Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0537796	02/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Union County General Hospital	300 Wilson St, Clayton, 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	The New Mexico Department of Health completed a validation survey on 02/04/2019 at Union County General Hospital for 42 CFR Part 493, Laboratory Requirements. The laboratory was found out of compliance with the following condition: 42 CFR Part 493.1403 Laboratory director, moderate complexity
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on the review of the coagulation analyzer installation records and interview with the laboratory manager, the laboratory failed to ensure that donors/study participants met the manufacturer's requirements for the Prothrombin Time mean patient normal range used in the calculation of the INR (International Normalized Ratio which is used to monitor anticoagulation therapy). The laboratory reported performing 317 tests per year. Findings are: A. Record review of the installation records for the Sysmex CA-620 coagulation analyzer in June 2017 revealed no documentation of the process used to establish the mean patient normal range. The only current record available was the "MVP Reference Range Verification" which only listed the values for each test run and the calculations used to verify the reference range. B. There was no documentation found in the installation/validation records of medical questionnaires, sex or age of the participants that volunteered to participate in the mean patient normal range study . Review of the manufacturer's instructions "Verification of Reference Interval" indicated the following requirements for the study: "Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients) Donors should not take any medications,

	including aspirin. A minimum of 20 donors with a reasonably even distribution of males and females should be included. Donors should span the adult age range." C. During interview on 01/17/19 at 1:45 pm, the laboratory manager stated she could not find the questionnaires. She also stated that the laboratory had drawn 20 samples, "maybe more," and that the donors did not take hormones. D. Review of the reagent lot rollover study performed on the Sysmex CA-560 coagulation in August 2015 also revealed no documentation of medical questionnaires, sex or age of the donors.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control records, laboratory procedure manual and interview with the laboratory manager, the laboratory failed to perform and document the use of quality control organisms for each lot/shipment of microbiology media received. The laboratory reported performing 347 urine, 11 throat, 88 wound, 180 blood, 15 body fluid, 14 sputum, and 74 vaginal cultures and 348 antibiotic sensitivities per year. Findings are: A. Review of 2018 microbiology media quality control records revealed no documentation of the use of quality controls organisms for each lot/shipment of media received. B. Review of the laboratory's microbiology manual, signed by the laboratory director on 09/12/16, did not require the laboratory to perform quality control organisms for each lot/shipment of "Exempt Culture Media" such as Blood, Columbia, Hektoen, Salmonella-Shigella, MacConkey, Brucella Agar and GN (Gram Negative) broth. C. During interview on 01/17/19 at 3: 39 pm, the laboratory manager confirmed that the laboratory had not developed an Individualized Quality Control Plan (IQCP) for the "Exempt" media since quality control regulations were updated as of 01/01/16.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control records, manufacturer instructions, individualized quality control plan (IQCP), and interview with the laboratory manager, the laboratory failed to maintain records used to support the laboratory's (QCP) Quality Control Plans. The laboratory reported performing 187 D-Dimer, 47 C. diff, and 34 serum hCG tests per year. Findings are: A. The laboratory failed to maintain all records used in the development of the IQCP for each of the following analytes:Serum hCG (human chorionic gonadotropin), clostridium difficile (C. diff),

	and D-Dimer. B. Review of the laboratory's IQCP records for Serum hCG, C. diff, and D-Dimer revealed no documentation that the laboratory had reviewed historical data or performed studies to support the Quality Control Plan (QCP) approved by the laboratory director on 12/14/16. C. During interview on 01/15/19 at 4 pm, the laboratory manager stated that she did not keep the records used to support the development of the IQCP.
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 the review of serology quality control and patient records, manufacturer instructions, the laboratory Quality Control Plan (QCP), and interview with the Laboratory Manager, the laboratory failed to have an effective quality assurance policy. Findings are: A. Review of 2018-2019 serology quality control and patient logs revealed the laboratory failed to ensure that the lot number of each kit was linked to patient tests performed. B. Observation of laboratory supplies on 01/17/19 at 9:00 am revealed the laboratory used Alere C. Diff Quik Chek Complete test kit for Clostridium difficile testing. According to the box, each test kit had 25 cassettes. C. During interview on 01/17/19 at 9:00 am, the laboratory manager stated that the laboratory's practice was to order a new kit each time a kit was opened so 2 boxes were available at all times. D. Review of the manufacturer's instructions indicated that the laboratory should perform external quality control materials at least once per kit. 2 cassettes were required to perform the positive and negative controls upon opening the kit and monthly thereafter according to the laboratory's QCP. However, review of the patient and quality control logs indicated that the laboratory did not document which kit was used for patient testing. 1. The lot number and expiration date of 5 cassettes used for testing were not documented. Lot 0717075 expiration date 09/01/18 A total of 4 cassettes were used for Quality control testing on 01/19/18 and 02/1/18. 4 proficiency samples and 22 patients were listed on the log (01/09/18 - 06/29/18) for a total of 30 cassettes. The patient log was reviewed the Laboratory Manager on 03/28 /18. 2. The lot number and expiration date of 1 cassette used for testing was not documented. Lot 1017153 expiration date 11/01/18 A total of 8 cassettes were used for Quality control testing on 03/05/18, 04/03/18, 05/08/18, and 06/01/18. 18 patients were listed on the log (07/11/18 - 10/05/18) for this lot number for a total of 26 cassettes. The patient log was reviewed by the laboratory staff on 11/06/18. 3. There was no record of any patient testing using the following lot of cassettes: Lot 1117015 expiration date 01/01/19 A total of 6 cassettes were used for Quality control testing on 07/03/18, 08/02/18 and 09/04/18. 4. The disposition of 13 test cassettes was not documented for the following lot of cassettes. Lot 0318003 expiration date 05/01/19 - A total of 2 cassettes were used for Quality control on 10/03/18. 2 proficiency samples and 8 patients were listed on the log (10/02/18- 12/18/18) for a total of 12 cassettes out of 25. E. Observation of laboratory supplies on 01/17/19 at 9:00 am revealed that the laboratory was using a new lot, Lot 0578167 expiration date 08/01 /19, on the day of the survey. 12 of 25 test cassettes were remaining in the box. 1. Review of the quality control log revealed that a total of 8 cassettes were used for

	quality control on 10/20/18, 11/01/18,12/03/18 and 01/02/19. Only 1 patient was listed on the log (01/12/19) for this lot for a total of 9 cassettes. The disposition of the remaining 4 test cassettes was not documented in the patient or quality control log.
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 2018 proficiency testing records, serology quality control and patient records, coagulation analyzer installation records, manufacturer instructions, the laboratory Quality Control Plan (QCP), and interview with the laboratory manager, the laboratory director failed to provide overall management and direction of the laboratory. Findings are: A. The laboratory director failed to ensure the verification studies for the Sysmex 640 coagulation analyzer were performed as required by the manufacturer. See D6013 B. The laboratory director failed to ensure that the laboratory had an effective quality assurance policy. See D6021 C. The laboratory director failed to ensure a corrective action policy was followed for all failed analytes. See D6019
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 the coagulation analyzer installation records and interview with the laboratory manager, the laboratory director failed to ensure the verification studies for the Sysmex 640 coagulation analyzer were performed as required by the manufacturer. Findings are: The laboratory failed to ensure that donors/study participants met the manufacturer's requirements for the Prothrombin Time mean patient normal range used in the calculation of the INR (International Normalized Ratio which is used to monitor anticoagulation therapy). See D5411
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed

	when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of 2018 proficiency testing records and interview with the laboratory manager, the Laboratory Director failed to ensure a corrective action policy was followed for all failed analytes. This deficient practice may result in the laboratory's failure to identify system errors. Findings are: A. Review of the 2018 proficiency records revealed no documentation of corrective actions for the 1st event of 2018, urine drug screens, sample UDS-02 which was reported as positive but the correct result was negative. B. Review of the proficiency agency's 1st event 2018 "Participant Data Summaries" revealed that sample UDS-02 contained "700 nanograms/milliliter of Hydrocodone (a pain medication.) Hydrocodone can cross react and cause false positive results with some test methods. Please refer to your package insert for additional information." C. During interview on 01/16/19 at 08:30 am, the Laboratory Manager confirmed that she did not review the package insert for the reagent used to detect opiates on the Dimension EXL chemistry analyzer nor did she perform any corrective actions.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of serology quality control and patient records, manufacturer instructions, the laboratory Quality Control Plan (QCP), and interview with the laboratory manager, the laboratory director failed to ensure that the laboratory had an effective quality assurance policy. Findings are: Review of serology quality control and patient logs revealed the laboratory director failed to ensure that the laboratory accurately recorded the lot number and expiration date of each Clostridium Difficile test kit used for patient testing. See D5793