Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0537331	08/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
De Baca Family Practice Clinic	546 N 10th St, Fort Sumner, 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	Based upon the onsite recertification survey conducted on 08/24/2022, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 42 CFR Part 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant
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 observation, review of laboratory's environmental records, and interview with staff, the laboratory failed to define an acceptable temperature and humidity range according to manufacturer's instructions for the laboratory where test kits, reagents, and equipment were stored, for 12 of 12 months in 2020, 12 of 12 months in 2021, and 8 of 8 months in 2022. Findings included: 1. During a tour of the laboratory on 08/22/2022 at 02:30 pm, the following test kits, reagents, and equipment were observed which had manufacturer's storage requirements: The Piccolo Xpress Chemistry analyzer's operating manual stated: "Operating temperature 15-30C (59-90F), Relative humidity 0-95%, non-condensing." Clarity Urocheck 120 Urine Analyzer and 3 pkgs of Clarity Urocheck 10SG Reagent urine strips. Lot #U1050121, expiration date 08/24/2023. Manufacturer's operating temperature requirement was 15-30C (59-86F). Insure ONE-One day fecal immunochemical Test. The manufacturer's temperature requirement on the packaged box was 2 - 25C. Quidel Sofia Influenza A+B FIA, 15 test kits, lot #707281, expiration 7/31/2023. 7 test kits, lot #707138, expiration 06/4/2023. The manufacturer's temperature requirement on the packaged box was 15 - 30C (59-86F). Quidel Sofia SARS Antigen FIA, 5 test kits, Lot #707120, expiration 09/18/2023, 6 test kits, lot# 77336, expiration 11/27/2023. The

	manufacturer's temperature requirement on the packaged box was 15-30C (59-86F). Quidel Sofia 2 FLU + SARS Ag FIA, 8 test kits, Lot# 707336, expiration 11/27/2023. The manufacturer's temperature requirement on the packaged box was 15 - 30C (59-86F). Quidel Sofia Step A + FIA, 16 test kits, Lot# 707281, expiration 07/31/2023. The manufacturer's temperature requirement on the packaged box was 15 - 30C (59-86F). Alere HCG Combo Cassette, 1 test kit, Lot# HCG1012060, expiration 12/31 /2022. The manufacturer's temperature requirement on the packaged box was 2 - 30C. Alere HIV-1/2 Ag/Ab Combo, 1 test kit, Lot#166679, expiration 1/28/2023. The manufacturer's storage requirement for the test kit and for the Chase Buffer was 2 to 30C. Osom Mono Test, 2 test kits, Lot# 211275A, expiration 10/31/22, and Lot# 221140, expiration 3/31/2023. The manufacturer's temperature requirement on the packaged box was 15 - 30C (59-86F). BinaxNow RSV Card, 3 test kits/boxes, Lot# 170802, expiration 09/28/2023. The manufacturer's temperature requirement on the packaged box was 2 - 30C. 2. A random review of the laboratory's environmental records from 2020, 2021 and 2022 titled, "Temperature and Humidity Log", revealed the laboratory failed to define an acceptable temperature and relative humidity range according to manufacturer's instructions. 3. During an interview with laboratory supervisor on 08/24/22 at 3:39 pm, she confirmed that they had not defined the temperature, or the humidity range, for the laboratory. Word Key: C=Degree Celsius F=Degree Fahrenheit
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 the policies/procedures, and staff interviews, the laboratory failed to provide a written procedure for the Tosoh AIA-360 immunoassay analyzer and for the Sysmex XS 1000i hematology analyzer. Findings included: 1. Review of the laboratory's policies and procedures revealed the laboratory did not provide a procedure for their testing personnel. 2. During an interview on 08/23/2022 at 2:34 pm, the laboratory supervisor confirmed the above findings. 3. During a telephone interview on 08/23/2022 at 3:58 pm, the technical consultant confirmed that he had not written a procedure.
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 direct observation, review of Operator's training manual for the Tosoh AIA 360, laboratory's environmental logs, and confirmed in interview, the laboratory failed to ensure humidity was within the Tosoh AIA 360 required manufacturer's specifications for 66 of 145 days from February through August in 2022. Findings included: 1. During a tour of the laboratory on 08/22/2022 at 02:30 pm, a Tosoh AIA 360 analyzer (Serial number 29601504) was observed. The analyzer was used to test patient specimens for TSH and PSA. 2. The operator's training manual for the Tosoh AIA 360 analyzer (Version 12.0) gave the following system specifications; "Temperature: 15-30C, Relative humidity*: 40% - 80% (no condensation)." 3. A review of the laboratory's environmental record from February through August in 2022, titled "Temperature and Humidity Log", revealed 66 of 145 recorded relative humidity % were not within the manufacturer's specifications of 40% - 80% for the Tosoh AIA 360 analyzer. A random review of the laboratory's environmental logs revealed the following: 02/07/2022 = humidity recorded as 28% 02/08/2022 = humidity recorded as 30% 02/09/2022 = humidity recorded as 30% 02/10/2022 = humidity recorded as 32% 02/11/2022 = humidity recorded as 32% 03/07/2022 = humidity recorded as 36% 03/08/2022 = humidity recorded as 28% 03/09/2022 = humidity recorded as 26% 03/10/2022 = humidity recorded as 30% 03/11/2022 = humidity recorded as 30% 04/04/2022 = humidity recorded as 39% 04/05/2022 = humidity recorded as 39% 04/06/2022 = humidity recorded as 36% 04/07/2022 = humidity recorded as 28% 04/08/2022 = humidity recorded as 28% 05/06/2022 = humidity recorded as 39% 05/09/2022 = humidity recorded as 32% 05/10/2022 = humidity recorded as 32% 05/13/2022 = humidity recorded as 34% 05/31/2022 = humidity recorded as 33% 08/23/2022 = humidity recorded as 86% 08/24/2022 = humidity recorded as 82% The laboratory failed to ensure the humidity was within the manufacturer's relative humidity specifications of 40% -80% for the Tosoh AIA 360 analyzer. 4. During an interview on 08/24/2022 at 3:39 pm, the laboratory supervisor confirmed the findings. Word Key: TSH=Thyroid Stimulating Hormone PSA=Prostate Specific Antigen
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 the laboratory's verification studies for the Tosoh AIA-360 (PSA and TSH), and interview with laboratory staff, the laboratory failed to verify patient reference ranges for PSA and TSH. Findings included: 1. Review of the Tosoh AIA-360 verification studies for TSH and PSA, reviewed and signed by Laboratory Director on 09/26/2021, revealed that the study did not include verification of the manufacturer's reference range (normal values) to ensure the ranges were appropriate for the laboratory's patient population. The volume for PSA testing was 103 and 353 for TSH from February 2022 to August 22, 2022. 2. During telephone interview on 08/24/2022 at 3:58 pm, the Technical Consultant confirmed the above findings. Word Key: PSA=Prostate Specific Antigen TSH=Thyroid Stimulating Hormone

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the review of Quality Control (QC) records for PSA, review of the Tosoh AIA-360 analyzer records (February through August), and interview with the laboratory supervisor, the laboratory failed to implement a written procedure for performing calibration verification for PSA every 6 months on the Tosoh AIA-360 analyzer. Findings included: 1. Review of Quality Control records from 2022 for PSA, revealed that the laboratory performed only 2 levels of QC material (Clinica Immunoassay Controls, level 1, and level 2) weekly, and not 3 levels more than once a day of testing, as required for the calibration verification exception. 2. Review of the Tosoh AIA-360 analyzer records, revealed patient PSA testing began February 2022. The laboratory did not have a written procedure for completing calibration verification for PSA at least every 6 months, as required. 3. During an interview on 08 /23/2022 at 2:00 pm, the laboratory supervisor was unable to provide a written procedure for performing PSA calibration verification. Word Key: PSA=Prostate Specific Antigen TSH=Thyroid Stimulating Hormone
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the review of laboratories policies/procedures, CMS personnel Report form 209, personnel records/credentials, personnel competency records, and interview with laboratory staff, the laboratory failed to have a qualified Technical Consultant that could provide technical oversight of the laboratory. Findings included: 1. The

	laboratory failed to employ a qualified Technical Consultant to provide the oversight of the laboratory. Refer to D6035 2. The technical consultant failed to assess annual competency using the 6 competency assessment criteria for 2 of 2 testing personnel (TP#1 and TP#2). Refer to D6046
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on the review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, personnel records/credentials, and interview with the laboratory staff, the laboratory failed to employ a qualified Technical Consultant (TC) to provide the technical oversight of the laboratory. Findings included: 1. Review of the CMS Personnel Report Form 209 signed by the laboratory director on 08-12-2022 identified one individual as the Technical Consultant. 2. Review of personnel credentials and college/university transcripts revealed the TC failed to meet the education requirement necessary to qualify as a Technical Consultant for a moderate complexity laboratory.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of the CMS (Centers for Medicare and Medicaid Services) Personnel Report form 209, laboratory policy/procedure, laboratory personnel competency records, and staff interview, the Technical Consultant (TC) failed to assess annual competency, using the 6 competency assessment criteria, for 2 of 2 testing persons (TP#1 and TP#2) in 2020 and 2021. Findings included: 1. Review of the CMS Personnel Report Form 209 signed by the laboratory director on 08-12-2022 identified 2 Testing Personnel (TP#1, TP#2). 2. Review of the laboratory policy revealed the laboratory failed to follow their written policy/procedure and failed to use the 6 competency assessment criteria when performing the competency assessments for TP#1 and TP#2. The policy titled "Technical Consultant Job Description" stated, "10. Assess competency of staff to adequately perform all phases of assigned laboratory activities, including pre-analytic, analytic, and post-analytic duties. This may include: Direct observation of the test performances, including pre-analytic, analytic, and post-analytic activities, as applicable. Monitoring the reporting of test results. Reviewing worksheets, logs, quality control results, proficiency testing results, and maintenance records. Assessment of test performance by utilizing previously analyzed samples, proficiency testing samples or internal blind testing samples. Assessment of problem-solving skills." 3. Review of the personnel competency records for TP#1 and TP#2 revealed the Technical Consultant did not assess competency using the 6 competency assessment criteria for the 2 testing personnel (TP#1 And TP#2) for 2020 and for 2021. 4. During a telephone interview on 08/24 /2022 at 1:45 pm, the Technical Consultant confirmed the above findings.