Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1059113	07/13/2021
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	The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview of facility personnel, the laboratory failed to test proficiency samples in the same manner as it tests patient specimens. The findings included: 1. This is a repeat deficiency from the survey conducted October 18, 2018. 2. Review of the laboratory's submitted Form CMS-209 approved by the laboratory director on July 1, 2021 revealed the laboratory identified fourteen testing personnel. 3. Review of proficiency testing events 2019 (events 1, 2, and 3), 2020 (events 1, 2, and 3), and 2021 (event 1) revealed that three out of fourteen testing persons participated in proficiency testing. a. By not involving all testing personnel who normally test patient specimens in the testing of proficiency testing samples, the facility failed to treat proficiency samples in the same manner as patient samples. 4. An interview of the Lead Respiratory Therapist on July 13, 2021 at 10:20 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Review of patient final reports and interview with facility personnel found the laboratory failed to ensure test requisitions included specimen collection time for three of six patient final patient reports reviewed. The findings included: 1. Review of six patient final reports found that the laboratory failed to document time of collection for three Arterial Blood Gas specimens. Last 4 digits of Patient Number: 8132 Date of Collection: 05-23-2021 Time Drawn: blank Last 4 digits of Patient Number: 8148 Date of Collection: 05-25-2021 Time Drawn: blank Last 4 digits of Patient Number: 8162 Date of Collection: 06-11-2021 Time Drawn: blank 2. Interview with the Lead Respiratory Therapist on July 13, 2021 at 10:45 hours confirmed the findings. He agreed the time of collection was missing on the reports.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Review of patient final reports and interview with facility personnel found the laboratory failed to document specimen receive time for six of six patient final reports reviewed. The findings included: 1. Review of six of six patient final reports found that on Chemistry/Arterial Blood Gas Result Form there was not area to document specimen receive time. 2. Review of six of six patient final reports found the laboratory failed to document specimen receive times as follows: Last 4 digits of Patient Number: 8124 Date of Collection: 05-14-2021 No receive time Last 4 digits of Patient Number: 8130 Date of Collection: 05-15-2021 No receive time Last 4 digits of Patient Number: 8132 Date of Collection: 05-23-2021 No receive time Last 4 digits of Patient Number: 8148 Date of Collection: 05-25-2021 No receive time Last 4 digits of Patient Number: 8162 Date of Collection: 06-11-2021 No receive time Last 4 digits of Patient Number: 8207 Date of Collection: 06-30-2021 No receive time 3. An interview with the Lead Respiratory Therapist on July 13, 2021 at 11:15 hours in the laboratory confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by:

	Based on review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to ensure specimens for Arterial Blood Gas (ABG) were tested within 10 minutes of collection. The findings included: 1. Review of the manufacturer's instructions for the Abbott i-STAT (Art. 714372-00P, Rev. 17-Apr-2020) stated, "Time to Test: For the most accurate results, test samples immediately after drawing. Samples for lactate must be tested immediately. Samples for pH, PCO2, PO2, TCO2, and ionized calcium should be tested within 10 minutes ..." 2. Random review of patient final reports from May and June 2021 found the following six of six samples were tested and were not tested within 10 minutes or because time of collection was not documented it could not be determined is specimens were tested within 10 minutes of collection. Last 4 digits of Patient Number: 8124 Date of Collection: 05-14-2021 Time of Collection: 14:00 hours Analyzed Time: 14:41 hours (elapsed time past 10 minutes: 31 minutes) Last 4 digits of Patient Number: 8130 Date of Collection: 05-15-2021 Time of Collection: 02:15 hours Analyzed Time: 02:31 hours (elapsed time past 10 minutes: 6 minutes) Last 4 digits of Patient Number: 8132 Date of Collection: 05-23-2021 Time of Collection: blank Analyzed Time: 19:40 hours Note: Could not determine if specimen was tested within 10 minutes due to no time of collection Last 4 digits of Patient Number: 8148 Date of Collection: 05-25-2021 Time of Collection: blank Analyzed Time: 12:56 hours Note: Could not determine if specimen was tested within 10 minutes due to no time of collection Last 4 digits of Patient Number: 8162 Date of Collection: 06-11-2021 Time of Collection: blank Analyzed Time: 01:58 hours Note: Could not determine if specimen was tested within 10 minutes due to no time of collection Last 4 digits of Patient Number: 8207 Date of Collection: 06-30-2021 Time of Collection: 09:00 Analyzed Time: 09:13 hours (elapsed time past 10 minutes: 1 minute) 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to ensure specimens were tested within 10 minutes of collection. No documentation was provided. 4. An interview with the Lead Respiratory Therapist on July 13, 2021 at 10:45 hours confirmed the findings. He stated that some of the discrepancies were most likely due to wrong times being documented and agreed that if times were not written at all, the elapsed time could not be determined.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of patient final reports, and confirmed in interview of facility personnel, it was revealed the laboratory's quality assurance plan failed to ensure patient normal ranges on final reports matched its current policy. The findings included: 1. Review of the laboratory's Blood Gas Lab Quality Assurance /Quality Improvement Program policy, not signed by the current laboratory director, stated, "A laboratory quality assurance program is utilized to continually assess the effectiveness of the departmental policies and procedures. A comprehensive quality assurance program is designed to monitor and evaluate ongoing and overall quality of the total testing process, to include the pre-analytic, analytic, and post-analytic phases

	of testing. The program will: evaluate the effectiveness of standard operating procedures, assure accurate, reliable, and prompt reporting of testing results; and assure the adequacy and competency of the staff. The department will revise policies, when indicated, by the results of the quality assurance." 2. Review of the laboratory's policy title, "Reference Ranges, Reportable Ranges and Unit Conversions" not approved by the current laboratory director revealed the laboratory's current normal ranges for Arterial Blood Gases (ABGs) were as follows: Analyte Reference Range Unit Conversion (arterial) pH 7.35 - 7.45 Not applicable PCO2 35 - 45 mmHg PO2 80 - 105 mmHg HCO3 22 - 26 mmol/L 3. Review of six of six patient final reports found the laboratory's ABG reference ranges were as follows: Analyte Reference Range Unit Conversion (arterial) pH 7.35 - 7.45 Not applicable PCO2 35 - 45 mmHg PO2 80 - 100 mmHg HCO3 22 - 26 mmol/L 4. The laboratory's quality assurance plan failed to identify and correct that the reference range for PO2 on patient final reports did not match its current policy. 5. An interview with the Lead Respiratory Therapist on July 13, 2021 at 11:30 hours confirmed the findings.
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: Review of policies and procedures, patient test records, and interview of facility personnel found that the laboratory director failed to ensure that all procedures available to testing personnel had been approved, signed, and dated by the current laboratory director.
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 laboratory's personnel records and confirmed in staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing the competency assessments on 6 of 6 testing personnel competencies reviewed for 2020. The findings were: 1. A review of the laboratory's personnel records revealed competency assessment were performed on Testing personnel numbers 1, 4, 5, 6, 7, and 9 as follows: Testing personnel 1 (as listed on Form CMS-209) Date: 09-20-2020 The competency assessments were documented as being performed by testing personnel 3 Testing personnel 4 (as listed on Form CMS-209) Date: 09-27-2020 The competency assessments were documented as being performed by testing personnel 3 Testing personnel 5 (as listed on Form CMS-209) Date: 09-228-2020 The competency assessments were documented as being performed by testing

	personnel 3 Testing personnel 6 (as listed on Form CMS-209) Date: 08-25-2020 The competency assessments were documented as being performed by testing personnel 3 Testing personnel 7 (as listed on Form CMS-209) Date: 09-27-2020 The competency assessments were documented as being performed by testing personnel 3 Testing personnel 9 (as listed on Form CMS-209) Date: 09-24-2020 The competency assessments were documented as being performed by testing personnel 3 2. A review of the personnel records for testing personnel number 3 revealed he did not meet the requirements to be a technical consultant. He did not have a bachelor's degree in a biological, chemical, physical, or medical laboratory science field. 3. The laboratory was asked to provide documentation of the technical consultant performing the competency assessments. No documentation was provided. 4. An interview with the Lead Respiratory Therapist on July 13, 2021 at 09:45 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services