Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1059113	11/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Solara Hospital Harlingen L P	508 Victoria Lane, Harlingen, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the facility failed to have documentation of performing /evaluating verification studies for 1 of 1 new test cartridges on the iSTAT analyzer. The findings include: 1. A review of the laboratory's test menu revealed the laboratory starting using the iSTAT CG4+ cartridge in October 2021. 2. A review of the laboratory's verification records revealed the laboratory failed to have documentation of: a) evaluation of accuracy b) evaluation of precision c) performing reportable range analysis d) performing verification of patient normal ranges. 3. The laboratory was asked to provide documentation of the missing studies/evaluations. No documentation was provided. 4. An interview with the technical consultant on 11/30/2022 at 1122 hours in the laboratory - after his review of the records- confirmed the findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records from 2022, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments in 2022. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 15 testing personnel. 2. A review of the laboratory's personnel records revealed 15 of 15 competency assessments performed on testing personnel were performed by someone other than the technical consultant. The person who performed the competency assessments was not qualified as a technical consultant. 3. The laboratory was asked to provide documentation of the technical consultant performing competency assessments in 2022. No documentation was provided. 4. An interview with the technical consultant on 11/30/2022 at 1055 hours in the laboratory confirmed the findings.