Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2178190	03/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bridges Clinic Llc	920 Ebenezer Blvd Ste A, Madison, MS	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records and interview with the technical consultant, the laboratory failed to retain all proficiency testing records to include attestation statements, submitted results and analyzer printouts for five of six hematology proficiency testing events reviewed for 2023 and 2024. Findings include: 1. Review of the proficiency testing records for the 1st, 2nd and 3rd events of 2023 and the 1st, 2nd and 3rd events of 2024 revealed the laboratory did not retain the following records: a. Attestation statements for the 1st and 2nd events of 2023 and the 1st event of 2024. (3 of 6 events attestation statements not retained) b. Submitted result sheets for the 1st and 2nd events of 2023 and the 3rd event of 2024. (3 of 6 events submitted result sheets not retained) c. Analyzer printouts for the 1st, 2nd and 3rd events of 2023, and the 1st event of 2024 (4 of 6 events analyzer printouts not retained) 2. The technical consultant confirmed on 3/27/2025 at 11:00 a.m. the listed proficiency records were not retained after completion of each proficiency testing event.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on review of proficiency testing records since the last survey on 1/26/2023 and lack of documentation of verification of accuracy for parathyroid hormone (PTH), prostate-specific antigen (PSA), testosterone, and Vitamin D performed on the Tosoh AIA-900 chemistry analyzer, the laboratory failed to verify the accuracy of these analytes for the 2nd event of 2024 (1 of 4 events) when proficiency testing scores were unsatisfactory. The laboratory must verify the accuracy of tests not listed in subpart I twice annually. Findings include: 1. Review of proficiency testing records for 2024 revealed the following scores for 2nd event: a. Parathyroid hormone (PTH) - 50% b. Prostate-specific antigen (PSA) - 50% c. Testosterone - 0% d. Vitamin D - 0% 2. The technical consultant confirmed in an interview on 3/27/25 at 11:45 a.m. the laboratory failed to verify the accuracy of parathyroid hormone (PTH), prostate-specific antigen (PSA), testosterone, and Vitamin D twice annually for 2024 as required by the CLIA regulations.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on an interview with the technical consultant, review of Orthoclinical Diagnostic Vitros XT 3400 system verification validation records used as the procedure manual for chemistry testing and lack of documentation of review by the laboratory director, the laboratory director failed to approve, sign, and date the procedure manual before the Orthoclinical Diagnostic Vitros XT 3400 was put into use for patient testing. Findings include: 1. An interview with the Technical Consultant on 3/27/25 at 10:30 a.m., revealed the validation records were not signed and approved by the laboratory director. 2. Review of the Vitros XT 3400 validation records emailed on 3/27/25 at 10:47 a.m., revealed no documentation of the laboratory director's approval and signature.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 review of quality control records, patient test counts, and review of verification of performance specifications for the Tosoh AIA-900 chemistry system from 9/19/2023 (date of installation) through 3/27/2025, the laboratory failed to verify the manufacturer's performance specifications for three of nine analytes before reporting patient test results. The laboratory must verify the performance specifications of each nonwaived test system it introduces prior to reporting patient results. Findings include: Review of verification of performance specifications for the

	Tosoh AIA-900 chemistry system revealed on the day of the survey, 3/27/2025, there was no documentation of verification of performance specifications for parathyroid hormone (PTH), luteinizing hormone (LH), and cortisol testing available for review to include accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for the laboratory's patient population. The laboratory's annual patient test count for PTH, LH and cortisol testing was 167. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Orthoclinical Diagnostic Vitros XT 3400 analyzer maintenance logs from 10/1/23 through 3/27/25 and review of Orthoclinical Diagnostic Vitros XT 3400 periodic maintenance activity list printed from the instrument, the laboratory failed to document, as performed, weekly maintenance for seventy-four of seventy-eight weeks and monthly maintenance for fifthteen of sixteen months. Findings include: 1. The Orthoclinical Diagnostic Vitros XT 3400 analyzer defines the following weekly and monthly maintenance procedures: Weekly Maintenance: 1. Clean Tip Sealer 2. Clean Sample Supply 3. Clean Tip locator 4. Clean Dispense Blade and Sensors 5. Clean Leak Pad 6. Clean touchscreen monitor and keyboard 7. Process VITROS MicroSensor Check Fluids I and II Monthly Maintenance: 1. Clean PM Discard Chute 2. Clean/Replace PM Evaporation Caps 3. Clean PM Incubator Slot and Insert Balde Channels 4. Clean MicroSensor Cover 5. Perform System Backup 6. Inspect/Clean master Computer Filter 7. Perform Correction Factors 8. Replace System Filter 9. Perform Pad Reflectance Test 2. Review of the Orthoclinical Diagnostic Vitros XT 3400 analyzer maintenance logs from 10/1/23 through 3/27/25 revealed the laboratory failed to document, as performed, the weekly maintenance procedure for 74 of 78 weeks. 3. Review of the Orthoclinical Diagnostic Vitros XT 3400 analyzer maintenance logs from 10/1/23 through 3/27/25 revealed the laboratory failed to document, as performed, the monthly maintenance procedure for 15 of 16 months.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for the Orthoclinical Diagnostic Vitros XT 3400 system, manufacturer's Performance Verifier's (PV) package inserts

	for lot #T1396, lot #U1398 and lot #X1901, and interview with the technical consultant, the laboratory failed to document, as performed, the establishment of statistical parameters for acceptable ranges for Chemistry testing for thirteen of thirteen months. Findings include: 1. Review of quality control records from 10/1/23 through 11/30/24 revealed no documentation of acceptable ranges on the QC reports for PV I lot #T1396, PV II lot #U1398 and lot #X1901. Testing Personnel used Range of Means listed on Performance Verifier's package insert as statistical parameters for acceptable ranges. 2. The technical consultant confirmed in an interview on 3/27/25 at 12:30 p.m., there were no establishment of statistical parameters for acceptable ranges for thirteen of thirteen months while using PV I and PV II. Approximately 1,592 patients were tested during this time.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of chemistry proficiency testing (PT) events performed since the last survey on 1/26/2023, lack of documentation of corrective action for unsatisfactory scores for 2nd event of 2024 and 1st event of 2025, the laboratory director failed to ensure that an approved corrective action plan was followed when PT results were found to be unsatisfactory for two of four events. Findings include: 1. Review of the chemistry PT scores for 1st, 2nd, and 3rd events of 2024 and 1st event of 2025 revealed a score of 40% for Glucose for 2nd event of 2024 and 0% for AST for 1st event of 2025. 2. There was no documentation of corrective action for the unsatisfactory scores available for review on the day of the survey. 3. In an interview on 3/27/2025 at 2:00 p.m., the technical consultant confirmed there was no documentation of corrective action for the unsatisfactory scores of 40% for Glucose for 2nd event of 2024 and 0% for AST for 1st event of 2025.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) (b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing records from 1/26/2023 through 3/27/2025 and lack of documentation of review by the technical consultant, the technical consultant failed to document review of the proficiency testing (PT) records for evaluation of the competency of the testing personnel for seven of seven PT events. Findings include: 1. There was no technical consultant review documented for the PT records for all events of 2023 and 2024 when the following failures occurred: a. Regulated analytes - 2nd event 2024 Glucose (40%) and 1st event 2025 AST (0%) b. Non-regulated analytes - 2nd event 2024 PTH (50%), PSA (50%), Testosterone (0%) and Vitamin D (0%) 2. An interview with the technical consultant on 3/27/2025 at 12:30 p.m. confirmed there was no documented review of PT records by the technical consultant for seven of seven PT events.