

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0465142	(X3) Date Survey Completed 02/01/2023
Name of Provider or Supplier Hardtner Medical Center	Street Address, City, State 1102 North Pine Road, Olla, 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
D0000	A Recertification survey was performed at Hardtner Medical Center, CLIA #19D0465142 on January 30, 2023 through February 1, 2023. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's test menu, proficiency test (PT) records and interview with personnel, the laboratory failed to verify the accuracy of performance for C-Reactive Protein (CRP) at least twice per year. Findings: 1. Observation by the surveyor during the laboratory tour on January 30, 2023 at 2:00 pm revealed the laboratory utilizes the Ortho Diagnostics Vitros 350 Chemistry analyzer for patient testing. 2. Review of the laboratory's test menu provided by the facility revealed the laboratory performs patient testing on the Vitros 350 chemistry analyzer for C-Reactive Protein (CRP). 3. Review of the laboratory's 2021 and 2022 proficiency testing records revealed the laboratory did not have documentation of testing for the verification of accuracy of performance at least twice annually for CRP. 4. In interview on January 31, 2023 at 11:18 am, Technical Consultant 1 stated she was unaware that CRP was not included on the proficiency testing events in 2021 and 2022. Technical Consultant 1 confirmed the laboratory did not verify the accuracy for CRP at least twice annually.</p>

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 policy and procedures and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies that included the following: a) Blood Bank: detailed, written procedures for performing new lot of reagent verifications b) Blood Bank: detailed, written procedures for labeling uncrossmatched blood as such upon release from the laboratory 2. In interview on January 31, 2023 at 2:15 pm, General Supervisor 2 confirmed the laboratory did not have written policies for the identified items above.

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, Platelet Poor Plasma records and interview with personnel, the laboratory failed to perform Platelet Poor Plasma studies quarterly in 2022 as required by laboratory policy. Findings: 1. Review of the laboratory's policy and procedure revealed the laboratory performs Platelet Poor Plasma studies quarterly. 2. Review of the Platelet Poor Plasma records for 2022 revealed the laboratory did perform Platelet Poor Plasma studies in January 2022 and July 2022; However, the laboratory did not perform the studies in April 2022 and October 2022. 3. In interview on January 31, 2023 at 4:09 pm, General Supervisor 2 stated that the laboratory policy was changed to perform Platelet Poor Plasma every six (6) months but she could not locate the policy change. General Supervisor 2

confirmed the laboratory did not perform Platelet Poor Plasma studies quarterly per laboratory policy.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records and interview with personnel, the Laboratory Director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D5215.

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 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 establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to perform Platelet Poor Plasma studies quarterly in 2022 as required by laboratory policy. Refer to D5403.