Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0682457	10/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bayside Community Hospital	200 Hospital Drive, Anahuac, 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.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient test records from 2020 to 2021, reference interval studies (patient normal prothrombin time), and confirmed in interview, the laboratory failed to include a policy when establishing the Reference Intervals (patient normal range) for PT (Prothrombin Time) and/or reagent lot rollovers for PT and APTT (activated partial thromboplastin time). Findings included: 1. Review of the laboratory records from 2020 to 2021 revealed the laboratory performed PT and APTT patient testing on on the ACL Elite hematology analyzer. 2. Review of package insert for the Recombiplastin 2G (00200002950, 03 /2019) used for PT testing on the ACL Elite under expected values revealed "ranges were calculated as recommended by CLSI document C28-A. These results were obtained using specific lot of reagent. Due to many variables which may affect clotting times, each laboratory should verify its own normal range." 3. Review of the laboratory's procedure manual revealed there was not a policy for establishing the Reference Intervals (patient normal range) for PT (Prothrombin Time) or lot rollover

	for new reagent lots of PT and/or APTT. 4. Review of the CMS116 signed by the laboratory director on 10/21/21 revealed the laboratory performed 7900 hematology tests annually. 5. An interview with the laboratory manager on 10/26/21 at 1540 hours in the educational room confirmed the above 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 the review of the manufacturer's instructions, the laboratory's policy, patient results from 10/21/21 to 10/25/21, and confirmed in an interview found that the laboratory failed to follow the manufacturer's instruction to review peripheral blood smears prior to reporting manual differential for patients for two of five days reviewed for one of one test on COULTER DxH 900 hematology analyzer (SN#: BB07107): CBC with Differential. The findings were: 1. Review of the manufacturer's Instructions for Use (PN C06947AC (May 2019)) under System Messages (p. 6-25) revealed "Suspected messages are generated by internal algorithms to convey that a clinical condition may exist with a specimen based on an abnormal cell distribution or population, Beckman Coulter recommends the review of results displaying a suspect message appropriate to your patient population and laboratory practice." The suspect messages were: Imm Grans: Pattern characteristic of specimen containing: a) Metamyelocytes and myelocytes and/or promyelocytes, or b) myelocytes and/or promyelocytes without metamyelocytes. Left Shift: Pattern is characteristic of specimen containing metamyelocytes, but without myelocytes, promyelocytes, or blasts. LY Blast: Blasts in the Lymphocyte region of the dataplot. MO Blast: Blasts in the Monocyte region of the dataplot. NE Blast: Blasts in the Neutrophil region of the dataplot. Variant LY: Pattern characteristic of specimen with variant lymphs, including mature lymphocytes such as those observed in viral infections, as well as immature and/or abnormal lymphocytes. 2. Further review of the manufacturer's Instructions for Use under Blasts (p. 6-26) revealed "A blast suspect message is not diagnostic. You should not rely upon instrument results alone to replace the need for manual microscopic review of blood samples if indicated by other clinical and laboratory features of the patient." 3. Review of the laboratory's policy titled "Criteria for Review of Peripheral Blood Smears" under Procedure revealed "1. Criteria for Review of Peripheral Blood Smear ...C. Suspect Messages: blasts, Imm Grans, Variant Ly." 4. Random review of patient records from 10/21/21 -10/25/21 revealed 3 patient CBC with manual differential with above suspect messages reported prior to peripheral blood smear reviews. 10/21/21 Patient ID: 10181057 10/21/21 Patient ID: 10181055 10/25/21 Patient ID: 10181209 5. An interview with the laboratory manager on 10/27/21 at 9:40 am in the educational room confirmed the above findings. She stated the laboratory reported the CBC results with differential from the instrument without reviewing the peripheral blood smears instead of reporting the manual differential from the reference lab after reviewing of peripheral blood smears. Key: CBC=Complete blood count Abs=Absolute
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 and patient test records from 2020 to 2021, manufacturer's instructions, and confirmed in interview, the laboratory failed to document complete verification studies for one of one new Medtox instrument installed in 2020. (accuracy) Findings include: 1. Review of the laboratory records revealed the laboratory installed a new MedToxscan Drugs of Abuse Test System in 05/21/2020. 2. Review of the manufacturer's instructions for the Method Validation for Profile-V MedtoxScan Drugs of Abuse Test System (P/N 102428, Rev 02/19) revealed "determine the number of true positives, false positives, true negatives, false negatives. Calculate agreement for Profile-V Medtox Drugs of Abuse Test System verses reference." 3. Review of the laboratory records from 2020 to 2021 revealed no documentation of the accuracy studies for the new MedToxscan Drugs of Abuse Test System. 4. Review of the CMS116 signed by the laboratory director on 10/21/21 revealed the laboratory performed 200 toxicology testing annually. 5. An interview with the laboratory manager on 10/26/21 at 1520 hours in the educational room confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control and patient test records for the Alere Triage meter from 2021 and confirmed in interview, the laboratory failed to monitor quality control values over time to detect shifts and trends for one of two analytes(DDimer) analyzed on the Alere Triage meter. Findings include: 1. Review of the laboratory's IQCP for the Alere Triage meter for DDimer revealed the laboratory performed the Alere Total 5 Controls, levels 1 and 2, every 30 days. 2. Further review of the quality control records from May to October 2021 revealed no documentation of the laboratory monitoring and evaluating quality control results over time for one of two analytes performed on the Alere Triage meter for the following six quality control lot numbers for DDimer. DDIM (d-dimer) C3769, C3793, C3663, C3789,

	C3658, C3669 3. Random review of laboratory patient test records from May to October 2021 revealed the laboratory performed the following ten patient for DDimer using the above quality controls. 6/2/21: Patient ID 10171046 6/12/21: Patient ID 10171674 7/16/21: Patient ID 10173524 7/23/21: Patient ID 10173987 8/27/21: Patient ID 10176033 8/28/21: Patient ID 10176877 09/07/21: Patient ID 10177795 09 /13/21: patient ID 10178298 10/14/21: Patient ID 10180555 10/23/21: Patient ID 10181162 4. An interview with the laboratory manager on 10/27/21 at 1020 hours in the lab confirmed the above findings. key: INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control and patient test records for the Alere Triage meter from 2021 and confirmed in interview, the laboratory failed to document quality control in the frequency established in the laboratory IQCP for one of two analytes(DDimer) analyzed on the Alere Triage meter. Findings include: 1. Review of the laboratory's IQCP for the Alere Triage meter for DDimer revealed the laboratory performed the Alere Total 5 Controls, levels 1 and 2, every 30 days. 2. Further review of the quality control records from May to October 2021 revealed the laboratory performed quality control beyond the frequency of 30 days for three of seven months reviewed. DDIM (d-dimer) quality control on 9/11/21 C3769, C3793; next quality control due on 10/11/21; elapsed time 39 days as of day of survey on 10 /27/21 quality control on 6/11/21 C3658, C3669; next quality control due on 7/11/21; performed on 7/23/21; elapsed time of 42 days quality control on 7/23/21 C3663, C3789; next quality control due on 8/23/21; performed on 8/28/21; elapsed time of 35 days 3. Random review of laboratory patient test records from May to October 2021 revealed the laboratory performed the following ten patient for DDimer using the above quality controls. 6/2/21: Patient ID 10171046 6/12/21: Patient ID 10171674 7 /16/21: Patient ID 10173524 7/23/21: Patient ID 10173987 8/27/21: Patient ID 10176033 8/28/21: Patient ID 10176877 09/07/21: Patient ID 10177795 09/13/21: patient ID 10178298 10/14/21: Patient ID 10180555 10/23/21: Patient ID 10181162 4. An interview with the laboratory manger on 10/27/21 at 1020 hours in the lab confirmed the above findings. key: INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test

	results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on the review of CBC QC records from 1/1/21 to 7/31/21, Maintenance and Action Log from 1/1/21 to 9/30/21, patient reports, and confirmed in an interview found the laboratory failed to document corrective actions for QC outside of acceptable ranges for four of 50 days reviewed. The findings were: 1. Review of CBC QC records from 1/1/21 to 7/31/21 for COULTER DxH 900 (SN# BB07107) revealed QC that was outside of acceptable ranges and repeated for four of 50 days reviewed. 1 /13/21: Level 1 repeated 5/24/21: Level 2 repeated 5/31/21: Level 1 repeated Level 3 repeated 7/29/21: Level 1 repeated 2. Review of COULTER DxH 900 Maintenance & Action Log from 1/1/21 to 9/30/21 revealed no documentation of the QC corrective actions for the above dates. 3. Random review of patient reports for the above dates revealed 11 patients had CBC testing performed. 1/13/21 Patient #: 10161708 1/13/21 Patient #: 10161689 1/13/21 Patient #: 10161671 5/24/21 Patient #: 10170560 5/24/21 Patient #: 10170603 5/24/21 Patient #: 10170531 5/31/21 Patient #: 10170955 5/31/21 Patient #: 10170954 7/29/21 Patient #: 10174294 7/29/21 Patient #: 10174296 7/29/21 Patient #: 10174267 4. An interview with the laboratory manager on 10/26/21 at 2:00 pm in the educational room confirmed the above findings. Key: CBC=Complete blood count QC=Quality Control Diff=CBC Differential WBC=White blood cell
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of quality assessment reports and confirmed in interview, the laboratory quality assessment policies and procedures failed to identify and correct problems identified in analytical systems. Refer to D5405, D5411, D5421, D5441, D5445, D5783