Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0984477	11/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Roosevelt Co Hospital District	42121 Us Hwy 70, Portales, 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	During a Recertification survey completed on 11/07/19 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 42 CFR Part 493.803 Proficiency Testing, Successful Participation 42 CFR Part 493.1403 Laboratory Director, Moderate 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 2019 proficiency test records from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interview with laboratory staff, the laboratory failed to successfully participate in

	proficiency testing for APTT (Activated Partial Prothrombin Time). The laboratory reported performing 2,208 APTT tests in a 12 month period. Findings are: A. Review of CASPER Report 153 and 96 from the CMS proficiency database revealed the laboratory received failing scores for the analyte APTT for two (2) consecutive test events in 2019. B. Review of proficiency test records from the proficiency testing agency also indicated the laboratory received failing scores for the analyte APTT for two (2) consecutive test events in 2019. See D2121 and D2130
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the review of 2019 proficiency test records from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interview with laboratory staff, the laboratory received failing scores for the analyte APTT (Activated Partial Prothrombin Time) for two consecutive events in 2019. The laboratory reported performing 2,208 APTT tests in a 12 month period. Findings are: A. Review of CASPER Reports 153 and 96 from the CMS proficiency database revealed the laboratory received failing scores for the analyte APTT for two (2) consecutive test events in 2019. 1. 2019 - 1, the score was reported as 20%. 2. 2019 - 2, the score was reported as 60% B. Review of proficiency test records from the proficiency testing agency also indicated the laboratory received failing scores for the analyte APTT for two (2) consecutive test events in 2019. 1. Event 2019 - 1, 5 of 5 results were low (greater than 2 SDI or Standard Deviation Interval,) when compared to participating laboratories according to the 04/18/19 report. 2. Event 2019 - 2, 4 of 5 results were low in comparison with participating laboratories according to the 08/15 /19 report. C. Review of the laboratory's proficiency testing records revealed: 1. The laboratory ordered and tested a new set of samples (same test event samples) in response to the 2019 - 1 failure on 04/29/19. The laboratory performed a self evaluation of the results since the ranges were previously provided by the proficiency agency and all results were acceptable. The original test date was 03/18/19. 2. The laboratory tested the 2019 - 2 samples on 07/11/19. The laboratory was unable to repeat testing for this event because the STAGO analyzer was replaced on 08/05/19 with a Sysmex CS-2500 coagulation analyzer. D. During interview on 11/05/19 at 9: 00 am, the Laboratory Supervisor stated she believed the failures were due to pipetting or reconstitution errors. She also stated the lower APTT results did not affect patients because the hospital did not use heparin therapy.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or 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 unacceptable analyte or 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 2019 proficiency test records from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interview with laboratory staff, the laboratory must undertake training and technical assistance for APTT (Activated Partial Prothrombin Time) proficiency testing failures. The laboratory reported performing 2,208 APTT tests in a 12 month period. Findings are: A. Review of CASPER Reports 153 and 96 from the CMS proficiency database and proficiency testing agency reports revealed the laboratory received failing scores for the analyte APTT for two (2) consecutive test events in 2019. See D2021 1. 2019 - 1, the score was reported as 20%. 2. 2019 - 2, the score was reported as 60% B. Review of the laboratory's proficiency testing records revealed: 1. The laboratory ordered and tested a new set of samples (same test event samples) in response to the 2019 - 1 failure on 04/29/19. The laboratory performed a self evaluation of the results and all results were acceptable. The original test date was 03 /18/19. The laboratory reviewed the test records, the previous 3 surveys, and quality control. The laboratory's conclusion: "Probable sample reconstitution error that was more manifested with the greater times of the PTT's. Technologist will be retrained on proper pipetting and reconstitution techniques." 2. The laboratory tested the 2019 - 2 samples on 07/11/19. The laboratory was unable to repeat testing for this event because the STAGO analyzer was replaced on 08/05/19 with a Sysmex CS-2500 coagulation analyzer. The laboratory reviewed the test records, results for 602 patients tested 04/29/19-08/05/19, maintenance and quality control records. The laboratory's conclusion: 'All patient PTT's review from 4/29/19-8/5/19 have been reviewed and it is felt that no remediation is needed." C. During interview on 11/05/19 at 9 am, the Laboratory Supervisor stated she believed the failures were due to pipetting or reconstitution errors. She also stated the lower APTT results did not affect patients because the hospital did not use heparin therapy.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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 2019 proficiency test records from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, laboratory proficiency testing records, laboratory policy, patient records, and interview with laboratory staff, the laboratory received failing scores for the analyte APTT (Activated Partial Prothrombin Time) for two consecutive events in 2019 resulting in unsuccessful participation in proficiency testing. The laboratory reported performing 2,208 APTT tests in a 12 month period. Findings are: A. Review of CASPER Reports 153 and 96 from the CMS proficiency database revealed the laboratory received failing scores for the analyte APTT for two (2) consecutive test events in 2019. 1. 2019 - 1, the score was reported as 20%. 2. 2019 - 2, the score was reported as 60% B. Review of proficiency test records from the proficiency testing agency also indicated the laboratory received failing scores for the analyte APTT for two (2) consecutive test events in 2019. 1. Event 2019 - 1, 5 of 5 results were low (greater than 2 SDI or Standard Deviation Index) when compared to participating

	laboratories according to the 04/18/19 report. 2. Event 2019 - 2, 4 of 5 results were low in comparison with participating laboratories according to the 08/15/19 report. C. Review of the laboratory's proficiency testing records revealed: 1. The laboratory ordered and tested a new set of samples (from the same test event) in response to the 2019 - 1 failure on 04/29/19. The laboratory performed a self evaluation of the results since the ranges were previously provided by the proficiency agency and all results were acceptable. The original test date was 03/18/19. 2. The laboratory tested the 2019 - 2 samples on 07/11/19. The laboratory was unable to repeat testing for this event because the STAGO analyzer was replaced on 08/05/19 with a Sysmex CS-2500 coagulation analyzer. D. During interview on 11/05/19 at 9:00 am, the Laboratory Supervisor stated she believed the failures were due to pipetting or reconstitution errors. She also stated the lower APTT results did not affect patients because the hospital did not use heparin therapy.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of turn-around-time reports, patient test records, laboratory policies, manufacturer instructions, and interviews with laboratory staff, the laboratory failed to ensure 29 of 163 patient samples for lactate (or lactic acid) were received, spun, and tested as required by the manufacturer in December 2018 and October 2019. Findings are: A. Review of the Siemens Dimension clinical chemistry instructions for Lactic Acid, dated 01/30/2015, indicated "Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate followed by immediate chilling of the specimen and separation of the cells within 15 minutes... Keep sample on ice and analyze promptly. If testing cannot be performed immediately, refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month.' B. Review of the laboratory's CHE-160 Lactic Acid R2 policy, dated 01/09/18, met the manufacturer's requirements listed above. C. Review of laboratory procedures revealed no reference to the speed or time required to spin the samples. See D5403 1. During interview on 11/06/19 at 09:44 am, Phlebotomist #1 stated that if the samples are not drawn by the lab and if there are no orders, the samples are spun in the Drucker 614B in the phlebotomy area and the plasma stored in the refrigerator. 2. During interview on 11/06/19 at 09:52 am, TP (Testing Person) #1 stated the phlebotomists brought laboratory collected samples directly to chemistry and the samples are spun for 5 minutes in the EBA 21 Centrifuge at 6,000 RPM (Revolutions Per Minute). D. Review of patient records and the laboratory Turnaround Time Reports for December 2018 and October 2019 revealed the laboratory failed to ensure the collection and receipt times were documented accurately and met the manufacturer's requirements. 1. The laboratory failed to document the collection and receipt times for lactic acid in the LIS (Laboratory Information System). See D5787 2. The collection to receipt (into the laboratory) time exceeded 10 minutes (allowing 5 minutes for centrifugation and placement on the analyzer) for 15 of 100 patients in December 2018. 6 of the 15 patients had physician

	orders after the collection of the sample. 2 samples, LA 72 and LA 59, did not have documentation in the LIS indicating the laboratory had spun and refrigerated the plasma until the samples could be tested. Orders received prior to collection LA54, collected on 12/07/18 at 06:30 am, was received by the laboratory at 06:44 am, 14 minutes after collection. LA69, collected on 12/27/18 at 11:45 pm, was received by the laboratory at 12:02 pm, 17 minutes after collection. LA72, collected on 12/07/18 at 13:29 pm, was received by the laboratory at 13:36 pm, 235 minutes after collection. LA84, collected on 12/05/18 at 17:04 pm, was received by the laboratory at 17:53 pm, 49 minutes after collection. LA86, collected on 12/11/18 at 17:45 pm, was received by the laboratory at 17:57 pm, 12 minutes after collection. LA87, collected on 12/27/18 at 20:15 pm, was received by the laboratory at 20:43 pm, 28 minutes after collection. LA88, collected on 12/27/18 at 21:56 pm, was received by the laboratory at 22:00 pm, 50 minutes after collection. LA92, collected on 12/19/18 at 15:05 pm, was received by the laboratory at 15:18 pm, 50 minutes after collection. LA88, collected on 12/27/18 at 21:56 pm, was received by the laboratory at 22:00 pm, 50 minutes after collection. Orders received after collection LA43, collected on 12/26/18 at 04:30 am, was received by the laboratory at 05:48 am, 78 minutes after collection. LA59, collected on 12/18/18 at 09:45 am, was received by the laboratory at 10:54 am, 69 minutes after collection. LA70, collected on 12/28/18 at 11:58 am, was received by the laboratory at 12:27 pm, 29 minutes after collection. LA77, collected on 12/30/18 at 18:40 pm, was received by the laboratory at 18:52 pm, 12 minutes after collection. LA94, collected on 12/11/18 at 18:06 pm, was received by the laboratory at 19:09 pm, 50 minutes after collection. LA95, collected on 12/03/18 at 16:40 pm, was received by the laboratory at 16:52 pm, 12 minutes after collection. 3. The collection to receipt (into the laboratory) time exceeded 10 minutes (allowing 5 minutes for centrifugation and placement on the analyzer) for 14 of 63 patients in October 2019. 11 of the 14 patients had physician orders after the collection of the sample. Orders received prior to collection LA111, collected on 10/08/19 at 13:10 pm, was received by the laboratory at 13:22 am, 12 minutes after collection. LA125, collected on 10/14/19 at 06:30 am, was received by the laboratory at 07:22 am, 52 minutes after collection. LA126, collected on 10/14/19 at 12:30 pm, was received by the laboratory at 12:43 pm, 13 minutes after collection. Orders received after collection LA104, collected on 10/03 /19 at 00:39 am, was received by the laboratory at 00:58 am, 19 minutes after collection. LA105, collected on 10/03/19 at 11:07 am, was received by the laboratory at 12:26 am, 79 minutes after collection. LA106, collected on 10/04/19 at 19:25 pm, was received by the laboratory at 19:25 am, 117 minutes after collection. LA112, collected on 10/08/19 at 14:46 pm, was received by the laboratory at 15:58 pm, 22 minutes after collection. LA114, collected on 10/08/19 at 21:06 pm, was received by the laboratory at 23:33 pm, 147 minutes after collection. LA127, collected on 10/14 /19 at 15:37 pm, was received by the laboratory at 15:55 pm, 18 minutes after collection. LA128, collected on 10/14/19 at 19:50 pm, was received by the laboratory at 20:26 pm, 36 minutes after collection. LA137, collected on 10/19/19 at 14:03 pm, was received by the laboratory at 15:18 pm, 75 minutes after collection. LA138, collected on 10/19/19 at 18:45 pm, was received by the laboratory at 20:02 pm, 77 minutes after collection. LA139, collected on 10/19/19 at 15:48 pm, was received by the laboratory at 20:03 pm, 255 minutes after collection. LA140, collected on 10/20 /19 at 23:25 pm, was received by the laboratory at 23:55 pm, 30 minutes after collection.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of turn-around-time reports, patient test records, laboratory policies, manufacturer instructions and interviews with laboratory staff, the laboratory failed to have a written procedure for lactic acid (lactate) that included the sample preparation and processing of the patient samples. Findings are: A. Review of the laboratory's CHE-160 Lactic Acid R2 policy, dated 01/09/18, revealed no reference to the speed or time required to spin the samples. B. Review of the laboratory's PoC and Phlebotomy policies, dated 08/23/14, revealed no no reference to the speed or time required to spin the samples. C. During interview on 11/06/19 at 09:44 am, Phlebotomist #1 stated that if the samples are not drawn by the lab and if there are no orders, the samples are spun in the Drucker 614B in the phlebotomy area and the plasma stored in the refrigerator. D. During interview on 11/06/19 at 09:52 am, TP (Testing Person) #1 stated the phlebotomists brought laboratory collected samples directly to chemistry and the samples are spun for 5 minutes in the EBA 21 Centrifuge at 6,000 RPM (Revolutions Per Minute).
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the review of turn-around-time reports and interview with laboratory staff, the laboratory failed to ensure collection and receipt times for lactic acid (lactate) samples were accurately documented. Findings are: A. Review of the laboratory Turnaround Time Reports for December 2018 and October 2019 revealed the laboratory failed to ensure the collection and receipt times were documented accurately in the LIS (Laboratory Information System). 1. In December 2018, the collection and receipt times were identical for 50 of 100 patient samples. 30 of the 50

	samples were collected by a different person than the receiving laboratory staff person. 2. In October 2019, the collection and receipt times were identical for 45 of 63 patient samples. 22 of the 45 samples were collected by a different person than the receiving laboratory staff person. B. During interview on 11/06/19 at 09:52 am, Phlebotomist #1 stated that they (the phlebotomy staff) update the collection time in the LIS "most of the time."
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on interview and review of installation records, the laboratory failed to have a system to review manually entered coagulation test results for accuracy. The laboratory reported performing 1,705 patient tests (Prothrombin Time, Activated Partial Thrombin Time, and D-Dimer) 08/05/19-11/06/19 using the Sysmex CS-2500 analyzer. Findings are: A. Review of installation records coagulation indicated the studies on the new analyzer were completed on 07/26/19 and approved by the Laboratory Director on 08/13/19. B. During interview on 11/06/19 at 11:25 am, the Laboratory Supervisor stated the Sysmex CS-2500 Coagulation analyzer was not interfaced with the (LIS) Laboratory Information System and the laboratory had to manually enter the results. She also stated the laboratory did not have a system in place to review and verify results manually entered into the LIS.
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 turn-around-time reports, patient test records, laboratory policies, manufacturer instructions and interviews with laboratory staff, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings are: A. The Laboratory Director failed to ensure the laboratory systems provided quality services in the areas of Pre-Analytic and Post-Analytic phases of testing. See D6007 B. The Laboratory Director failed to ensure that written procedures included sample preparation and processing of lactic acid. See D6031
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)

	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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the review of turn-around-time reports, patient test records, laboratory policies, and manufacturer instructions, the Laboratory Director failed to ensure the laboratory systems provided quality services in the areas of Pre-Analytic and Post-Analytic phases of testing. Findings are: A. The laboratory failed to ensure 29 of 163 patient samples for lactate (or lactic acid) were received, spun, and tested as required by the manufacturer in December 2018 and October 2019. See D5311 B. The laboratory failed to ensure collection and receipt times for lactic acid (lactate) samples were accurately documented. See D5787 C. The laboratory failed to have a system to review manually entered coagulation test results for accuracy. See D5801
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the review of turn-around-time reports, patient test records, laboratory policies, and manufacturer instructions, the Laboratory Director failed to ensure that written procedures included sample preparation and processing. Findings are: The laboratory failed to have a written procedure for lactic acid (lactate) that included the sample preparation and processing of the patient samples. See D5403