

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1000384	(X3) Date Survey Completed 10/13/2020
Name of Provider or Supplier Houma Health Clinic	Street Address, City, State 827 Bayou Gardens Blvd, Houma, LA	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Houma Health Clinic, CLIA ID # 19D1000384, on October 13, 2020. Based on review of the laboratory's maintenance logs and interview with personnel, the laboratory failed to perform daily and weekly maintenance per manufacturer's requirements for the Indiko Plus analyzer for one (1) of four (4) months reviewed. Findings: 1. Review of the "Indiko Plus Maintenance Checklist" for July 2020 through October 13, 2020 revealed the laboratory did not have documentation of daily and weekly maintenance during the following month: September 2020: a) Daily maintenance was not recorded for the following fourteen (14) days : September 8, 2020, September 9, 2020, September 10, 2020 , September 11, 2020. September 14, 2020, September 15, 2020, September 16, 2020, September 17, 2020, September 18, 2020. September 21, 2020, September 22, 2020, September 23, 2020, September 24, 2020, September 25, 2020 b) Weekly maintenance was not recorded the following three (3) weeks: Week of September 7, 2020 Week of September 14, 2020 Week of September 21, 2020 2. In interview on October 13, 2020 at 10:56 am, the Testing Personnel stated during the identified dates he was on leave. The Testing Personnel confirmed the laboratory's closure during the identified dates were not indicated on the maintenance log.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification</p>

requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
A Revisit survey was performed at Houma Health Clinic, CLIA ID # 19D1000384, on October 13, 2020. Based on review of the laboratory's Plan of Correction, observation, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to provide on-site consultation per the laboratory's Plan of Correction. Refer to D6038. 3. The Technical Consultant failed to ensure performance verification studies were complete. Refer to D6040. 4. The Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Refer to D6042. 5. The Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6043.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
A Revisit survey was performed at Houma Health Clinic, CLIA ID # 19D1000384, on October 13, 2020. Based on review of the laboratory's Plan of Correction, observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually per their Plan of Correction. Review of D5217. 2. The laboratory failed to ensure reagents did not exceed their expiration dates. Refer to D5417. 3. The laboratory failed to perform daily and weekly maintenance per manufacturer's requirements for the Indiko Plus analyzer for one (1) of four (4) months reviewed. Refer to D5429.

D6038

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(a)

The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation.

This STANDARD is not met as evidenced by:
A Revisit survey was performed at Houma Health Clinic, CLIA ID # 19D1000384, on October 13, 2020. Based on review of the laboratory's Plan of Correction, record review, and interview with personnel, the Technical Consultant failed to provide on-site consultation per the laboratory's Plan of Correction. Findings: 1. Review of the laboratory's Plan of Correction revealed the laboratory stated the "on-site Technical Consultant" would be responsible for corrective actions. 2. Review of the Technical Consultant's on-site logs revealed the Technical Consultant had not been on-site to the laboratory since July 30, 2020. 3. In phone interview on October 13, 2020 at 10:25

	<p>am, the Consultant Management personnel stated the laboratory's Technical Consultant could no longer be on-site as required. He further stated the laboratory will have a new Technical Consultant, who has not started. The Consultant Management personnel stated the new Technical Consultant was supposed to start next week. 4. In interview on October 13, 2020 at 12:36 pm, the Testing Personnel confirmed the Technical Consultant was last on site in July 2020.</p>
<p>D6040</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Houma Health Clinic, CLIA ID # 19D1000384, on October 13, 2020. Based on review of the laboratory's Plan of Correction, record review, and interview with personnel, the Technical Consultant failed to ensure performance verification studies were complete. Refer to D5421.</p>
<p>D6042</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Houma Health Clinic, CLIA ID # 19D1000384, on October 13, 2020. Based on review of the laboratory's Plan of Correction, records, and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Refer to D5469.</p>
<p>D6043</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5)</p> <p>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Houma Health Clinic, CLIA ID # 19D1000384, on October 13, 2020. Based on review of the laboratory's Plan of Correction, policies and procedures, quality control records, and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.</p>