Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2191023	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Well Health Labs	3776 Greenbriar Drive, Stafford, TX	

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 announced validation survey of the laboratory was conducted on 11/20/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
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 review of laboratory's policies/procedures, instructions to clients, surveyor's observations and staff interview, the laboratory failed to ensure specimens were labeled with collection date and/or patient's date of birth for thirty-two of thirty-four specimens observed. Findings included: 1. Review of laboratory's policy/procedure "General Laboratory Information" (GEN-001, Version 1.0, last reviewed 04/28/2022) revealed: "SPECIMEN LABELING Specimens should be labeled with: the patient's name, date of birth, date and time collected, and initials of the collector." And, "Specimens that are not properly labeled or are labeled incorrectly will be rejected." 2. Review of laboratory's instructions to clients "Nasopharyngeal Specimen Collection Instructions" and "Urine Specimen Collection Instructions" revealed: "All specimens submitted to laboratory must have a completed requisition form and the following information labeled on the collection tube in legible format: - full name of patient - date of birth - date of specimen collection" 3. Surveyor's observations on 11/20/2024 at 1315 hours in the laboratory's specimen preparation/extraction room revealed 23

	urine samples and 11 Viral Transport media samples stored in the refrigerator. Examination of specimen labeling revealed thirty-two of the thirty-four stored samples did not have annotations of collection date/time on the specimen container and three of the thirty-four stored samples did not have documentation of patient's date of birth. These were: UTI (urinary tract infection) 11/20 Run 1: Sample # (number) 1 - not labeled with date/time of collection Sample #2 - not labeled with date /time of collection Sample #3 - not labeled with date/time of collection Sample #4 - not labeled with date/time of collection Sample #5 - not labeled with date/time of collection Sample #6 - not labeled with date/time of collection Sample #7 - not labeled with date/time of collection Sample #8 - not labeled with date/time of collection Sample #9 - not labeled with date/time of collection Sample #10 - not labeled with date/time of collection Sample #11 - not labeled with date/time of collection, or patient's date of birth Sample #13 - not labeled with date/time of collection Sample #14 - not labeled with date/time of collection, or patient's date of birth Sample #15 - not labeled with date/time of collection, or patient's date of birth Sample #17 - not labeled with date/time of collection Sample #18 - not labeled with date/time of collection Sample #19 - not labeled with date/time of collection Sample #20 - not labeled with date/time of collection Sample #21 - not labeled with date/time of collection Sample #22 - not labeled with date/time of collection Sample #23 - not labeled with date/time of collection COVID 11/20 Run 1: Sample #1 - not labeled with date/time of collection Sample #2 - not labeled with date/time of collection Sample #3 - not labeled with date/time of collection Sample #4 - not labeled with date /time of collection Sample #5 - not labeled with date/time of collection Sample #6 - not labeled with date/time of collection Sample #7 - not labeled with date/time of collection Sample #8 - not labeled with date/time of collection Sample #9 - not labeled with date/time of collection Sample #10 - not labeled with date/time of collection Sample #11 - not labeled with date/time of collection 4. In an interview on 11/20/2024 at 1325 hours in the office, the laboratory's General Supervisor (as indicated on submitted Form CMS 209) confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, instructions to clients, surveyor's observations, FedEx packaging and labeling instructions, patient test volumes and staff interview, the laboratory's Quality Assurance failed to identify and correct issues with specimen labeling for two of four test platforms performed by the laboratory in 2023 and 2024. Refer to D5311 A and B.
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: A. Based on review of laboratory's quality control (QC) records, policies/procedures, patient test/instrument records, patient final reports and staff interview, the laboratory failed to ensure all controls were acceptable prior to releasing patient reports for three of eleven patients' UTI (urinary tract infection) Assay tests with failed internal controls reviewed from April of 2024. Findings included: 1. Review of laboratory's "Quality Control Log/UTI Biorad #269" revealed UTI Run 1 from 04/30/2024 had the following annotation for corrective action: "*Internal control Failure 4pts, re test (sic) following day on next batch." 2. Review of instrument data for UTI Run 1 from 04/30 /2024 revealed the instrument had "Invalid" Auto Interpretation for eleven samples. 3. Review of laboratory's protocols for the UTI Assay (last reviewed November 2022) revealed: "INTERPRETATION OF TEST RESULTS Interpretation: Invalid - Weak or negative IC (internal control) signal suggests inadequate samples collection, processing or presence of inhibitors. - Repeat the test from nucleic acid extraction using another aliquot of the original samples." 4. Review of final test reports for the eleven samples with failed internal controls revealed the following four sample results were released on 04/30/2024 without repeat testing: Sample: 240430100041 240430100045 240430100049 5. In an interview on 11/20/2024 at 1445 hours in the office, the laboratory's General Supervisor (as indicated on submitted Form CMS 209) confirmed the findings. B. Based on review of laboratory's quality control (QC) records, policies/procedures, patient test/instrument records, patient final reports and staff interview, the laboratory failed to ensure all controls were acceptable prior to releasing patient reports for one of two patients' RPP (respiratory pathogen panel) tests with failed internal controls reviewed from August of 2024. Findings included: 1. Review of laboratory's "Quality Control Log/RPP Biorad #642" revealed RPP Run 2 from 08/06/2024 had the following annotation for corrective action: "Panel 2,3 IC (internal control) failure - sample dispensing error - retest" 2. Review of laboratory's protocols for the RPP panel (last reviewed November 2022) revealed: "INTERPRETATION OF TEST RESULTS Interpretation: Invalid - Weak or negative IC (internal control) signal suggests inadequate samples collection, processing or presence of inhibitors. - Repeat the test from nucleic acid extraction using another aliquot of the original samples." 3. Further review of the RPP QC log revealed the run was repeated on 08/07/2024. This was confirmed with instrument data. However, instrument data showed repeat failure of IC for sample 240806100096, but no further action was documented. 4. Review of final test reports for sample 240806100096 revealed sample results were released on 08/07/2024. 5. In an interview on 11/20 /2024 at 1445 hours in the office, the laboratory's General Supervisor (as indicated on submitted Form CMS 209) confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records, policies/procedures, patient test/instrument records, patient final reports and staff interview, the

	laboratory's Quality Assurance failed to identify and correct issues with unacceptable controls prior to releasing patient reports for two of four test platforms performed by the laboratory in 2023 and 2024. Refer to D5487 A and B.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of a sampling of laboratory's test reports, policies/procedures and staff interview, the laboratory failed to define the interpretation of reported semiquantitative results and their clinical relevance for one of 4 test platforms performed by the laboratory in 2023 and 2024, the Urinary Tract Infection Assay by PCR (polymerase chain reaction). Findings included: 1. Review of a sampling of laboratory reports for its Urinary Tract Infection Assay revealed the laboratory reported levels of detection for pathogens as follows: Accession ID: 241113100023 Detected pathogens: Streptococcus anginosus Level: Low Accession ID: 241115100028 Detected pathogens: Staphylococcus epidermidis Level: High Accession ID: 241119101048 Detected pathogens: Enterococcus faecalis Level: Low 2. Further review of the above reports revealed the laboratory did not have interpretative criteria for clinical significance of the above levels (low; high) of pathogen detection. 3. Review of laboratory "Interpretation of Test Results" guideline for the Urinary Tract Infection Assay revealed the interpretations were defined as "Detected" or "Not detected". There were no interpretative guidelines defined for the "low" and/or "high" level of detection reported. 4. In an interview on 11/20/2024 at 1340 hours in the office, the laboratory's General Supervisor (as indicated on submitted Form CMS 209) confirmed the findings.