

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2016117	(X3) Date Survey Completed 09/25/2020
Name of Provider or Supplier Crescent City Surgical Centre Diagnostics, Llc	Street Address, City, State 3016 Galleria Drive, Metairie, 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
D5809	<p>TEST REPORT CFR(s): 493.1291(e)</p> <p>The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Crescent City Surgical Centre, CLIA ID # 19D2016117, on September 23, 2020 through September 25, 2020. Based on direct observation, review of Emergency Use Authorization (EUA) instructions test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to providers or patients for EUA COVID tests. Findings: 1. Observation by surveyor during laboratory tour and review of laboratory's test menu revealed the laboratory performs the following COVID test methods: a) Abbott ID Now b) DTPM COVID method on Quant Studio 5 analyzer c) Elecsys Anti-SARS-CoV-2 on Roche Cobas e801 analyzer 2. Review of the EUA instructions for the indicated tests revealed "Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets." 3. In interview on September 25, 2020 at 9:24 am, Technical Consultant 1 stated she gives fact sheets to patients collected at the laboratory for the Abbott ID Now tests. Technical Consultant 1 stated she was unaware there were "Fact Sheets" for the other two test methods.</p>
D6082	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p>

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

A Revisit survey was performed at Crescent City Surgical Centre, CLIA ID # 19D2016117, on September 23, 2020 through September 25, 2020. Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed performance specification studies for the Coronachek antibody test. Findings: 1. In interview on September 24, 2020 at approximately 9:22 am Technical Consultant 1 stated the laboratory previously used the Coronachek kits for antibody testing. Technical Consultant 1 stated the kits were waived. 2. Review of the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) COVID test list revealed the "Coronachek COVID-19 IgM/IgG Rapid Test Cassettes" were not listed as having an EUA authorization. 3. Review of the manufacturer's package insert revealed the manufacturer as Hangzhou Biotest Biotech Co., Ltd. 4. In interview on September 24, 2020 at 11:44 am, Technical Consultant 1 stated the Coronachek antibody test had an EUA. Technical Consultant 1 further stated the laboratory did not perform validation studies. 5. Review of the records provided by Technical Consultant 1 revealed an abstract article and EUA from a different manufacturer, "COVID-19 IgG/IgM Rapid Test Cassette by Healgen Scientific, LLC" issued May 29, 2020, not the indicated Coronachek kit. 6. Review of the laboratory's "Coronachek COVID-19 IgG/Ig M Test Cassette QC Log" and patient logs revealed the laboratory reported the following patients: Patient 0010889240 Patient 0010889241 Patient 0000001711 Patient 0010889242 Patient 0000001279 7. Further review of the laboratory's Coronachek patient logs revealed the laboratory reported a total of 176 patient results in April 2020 and eighteen (18) patient results in May 2020.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

A Revisit survey was performed at Crescent City Surgical Centre, CLIA ID # 19D2016117, on September 23, 2020 through September 25, 2020. Based on record review and interview with personnel, the Laboratory Director failed to ensure "Fact Sheets" were provided to patients and providers for EUA COVID tests. Refer to D5809.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting

and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
A Revisit survey was performed at Crescent City Surgical Centre, CLIA ID # 19D2016117, on September 23, 2020 through September 25, 2020. Based on record review and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Supervisor and General Supervisor.
Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed Technical Consultant 1 serves as Technical Supervisor and General Supervisor. 2. Review of personnel records for Technical Consultant 1 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks of Technical Supervisor and General Supervisor to her. 3. In interview on September 24, 2020 at 9:22 am, Technical Consultant 1 confirmed the laboratory did not have documentation of the Laboratory Director delegating responsibilities of Technical Supervisor and General Supervisor to her.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for 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.

This STANDARD is not met as evidenced by:
A Revisit survey was performed at Crescent City Surgical Centre, CLIA ID # 19D2016117, on September 23, 2020 through September 25, 2020. Based on record review and interview with personnel, the Technical Supervisor failed to ensure that a quality control program was established to assure the quality of testing for COVID testing. Refer to D5401.