Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2257706	01/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Choice Diagnostic Lab Llc	731 E Southlake Blvd Suite 180, Southlake, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. 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 surveyor observation, review of manufacturer's instructions, client services manual, personnel interview, final patient reports, laboratory specimen rejection log, and confirmed in interview, the laboratory failed to ensure the correct specimen storage, preservation, and conditions for transportation, for 6 of 7 STI (Sexually Transmitted Infection) specimens in January 2024. Findings Included: 1. During a tour of the facility on 01/18/2024 at 10:24 AM, the surveyor observed 1 KingFisher PCR Flex Purification Analyzer (Serial Number:711-2304) and 1 QuantStudio PCR Analyzer (Serial Number: 272530849) in the urine PCR patient processing area. 2. Review of manufacturer's instructions (also used as the laboratory policy), "STI Panel Quadraplex Assay" (Approved by the Laboratory Director on: 01/04/2024) revealed the following: " ...4. Specimens and Panel Types: ...Storage/Transport Conditions 72 hours at Room Temperature 3 days at 4 C or below ...4.2 Specimen Rejection Criteria: ...Specimens that do not meet the requirements listed in the acceptable specimen criteria table above." 3. Review of laboratory client services manual, "Urine Collection Guide", provided to facilities to ensure specimen acceptability, revealed the following: "Post Collection/Transport Procedure ...6. Store specimens at 2 to 8 C

	till ready to ship. Samples need to be shipped with cool/ice pack. 7. Using your predetermined shipping method, prepare package/specimen for shipment/pickup. Viability: Refrigerated (2-8 C) =48 hours Room Temperature (20-25 C) =48 hours" The surveyor asked for documentation of the acceptable extended refrigerator temperature range as stated by the manufacturer (4 C and below), and none was provided. 4. During an interview in the laboratory office on 01/18/2024 at 10:54 AM, with Testing Person 1 (TP-1), TP-1 stated outside clients sent specimens with cool OR ice packs. The surveyor requested separate specimen shipping studies for both cool AND ice packs, and none were provided. TP-1 also stated patient specimens were not checked for an acceptable temperature upon receipt in the laboratory. 5. Review of patient final reports revealed the following patients processed in January 2024, when temperature of specimens was not documented upon receipt and were not processed within a 48-hour period (as stated in the client services manual) prior to analysis: a. Specimen ID: 6070966 Collection Date/Time: 01/09/2024; 12:19 PM Received in Lab: 01/11/2024; 05:20 PM Hours Elapsed: 53 Hours b. Specimen ID: 6070974 Collection Date/Time: 01/09/2024; 12:20 PM Received in Lab: 01/11/2024; 05:20 PM Hours Elapsed: 53 Hours c. Specimen ID: 6070995 Collection Date/Time: 01/09 /2024; 12:24 PM Received in Lab: 01/11/2024; 05:20 PM Hours Elapsed: 52 Hours d. Specimen ID: 6070997 Collection Date/Time: 01/09/2024; 12:24 PM Received in Lab: 01/11/2024; 05:20 PM Hours Elapsed: 52 Hours e. Specimen ID: 6071009 Collection Date/Time: 01/09/2024; 12:27 PM Received in Lab: 01/11/2024; 05:20 PM Hours Elapsed: 52 Hours f. Specimen ID: 6070966 Collection Date/Time: 01/09 /2024; 05:00 PM Received in Lab: 01/11/2024; 05:20 PM Hours Elapsed: 48 hours and 20 minutes. 6. Review of laboratory rejection log revealed the laboratory failed to reject the above specimens in January 2024 based on the laboratory's acceptable specimen criteria. 7. During an interview in the laboratory office with Testing Person 1 (TP-1) on 01/18/2024 at 12:15 PM, TP-1 confirmed the laboratory failed to ensure the correct specimen storage, preservation, and conditions for transportation, for 6 of 7 specimens in January 2024.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory documentation, manufacturer's instructions, laboratory establishment studies for the STI and UTI panels, environmental records, final patient reports, and confirmed in interview, the laboratory failed to establish refrigerated specimen stability for 2 of 2 panels performed on the ThermoFisher Quant Studio in 2024. Findings Included: 1. Review of laboratory documentation submitted at time of survey, revealed the laboratory performed PCR analysis on patient urine specimens, for sexually transmitted infections (STI) and urinary tract infections (UTI) in January

	2024. 2. Review of manufacturer's instructions (also used as the laboratory policy), "STI Panel Quadraplex Assay" (Approved by the Laboratory Director on: 01/04/2024) revealed the following: " ...4. Specimens and Panel Types: ...Storage/Transport Conditions 72 hours at Room Temperature 3 days at 4 C or below ...4.2 Specimen Rejection Criteria: ...Specimens that do not meet the requirements listed in the acceptable specimen criteria table above." Review of manufacturer's instructions (also used as the laboratory policy), "UTI Panel Quadraplex Assay" (Approved by the Laboratory Director on: 01/04/2024) revealed the following: " ...4. Specimens and Panel Types: ...Storage/Transport Conditions 72 hours at Room Temperature 72 hours at 4 C or below ...4.2 Specimen Rejection Criteria: ...Specimens that do not meet the requirements listed in the acceptable specimen criteria table above." 3. Review of laboratory establishment studies, "Solaris Diagnostics Laboratory STI Validation" (Approved by the Laboratory Director on: 01/04/2024) revealed the following: " ... Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval ...must, before reporting patient results, establish for each test system the performance specifications for the following performance characteristics, as applicable: ...Any other performance characteristics required for test performance. The validation for the UTI panel is performed per CLIA ... ...3. Specimen Transportation and Storage ...Store sample at 2-8 C till it is ready to ship. Specimens can be stored at 2-8 degrees Celsius up to 72 hours after collection or stored at room temperature 20-25 degrees Celsius for up to 72 hours." Review of laboratory establishment studies, "Solaris Diagnostics Laboratory UTI Validation" (Approved by the Laboratory Director on: 01/04/2024) revealed the following: " ...Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval ...must, before reporting patient results, establish for each test system the performance specifications for the following performance characteristics, as applicable: ...Any other performance characteristics required for test performance. The validation for the UTI panel is performed per CLIA ... ...3. Specimen Transportation and Storage ...Store sample at 2-8 C till it is ready to ship. Specimens can be stored at 2-8 degrees Celsius up to 72 hours after collection or stored at room temperature 20-25 degrees Celsius for up to 72 hours." The surveyor asked for documentation of the acceptable extended refrigerator temperature range as stated by the manufacturer (4 C and below) during the establishment study, and none was provided. 4. Review of laboratory environmental records, revealed NO documentation of specimen refrigerator temperatures recorded during the specimen stability establishment study in January 2024. The surveyor requested the above environmental records, and none were provided. 5. Review of patient final reports, revealed the following 7 of 7 patients tested in January 2024, stored at 2-8 C prior to shipping: STI Patients a. Specimen ID: 6070966 Collection Date/Time: 01/09/2024; 12:19 PM Received in Lab: 01/11/2024; 05:20 PM b. Specimen ID: 6070974 Collection Date/Time: 01/09/2024; 12:20 PM Received in Lab: 01/11/2024; 05:20 PM c. Specimen ID: 6070995 Collection Date/Time: 01/09 /2024; 12:24 PM Received in Lab: 01/11/2024; 05:20 PM d. Specimen ID: 6070997 Collection Date/Time: 01/09/2024; 12:24 PM Received in Lab: 01/11/2024; 05:20 PM e. Specimen ID: 6071009 Collection Date/Time: 01/09/2024; 12:27 PM Received in Lab: 01/11/2024; 05:20 PM f. Specimen ID: 6070966 Collection Date/Time: 01/09 /2024; 05:00 PM Received in Lab: 01/11/2024; 05:20 PM UTI Patient g. Specimen ID: 6070579 Collection Date/Time: 01/10/2024; 10:51 AM Received in Lab: 01/11 /2024; 12:03 PM 6. During an interview in the laboratory office with Testing Person 1 (TP-1) on 01/18/2024 at 01:02 PM, TP-1 confirmed the laboratory failed to establish refrigerated specimen stability for 2 of 2 panels performed on the ThermoFisher Quant Studio in January 2024. Word Key UTI- Urinary Tract Infection C- Celsius