Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506530	10/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hemphill County Hospital Laboratory	1020 South Fourth Street, Canadian, TX	

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	Based on a proficiency testing desk review survey performed on October 3, 2025, the laboratory was found to be out of compliance based on the following condition level deficiencies: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6076 - 42 C.F.R 493.1441 Condition: Laboratory Director, High complexity
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 a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute

	(API) Proficiency testing (PT) records, the laboratory failed to achieve successful performance in two of three consecutive testing events in 2024 and 2025, resulting in unsuccessful performance. Refer to D2181.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) (e) Failure to achieve an overall testing event score of satisfactory for 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) Proficiency testing (PT) testing records for 2024 and 2025, the laboratory failed to achieve an overall testing event score of satisfactory performance (100%) for two of three consecutive testing events for immunohematology compatibility testing. Two out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. The findings included: 1. A review of the CASPER Report 155 listed the following scores for immunohematology compatibility PT: Event, Analyte/Test: Score 2025 Event 2, Compatibility Testing: 0% 2024 Event 3, Compatibility Testing: 80% 2. A desk review of API proficiency testing records for 2024 and 2025 confirmed that the laboratory received an immunohematology compatibility testing score of 0% for 2025 event 2, and 80% for 2024 event 3.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) Proficiency testing (PT) testing records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program in immunohematology, compatibility testing for two of three events reviewed in 2024 and 2025. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) Proficiency testing (PT) proficiency testing records, the laboratory director

	failed to ensure successful participation in a HHS approved proficiency testing program for immunohematology compatibility testing for two of three reviewed in 2024 and 2025. Refer to D2181.