Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0442495	02/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Belton Regional Medical Center	17065 South 71 Hwy, Belton, MO	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with testing personnel # 8 and the general supervisor on February 8, 2018 at 11:00 AM confirmed the laboratory director failed to approve, sign and date nine of nine procedures before use. Findings: 1. Review of nine selected laboratory procedures revealed the laboratory director failed to approve the following procedures: a.) Sysmex XT Hematology analyzer operating procedure b.) Plasma components c.) Transfusion investigation d.) PTT reagent conversion protocol e.) General quality control procedures f.) Competency assessment procedures g.) Body fluid procedure h.) Individualized quality control plan (procedures) for blood gas analytes performed on I-stat. i) Laboratory Quality Assessment and Performance Improvement Plan 2. Interview with testing personnel # 8 and the general supervisor on February 8, 2018 at 11:00 AM confirmed the laboratory director failed to approve, sign and date laboratory procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation of environmental conditions, review of manufacturer's instructions, lack of documentation and interview with testing personnel # 8, the laboratory failed to define criteria consistent with manufacturers instructions and document humidity conditions for 2016, 2017 and to date 2018. Findings: 1. Observation of environmental conditions revealed a humidifier operating in the core laboratory area. 2. The manufacturer's instructions for the chemistry analyzer states, " Relative humidity must be maintained between equal to or greater than twenty percent and equal to or less than eighty percent." 3. No documentation was available to show the laboratory defined criteria consistent with the manufacturer's instructions for humidity conditions. No documentation was available to show the laboratory monitored and documented humidity conditions. 4. Interview with testing personnel # 8 on February 8, 2018 at 10:30 AM confirmed the laboratory failed to define criteria for humidity consistent with manufacturer's instructions and document those conditions.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review on instrument comparisons and interview with testing personnel #8 on February 8, 2018 at 10:00 AM confirmed, the laboratory failed to evaluate and define a relationship twice a year between analyzers performing troponin testing for 2016 and 2017. Findings: 1. Review of instrument comparisons revealed the laboratory did not have a system to define and evaluate a relationship between the Dimension EXL instrument and I-stat instrument performing troponin testing twice a year. 2. Interview with testing personnel # 8 on February 8, 2018 at 10:00 AM confirmed, the laboratory failed to define, evaluate and document instrument comparisons between the two instruments performing troponin testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the quality control (QC) program, quality assessment (QA) program, personnel records, procedure manual and interviews, the director failed to provide overall management and direction to the laboratory. The laboratory director failed to approve and ensure adequate validations (refer to #D6086); failed to ensure all proficiency testing reports received are reviewed by appropriate staff (refer to

	#D6091); failed to approve and maintain the QC program (refer to #D6093); failed to approve and maintain the QA program (refer to #D6094); failed to ensure individuals serving as clinical consultants have appropriate education for providing consultation for laboratory services (refer to # D6101); failed to ensure all personnel have appropriate education for the type and complexity of services offered (refer to #D6102) and failed to ensure approved procedure manuals were available to all personnel responsible for testing (refer to #D6106). Based on these findings the laboratory failed to have an individual serving in the position of laboratory director.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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: Based on review of i-stat validation and interview with testing personnel #8 the laboratory director failed to ensure troponin vaildation on i-stat was adequate. Findings: 1. Review of i-stat troponin validation showed, no accuracy, reportable range verification and no laboratory director approval. 2. Interview with testing personnel #8 on February 8, 2018 at 3:30 PM confirmed the laboratory director failed to ensure troponin i-stat validation was adequate.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) and interview with laboratory manager, the laboratory director failed to ensure all proficiency testing reports received are reviewed by appropriate staff for five of six PT events in 2016 and 2017. Findings: 1. Review of PT for microbiology, chemistry, hematology, immunohematology and diagnostic immunology for 2016 showed no accessible records and data could be provided within a reasonable time frame during the course of the inspection for all three PT testing events in 2016. No data could be provided to show PT reports received are reviewed by appropriate staff. 2. Review of PT for microbiology, chemistry, hematology, immunohematology and diagnostic immunology for 2017 showed no accessible records and data could be provided within a reasonable time frame during the course of the inspection for two PT testing events in 2017. No data could be provided to show PT reports received are reviewed by the appropriate staff. 3. Interview with the laboratory manager on February 8, 2018 at 4:00 PM confirmed the laboratory director failed to ensure all proficiency testing reports received are reviewed by appropriate staff.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) program and interview with the general supervisor, the laboratory director failed to maintain the QC program to assure quality of services. Findings: 1. Review of the QC program revealed no documentation to show the laboratory director reviewed, approved, dated or signed the laboratory QC policies and procedures. 2. Interview with the general supervisor on February 8, 2018 at 2:00 PM revealed no evidence a laboratory director provided management and direction since September 2017. Interview confirmed the laboratory director failed to ensure the QC program was maintained.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) program, QA reports for 2017 and interview with the general supervisor, the laboratory director failed to maintain the laboratory's QA program to assure quality of services. Findings: 1. Review of the "Quality Assessment and Performance Improvement Plan" (policies) showed no documentation the laboratory director approved the QA program 2. Review of the QA program monitoring review form for third quarter 2017 (July, August, September) revealed no review by the laboratory director. The form / procedure requires director signature of approval for quarterly QA activities. Fourth quarter QA program reports were not available. 3. Interview with the general supervisor on February 8, 2017 revealed she has been waiting for laboratory director position individual to review and approve third quarter 2017 QA activities. Interview confirmed the laboratory director failed to maintain the QA program since third quarter 2017.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of personnel records, on-call pathology calendars and interview with general supervisor and Quality Assurance (QA) specialist on February 8, 2018 at 2:00 PM confirmed, the laboratory director failed to ensure the laboratory maintain appropriate academic and state licensure credentials for five of seven pathology individuals serving as clinical consultants responsible for laboratory consultation.

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 personnel academic credentials and interview with the general supervisor, the laboratory director failed to ensure the laboratory maintain academic credentials for nine of thirteen testing personnel and one of one general supervisor personnel to verify educational qualifications for the complexity of testing performed.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 laboratory procedure manuals and interview with testing personnel # 8 and the general supervisor, the laboratory director failed to approve six of six procedure manuals available to testing personnel. Findings: 1. Review of the hematology, urinalysis, coagulation, blood bank, blood gas and chemistry manual revealed no documentation the director approved the procedure manuals. 2. Interview with testing personnel # 8 and the general supervisor on February 8, 2018 at 2:00 PM confirmed, the laboratory director failed to approve the manuals available for use.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel records and interviews, the laboratory failed to provide evidence it employed one or more individuals qualified to provide technical supervison for each specialty/subspecialty (refer to #6109); failed to provide technical supervision and scientific oversight for the specialty of immunohematology (refer to # D6112) and failed to evaluate and document performance of testing personnel at least annually (refer to #D6128).
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the

	specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel roster and interview with the general supervisor on February 8, 2018 at 2:00 PM confirmed, the laboratory failed to provide evidence it employed a technical supervisor(s) to provide supervision for five of five specialities (with subspecialties) the laboratory performs.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with testing personnel #8, the laboratory failed to provide evidence it filled the position of technical supervisor for oversight of high complexity immunohematology testing. Findings: 1. The laboratory did not have documentation to show a current technical supervisor or director qualified to serve as technical supervisor provided supervision for the specialty of immunohematology (blood bank). 2. Interview with testing personnel #8 on February 8, 2018 at 2:00 PM confirmed, the laboratory did not have evidence the laboratory currently employs a technical supervisor to provide supervision of immunohematology testing.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's 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 personnel records for 2016 and 2017, personnel competency policy and interview with the general supervisor , the technical supervisor failed to evaluate and document competency/performance assessments for two of two testing personnel for 2016 and 2017. Findings: 1. Review of competency/performance assessments for two testing personnel revealed the technical supervisor position did not perform the competency assessments. The records showed the competency assessments were documented by peer review. 2. The competency assessment for laboratory personnel policy states, "Competency assessments by routine supervisory or peer review will be documented. Direct observation may be performed by peers, lead techs, managers or directors. At the time of the employees' performance the

	director will review the proof of compliance documentation." 3. The laboratory did not have documentation to show a technical supervisor or director serving in the position of technical supervisor evaluated and documented the performance of the two testing personnel. 4. The laboratory's competency assessment policy for laboratory personnel does not meet the regulatory requirements for assessing competency of personnel as stated in 493.1451 (b)(9). 5. Interview with the general supervisor on February 8, 2018 at 3:00 PM confirmed the competency assessments were performed by individuals not listed as a technical supervisor.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with general supervisor and quality assurance (QA) specialist the laboratory failed to have academic credentials required to qualify five of seven individuals serving as clinical consultants. (refer to #D6135).
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of pathology on-call weekly schedules, personnel rosters and interview with general supervisor and QA specialist, the laboratory failed to have academic and state licensure credentials to qualify five of seven pathology individuals serving as clinical consultants for eight of thirteen weeks from October 9, 2017 through the week of January 1, 2018. Findings: 1. Review of pathology on-call schedules revealed five of seven individuals serving as clinical consultants did not have credentials available and are not listed on the CMS-personnel roster form 209. 2. Interview with general supervisor and QA specialist on February 8, 2018 at approximately 2:00 PM confirmed the laboratory did not maintain qualifications for five pathology individuals serving as clinical consultants for the laboratory.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of personnel records and interview with general supervisor #1 and the quality assurance (QA) specialist, the laboratory failed to have academic credentials required to qualify one of two general supervisor personnel (refer to tag # D6142).
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with general supervisor #1 and quality assurance (QA) specialist, the laboratory failed to have documentation of academic credentials to qualify one of two general supervisor personnel. Findings: 1. Review of personnel records revealed the laboratory did not have academic credentials to qualify general supervisor #2. 2. Interview with the general supervisor #1 and QA specialist on February 8, 2018 at 2:00 PM confirmed the laboratory did not have academic credentials required to qualify geneneral supervisor #2.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the general supervisor and the quality assurance (QA) specialist, the laboratory failed to have academic credentials required to qualify eleven of twenty-three testing personnel (refer to tag #6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum,

include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the general supervisor and Quality Assurance (QA) specialist, the laboratory failed to have academic credentials to qualify eleven of twenty-three testing personnel. Findings: 1. Review of personnel records revealed the laboratory did not have academic credentials to qualify eleven testing personnel. 2. Interview with the general supervisor and QA specialists on February 8, 2018 at 2:00 PM confirmed the laboratory did not have academic credentials required to qualify eleven testing personnel.

D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) and interview with laboratory manager the laboratory failed to provide documentation for five of six PT events for 2016 and 2017. Findings: 1. Review of PT testing for 2016 showed no accessible records and data could be provided within a reasonable time frame during the course of the inspection for all three PT testing events in 2016. 2. Review of PT testing for 2017 showed no accessible records and data could be provided within a reasonable time frame during the course of the inspection for two PT testing events in 2017. 3. Interview with the laboratory manager on February 8, 2018 at 4:00 PM confirmed laboratory failed to provide five PT events within a reasonable time frame during the course of the inspection for 2016 and 2017.