

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0976007	<b>(X3) Date Survey Completed</b>  03/31/2022
<b>Name of Provider or Supplier</b>  Homer Medical Clinic	<b>Street Address, City, State</b>  104 Morris Circle, Homer, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification Survey was performed at Homer Medical Clinic - CLIA # 19D0976007 on March 29, 2022 through March 31, 2022. Homer Medical Clinic was found not in compliance with the following <b>CONDITION LEVEL DEFICIENCIES</b> : 42 CFR 493.1415 <b>CONDITION</b> : Laboratories Performing Moderate Complexity Testing; Clinical Consultant 42 CFR 493.1403 <b>CONDITION</b> : Laboratories Performing Moderate Complexity Testing; Laboratory Director
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This <b>STANDARD</b> is not met as evidenced by: Based on review of the laboratory's policies and procedures for waived testing and interview with personnel, the laboratory failed to have a complete policy and procedure for the reporting of SARS CoV-2 test results to the appropriate state agency. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not include the following written policy: a) Written, detailed instructions for the reporting of SARS CoV-2 test results to the state public health agency, to include but not limited to who is responsible for reporting test results and the frequency at which reporting is performed.</p>
<b>D5205</b>	<p><b>COMPLAINT INVESTIGATIONS</b> CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a system for handling complaints and problems reported to the laboratory. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have detailed, written instructions for reporting complaints which includes who is responsible for handling the complaints. 2. In interview on March 31, 2022 at 10:56 am, the Laboratory Director confirmed the laboratory did not have a written procedure for reporting/handling complaints.

**D5207**

**COMMUNICATIONS**  
CFR(s): 493.1234

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a system in place to ensure that the documentation of communication problems are reported to the laboratory. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have detailed, written instructions to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. In in interview on March 31, 2022 at 10:56 am, the Laboratory Director confirmed the laboratory did not have a communication policy in place.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:  
I. Based on review of policies and procedures, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include frequency of performance and the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on March 29, 2022 at 11:03 am, the

Laboratory Director confirmed the laboratory did not include a competency assessment policy for testing personnel. II. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have complete policies for competency assessment of the Clinical Consultant. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not define competency assessment policy for the duties assigned to the Clinical Consultant along with the frequency of performance. 2. In interview on March 29, 2022 at 11:03 am, the Laboratory Director confirmed the laboratory did not include a policy for the assessment of the Clinical Consultant.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not include the following written policies: a) Retention of records requirements b) Temperature and humidity monitoring to include corrective actions for temperatures outside of acceptable ranges c) Course of action if test system becomes inoperable 2. In interview on March 31, 2022 at 10:56 am, the Laboratory Director confirmed the above identified policies were not included.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy and procedure manual and interview with

personnel, the laboratory failed to have complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure revealed the laboratory did not include detailed, written instructions to include, but not limited to: a) Quality control to include, but not limited to: the establishment and/or verification of means and ranges for new lots of Hematology and Urinalysis quality control materials b) Corrective actions for testing personnel to take when quality control results are unacceptable and do not meet the laboratory's criteria for acceptability c) Complete Blood Count: to include what tests are performed and resulted for patient testing and the actions to take when flags occur on patient results 2. In interview on March 31, 2022 at 10:56 am, the Laboratory Director confirmed the laboratory did not include the above identified policies and procedures.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:  
Based on observation by surveyor, review of the laboratory's maintenance logs and interview with personnel, the laboratory failed to ensure monthly maintenance for the Beckman Coulter DxH 520 Hematology analyzer was performed per manufacturer instructions for five (5) of ten (10) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on March 31, 2022 at 12:29 pm revealed the laboratory utilizes the Beckman Coulter DxH 520 Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's "DxH 520 Instrument Maintenance Checklist" revealed the following monthly maintenance tasks: a) Perform Bleach Cycle b) Clean the WBC Bath Filter 3. Further review of the laboratory's "DxH 520 Instrument Maintenance Checklist" from June 2021 through March 2022 revealed the laboratory did not have documentation of performing the monthly maintenance for the following five (5) of ten (10) months reviewed: a) October 2021: Perform Bleach Cycle b) November 2021: Perform Bleach Cycle c) December 2021: Clean the WBC Bath Filter d) January 2022: Clean the WBC Bath Filter e) February 2022: Clean the WBC Bath Filter 4. In interview on March 31, 2022 at 12:09 pm, the Laboratory Director confirmed the above monthly maintenance was not documented as performed for identified months.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on observation by surveyor, review of laboratory records, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6023 2. The Laboratory Director failed to ensure

the laboratory employed a Clinical Consultant to consult with and render opinions to the laboratory's clients. Refer to D6028 3. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Refer to D6030 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031 5. the Laboratory Director failed to delegate, in writing, the responsibilities of Clinical Consultant. Refer to D6032

**D6023**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(6)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on observation by surveyor during laboratory tour, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to ensure monthly maintenance for the Beckman Coulter DxH 520 Hematology analyzer was performed per manufacturer instructions for five (5) of ten (10) months reviewed. Refer to D5429.

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(10)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure the laboratory employed a Clinical Consultant to consult with and render opinions to the laboratory's clients. Refer to D6057.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency for testing personnel. Refer to D5209 I. 2. The laboratory failed to have complete policies for competency assessment of the Clinical Consultant. Refer to D5209 II.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to have a system for handling complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that the documentation of communication problems are reported to the laboratory. Refer to D5207. 3. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 4. The laboratory failed to have complete policies and procedures. Refer to D5403.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, personnel records and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Clinical Consultant. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities for the Clinical Consultant. 2. In interview on March 29, 2022 at 11:03 am, the Laboratory Director confirmed she did not have written documentation of delegation of responsibilities for the Clinical Consultant.</p>
<p><b>D6056</b></p>	<p><b>CLINICAL CONSULTANT</b> CFR(s): 493.1415</p> <p>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to provide documentation that the Clinical Consultant met education requirements for moderate complexity testing. Findings: 1. The laboratory failed to ensure the Clinical Consultant met the education qualification required. Refer to D6057.</p>
<p><b>D6057</b></p>	<p><b>CLINICAL CONSULTANT QUALIFICATIONS</b> CFR(s): 493.1417</p> <p>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (CMS 209) and personnel records as well as interview with personnel, the laboratory failed to ensure the Clinical Consultant met the education qualification required. Findings: 1. Review of the Laboratory Personnel Report (CMS 209) revealed the laboratory listed Personnel 1 as serving as the Clinical Consultant. 2. Review of the laboratory's personnel records revealed Personnel 1 has proof of education consisting of a Bachelor of Science in Clinical Laboratory Science; however, Personnel 1 does not meet the qualification of education for the position of Clinical Consultant. 3. In interview on March 29, 2022 at 11:09 am, the Laboratory Director stated she was unaware of the education qualification required for the position of Clinical Consultant.</p>