Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0508911	08/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Winkler County Memorial Hospital	821 Jeffee Dr, Kermit, 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 August 4, 2022, 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 D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts evaluation reports, the laboratory failed to achieve successful

	performance in two of three consecutive testing events for the specialty Routine Chemistry for the analyte Bilirubin, Total, resulting in unsuccessful performance. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts evaluation reports, the laboratory failed to achieve successful performance in two of three consecutive testing events for the specialty Routine Chemistry for the analyte Bilirubin, Total, resulting in unsuccessful performance. The finding included: 1. Based on review of the American Association of Bioanalysts evaluation reports for the third event of 2021 and the second event of 2022, the laboratory received the following unsatisfactory scores for the analyte Bilirubin, Total: 1) Third event, 2021, Bilirubin, Total - score of 60 percent 2) Second event of 2022, Bilirubin, Total - score of 40 percent
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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts evaluation reports, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for analyte Bilirubin, Total in the specialty of Routine Chemistry for two of three events in 2021 and 2022. 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: Based on desk review of the Certification and Survey Provider Enhanced Reporting

	(CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analyte Bilirubin, Total, in the specialty of Routine Chemistry for two of three events in 2021 and 2022. Refer to D2096.