

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0465142	(X3) Date Survey Completed 09/08/2021
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 PT Desk Review was performed on September 8, 2021. Hardtner Medical Group-19D04625142 was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing results from the CMS-153, CMS-155D and College of American Pathologist (CAP), the laboratory failed to successfully perform in proficiency testing as evidence by: 1. The laboratory failed to achieve satisfactory

	performance of at least 80% for Lithium in two consecutive events resulting in initial unsuccessful performance. Refer to D2118.
D2118	TOXICOLOGY CFR(s): 493.845(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of proficiency testing results from the CMS-153, CMS-155D and College of American Pathologist (CAP), the laboratory failed to achieve satisfactory performance for Lithium in two consecutive events resulting in initial unsuccessful performance. Findings are: 1. Review of College of American Pathologist (CAP) proficiency testing results and CMS Report 0153D and 0155D revealed the laboratory failed to score at least 80% for Lithium in the following events: Event 1 of 2021: 60% Event 2 of 2021: 60%
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 record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: The laboratory director failed to ensure that proficiency testing samples are satisfactory as required. Findings: 1. The laboratory failed to achieve a score of at least 80% for Lithium in two consecutive events, resulting in initial unsuccessful performance. Refer to D2118.