Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506530	03/05/2019
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	As a result of the CLIA recertification inspection, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director;
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 American Proficiency Institute proficiency testing records and

	interview with facility personnel, the laboratory failed to successfully participate in Compatibility Testing for 2 out of 3 testing events in 2017 in Immunohematology. Refer to D2181.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(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 review of the laboratory's proficiency test records and interview, the laboratory director failed to ensure the laboratory successfully participated in Compatibility Testing for 2 out of 3 testing events in 2017 in Immunohematology. The findings included: 1. Failure to attain an overall testing event score (in Compatibility testing) of at least 100 percent is unsatisfactory performance. 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. 2. Based on a review of American Proficiency Institute proficiency testing records, the laboratory failed to achieve a score of at least 100 percent on 2 of 3 events in 2017: 2017 - First event score - 80 percent 2017 - Third event score - 80 percent 3. In an interview at 13:20 hours on 3/5/2019 in the laboratory, the General Supervisor confirmed the scores were accurate.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Review of policies and procedures, personnel records and interview of facility personnel found that the laboratory failed to ensure that all policies and procedures had been approved , signed and dated by the current laboratory director. The findings included: 1. Review of policies and procedures in the Coagulation, Hematology and Blood Bank procedure manuals found no documentation of approval by the current laboratory director. The coagulation procedure manual contained 3 policies/ procedures not approved by the current laboratory director. The Blood Bank Manual found 15 of 15 procedures had no documentation of approval by the current laboratory director. The Hematology procedure manual contained 3 procedures without documented approval by the current laboratory director. 2. Review of personnel records found that the current laboratory director was hired November 1, 2018. 3. Interview of the general supervisor conducted on March 5, 2019 at 10:42 AM confirmed the Laboratory Director had not approved the procedures currently in use by testing personnel.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observations, manufacturer's instructions for use and interview of testing personnel, the laboratory failed to ensure 4 of 12 blood collection tubes had not exceeded the expiration date and were available for patient testing . The findings included: 1. Observations made at 3:21 PM in the phlebotomy area of the laboratory found 4 of 12 Vacuette Sodium Citrate tubes in the tray were expired. 2 Sodium Citrate tubes lot B18013EM Expiration 2019-01-16 2 Sodium Citrate tubes lot B18023HU Expiration 2019-02-07 One Patient specimen collected in Sodium Citrate tube on March 5, 2019 was not expired. 2. Review of the manufacturer's instructions for use found under the heading Vacuette Precautions/ Cautions - "Do not use the tubes after the expiration date." 3. Interview of testing person 2 on the CMS Report 209 Laboratory Personnel Report conducted on March 5, 2019 at 3:27 AM confirmed that expired tubes were available for use but had not been used today.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of Hematology quality control records, patient test records and interview of facility personnel found that the laboratory failed to test at least two levels of quality control materials on 2 of 69 days between October 11, 2017 and December 17, 2017. The findings included: 1. Review of quality control records found no documentation of quality control materials tested on Thursday, November 2, 2017 and Monday, December 4, 2017. 2. Review of patient test records found 21 patient specimens were tested without quality control materials being tested. November 2, 2017 - 15 patients tested. patient 2157080 patient 2155751 patient 2150584 patient 2150611 patient 2150983 patient 2150611 patient 2153754 patient 2155785 patient 2154741 patient 2150803 patient 2157081 patient 2152810 patient 2154307 patient 2156849 patient 2150974 December 4, 2017 patient 2150139 patient 2150332 patient 2152632 patient 2150440 patient 2156511 patient 2153826 3. Interview of the Technical Consultant conducted on March 5, 2019 at 11:08 AM confirmed the above findings.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by:

	Based on a review of the OPTI CCA-TS blood gas analyzer operator's manual, laboratory policy, quality control records, patient test records, and interview with facility personnel, the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 5 of 5 patients tested between December 23, 2017 and December 7, 2018. The findings included: 1. Based on review of the Opti-CCA-TS blood gas analyzer operator's manual (PD7202, Rev.B), on page 4-3, the document states the following: "4.5 QC Recommendations Two standard Reference Cassettes (SRC) should be used as a control for the OPTI CCA-TS analyzer. The level 1 and level 3 SRCs represent high and low samples. The SRCs contain a stable optical sensor simulator which is measured by the device in exactly the same manner as any other cassette and provides assurance that all measured parameters by the analyzer are consistent. The results obtained should fall within limits contained in the SRC barcode. NOTE: Hospitals should develop their own policy and procedures on the number of QC samples to be run on a daily basis as mandated by the regulatory agency under which they operate. After receipt of a shipment of cassettes and at monthly intervals thereafter, validation should be performed by analysis of OPTI CHECK or OPTI CHECK PLUS Blood Gas Controls or other equivalent material as recommended by OPTI Medical Systems. These materials should provide target values for pH, PCO2, and all other measured parameters over a range of measurement values typically seen in each testing site laboratory. The results obtained should fall within limits defined by the day-to-day variability as measured in the user's laboratory facility. OPTI Medical recommends the following as a minimum testing frequency of QC materials: Control: SRC level 1 Frequency: At least 1x per day in operation Control: SRC level 3 Frequency: At least 1x per day in operation Control: Opti Check or Opti Check Plus liquid controls Frequency: 1 month intervals and each new shipment of cassettes" 2. Based on review of the laboratory procedure "OPTI CCA", the procedure states the following: "Manufacturer Standard: SRC level 1 and 3/each day of use. Three levels liquid control each month and new cassette shipment. HCH Standard Three levels SRC each day. Three levels liquid control each month and new cassette box. 2 levels SR every 8 hours as needed." This procedure is signed by the previous Lab Director on 4/21 /2015. 2. Based on review of patient records and quality control records: A patient specimen was tested on 9/3/2018. A patient specimen was tested on 5/15/2018. A patient specimen was tested on 5/9/2018. A patient specimen was tested on 5/6/2018. A patient specimen was tested on 12/23/2017. Based on review of function check records and quality control records, the liquid external quality control materials were not performed on 9/3/2018, 5/15/2018, 5/9/2018, 5/6/2018, or 12/23/2017. 3. In an interview with the Laboratory Director on 03/05/2018 at 14:12 hours in the laboratory, the Laboratory Manager stated the laboratory had not implemented an Individualized Quality Control Plan to modify the frequency of testing liquid controls at least one level every 8 hours of patient testing to include both a low and high control each day of patient testing and stated "it has always been acceptable to test the SRC's each day of patient testing."
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: Observations, review of policies and procedures, patient test records and interview of facility personnel found that the quality assessment program failed to identify and correct problems in the analytic systems. The quality assessment program failed to identify and correct that all procedures available to testing personnel had been approved signed and dated by the current laboratory director. (See D5407) the quality assessment program failed to identify that expiredVacuette sodium citrate tubes were available for use in patient testing. (See D5417) The quality assessment program failed to identify that at least two levels of quality control materials were tested for Complete Blood Counts (CBC), and at least one level of quality control material was tested each eight hours of patient testing for arterial blood gases, prior to testing patient specimens. (See D5447 and 5537)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: The laboratory director failed to establish and maintain a quality control program for hematology. (See D5447)
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: The laboratory director failed to ensure that an approved written procedure for Hematology testing was available to all testing personnel outlining the step by step performance of the tests performed by the laboratory. (see D 5407)
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 review of proficiency testing records and interview with facility personnel, the Laboratory Director failed to provide overall management and director of the laboratory. Refer to D6089, D6103 and D6106.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency test records and interview, the laboratory director failed to ensure the laboratory successfully participated in Compatibility Testing for 2 out of 3 testing events in 2017 in Immunohematology. Refer to D2181.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Review of policies and procedures operators guide and interview of facility personnel found that the laboratory director failed to ensure that an approved procedure was available to all testing personnel . (See D5407)
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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: Based on review of the laboratory's written polices and procedures, and staff interview, revealed the laboratory director failed to ensure an approved procedure manual was available to testing personnel for performing compatibility testing. (see D5407)