Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2207534	(X3) Date Survey Completed 02/22/2022
Name of Provider or Supplier Absolute Diagnostics, Llc	**Street Address, City, State** 3460 N Ridge Road, Ste 130, Wichita, KS	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of documents and interview, the laboratory failed to have and follow policies and procedures to monitor, assess, and when indicated correct problems identified in general laboratory system. Findings: 1. No Quality Assurance (QA) plan or procedure was made available at the time of survey. 2. Interview with the general supervisor (GS) 2/22/22 at 8:55 a.m. confirmed, the laboratory failed to have and follow policies and procedures to monitor, assess, and when indicated correct problems identified in general laboratory system.
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 the procedure manual and interview, the laboratory failed to

	establish and follow written procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, and specimen acceptability and rejection. Findings: 1. Review of the procedure manual for "Covid PCR Testing" revealed no information for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, and specimen acceptability and rejection. 2. When asked if the laboratory had a separate specimen requirement procedure, the GS stated the lab did not. 3. Interview with the GS on 2/22/22 at 10:50 a.m. confirmed, the laboratory failed to establish and follow written procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, and specimen acceptability and rejection.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient reports, lack of reference ranges in the laboratory procedure manual and interview, the laboratory failed to ensure the test report included normal ranges as determined by the laboratory. Findings: 1. Review of the patient reports from the EMR revealed 34 of 34 analytes for vaginitis panel and 1 of 1 analyte for SARS-CoV-2/COVID-19 did not include reference ranges. 2. Review of the procedure for "COVID PCR" did not list normal ranges or expected values for laboratory's patient population. 3. Interview with the GS 2/22/22 at 10 a.m. confirmed, the laboratory failed to ensure the test report included normal ranges as determined by the laboratory.