Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1050947	11/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Joshua Brown Md Pc	1650 Hospital Drive Suite 800, Santa Fe, 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	An onsite recertification survey conducted on 11/28/2023, at Joshua Brown MD PC found the laboratory to be in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review of American Proficiency Institute (API) and staff interview, the laboratory director failed to sign proficiency testing attestation forms for 3 of 6 events from January 2022 through November 2023. Findings included: 1. Review of American Proficiency Institute (API) microbiology events reveled the following attestations unsigned by laboratory director or designee: 1. Microbiology 2022 Event 2 2. Microbiology 2023 Event 2 3. Microbiology 2023 Event 3 2. Interview on 11/28 /2023 at 11:45 am with technical supervisor #1 (as listed on CMS form 209) confirmed the findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Based on review of CMS 209 form and in staff interview, the laboratory failed to establish and follow a policy for assessing competency of 1 of 1 technical supervisor and 1 of 1 general supervisor. Findings included: 1. Review of the submitted CMS 209 form listed 1 technical supervisor and 1 general supervisor. 2. A request was made for a policy to assess the competency of technical supervisor and general supervisor. None was provided. 3. During an interview on 11/28/2023 at 1:05 pm the technical supervisor #1 (as listed on CMS form 209) confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on Review of American Proficiency Institute (API) records and confirmed in staff interview, the laboratory failed to verify the accuracy of ungraded proficiency testing results for 2 of 3 events in 2023. Finding included: 1. Review of American Proficiency Institute (API) microbiology events revealed ungraded proficiency testing analytes were not reviewed for accurate results for: 1. Microbiology event 1 of 2023 2. Microbiology event 3 of 2023 2. Laboratory was asked to provide documentation verifying the accuracy of their ungraded results. None were provided. 3. Interview on 11/28/2023 at 11:30 am the technical supervisor #1 (as listed on CMS form 209) confirmed the finding
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 Review of Respiratory Pathogens Panel (RPP) Standards Operating Procedure, IMS (Internal Medicine Specialist) PCR (polymerase chain reaction) Patient Result Log for RPP testing, and in staff interview, the laboratory failed to follow established policies and procedures for running quality control for RPP testing for 6 of 6 events in November of 2023. Finding included: 1. Review of the "Respiratory Pathogens Panel (RPP) Standards Operating Procedure", states, "Each patient run for RPP must be accompanied with, and must pass the 4 quality control indictors for result acceptance". The procedure lists the 4 quality control indictors as follows: 1. Postive extract control (PCE) 2. Negative extract control (NCE) 3. Postive Control (PC) 4. Negative Control (NC) 2. Review of IMS PCR Patient Result Log for RPP revealed only 1 positive and 1 negative control tested for the following dates: 1. 11/1/2023: 10 patients tested 2. 11/3/2023: 6 patients tested 3. 11/7/2023: 14 patients tested 4. 11/9/2023: 14 patients tested 5. 11/15/2023: 14 patients tested 6. 11/20/2023: 14 patients tested The laboratory failed to perform PCE and NCE. 3. Interview on 11 /28/2023 at 2:24 pm with testing person #1 (as listed on CMS form 209) confirmed the findings

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 LabTurbo Proteinase K manufacturer's instructions, IMS (Internal Medicine Specialist) Lab Temperature and Humidity Log, and staff interview, the laboratory failed to follow manufacturer's acceptable temperature ranges for 3 of 40 events from June 2023 through November 2023. Findings included: 1. During a tour of the facility on 11/28/2023 at 9:30 am the following reagents were observed in the laboratory cabinets: 4 boxes of Proteinase K reference number 486610052201. 2. Review of LabTurbo Proteinase K manufacturer's instructions states reagents should be stored at 15 to 25Celsius (C) 3. Review of IMS Lab Temperature and Humidity Log showed an acceptable range of 15 to 30C, which is outside manufacturer approved range. 4. Review of IMS Lab Temperature and Humidity Log showed the following dates out of manufacturers acceptable range. 1. 7/17/2023: Room temperature 26.1C 2. 7/19/2023: Room temperature 29.1C 3. 11/7/2023: Room temperature 26C 5.Interview on 11/28/2023 at 3:00 pm with technical supervisor #1 (as listed on CMS form 209) confirmed the findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of CMS 209 form, training records, education records, competency records, and confirmed in staff interview, the laboratory director failed to ensure that all testing personnel have the appropriate education, training, and competencies for 4 of 4 testing persons (TP#1 - TP#4). Findings included: 1. Review of CMS 209 form showed TP#1 through TP#4 listed to perform high complexity testing. 2. Review of training records showed missing initial training records for TP#1, TP#3, and TP#4. The laboratory was asked to provide records. None were provided. 3. Review of education records revealed missing education records for TP#2, TP#3, and TP#4. The laboratory was asked to provide records. None were provided. 4. Review of competency records showed missing competency records for TP#2 and TP#4. The laboratory was asked to provide records. None were provided. 5.Interview on 11/28 /2023 at 10:30 am with technical supervisor #1 (as listed on CMS form 209) confirmed the findings.