Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0714232	04/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Guadalupe County Hospital	117 Camino De Vida, Santa Rosa, 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 04/16/2021 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493. Laboratory Director, moderate complexity
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on the review of patient test records, manufacturer's instructions, and interview with the General Supervisor and Testing Person #5, the laboratory failed to follow the manufacturer's instructions and hand out the Patient Fact Sheets to all patients tested for COVID-19 using the Abbott Binax Now test system, authorized for use by the Food & Drug Administration under an Emergency Use Authorization. The laboratory performed 347 COVID-19 antigen tests 11/14/2020-04/13/2021. Findings are: A. Review of the manufacturer's instructions indicated the Patient Fact Sheets must be provided to each patient. B. During interview on 04/15/2021 at 2:30 pm, the General Supervisor and Testing Person #5 stated the laboratory did not provide copies of the Patient Fact Sheet to patients. Testing Person #5 further stated that she kept the Patient Fact Sheets in the cabinet in the phlebotomy (blood collection area) room and pulled out a copy to show the surveyor. C. Review of the patient test records revealed a total of 347 tests performed 11/14/2020-04/13/2021. 308 negative and 37 positive tests were reported.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100

	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the review of patient test records and interviews with laboratory staff, the laboratory failed to provide and retain written verification that all SARS-CoV-2 results were reported to the New Mexico Department of Health (NMDOH). The laboratory performed 297 tests from January 8, 2021 through April 13, 2021. Findings are: A. Review of the batched faxed patient reports contained no documentation proving receipt by the New Mexico Department of Health. B. During interview on April 13, 2021 at 3:35 pm, the General Supervisor and Testing person (TP) #4 stated the laboratory faxed positive COVID-19 test results daily and negative COVID-19 test results weekly to the New Mexico Department of Health, but the confirmation sheets were shredded after faxing.
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 observation, review of laboratory policy, and interview with the General Supervisor, the laboratory failed to ensure urine specimens collected for urinalysis and urine drug screens were labeled according to laboratory policy and failed to have systems to identify the specimen source for pregnancy (hCG) testing.. Findings are: A. During observation on 04/15/2021 at 10:04 am, 4 of 9 urine specimen cups collected within the past 24 hours failed to be labeled with the patient's name, other unique identifier, the date and time of collection on the side of the container. 1. There was no second identifier on 2 of the urine cups found inside plastic bags. Patient UA #1 - collection date 04/15/21 Patient UA #2 - the outside of the plastic bag had the date of birth written on it and not on the container itself. 2. There was no second identifier on the urine container for patient UA #3 or a collection date and time. 3. The urine container for patient UA #4 had no label on the container itself, only the lid. B. Review of the laboratory's "Urinalysis Policy and Procedure" reviewed by the Laboratory Director on 01/30/2021 indicated urine containers must be labeled on the side of the container. C. Review of the laboratory's written policy titled "Urinalysis Collection" reviewed by the Laboratory Director on 01/30/2021 indicated urine containers must be labeled with the patient's first and last name, date, time of collection, room number and type of specimen. D. During interview on 04/15/2021 at

	10:14 am, the General Supervisor stated that there had been issues with specimen labeling from the clinic next door. He also stated that there was no quality assurance project to monitor labeling problems for hospital or client collected specimens. E. Observation of laboratory supplies on 04/15/2021 at 9:44 am revealed the laboratory used a pregnancy test that could be used for either serum or urine; Tanner Scientific hCG (human chorionic gonadotropin) Pregnancy Urine/Serum Combo Test, lot F2006002 expiration date 06/23/2022. 1. Review of the patient test log, the laboratory procedures, and of the laboratory's accessioning software used to order pregnancy tests, the laboratory failed to indicate what type of specimen the laboratory used to perform the pregnancy tests. 2. During interview on 04/14/2021 at 10:28 am, the General Supervisor stated that he contacted the Information Technology Specialist for the laboratory to request a list of patients that had hCG tests performed. There was no indication on the list whether the sample type was urine or serum.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, patient test records, 2019-2021 proficiency testing records and interview with the General Supervisor, the laboratory failed to have an updated procedure manual that reflected the current practices and testing for: assuring accuracy of manually entered test results, reporting of the COVID-19 test results, handling and processing of Fresh Frozen Plasma and discontinuing the urine culture and susceptibility testing in the laboratory. Findings are: A. Review of proficiency test records for 2019-2021 revealed failures due to data entry error 6 times over the 2 year period but there were no reference in the laboratory's written policy for "Report Review," reviewed by the Laboratory Director on 01/30/2021, to a second clerical check for manually entered test results. B. Review of the laboratory's "In House Procedures," reviewed by the Laboratory Director on 01/30/2021, revealed no reference to COVID19 testing using either the Abbott Binax Now or the BioFire FilmArray test systems. Review of the patient test records revealed 335 patients were tested using the Abbott Binax Now 11/14/2020 - 04/11/2021 and 26 patients were tested using the BioFire FilmArray test system 03/25/2021 - 04/13/2021. C. Review of the laboratory's "In House Procedures," reviewed by the Laboratory Director on 01/30 /2021 and Blood Bank policies, revealed no reference to the processing and labeling (after thawing) of FFP (Fresh Frozen Plasma, used to replace blood volume or help patients with clotting problems). D. Review of the laboratory's Microbiology policy revealed the laboratory failed to remove procedures for urine cultures and susceptibilities (testing to identify the most appropriate antibiotic for a bacterial infection) even though the laboratory did not perform these procedures at the time of the survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the review of manufacturer instructions for the use of the BNP (brain natriuretic peptide, a hormone that can be used to assess heart failure) cartridges used on i-STAT chemistry analyzer and observation, the laboratory failed to discard the cartridges when expired. Findings are: A. During observation of on 04/13/2021 revealed 2 BNP cartridges on the counter, lot 20357A, with a room temperature expiration date of 04/14/2021. Further observations on 04/15/21 at 8:08 am and at 3: 00 pm revealed the laboratory had not discarded the cartridges. B. Review of the manufacturer's instructions for the BNP cartridges indicated that the cartridges expire 14 days from the date they are removed from the refrigerator and stored at room temperature. C. On 04/15/21 at 3:00 pm, the cartridges were discarded after the surveyor showed them to the General Supervisor.
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 manufacturer's instructions, validation study, quality control records, patient test reports, laboratory policies, and interview with the General Supervisor, the laboratory failed to perform a 4 four-day validation/verification study as required by the manufacturer of the BioFire Respiratory Panel Please including COVID19. The laboratory reported results for 26 patients (BF(BioFire) 01-BF26) 03 /25/2021 - 04/10/2021. Findings are: This is a repeat deficiency from 02/28/2019. A. Review of the manufacturer's instructions for the BioFire Respiratory Panel Validation Protocol indicated the laboratory should conduct the study over 4 days for the Respiratory Panel. The Respiratory Panel tested for the presence of 18 pathogens (viruses/bacteria) known to cause respiratory illnesses: Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 COVID-19 (SARS-CoV 2) Human Metapneumovirus Influenza A Influenza B Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus Bordetella parapertussis ISI1001 Bordetella pertussis Chlamydia pneumoniae Mycoplasma pneumoniae B. Review of the validation study and quality control records for the BioFire Respiratory Panel with COVID19 (product name BioFire RP2.1) revealed the study was conducted over 2 days and put into use on 03 /10/2021. C. Review of the manufacturer's instructions for the BioFire COVID19 Validation Protocol indicated the laboratory could perform a 2 day study for COVID19 but the laboratory must complete the 4 - day study for the other pathogens on the Respiratory Panel in order to report those results. The "Protocols for Laboratory Verification of Performance of the BioFire Respiratory Panel 2.1 (RP2.1)" from Technical Note document BFR0000-8668-02 further indicated: "While the ultimate objective is to fully verify the method performance of the assay, the

	pandemic crisis, the urgent need for patient testing, and the possible lack of reagents and supplies make it difficult to fully evaluate the accuracy, precision, and reportable range, as stated in COM.40300. A more limited approach may be acceptable. Each laboratory, in coordination with the laboratory director, should determine the depth of verification needed to begin testing and the laboratory director (or qualified alternate designee) must approve the verification study prior to testing." D. Review of laboratory policies revealed no policy approved by the Laboratory Director for the use of the BioFire Respiratory Panel 2.1 or an alternative method for the validation protocol. E. During interview on 04/13/20121 at 9:02 am, the General Supervisor confirmed the laboratory ran the 4 pools of validation materials over 2 days, for the BioFire Respiratory Panel, and not 4 days as required by the manufacturer in the written protocol. F. Review of the patient test reports revealed 26 patients (BF01-BF26) were tested 03/25/2021 - 04/10/2021 using the BioFire RP2.1 Respiratory Panel and all 19 pathogens were reported.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Review of laboratory policies and interviews with the General Supervisor, the laboratory failed to perform instrument - to - instrument comparisons between the i-STAT chemistry analyzer, and the Dimension chemistry analyzer and between the i-STAT and the Sysmex hematology analyzer. Findings are: A. During interview on 04 /14/2021 at 1:15 pm, the General Supervisor stated that the laboratory had expanded the test menu of the i-STAT chemistry analyzer to include Chem 8+ cartridges (Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, and Hematocrit) in August 2020 as a back up to the primary chemistry and hematology analyzers. The General Supervisor further stated that all of the analytes are reported for all test cartridges. B. Review of laboratory policies revealed no policy for the performance of a twice per year comparisons between the Siemens Dimension EXL 200 (chemistry), Sysmex XS 1000i (hematology including the Hemoglobin and Hematocrit, indicators of anemia) and the Abbott i-STAT analyzer. C. During interview on 04/14/2021 at 1:32 pm, the General Supervisor stated no, the laboratory was not performing comparisons between the analyzers and that any medical decisions regarding Hemoglobin are made based on the results from the Sysmex analyzer, not the i-STAT.
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 manufacturer's instructions, 2021 chemistry quality control records, patient test records, laboratory policies, and interview with the General Supervisor, the laboratory failed to have an effective quality assessment system. Findings are: A. The laboratory failed to perform a 4 - day validation/verification study as required by the manufacturer of the BioFire Respiratory Panel including COVID19. The laboratory reported results for 26 patients (BF01-BF26) 03/25/2021 - 04/10/2021. See D5421 B. Review of the electronic chemistry quality control records for January 2021 revealed 2 days in January 2021 that quality control results were not in the LIS (Laboratory Information System). 1. 01/09/2021 - No quality control results were found in the electronic records for Multiqual Chemistry controls. Review of the LIS by the General Supervisor revealed no patients had chemistry tests performed that day. 2. 01/12/2021 - No quality control results were found in the electronic records for Multiqual Chemistry controls. Review of the LIS by the General Supervisor revealed 9 patients (CHM P01 - CHM 09) had chemistry tests performed that day. 3. Further investigation of the Chemistry Quality Control records on 04/14/2021 at 3:43 pm by the General Supervisor revealed the testing person failed to accept the quality control results both days so the values did not transfer to the LIS. C. The laboratory failed to have a procedure manual that reflected the current practices and testing in the laboratory. See D5401 D. The laboratory failed to perform instrument - to - instrument comparisons for the i-STAT chemistry analyzer, Dimension chemistry analyzer and the Sysmex hematology analyzer. See D5775
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 observation, the review of personnel records, manufacturer's instructions, validation study, quality control records, patient test reports, laboratory policies, and interview with the General Supervisor, the Laboratory Director failed to provide overall oversight and management of the laboratory. Findings are: A. The Laboratory Director failed to ensure competency evaluations were performed at least annually by the Technical Consultant. See D6004 B. The Laboratory Director failed to ensure written validation policies were followed for new test methods added by the laboratory. See D6013 C. The Laboratory Director failed to ensure an effective written quality assurance policy was established and followed. See D6021
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If

	the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of personnel records and interview with the General Supervisor, the Laboratory Director failed to ensure competency evaluations were performed at least annually by the Technical Consultant. Findings are: The Technical Consultant failed to perform and document the 2019 competency evaluations for 2 testing personal (TP #1, TP #2) of 7 (TP#1 - TP#7) moderate complexity testing personnel. See D6054
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 manufacturer's instructions, validation study, quality control records, patient test reports, laboratory policies, and interview with the General Supervisor, the Laboratory Director failed to ensure written validation policies were followed for new test methods added by the laboratory. Findings are: The laboratory failed to perform a 4 - day validation/verification study as required by the manufacturer of the BioFire Respiratory Panel including COVID19. The laboratory reported results for 26 patients (BF01-BF26) 03/25/2021 - 04/10/2021. See D5401
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 observation, review of laboratory policy, manufacturer instructions for the use of the BNP (brain natriuretic peptide, a hormone that can be used to assess heart failure) cartridges used on i-STAT chemistry analyzer and interview with the General Supervisor, the Laboratory Director failed to ensure an effective written quality assurance policy was established and followed. Findings are: A. The laboratory failed to ensure urine specimens collected for urinalysis and urine drug screens were labeled according to laboratory policy and failed to have systems to identify the specimen source for pregnancy (hCG) testing. See D5311 B. The laboratory failed to discard the

	cartridges when expired. See D5417 C. The laboratory failed to perform instrument - to - instrument comparisons for the i-STAT chemistry analyzer, Dimension chemistry analyzer and the Sysmex hematology analyzer. See D5775
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of personnel records and interview with the General Supervisor, the Technical Consultant failed to perform and document the 2019 competency evaluations for 2 two testing personal (TP #1, TP #2) of 7 (TP#1 - TP#7) moderate complexity testing personnel. Findings are: A. Review of the personnel files revealed no documentation of competency evaluations for 2 (TP #1, TP #2) of 2 (TP#1, TP#2) moderate complexity testing personnel hired prior to 2019. B. During interview on 04 /13/2021 at 2:42 pm, the General Supervisor stated he "might have missed it" when asked about the missing competency files and was unable to locate the records prior to the exit date of the survey on 04/16/2021.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, patient test records, and interview with the General Supervisor, the laboratory failed to have a procedure manual that reflected the current practices and testing in the laboratory. Findings are: A. Review of the laboratory's "In House Procedures," reviewed by the Laboratory Director on 01/30 /2021 and Blood Bank policies, revealed no reference to the processing and labeling (after thawing) of FFP (Fresh Frozen Plasma, used to replace blood volume or help patients with clotting problems). B. During interview on 04/15/2021 at 3:00 pm, the General Supervisor stated the laboratory had started stocking FFP about two years ago but none of the providers had ever ordered any for patient treatment. C. Review of the laboratory's Microbiology policy indicated the laboratory performed urine cultures and susceptibilities (testing to identify the most appropriate antibiotic for a bacterial infection) even though the laboratory did not perform these procedures at the time of the survey. See D5401
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

	This STANDARD is not met as evidenced by: Based on the review of personnel records and interview with the General Supervisor, the General Supervisor failed to perform and document the 2019 competency evaluations for two testing personnel (TP #1, TP #2) of five staff (TP#1 - TP#4, TP#7) high complexity testing personnel. Findings are: A. Review of the personnel files revealed no documentation of competency evaluations for two (TP #1, TP #2) of two (TP#1 - TP#2) high complexity testing personnel hired prior to 2019. B. During interview on 04/13/2021 at 2:42 pm, the General Supervisor stated he "might have missed it" when asked about the missing competency files and was unable to locate the records prior to the exit date of the survey on 04/16/2021.