Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0507358	10/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Crosbyton Clinic Hospital	710 W Main St, Crosbyton, 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: 493.803 Condition: Successful participation 493.1215 Condition: Hematology 493.1441 Condition: Laboratories Performing High Complexity testing; Laboratory Director 493.1409 Condition: Laboratories Performing Moderate Complexity testing; Technical Consultant
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CMS-155 proficiency testing report, the American proficiency

	Institute (API) proficiency testing records for 2015, 2016 and 2017, and interview of facility personnel the laboratory failed to successfully participate in a proficiency testing program for antibody identification. (See D2188 and D2191)
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records (3 testing events per year) from 2017 and 2018, and interview facility personnel the laboratory failed to attain an overall compatibility testing event score of at least 100% which constitutes unsatisfactory performance. Findings included: 1. Review of proficiency testing records found that the laboratory attained a score of 60% in the American Association of Bioanalysts (AAB) 2017 Q2 testing event for compatibility testing. The laboratory submitted unacceptable responses for specimens two and three. 2. Interview of the general supervisor conducted on October 16, 2018 at 11:07 AM confirmed that the laboratory made a transcription error for compatibility testing specimen two, and the specimen one was repeated and the correct results were obtained.
D2182	ANTIBODY IDENTIFICATION CFR(s): 493.865(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Review of the CMS report 155, proficiency testing records and interview of facility personnel found that the laboratory failed to attain a satisfactory score (80% or higher) in two of three consecutive testing events for antibody identification. The findings included: 1. Review of the CMS report 155 found that the laboratory attained and unacceptable score of 0% for antibody identification in the third testing event of 2017 and the second testing event of 2018 . 2. Review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records found that the laboratory received a score of 0% for anybody identification in the third testing event of 2017 in the second testing event of 2018 with no documentation of corrective actions. 3. Interview of the general supervisor conducted on October 16, 2018 11:07 AM found that he didn't even notice that the antibody identification score was 0% because the laboratory doesn't test antibody identification at this facility. He went on to say that if the laboratory determined that an antibody screen was positive they would refer all specimens to a reference laboratory for identification.
D2188	ANTIBODY IDENTIFICATION CFR(s): 493.865(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing event score, remedial action must be taken and documented, and

	the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Review of the CMS report 155, proficiency testing records and interview of facility personnel found that the laboratory failed to take and document corrective actions when proficiency testing failures occurred in two of three consecutive testing events for antibody identification. The findings included: 1. Review of the CMS report 155 found that the laboratory attained and unacceptable score of 0% for antibody identification in the third testing event of 2017 and the second testing event of 2018 . 2. Review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records found that the laboratory received a score of 0% for anybody identification in the third testing event of 2017 in the second testing event of 2018 with no documentation of corrective actions. 3. Interview of the general supervisor conducted on October 16, 2018 11:07 AM found that he didn't even notice that the antibody identification score was 0% because the laboratory doesn't test antibody identification at this facility. He went on to say that if the laboratory determined that an antibody screen was positive they would refer all specimens to a reference laboratory for identification
D2191	ANTIBODY IDENTIFICATION CFR(s): 493.865(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Review of the CMS report 155, proficiency testing records and interview of facility personnel found that the laboratory failed to attain a satisfactory score (80% or higher) in two of three consecutive testing events for antibody identification, resulting in unsuccessful performance. The findings included: 1. Review of the CMS report 155 found that the laboratory attained and unacceptable score of 0% for antibody identification in the third testing event of 2017 and the second testing event of 2018 . 2. Review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records found that the laboratory received a score of 0% for anybody identification in the third testing event of 2017 in the second testing event of 2018 with no documentation of corrective actions. 3. Interview of the general supervisor conducted on October 16, 2018 11:07 AM found that he didn't even notice that the antibody identification score was 0% because the laboratory doesn't test antibody identification at this facility. He went on to say that if the laboratory determined that an antibody screen was positive they would refer all specimens to a reference laboratory for identification.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299.

	This CONDITION is not met as evidenced by: Review of patient test records, quality control records and interview of facility personnel found the laboratory failed to meet the requirements for the specialty of Hematology. Findings Included: 1. The Laboratory failed to establish and maintain a quality control program for Prothrombin Time. (See D5441)
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of facility personnel found that the laboratory's quality assurance procedure failed to identify and correct problems in proficiency testing. (See D2173, D2182, D2188 and D2191)
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: Review of policies and procedures, calibration records and interview of facility personnel found that the laboratory failed to perform calibration procedures at least once every six months when using the Coulter DX H 600 hematology analyzer serial number AW 23179 for complete blood count (CBC) testing. Findings included: 1. Review of the laboratory's quality assurance management procedure found on page 12 under the heading Beckman Coulter DX H - "S Cal calibrator will be run biannually for the determination of calibration factors for the DX H (per manufacturer guidelines for WBC, RBC, Hgb, MCV, PLT, and MPV parameters)" 2. Review of calibration records found that the laboratory performed calibration procedures on May 20, 2017, December 4, 2017 and September 19, 2018. There were no other calibration records available for review. Three. Interview of the technical consultant conducted on October 17, 2018 at 11:35 AM confirmed that the laboratory failed to perform biannual calibration as defined in their own policy.
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 the laboratory's calibration verification records for 2017 and 2018, and staff interview, the laboratory failed to perform calibration verification of Sodium, Potassium, and Chloride tested on the Dimension Xpand chemistry analyzer serial number 2004082124 at least once every six months. The findings include: 1. Review of calibration verification (linearity) procedures found documentation of calibration verification activities for sodium potassium and chloride (calibrated with two standards) being done on December's 26 2016, June 28, 2017 and February 23, 2018. Additional calibration verification records were requested but not provided. 2. Interview of the technical consultant conducted on October 17, 2018 and 12:00 PM confirmed that no additional records for calibration verification were available for review. He stated that they "had received standard sometime last month but they didn't perform well so they had to order new ones and they just barely got them."
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observations, review of the laboratory's quality control records for the

	Sysmex CA 540, patient test records, quality assessment records and interview of facility personnel, the laboratory failed to have a quality control program to detect immediate errors and monitor accuracy and precision over time for three of three months reviewed. The findings included: 1. Observations made during the tour the facility found that the laboratory was using the Sysmex CA 540 coagulation analyzer serial number A3262 to perform ProTime (PT) and Activated Partial Thromboplastin Time (APTT). Further observations found that the laboratory was currently using CiTrol quality control material levels one (lot of 548070) and level 3 (lot 548497). 2. Review of the laboratory's quality control records for August 2018 through October 2018 found: a. Acceptable limits recorded on the coagulation maintenance log for ProTime were 8 to 12 seconds for Citrol 1 lot 548070 and 42 to 52 seconds for Citrol 3 lot 548497. b. Review of the quality control files in the Sysmex CA 540 coagulation analyzer found data for Lot number 548049 and 548483. c. Review of the quality control files found in the laboratory information system found acceptable limits defined as 9.7 to 10.3 seconds for Citrol 1 lot 548070 and 42 to 50 seconds for Citrol 3 lot 548497. d. Review of the raw data from the establishment study conducted prior to using the lot number found calculated means and ranges as follows: I. Citrol 1 lot 548070 - two standard deviation (SD) acceptable limits defined as 9.9 to 10.3 seconds. II. Citrol 3 lot 548497 - two standard deviation (SD) acceptable limits defined as 38.8 to 42.9 seconds e. Review of the quality control files for August 2018 found that the laboratory failed to obtain acceptable results (38.8 to 42.9 seconds) for Citrol 3 10 of 15 times between August 7 and August 31, 2018. August 7, 2018 at 15:14 - the laboratory obtained a result of 46.30 seconds with no repeat. August 15, 2018 at 14:17 - the laboratory obtained a result of 44.50 seconds with no repeat. August 16, 2018 at11:35 - the laboratory obtained a result of 47.80 seconds with no repeat. August 17, 2018 at 17:14 - laboratory obtained a result of 46.50 seconds with no repeat. August 21, 2018 at21:41 - the laboratory obtained a result of 46.8 seconds with no repeat August 24, 2018 at14:03 - the laboratory obtained a result of 45.70 seconds with no repeat. August 27, 2018 at 10: 34 - the laboratory obtained a result of 45.40 seconds with no repeat August 29, 2018 at 14:08 - the laboratory obtained a result of 48.80 seconds with no repeat August 31, 2018 at 11:50 - the laboratory obtained a result of 48.50 seconds with no repeat 3. Review of patient test reports found that the laboratory tested and reported patient results without two levels of acceptable quality control on the following dates: August 7, 2018 - one patient August 15, 2018 one patient August 16, 2018 one patient August 17, 2018 one patient August 20, 2018 one patient August 21, 2018 one patient August 24, 2018 one patient August 27, 2018 one patient August 29, 2018 two patients August 31, 2018 one patient 4. Review the laboratory's monthly internal quality checks for August 2018 found no documentation regarding quality control failures for Citrol 3. 5. Interview the technical consultant conducted on October 17, 2018 at 10:30 AM confirmed that the laboratory switched lots on August 1, 2018. He stated that the laboratory relied upon values injured into the LIS for quality control acceptability criteria. He went on to say that he submitted raw data to Siemens and received a report that didn't know what to do with the report. He further confirmed that values in the CA 540 analyzer were not changed when the lots which occurred August 1, 2018
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 package inserts, observations, patient test records, and interview of facility personnel found that the laboratory failed to test a negative and positive serum quality control material each day of patient testing for serum hCG when using the Sure Vue serum/urine hCG pregnancy test kit. Findings included: 1. Review of the package insert for the Sure Vue serum/urine hCG pregnancy test kit found under the heading quality control - "internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test results. It is recommended that a positive hCG control (containing greater than or equal to 25 mIU/mL in urine or greater than or equal to 25 mIU/mL hCG in serum) and a negative hCG control (containing"0"mIU/mL hCG) be evaluated to verify proper test performance. For urine testing, control should be tested with each new lot or shipment of product, with each new operator, monthly as a check on continued storage conditions, or as otherwise required by your laboratory's internal quality system procedures. For serum testing, federal, state, and local guidelines should be followed." 2. Observations made during the tour the facility found that the laboratory was currently using Sure Vue serum/urine hCG pregnancy test kit lot hCG 712-0166 expiration 2019-11-30. The laboratory was currently using Alta diagnostics liquid urine dipstick control lots 339733 and 111834 (negative and positive) as their sole quality control for theSure Vue serum/urine hCG pregnancy kit. 3. Review of patient test records found that the laboratory had tested 63 patient specimens for serum pregnancy since January 1, 2018 without testing a negative and positive serum control. 4. Interview of the technical consultant conducted on October 16, 2018 at 2: 55 PM confirmed that the laboratory does not test serum controls each day of patient testing when using theSure Vue serum/urine hCG pregnancy test kit. He went on to say that the laboratory's IQCP procedure for serum hCG was based on the use of the urine quality control materials.
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 laboratory policies and procedures and interview of facility personnel found the laboratory failed to have a written policy to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283. (See D5441, d5449, D5439 and D 5437)
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: The laboratory director failed to ensure that the quality control program for Hematology was established and maintained. (See D6020)
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 and interview of facility personnel found that the laboratory director failed to ensure that the quality control program was established and maintained for hematology. (See D5441 and D 5449)
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: The technical Consultang failed to ensure that the quality control program for Hematology was established and maintained. (See D6020)
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 interview of facility personnel found that the technical Consultant failed to ensure that the quality control program was established and maintained for hematology. (See D5441 and D 5449)
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: Review of proficiency testing records and interview of facility personnel found that the laboratory director failed to ensure that corrective actions were taken when proficiency testing failures occurred in compatability testing and antibody identification. (see D 6092)
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, corrective actions, and confirmed in interview, the laboratory director failed to ensure that an approved corrective action plan that included training or technical assistance and remedial actions was taken for the unsuccessful performance on 2nd event - 2016 Compatability proficiency testing. (See D2173, D2188 and D2191)