Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1027031	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Utmb Health The Children's Clinic Of Clear Lake	333 N Texas Ave #4300, Webster, 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.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the 2016, 2017 and 2018 American Association of Bioanalysts (AAB) proficiency testing (PT) records and confirmed in interview, the laboratory failed to obtain at least 80% for the hematology analyte red blood cells (RBC) for 2017 2nd event. Findings were: 1. Review of PT records for 2017 for red blood cells revealed the laboratory received the following scores for the 2017 Hematology 2nd event: AAB 2nd event = 40% sample lab result acceptable result 2 2.16 2.19 - 2.47 3 4.34 4.35 - 4.91 4 2.18 2.19 - 2.47 3. An interview with the technical consultant on 7 /25/18 at 1015 hours in the office confirmed the above findings.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score,

	remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the 2016, 2017 and 2018 American Association of Bioanalysts (AAB) proficiency testing (PT) records and confirmed in interview, the laboratory failed to document remedial action for PT failures for the analyte RBC (red blood cells) in hematology. Findings were: 1. Review of the laboratory PT records from 2017 revealed no remedial action for the PT failures for the 2017 2nd event. AAB 2nd event = 40% 2. Review of the laboratory CBC (complete blood count) revealed the laboratory performed patient testing from 02/2017 to 06/2017. Refer to patient alias list. 3. An interivew with the technical consultant on 7/25/18 at 1015 hours in the office confirmed the above findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records from 2016, 2017, and 2018, and confirmed in interview, the laboratory quality assessment policy failed to detect the laboratory did not perform remedial action for proficiency testing failures. Refer to D2128
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 the manufacturer's instructions, laboratory policy, patient records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to ensure system flags were verified prior to reporting patient results from the Cell-Dyn Emerald hematology analyzer. Findings were: 1. Review of the Cell-Dyn Emerald Operator's Manual (9140847E, June 2010) under WBC flags revealed the following actions for the following flags: L2 - check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required. L3 - check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required. P2 - Review a stained smear to determine the cause and confirm the PLT [platelet] count. 2. Review of the laboratory policy Cell Dyn Emerald Policy

	Manual under WBC and Platelet flags revealed "the WBC flags and platelet flags can be indicative of interfering substances or sample abnormality that the instrument may not be able to measure. If a WBC flag is displayed, then the testing personnel should take the following measures: s/ L2 flag - Check the specimen for clots or agglutination check the specimen for clots or agglutination. Mix the patient sample well. Place a wooden applicator stick into the patient specimen. If clots are noted on the wooden stick, then sample will need to be recollected. If no clots are noted then let the sample sit for 10-15 minutes, mix well and rerun specimen. Redraw and test new specimen as required. Mark actions taken on the CBC result page and inform physician of flag and actions taken. s/ L3 flag - check the specimen for clots or agglutination. Mix the patient sample well. Place a wooden applicator stick into the patient specimen. If clots are noted on the wooden stick, then sample will need to be recollected. If no clots are noted then let the sample sit for 10-15 minutes, mix well and rerun specimen. Redraw and test new specimen as required. Mark actions taken on the CBC result page and inform physician of flag and actions taken */ P2 - Inform physician platelet count should be verified at outside lab. Mark actions taken on CBC result page. 3. Random review of patient final reports from 05/2018 to 07/2018 revealed 6 of 8 patient reports with flags. date patient ID flag 6/08/18 63498850 L2 7/12/18 62722542 P2 7/24/18 64084497 P2 5/04/18 62697540 P2 5/21/18 62987674 L2, L3 5/23/18 63239734 L3 4. The laboratory was asked to provide documentation of the laboratory methods to review flags prior to reporting results that include redrawing and retesting; performing a manual differential; scanning the peripheral smear for abnormal cells; and/or checking the sample for the presence of clots. No documentation was provided. 5. An interview with the technical consultant on 7/25/18 at 0940 hours in the office confirmed the above findings.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records from 2016, 2017, and 2018, and confirmed in interview, the laboratory director performed remedial action for proficiency testing failures. Refer to D2128