Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0653322	02/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lincoln County Medical Center Laboratory	211 Sudderth Drive, Ruidoso, NM	

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 representative of the New Mexico State Agency completed a federal survey on 02 /07/2018. Based on survey findings the facility was not in compliance of 42 CFR 493, Laboratory Requirements. The laboratory was out of compliance with the following conditions: 42 CFR Part 493.803 Proficiency Testing, Successful Participation 42 CFR Part 493.807 Proficiency Testing, Reinstatement after failure 42 CFR Part 493.1403 Laboratory Director, moderate complexity 42 CFR Part 493.1441 Laboratory Director, high complexity
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 the review of 2016-2018 proficiency test reports from the proficiency testing

	agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interviews with laboratory staff, the laboratory failed to successfully participate in proficiency testing for compatibility testing. Findings are: 1. The laboratory failed to achieve overall satisfactory proficiency test scores for 2 consecutive test events for compatibility testing in 2016. See D2162 2. The laboratory failed to achieve overall satisfactory proficiency test scores for 3 of 5 test events for compatibility testing in 2016-2017. See D2181 3. The laboratory failed to successfully participate in proficiency testing for compatibility testing and must obtain training and technical assistance to identify the cause of the failures and perform corrective actions. See D2179 4. The laboratory failed to obtain an overall score of at least 100% for compatibility testing. See D2173
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on the review of 2016-2018 proficiency test reports from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interviews with laboratory staff, the laboratory failed 3 of 5 test events for compatibility testing. Findings are: 1. The laboratory failed to achieve overall satisfactory proficiency test scores for 2 consecutive test events for compatibility testing in 2016. See D2162 2. The laboratory failed to achieve overall satisfactory proficiency test scores for 3 of 5 test events for compatibility testing in 2016-2017. See D2181 3. The laboratory failed to successfully participate in proficiency testing for compatibility testing and must obtain training and technical assistance to identify the cause of the failures and perform corrective actions. See D2179 4. The laboratory failed to obtain an overall score of at least 100% for compatibility testing. See D2173
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: Based on the review of 2016-2018 proficiency test reports from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interviews with laboratory staff, the laboratory failed to achieve overall satisfactory proficiency test scores for 2 consecutive test events for compatibility testing in 2016. Findings are: 1. Review of CASPER Report 0155D (from the CMS proficiency database) indicated the laboratory received a failing score of 80% for the 2nd event of 2016 and the 3rd event of 2016. 2. Review of the scores from the College of American Pathologists confirmed this finding. 3. During interview on 2/01/18 at 8:15 am TP (Testing Person) # 3 stated that the laboratory had recently changed gel card systems. The new system only required the use of 1 card instead of 2. She also stated the the testing person obtained the correct results but failed to interpret the results correctly for one of the failed test events. 4. Review of the laboratory's proficiency records (including corrective actions) revealed: a. The failure for J-B 2016 (2nd event of 2016) was due to reporting the result for immediate spin crossmatch when an AHG crossmatch was required. b. The failure for J-C 2016 (3rd event of 2016) was due to the testing person's failure to add the sample for an AHG crossmatch. The corrective action for this failure was to require the testing person to retrain for IS and AHG crossmatches, perform both tests monthly over a period of six months and repeat all proficiency testing. 5. Review of the laboratory's corrective action documentation revealed CAP notified the laboratory on 10/19/16 of the initial unsuccessful participation in proficiency testing for compatibility testing.
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 the review of 2016-2018 proficiency test reports from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interviews with laboratory staff, the laboratory failed to obtain an overall score of at least 100% for compatibility testing. Findings are: 1. Review of CASPER Report 0155D (from the CMS proficiency database) indicated the laboratory received a failing score of 80% for the 2nd event of 2016, 3rd event of 2016 and 0% for the 2nd event of 2017. 2. Review of the scores from the College of American Pathologists confirmed this finding. 3. During interview on 2/01/18 at 8:15 am TP (Testing Person) # 3 stated that the laboratory had recently changed gel card systems. The new system only required the use of 1 card instead of 2. She also stated the the testing person obtained the correct results but failed to interpret the results correctly for one of the failed test events. TP #3 further stated that the 3rd failure (2nd event of 2017) was due to a failure to successfully submit results to the proficiency agency via the online submission program. 4. During interview on 2/1/18 at 8:15 am, the laboratory manager stated that the laboratory had ceased performing immediate spin crossmatches and all AHG (anti-human globulin) crossmatches were sent to the sister laboratory for testing. The laboratory manager also stated that the laboratory only performed electronic crossmatches for patients without a history of antibodies or a positive antibody screen. TP #3 confirmed that electronic and immediate spin crossmatches were the only crossmatch procedures performed in this laboratory. 5.

	Review of the laboratory's proficiency records (including corrective actions) revealed: a. The failure for J-B 2016 (2nd event of 2016) was due to reporting the result for immediate spin crossmatch when an AHG crossmatch was required. b. The failure for J-C 2016 (3rd event of 2016) was due to the testing person's failure to add the sample for an AHG crossmatch. The corrective action for this failure was to require the testing person to retrain for IS and AHG crossmatches, perform both tests monthly over a period of six months and repeat all proficiency testing. c. The results for J-B 2017 (2nd event of 2017) were not submitted to the proficiency agency. The laboratory did not retain proof that the data was submitted and accepted on 6/30/17. d. Review of the submission form for J-B 2017 also revealed that the laboratory noted errors by the testing person on the form. For 2 of the 5 samples, the testing person indicated that the laboratory would perform an AHG crossmatch. The reviewer indicated that this laboratory "is not suppose to do any AHG xmatchs!! Only IS (Immediate Spin) on a negative screen." 6. Review of the laboratory's corrective action documentation revealed CAP notified the laboratory on 10/19/16 of the initial unsuccessful participation in proficiency testing for compatibility testing. Cease testing notices were send by CAP on 8/29/17 and 9/15/17 for the subsequent failure in 2017. The laboratory submitted a cease testing acknowledgment effective for six months starting on 8/30/17.
D2179	COMPATIBILITY TESTING CFR(s): 493.863(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: Based on the review of 2016-2018 proficiency test reports from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interviews with laboratory staff, the laboratory failed to successfully participate in proficiency testing for compatibility testing and must obtain training and technical assistance to identify the cause of the failures and perform corrective actions. Findings are: 1. Review of CASPER Report 0155D (from the CMS proficiency database) indicated the laboratory received a failing score of 80% for the 2nd event of 2016, 3rd event of 2016 and 0& for the 2nd event of 2017. 2. During interview on 2/1/18 at 8:15 am, the laboratory manager stated that the laboratory had ceased performing immediate spin crossmatches and all AHG (anti-human globulin) crossmatches were sent to the sister laboratory for testing. The laboratory manager also stated that the laboratory only performed electronic crossmatches for patients without a history of antibodies or a positive antibody screen. TP #3 confirmed that electronic and immediate spin crossmatches were the only crossmatch procedures performed in this laboratory. 3. Review of the laboratory's proficiency records (including corrective actions) revealed: a. The failure for J-B 2016 (2nd event of 2016) was due to reporting the result for immediate spin crossmatch when an AHG crossmatch was required. b. The failure for J-C 2016 (3rd event of 2016) was due to the testing person's failure to add the sample for an AHG crossmatch. The corrective action for this failure was to require the testing person to retrain for IS and AHG crossmatches, perform both tests

	monthly over a period of six months and repeat all proficiency testing. c. The results for J-B 2017 (2nd event of 2017) were not submitted to the proficiency agency. The laboratory did not retain documentation that the data was submitted and accepted on 6 /30/17. d. Review of the submission form for J-B 2017 also revealed that the laboratory noted errors by the testing person on the form. For 2 of the 5 samples, the testing person indicated that the laboratory would perform an AHG crossmatch. The reviewer indicated that this laboratory "is not suppose to do any AHG xmatchs!! Only IS (Immediate Spin) on a negative screen." 4. Review of the laboratory's Compatibility Test Anti-IgG - ID MTS Gel Technology procedure, effective date 1/29 /16, revealed that it was a general procedure for all laboratories within the system and did not exempt this site from performing AHG crossmatches.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) 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: Based on the review of 2016-2018 proficiency test reports from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interviews with laboratory staff, the laboratory failed to achieve overall satisfactory proficiency test scores for 3 of 5 test events for compatibility testing in 2016-2017. Findings are: 1. Review of CASPER Report 0155D (from the CMS proficiency database) indicated the laboratory received a failing score of 80% for the 2nd event of 2016, 3rd event of 2016 and the 2nd event of 2017. See D 2179 2. Review of the laboratory's corrective action documentation revealed CAP notified the laboratory on 10/19/16 of the initial unsuccessful participation in proficiency testing for compatibility testing. Cease testing notices were send by CAP on 8/29/17 and 9/15/17 for the subsequent failure in 2017. The laboratory submitted a cease testing acknowledgment effective for six months starting on 8/30/17.
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, the review of 2016-2017 humidity records, manufacturer instructions and interview with laboratory staff, the laboratory failed to ensure the humidity of the laboratory met the manufacturer's requirements. Findings are: 1. Review of the manufacturer's instructions for the ACL TOP 350 CTS Coagulation analyzer indicated the manufacturer required 15% - 85% non-condensing humidity in

	the laboratory. Observation of the physical location of the laboratory's two coagulation analyzers revealed that they were in close proximity (5-10 feet) of the chemistry analyzers. 2. Review of the manufacturer's instructions for the Siemens Dimension EXL revealed the manufacturer required non-condensing humidity of 20% -80%. During observation on 02/02/18 at 11:49 am, the hygrometer (gauge used to monitor the level of humidity in the air) was noted to be located on one of the two Dimension EXL analyzers. The reading was 2%. 3. Review of 2016-2018 humidity records revealed the laboratory failed to take corrective actions for unacceptable humidity levels in the laboratory. a. January 2016 - the humidity was less than 20% for 31 of 31 days. There was no documentation indicating the laboratory identified the failure. b. February 2016 - the humidity was less than 20% for 29 of 29 days. There was no documentation indicating the laboratory identified the failure. c. March 2016 - the humidity was less than 20% for 31 of 31 days. There was no documentation indicating the laboratory identified the failure. d. April 2016 - the humidity was less than 20% for 22 of 30 days. The laboratory documented the following, "All QC (quality control) was in acceptable range." e. May 2016 - the humidity was less than 20% for 20 of 31 days. The laboratory documented the following, "All QC was in acceptable range." f. June 2016 - the humidity was less than 20% for 4 of 30 days. The laboratory documented the following, "All QC within range." g. November 2016 - the humidity was less than 20% for 13 of 30 days. The laboratory documented the following, "All QC reviewed. All QC within acceptable limits." h. December 2016 - the humidity was less than 20% for 23 of 31 days. The laboratory documented the following, "All QC within acceptable limits for the month of Dec 2016. Instrument operation within limits no instrument errors due to humidity (illegible)." i. January 2017 - the humidity was less than 20% for 22 of 31 days. The laboratory documented the following, "No corrective action. All system checks and QC within acceptable levels in January.' j. February 2017 - the humidity was less than 20% for 28 of 28 days. The laboratory documented the following, "No corrective action. All system check and QC within acceptable limits in 2/2017." k. March 2017- the humidity was less than 20% for 28 of 31 days. The laboratory documented the following, "All Chemistry QC within establish limit 4/5/17. No corrective action." l. April 2017 - the humidity was less than 20% for 25 of 30 days. The laboratory documented the following, "No Corrective Action. System checks & QC within Acceptable ranges within April." m. May 2017 - the humidity was less than 20% for 18 of 31 days. The laboratory documented the following, "QC and maint performed with no issues due to low humidity. Lab will continue to monitor." n. June 2017 - the humidity was less than 20% for 7 of 30 days. The laboratory documented the following, "No corrective action. All system checks/QC within acceptable ranges in June." o. October 2017 - the humidity was less than 20% for 8 of 31 days. The laboratory documented the following, "All system checks & QC within acceptable ranges. No issues documented due to humidity.' p. November 2017 - the humidity was less than 20% for 17 of 31 days. The laboratory documented the following, "All system checks & QC within acceptable ranges. No problems indicated." q. December 2017 - the humidity was less than 20% for 31 of 31 days. The laboratory documented the following, "System checks & QC within acceptable ranges @ this level of humidity." 2. During interview with the laboratory manager on 2/3/18 at 12:15 she confirmed that she had also seen the humidity records since she became laboratory manager in November 2017 and wished to review historical records for any trends. 3. The laboratory director did not comment on this finding during the exit conference on 2/17/18 at 1:30 pm.
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 the review of laboratory policy, verification studies, manufacturer's instructions and interviews with laboratory personnel, the laboratory failed to follow manufacturer's instructions and CLSI (Clinical Laboratory Standards Institute) protocols for establishing reference intervals (range) for Prothrombin Time (PT), International Normalized Ratio (INR), and Activated Partial Thrombin Time (APTT). Findings are: 1. Review of the laboratory's 2016 coagulation validation study revealed the laboratory failed to perform 120 patient reference range study as required by the manufacturer. 2. Review of the validation study indicated the laboratory (including all affiliated laboratories within the state) switched to a new coagulation analyzer, the ACL TOP 350 CTS, in August 2016 from a STAGO coagulation analyzer. 3. Review of the laboratory's plan for establishing the reference intervals revealed that each laboratory within the system would be required to test a minimum of 20 samples (collected locally) over 4 days for each analyzer. The data collected would be used for a "blended study." 4. Review of the manufacturer's instructions for the performance of the reference interval study indicated that each laboratory must test a minimum of 120 patient samples that represent the local geographic area or the laboratory could adopt the reference intervals established by another laboratory located within the geographical area using the same instrumentation/reagent combination that had already performed the full 120 patient study. A third option was to verify published reference intervals. The laboratory would be required to test a minimum of 20 patient samples from the local area to verify the published reference intervals or the other laboratory's reference ranges. 5. During interview on 2/06/18 at 3:05 pm, the hospital laboratory services director stated that none of the affiliated laboratories (state-wide) performed the 120 patient reference range study. 6. During interview on 2/06/18 at 3: 20 pm, the laboratory's coagulation technical specialist confirmed that no one laboratory within the system had performed the 120 patient reference range study. The technical specialist also stated that technical support for the ACL TOP had indicated that the laboratory could just validate and use the ranges developed by the manufacturer of the ACL TOP 350 CTS coagulation analyzer. However, the technical specialist further stated that the laboratory system did not adopt the the manufacturer's patient reference ranges. 7. During the exit conference on 2/07/18 at 1:30 pm, the laboratory director's only comment was " we'll figure it out." 8. The laboratory reported performing 5,099 Prothrombin Times and 1,082 Activated Partial Thrombin Times in a 12 month period.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's IQCP (Individual Quality Control Plan), FFN (Fetal Fibronectin) quality control and patient test records, manufacturer's instructions, monthly reviews and interview with laboratory staff, the laboratory failed to follow the quality control plan developed by the laboratory and approved by the laboratory director. Findings are: 1. Review of the FFN quality control records revealed that the laboratory did not follow the QCP (Quality Control Plan) approved by the laboratory director on 12/18/2015. The QCP indicated that the laboratory would perform two levels of external quality control materials for each new lot or shipment or every 31 days if a new shipment had not been received. Review of the manufacturer's instructions indicated that the laboratory was required to perform external controls for each new lot received. 2. Review of patient test records and quality control records for 2017 and January 2018 revealed the laboratory did not perform external quality control within 31 days prior to testing a patient. August 2017 - Lot C7053, the external controls were performed on 7/12/17. The external controls were not tested again until 8/29/17, 48 days later. 1 patient, FFN #1 was tested on 8/23 /17. 3. Review of the laboratory's monthly reviews revealed the laboratory failed to identify this failure. 4. The laboratory director did not comment on this finding during the exit conference on 2/17/18 at 1:30 pm.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, the review of 2016-2017 humidity records, manufacturer instructions and interview with laboratory staff, laboratory's IQCP (Individual Quality Control Plan), FFN (Fetal Fibronectin) quality control and patient test records, monthly reviews and interview with laboratory staff, the laboratory failed to have an effective system for quality assessment. Findings are: 1. The laboratory failed to follow the FFN quality control plan developed by the laboratory and approved by the laboratory director. See D5447 a. Review of the laboratory's monthly reviews revealed the laboratory failed to identify this failure. 2. The laboratory failed to ensure the humidity of the laboratory met the manufacturer's requirements for the hematology and coagulation analyzers. See D5413 a. Review of the temperature logs revealed the laboratory identified the failure but did not perform corrective actions. 3. The laboratory director did not comment on this finding during the exit conference on 2/17/18 at 1:30 pm.
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 the review of laboratory policy, humidity records, verification studies, manufacturer's instructions, IQCP (Individual Quality Control Plan), FFN (Fetal Fibronectin) quality control and patient test records, monthly reviews and interviews with laboratory personnel, the laboratory director failed to provide overall direction and management of the laboratory. Findings are: 1. The laboratory director failed to ensure the coagulation reference range studies were performed as required to establish a normal reference range. See D6013 2. The laboratory failed to have an effective quality assessment program. See D6022
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: Based on the review of laboratory policy, verification studies, manufacturer's instructions and interviews with laboratory personnel, the laboratory director failed to ensure the coagulation reference range studies were performed as required to establish a normal reference range. This failed failed practice could result in either misdiagnosis of coagulopathies (diseases related to abnormal blood clotting) or changes to patient's anticoagulation treatment. The laboratory reported performing 5,099 Prothrombin Times and 1,082 Activated Partial Thrombin Times in a 12 month period. Finding are: The laboratory failed to follow manufacturer's instructions and CLSI (Clinical Laboratory Standards Institute) protocols for establishing reference intervals (range) for Prothrombin Time (PT), International Normalized Ration (INR), and Activated Partial Thrombin Time (APTT). See D5421
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of the laboratory's IQCP (Individual Quality Control Plan), FFN (Fetal Fibronectin) quality control and patient test records, monthly reviews and interview with laboratory staff, the laboratory director failed to ensure that an effective quality control/quality assessment program was followed by the laboratory.

	Findings are: 1. The laboratory failed to follow the quality control plan developed by the laboratory and approved by the laboratory director. See D5447 2. The laboratory failed to ensure humidity levels in the laboratory were sufficient to meet the manufacturer's requirements for testing. See D5413 The laboratory director did not comment on this finding during the exit conference on 2/17/18 at 1:30 pm.
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 the review of 2016-2018 proficiency test reports from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interviews with laboratory staff, the laboratory director failed to provide overall management and direction of the laboratory. Findings are: The laboratory director failed to ensure that the laboratory had an effective corrective action plan for proficiency testing failures for compatibility testing. See D6076
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 the review of 2016-2018 proficiency test reports from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interviews with laboratory staff, the laboratory director failed to ensure that the laboratory had an effective corrective action plan for proficiency testing failures for compatibility testing. Findings are: 1. Review of CASPER Report 0155D (from the CMS proficiency database) indicated the laboratory received a failing score of 80% for the 2nd event of 2016, 3rd event of 2016 and the 2nd event of 2017. See D2173 and D2162 2. Review of corrective actions revealed that there were 2 primary reasons for the failures; testing personnel reported results for test methods (AHG crossmatch) not performed in this laboratory for 2 failed events in 2016 and online submission failure in 2017. Interviews with laboratory staff and review of patient records indicated that the laboratory did not perform AHG crossmatches. See D2179 and D2181 3. Review of the corrective action plans for 2016 revealed the laboratory did not address the cause for the failure and instead required the testing person to undergo retraining for AHG crossmatches.