Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0938565	11/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
South Texas Regional Laboratories Inc	1975 N Veterans Blvd, Suite 5-A, Eagle Pass, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of the laboratory's submitted CMS 209 form, a review of the laboratory's College of American Pathologists' hematology proficiency testing records from 2017 to 2019, and staff interview, it was revealed the laboratory failed to ensure that all testing personnel that performed hematology testing participated in proficiency testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/6/19) revealed the laboratory listed 2 testing personnel. 2. A review of the laboratory's College of American Pathologists' hematology proficiency testing records from 2017 (FH1- C), 2018 (FH1-A, FH1-B, FH1-C) and 2019 (FH1-A, FH1-B) revealed testing person #2 did not participate in

	the hematology proficiency testing. 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 11/6/19 at 10:15 a.m. in the laboratory revealed the laboratory did not rotate the proficiency testing among all testing personnel. This confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing a competency assessment for 1 of 1 technical consultants. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/6/19) revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing a competency assessment of the technical consultant. 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 11/6/19 at 10:10 a.m. in the laboratory revealed the laboratory did not assess the competency of the technical consultant. This confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists' proficiency testing results from 2017, 2018, and 2019, and staff interview, it was revealed the laboratory failed to have documentation of the review of 1 of 6 testing events. Findings include: 1. A review of the laboratory's College of American Pathologists' hematology proficiency testing results from 2017 (FH1- C), 2018 (FH1-A, FH1-B, FH1-C) and 2019 (FH1-A, FH1-B) revealed the laboratory failed to have documentation of the review of 1 of 6 events. The event without documentation of review was: 2018 FH1-C 2. The laboratory was asked to provide documentation of the review of the above testing event. No documentation was provided. 3. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 11/6/19) on 11/6/19at 11:07 in the office, after review of the records, confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on a review of the Cell-Dyn Emerald Operator's Manual, a review of the laboratory's maintenance records for the Cell-Dyn Emerald hematology analyzer from January 2018 - October 2019, and staff interview it was revealed the laboratory failed to have documentation of performing the required semi-annual maintenance. Findings include: 1. A review of the Cell-Dyn Emerald Operator's Manual (9140853-December 2009) states the following semi-annual maintenance is required: a) Lubricating the Pistons 2. A review of the laboratory's maintenance records for the Cell-Dyn Emerald hematology analyzer from January 2018 - October 2019 revealed the semi-annual maintenance, Lubricating the Pistons, procedure was performed: Performed: August 17, 2018 Performed: April 22, 2019 Time elapsed between the two above dates 248 days. There was no documentation of the semi-annual maintenance being performed in February 2018. There was no documentation of the semi-annual maintenance being performed in October 2019. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 11/6/19) on 11/6/19 at 10:50 a.m. in the laboratory, after review of the records, confirmed the above findings.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a random review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of the notification of the provider when the patient's Complete Blood Count (CBC) results indicated a panic value. Findings include: 1. A review of the laboratory's policy titled "Evaluation of Hematology Result - Panic or Flags" revealed the following: "The testing personnel will immediately notify the patient's physician or primary care provider when results of certain test are considered a panic value. The testing personnel will document the call of panic value together with the date and time on the Laboratory report." 2. A review of the laboratory's policy titled "Panic Values" revealed the following panic ranges: a) 0 to 6 months WBC: less than 6 or greater than 20 HGB: less than 9 or greater than 19 HCT: less than 27 or greater than 60 RBC: less than 3.8 or greater than 6.0 Plt: less than 100 or greater than 600 b) 7 months to 2 years WBC: less than 4 or greater than 17.5 HGB: less than 11 or greater than 16 HCT: less than 33 or greater than 48 RBC: less than 3.70 or greater than 5.20 Plt: less than 100 or greater than 600 c) 3 years to 11 years WBC: less than 5 or greater than 14.5 HGB: less than 12 or greater than 16 HCT: less than 35 or greater than 47 RBC: less than 3.7 or greater than 5.0 Plt: less than 100 or greater than 600 d) 12 years to 20 years WBC: less than 4 or greater than 17 HGB: less than 12 or greater than 16 HCT: less than 35 or greater than 48 RBC: less than 3.8 or greater than 5.2 Plt: less than 100 or greater than 600 e) Adult WBC: less than 2 or greater than 20 HGB: less than 7 or greater than 18 HCT: less than 25 or greater than 55 RBC: less than 4.2 or greater than 6.1 Plt: less than 50 or greater than 1000 3. A random review of patient CBC results from October 2019 identified the following patient results which met the laboratory's criteria as a panic value: a) Patient ID: 01032002 Resulted: 10/1/19 Age range: 12

	years to 20 years Test: RBC: 5.45 HGB: 48.8 No documentation of provider's notification b) Patient ID: 07102011 Resulted: 10/4/19 Age range: 3 years to 11 years Test: WBC: 18.9 No documentation of provider's notification c) Patient ID: 07252006 Resulted: 10/29/19 Age range: 12 years to 20 years Test: HGB: 16.7 RBC: 5.36 No documentation of provider's notification d) Patient ID: 04032014 Resulted: 10/14/19 Age range: 3 years to 11 years Test: WBC: 21.8 No documentation of provider's notification e) Patient ID: 10102002 Resulted: 10/14/19 Age range: 12 years to 20 years Test: WBC: 3.9 No documentation of provider's notification 4. The laboratory was asked to provide documentation of the notification of the provider for the patient's panic values on the CBC results. No documentation was provided. 5. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 11/6/19) on 11/6/19 at 11:15 a.m. in the office, after review of the records, confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 9/6/2017. KEY: WBC- white blood cell RBC- red blood cell HGB- hemoglobin HCT- hematocrit Plt- platelet
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 a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, and staff interview, it was revealed the technical consultant failed to perform competency assessments on 1 of 2 testing personnel for moderately complex testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/6/19), revealed the laboratory identified 2 testing personnel. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical consultant performing competency assessments for 1 of 2 testing personnel for moderately complex testing. The testing person with no documentation of competency assessments: Testing person #1 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 11/6/19 at 10:10 a.m. in the laboratory revealed there was no documentation of a competency assessment for testing person #1. This confirmed the above findings.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on a review of the laboratory's competency assessments performed for 2017 to 2019, review of the laboratory's proficiency testing results for 2017-2019, and staff interview, it was revealed the technical consultant failed to include the review of previously analyzed specimens or proficiency testing samples as part of the laboratory's competency assessments for 1 of 2 testing personnel. Findings include: 1.

	A review of the CMS 209 form (signed by the laboratory director on 11/6/19) indicated the laboratory identified 2 testing personnel who perform moderate complexity testing. 2. A review of the laboratory's competency assessments for testing person #2 (as indicated on the CMS 209 form) revealed the technical consultant performed competency assessments on the following dates: 8/30/2017 2/4/2018 8/13 /2019 3. A review of the laboratory's College of American Pathologists' hematology proficiency testing results for 2017 to 2019 revealed the following events were all performed by testing person #1: 2017- FH1-C 2018- FH1-A 2018- FH1-B 2018- FH1-C 2019- FH1-A 2019- FH1-B Testing person #2 did not perform any proficiency testing in 2017, 2018, or 2019. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 11/6/19 at 10:15 a.m. in the laboratory, after review of the records, confirmed the above findings.