

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0682457	(X3) Date Survey Completed 10/30/2024
Name of Provider or Supplier Bayside Community Hospital	Street Address, City, State 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	An announced survey of the laboratory was conducted 10/28/2024 through 10/30/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to achieve successful PT performance (80% or greater) for BNP (B-Neutropenic Peptide), and provide corrective action to ensure no recurrence, for one of ten Chemistry PT testing events reviewed from 2023 and 2024. Findings included: 1. Review of laboratory's American Proficiency Institute chemistry PT records for 2023 and 2024 revealed the following PT event had BNP score of less than 80%, constituting unsuccessful performance: 2024 Chemistry - Core - 3rd Event BNP (CM) score: 60% 2. Further review of the PT records for the 2024 Chemistry - Core - 3rd Event revealed the laboratory did not document the corrective action required to prevent future recurrence of issues. 3. In an interview on 10/28/2024 at 1120 hours in the office, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209), confirmed the findings.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-</p>

approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to document evaluation of "Not Graded" performance results for two of twenty-six PT testing events reviewed from 2023 and 2024. Findings included: 1. Review of laboratory's American Proficiency Institute (API) PT records revealed API provided following instructions for "Not Graded" performance results: "Laboratories are responsible for documenting and performing corrective action for failures and must perform self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Review of laboratory's API PT records for 2023 and 2024 revealed the following two of twenty-six PT events did not have evaluation of "Not Graded" performance results: 2024 Chemistry - Core - 1st Event Analyte: Bilirubin Total (mg/dL) Sample: Performance: CH-02 Not Graded CH-03 Not Graded CH-05 Not Graded 2024 Hematology/Coagulation - 2nd Event Analyte: Urobilinogen Sample: Performance: UA-04 Not Graded Analyte: Blood Cell ID Sample: Performance: ECI-06 Not Graded ECI-07 Not Graded ECI-08 Not Graded ECI-09 Not Graded ECI-10 Not Graded 3. In an interview on 10/28/2024 at 1120 hours in the office, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209), confirmed the findings. Key: mg/dL = milligrams per deciliter

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 surveyor's observations, review of manufacturer's instructions, Clinical and Laboratory Standards Institute (CLSI) documents, laboratory's policies/procedures, laboratory test volumes and staff interview, the laboratory failed to follow manufacturer instructions for ensuring correct anticoagulant to blood ratio was obtained prior to testing Activated Partial Thromboplastin Time (APTT) for one of two samples tested on 10/28/2024. Findings included: 1. Surveyor's observations on 10/28/2024 at 1400 hours in the laboratory revealed two blood samples in light blue top collection tubes sitting in a rack on the countertop. Further observations revealed one of the two tubes was filled 4/5 of the recommended volume for APTT testing. The under-filled sample was: Sample: 10252924 Test ordered: APTT Collected: 10/28/2024 at 1221 hours Reported: 10/28/2024 at 1246 hours 2. Review of manufacturer's instructions for laboratory's HemosIL APTT-SP reagent (document 0020006300, revision 04/2019) revealed: "Nine parts of freshly drawn venous blood are collected into one part 3.2% trisodium citrate. Refer to CLSI document H21-A5 for further instructions on specimen collection, handling and storage." 3. Review of Clinical and Laboratory Standards Institute (CLSI) document H21-A5 (released January 2012) revealed: "Many variables, including anticoagulant volume and concentration ... may affect plasma-based coagulation test results." And, "The following are not suitable for testing and are causes for specimen rejection: ... collection containers that have other than the appropriate blood/anticoagulant ratio (under- or over- filled)". 4. Review of

laboratory's "Activated Partial Thrombin Time" policy (last revised 2019) revealed: "Nine parts of freshly drawn venous blood are collected into one part trisodium citrate (blue top tube)." And, "Rejection Protocol ... some sample rejection criteria include, but not limited to are ... "Inadequate specimen volume" 5. Review of laboratory's test volumes from October 2023 to October 2024 revealed the laboratory performed 84 APTT tests annually. 6. In an interview on 10/28/2024 at 1430 hours in the office, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209), confirmed the findings.

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 laboratory's quality control (QC) records, new test/test device verification studies, annual test volumes and staff interview, the laboratory failed to document evaluation of verification of accuracy, precision and normal values for one of one test devices implemented in 2023, the Biosite Triage analyzer. Findings included: 1. Review of laboratory's 2023-2024 QC records for D-dimer test performed on the Biosite Triage analyzer revealed a new instrument (serial number 96335) was implemented in January 2023. 2. Review of laboratory's new test/test device verification studies revealed the verification studies for the above new Triage analyzer (performed in January 2023) did not have documentation of evaluation of instrument's accuracy, precision and normal values. 3. Review of laboratory's test volumes (from October 2023 to October 2024) for the D-dimer test performed on the Triage analyzer revealed the laboratory performed 120 D-dimer tests annually. 4. In an interview on 10/28/2024 at 1500 hours in the office, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209), confirmed the 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:
A. Based on review of manufacturer's instructions, laboratory's maintenance records for the Beckman Coulter ACL Elite coagulation analyzer and staff interview, the laboratory failed to document biweekly maintenance for two of twelve weeks reviewed from January through March 2023. Findings included: 1. Review of manufacturer's instructions from the "ACL ELITE/ELITE PRO Operator's Manual" revealed: "5.2.4 Biweekly Preventive Maintenance The rotor holder and the optical path components found in the analysis area must be cleaned every two weeks under

normal instrument use." 2. Review of laboratory's maintenance records for the Beckman Coulter ACL Elite coagulation analyzer from January through March 2023 revealed the laboratory failed to document biweekly maintenance for the following two of twelve weeks reviewed: Week of January 29 to February 4, 2023 - biweekly maintenance last recorded 01/18/2023 - biweekly maintenance next recorded 02/14/2023 Week of February 26 to March 4, 2023. - biweekly maintenance last recorded 02/14/2023 - biweekly maintenance next recorded 03/13/2023 3. In an interview on 10/28/2024 at 1430 hours in the office, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209), confirmed the findings. B. Based on review of manufacturer's instructions, laboratory's maintenance records for the Ortho Vitros 350 chemistry analyzer, patient test records and staff interview, the laboratory failed to document eight of thirty-five required Immuno-Wash changes within seventy-two hours of Digoxin/Dilantin testing in 2023 and 2024. Findings included: 1. Review of manufacturer's instructions for the "VITROS Chemistry Products Immuno-Wash Fluid" (document REF 183 0033, Version 12.0) revealed: "Discard the reservoir with the remaining fluid after 3 days." 2. Review of laboratory's maintenance records for the Ortho Vitros 350 chemistry analyzer for 2023 and 2024 revealed the following eight of thirty-five instances Immuno-Wash fluid change was required within seventy-two hour of Digoxin/Dilantin testing that the change was not documented: Digoxin tested: Immuno-Wash last changed: 02/11/2023 01/31/2023 02/26/2023 02/12/2023 03/01/2023 02/12/2023 03/16/2023 03/07/2023 09/26/2023 09/11/2023 05/24/2024 05/19/2024 06/04/2024 05/19/2024 06/07/2024 05/19/2024 3. Review of laboratory's patient test records for the days Digoxin/Dilantin was tested without Immuno-Wash fluid change documented within seventy-two hours of testing revealed the following patients were tested: Digoxin tested: Patient's ARPNUM (facility assigned): 02/11/2023 10210713 02/26/2023 10210842 03/01/2023 10210842 03/16/2023 10212820 09/26/2023 10225274 05/24/2024 10242046 06/04/2024 10242774 06/07/2024 10242967 4. In an interview on 10/29/2024 at 1100 hours in the office, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209), confirmed the findings.

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 manufacturer's instructions, laboratory's policies/procedures, proficiency testing records, patient test records, instrument maintenance records and staff interview, the laboratory's quality assurance (QA) failed to identify and correct issues with evaluation of proficiency testing ("not graded" results), specimen acceptability (underfilled samples) and instrument maintenance for three of nine testing platforms used by the laboratory in 2023 and 2024. Refer to D5213, D5411 and D5429 A and B.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the

	<p>laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policies/procedures, patient test records, instrument maintenance records and staff interview, the laboratory's Technical Consultants failed to provide technical oversight for three of nine testing platforms used by the laboratory in 2023 and 2024. Refer to D5411, and D5429 A and B.</p>
D6040	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records, new test/test device verification studies, annual test volumes and staff interview, the laboratory's Technical Consultants failed to ensure new test/test device verification studies were complete for one of nine testing platforms used by the laboratory in 2023 and 2024. Refer to D5421.</p>
D6091	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the Laboratory Director failed to ensure PT reports are reviewed by appropriate staff to identify any problems requiring corrective action for three of nine testing platforms used by the laboratory in 2023 and 2024. Refer to D5213.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policies/procedures, proficiency testing records, patient test records, instrument maintenance records and staff interview, the Laboratory Director failed to ensure laboratory's quality assurance (QA) was maintained for three of nine testing platforms used by the laboratory in 2023 and 2024. Refer to D5791.</p>