO % and MO # March 8, 2018 at 09:31: (*) flag on MO % and MO # March 8, 2018 at 11:51: (*) flag on MO % and MO # March 8, 2018 at 11:56: (*) flag on MO % and MO # March 8, 2018 at 12:04: (*) flag on MO % and MO # e) March 9, 2018 at 09:19: (*) flag on MO % and MO # March 9, 2018 at 09:41: (*) flag on MO % and MO # March 9, 2018 at 14:27: (*) flag on MO % and MO # March 9, 2018 at 14:32: (*) flag on MO % and MO # March 9, 2018 at 15:02: (*) flag on MO % and MO # f) March 23, 2018 at 08:34: (*) flag on MO % and MO # g) March 26, 2018 at 08:05: (*) flag on MO % and MO # h) March 27, 2018 at 07:59: (*) flag on MO % and MO # March 27, 2018 at 08:00: (*) flag on MO % and MO # i) March 28, 2018 at 08:31: (*) flag on MO % and MO # j) March 29, 2018 at 07:53: (*) flag on MO % and MO # Lot 089200 Exp 06/05/18 a) April 2, 2018 at 07:56: (*) flag on MO % and MO # b) April 3, 2018 at 07:59: (*) flag on MO % and MO # c) April 9, 2018 at 08:36: (*) flag on MO % and MO # April 9, 2018 at 10:20: (*) flag on MO % and MO # d) April 10, 2018 at 07:52: (*) flag on MO % and MO # e) April 16, 2018 at 08:08: (*) flag on MO % and MO # f) April 17, 2018 at 08:11: (*) flag on MO % and MO # g) April 18, 2018 at 07:54: (*) flag on MO % and MO # h) April 19, 2018 at 07:58: (*) flag on MO % and MO # i) April 20, 2018 at 07:44: (*) flag on MO % and MO # j) April 23, 2018 at 08:18: (*) flag on MO % and MO # Lot 089200 Exp 06/05/18 a) May 2, 2018 at 07:58: (*) flag on MO % and MO # b) May 3, 2018 at 07:56: (*) flag on MO % and MO # c) May 7, 2018 at 07:54: (*) flag on MO % and MO # d) May 8, 2018 at 07:44: (*) flag on MO % and MO # e) May 9, 2018 at 07:47: (*) flag on MO % and MO # f) May 10, 2018 at 07:58: (*) flag on MO % and MO # g) May 11, 2018 at 09:49: (*) flag on MO % and MO # h) May 14, 2018 at 07:47: (*) flag on MO % and MO # i) May 15, 2018 at 08:42: (*) flag on MO % and MO # j) May 16, 2018 at 07:48: (*) flag on MO % and MO # k) May 17, 2018 at 08:55: (*) flag on MO % and MO # l) May 18, 2018 at 07:49: (*) flag on MO % and MO # m) May 21, 2018 at 09:33: (*) flag on MO % and MO # n) May 22, 2018 at 08:00: (*) flag on MO % and MO # o) May 23, 2018 at 08:03: (*) flag on MO % and MO # p) May 24, 2018 at 08:00: (*) flag on MO % and MO # q) May 25, 2018 at 07:42: (*) flag on MO % and MO # r) May 29, 2018 at 07:42: (*) flag on MO % and MO # s) May 30, 2018 at 07:55: (*) flag on MO % and MO # t) May 31, 2018 at 08:15: (*) flag on MO % and MO # Lot 089900 Exp 09/10/2018 a) June 1, 2018 at 08:11: (*) flag on MO % and MO # b) June 4, 2018 at 07:55: (*) flag on MO % and MO # c) June 5, 2018 at 07:46: (*) flag on MO % and MO # d) June 12, 2018 at 16:12: (*) flag on MO % and MO # e) June 13, 2018 at 07:51: (*) flag on MO % and MO # f) June 14, 2018 at 07:51: (*) flag on MO % and MO # g) June 15,

	2018 at 07:50: (*) flag on MO % and MO # h) June 18, 2018 at 07:46: (*) flag on MO % and MO # i) June 19, 2018 at 07:59: (*) flag on MO % and MO # j) June 20, 2018 at 07:55: (*) flag on MO % and MO # k) June 21, 2018 at 07:56: (*) flag on MO % and MO # l) June 22, 2018 at 08:00: (*) flag on MO % and MO # m) June 25, 2018 at 11:11: (*) flag on MO % and MO # n) June 26, 2018 at 07:51: (*) flag on MO % and MO # o) June 27, 2018 at 08:15: (*) flag on MO % and MO # p) June 28, 2018 at 07:44: (*) flag on MO % and MO # q) June 29, 2018 at 07:50: (*) flag on MO % and MO # Lot 089900 Exp 09/10/18 a) July 2, 2018 at 07:51: (*) flag on MO % and MO # b) July 3, 2018 at 07:51: (*) flag on MO % and MO # c) July 5, 2018 at 07:56: (*) flag on MO % and MO # d) July 6, 2018 at 08:08: (*) flag on MO % and MO # e) July 9, 2018 at 07:40: (*) flag on MO % and MO # f) July 10, 2018 at 07:38: (*) flag on MO % and MO # g) July 11, 2018 at 07:43: (*) flag on MO % and MO # h) July 12, 2018 at 07:50: (*) flag on MO % and MO # i) July 13, 2018 at 07:48: (*) flag on MO % and MO # j) July 16, 2018 at 08:42: (*) flag on MO % and MO # k) July 17, 2018 at 07:49: (*) flag on MO % and MO # l) July 18, 2018 at 07:52: (*) flag on MO % and MO # m) July 19, 2018 at 07:39: (*) flag on MO % and MO # n) July 20, 2018 at 07:41: (*) flag on MO % and MO # o) July 23, 2018 at 07:46: (*) flag on MO % and MO # p) July 24, 2018 at 07:46: (*) flag on MO % and MO # q) July 25, 2018 at 07:41: (*) flag on MO % and MO # r) July 26, 2018 at 07:49: (*) flag on MO % and MO # s) July 27, 2018 at 07:45: (*) flag on MO % and MO # t) July 30, 2018 at 07:44: (*) flag on MO % and MO # u) July 31, 2018 at 07:54: (*) flag on MO % and MO # Lot 089900 Exp 09/10/18 a) August 1, 2018 at 07:40: (*) flag on MO % and MO # b) August 2, 2018 at 07:48: (*) flag on MO % and MO # c) August 3, 2018 at 07:52: (*) flag on MO % and MO # d) August 6, 2018 at 09:27: (*) flag on MO % and MO # e) August 7, 2018 at 07:37: (*) flag on MO % and MO # f) August 8, 2018 at 07:47: (*) flag on MO % and MO # g) August 9, 2018 at 07:53: (*) flag on MO % and MO # h) August 10, 2018 at 07:40: (*) flag on MO % and MO # i) August 13, 2018 at 09:47: (*) flag on MO % and MO # j) August 14, 2018 at 07:55: (*) flag on MO % and MO # k) August 15, 2018 at 07:41: (*) flag on MO % and MO # l) August 16, 2018 at 07:37: (*) flag on MO % and MO # m) August 17, 2018 at 08:20: (*) flag on MO % and MO # n) August 20, 2018 at 07:41: (*) flag on MO % and MO # o) August 21, 2018 at 07:44: (*) flag on MO % and MO # p) August 22, 2018 at 07:43: (*) flag on MO % and MO # q) August 23, 2018 at 07:50: (*) flag on MO % and MO # r) August 24, 2018 at 07:42: (*) flag on MO % and MO # s) August 27, 2018 at 07:59: (*) flag on MO % and MO # t) August 28, 2018 at 07:44: (*) flag on MO % and MO # u) August 29, 2018 at 07:45: (*) flag on MO % and MO # v) August 30, 2018 at 07:57: (*) flag on MO % and MO # w) August 31, 2018 at 07:46: (*) flag on MO % and MO # 7. In interview on September 17, 2018 at 4:22 pm, Personnel 2 stated the manufacturer said the asterick (*) flag on QC samples is acceptable however, the laboratory did not have any reference from the manufacturer. Personnel 2 confirmed the QC samples were not repeated according to laboratory policy.
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 observation, record review, and interview with personnel, the laboratory's

	Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to follow the laboratory's instructions for flags appearing on Complete Blood Counts (CBC) for four (4) of ten (10) patients reviewed. Refer to D5411. b) The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417. c) The laboratory failed to take corrective action when quality control samples were unacceptable for Hematology testing. Refer to D5783. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify the deficiencies identified. 3. Interview with Personnel 2 on September 17, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 3. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to follow the laboratory's instructions for flags appearing on Complete Blood Counts (CBC) for four (4) of ten (10) patients reviewed. Refer to D5411. 2. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5791.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5783.