| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D2036826 | 05/02/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Family First Er Atascocita | 19143 West Lake Houston Parkway, Humble, 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 validation survey was performed on 05/02/2023. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Instructions for Use for the BinaxNOW RSV card, a review of patient test records from October 2022 to January 2023, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions by ensuring the BinaxNOW RSV (Respiratory Syncytial Virus) test was run on patients five years of age or older for three of twelve patient test reports reviewed. Findings include: 1. A review of the Instructions for Use for the BinaxNOW RSV card test revealed the following: "ATTENTION Do not use the RSV test in patients 5 years or older." 2. A review of the laboratory's patient test records from October 2022 to January 2023 revealed the following 3 patient's samples were run using the BinaxNOW RSV card: Patient MRN: 157259 Patient date of birth: 11/11/91 Patient age: 30 years Date tested: 10/4/22 Patient MRN: 159099 Patient date of birth: 6/6/71 Patient age: 51 years Date tested: 1/10/23 Patient MRN: 159370 Patient date of birth: 12/13/2004 Patient age: 18 years Date tested: 1/26/23 3. An interview with the facility administrator on 5/2/23 at 12:40 p.m. in the break room, after review of the records, confirmed the above findings. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b) |

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, laboratory policies and patient test records from July 2022 to January 2023 and confirmed in interview, the laboratory failed to document the specimen acceptability and rejection of four of four chemistry testing: MetLac (Glucose, BUN (blood urea nitrogen), Creatinine, Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Phosphorus, Magnesium, Albumin, Lactate) testing on the Piccolo and CKMB, Troponin, and DDimer testing on the Biosite Triage chemistry analyzers. Findings included: MetLac 1. Review of the Piccolo Xpress Chemistry Analyzer Operator's Manual (PN: 1100-7108-1 Manual Text, Rev. E) under Interpreting Results stated "the sample indices are included at the bottom of the results printout. These indices indicate the degree of hemolysis, icterus, and lipemia found in the sample. Hemolysis, icterus, and lipemia are measured on a scale of 0 (clear), 1+ (slight), 2+ (moderate), and 3+ (gross)...T he effects of endogenous substances have been characterized for each of the Abaxis analytes test methods and cut-off levels have been set for each. The result will be automatically suppressed, and in its place HEM [hemolysis], ICT [icteric], or LIP [lipemic] will be indicated if the test results will be negatively affected. If the sample is identified as hemolytic, collect a new sample and run another reagent disc... Troubleshooting Problem Results HEM, LIP, or ICT is printed in place of the analyte concentration if hemolysis, lipemia, or icterus, respectively, has adversely affected the results. LIP is also printed if both lipemia and icterus have been affected. HEM is also printed if hemolysis and icterus, hemolysis and lipemia, or hemolysis, lipemia, and icterus have affected a particular analyte. Examine the sample indices to determine if more than one interferent is affecting a particular result." 2. Random sampling of patient test records for Metlac testing included the following ten specimens that had the following indices: Patient #159112 - HEM 3+ Patient #158768 - ICT 1+ Patient #157829 - HEM 2+ Patient #156272 - HEM 1+ Patient #157880 - HEM 2+ Patient #157909 - LIP 1+ Patient #154683 - LIP 2+ Patient #156052 - HEM 2+ Patient #157169 - HEM 2+ Patient #156763 - LIP 3+ 3. Review of the laboratory policy (Piccolo Analyzer Testing Procedure Policy # 1300) for Metlac testing on the Piccolo and did not include the above crieteria for specimen acceptability and rejection. CKMB, Troponin 4. Review of the package insert for the Quidel Triage test panels for CKMB and Troponin (PN: 26584en Rev. C 2020/10) under specimen requirements stated "A venous whole blood

| | |
|---|---|
| | or plasma specimen using EDTA as the anticoagulant is required for testing with this product. Other blood specimen types, draw methods or anticoagulants have not been evaluated. For specimen collection, follow the sample tube manufacturer's recommended procedure. If using whole blood, test the patient specimen within 4 hours of collection. If testing cannot be completed within 4 hours, the plasma should be separated and stored at -20 C until it can be tested. No more than a single freeze /thaw cycle is recommended. Transport specimens at room temperature or chilled and avoid extreme temperatures. Avoid using severely hemolyzed specimens whenever possible. If a specimen appears to be severely hemolyzed, another specimen should be obtained and tested." DDimer 5. Review of the package insert for the Quidel Triage DDimer (PN: 26589en Rev. C 2020/05) under specimen requirements stated "A venous whole blood or plasma specimen using EDTA as the anticoagulant is required for testing with this product. Other blood specimen types, draw methods or anticoagulants have not been evaluated. For specimen collection, follow the sample tube manufacturer's recommended procedure. If using whole blood, test the patient specimen within 24 hours of collection. If testing cannot be completed within 24 hours, the plasma should be separated and stored at -20 C until it can be tested. No more than a single freeze/thaw cycle is recommended. Transport specimens at room temperature or chilled and avoid extreme temperatures. Avoid using severely hemolyzed specimens whenever possible. If a specimen appears to be severely hemolyzed, another specimen should be obtained and tested." 6. Review of the laboratory policy revealed no documentation for CKMB, Troponin, or DDimer that included the above criteria for specimen acceptability and/or rejection. 7. Review of the CMS116 states the laboratory performed 10600 chemistry tests annually. 8. An interview with the technical consultant #3 on 05/02/2023 at 1310 hours in the break room confirmed the above findings. She agreed that their policy should include specimen requirements to account for the specimen integrity. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observations, review of manufacturer's instructions, laboratory and patient test records, and confirmed in interview, the laboratory failed to monitor and document the acceptable storage requirements for two of two types of tubes of vacutainers used for chemistry and hematology testing. Findings included: 1. Surveyor observed on 05/02/2023 at 0925 hours that the facility stored unused tubes of vacutainers on the countertop of the nursing station. A random sampling of those vacutainers included the following: 18 vacutainers of Vacuette LH Lithium Herparin (REF 456088) lot B220634T, exp 12/01/2023 18 vacutainers of Vacuette (Ref 454021) of K2EDTA lot 132208364, exp 12/01/2023 2. Review of the package insert for the Vacuette tubes (980200B_Rev09_02-2020) under storage stated "store tubes at 4-25C." 3. Review of the laboratory records available revealed no documentation the laboratory monitored nor documented the temperature in the nursing station to ensure |

| | |
|---|---|
| | proper storage of the vacutainers above. 4. Review of the CMS116 revealed the laboratory performed 5200 chemistry and 10600 hematology tests annually. 5. An interview with the facility administrator on 05/02/2023 at 1435 hours in the break room confirmed the above findings. She confirmed that the laboratory used those vacutainers for their testing. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's instructions, laboratory and patient test records from 2021 to 2022, and confirmed in interview, the laboratory failed to document four of four calibration verifications for CKMB, Troponin, and DDimer on the Biosite Triage and three of four calibration verifications for the Metlac panel on the Piccolo chemistry analyzers per manufacturer's instructions. A. Biosite Triage - CKMB, Troponin, DDimer B. Piccolo (MetLac 12 panel) - Glucose, BUN (blood urea nitrogen), Creatinine, Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Phosphorus, Magnesium, Albumin, Lactate Findings included: A. Biosite Triage 1. Review of the Quidel Triage Cardiac Panel Quick Reference (QR9700000EN01 (02 /18)) found online under QC (Quality Control) Cal Ver Controls stated "run every 6 months." 2. Review of the laboratory policy Calibration Verification (Policy #128, effective 10/01/2014) stated "calibration verification is performed every six months." 3. No documentation was available for review of the four required calibration verification from 2021 to 2022 for the three analytes CKMB, Troponin, and DDimer on the Biosite Triage. B. Piccolo MetLac panel 4. Review of the Piccolo user manual (100-7139 Rev A) stated "Verification of Accuracy and Precision every 6 months" 5. Review of the laboratory policy Calibration Verification (Policy #128, effective 10/01 /2014) stated "calibration verification is performed every six months." 6. No documentation was available for review for one of two calibration verification for the MetLac panel in 2021 and two of two calibration verification for 2022. 7. Review of |

| | |
|---|---|
| | the CMS116 revealed the laboratory performed 5200 chemistry tests annually. 8. An interview with the technical consultant # 2 on 05/02/2023 at 1310 hours in the break room confirmed the above findings. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the laboratory INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP), quality control and patient test records from July 2022 to December 2022, and confirmed in interview, the laboratory failed to perform control procedures per the IQCP for five of six months reviewed for the Metlac panel on the Piccolo analyzers. Findings included: 1. Review of the laboratory Qualiy Control Plan for the IQCP for the Piccolo analyzer stated "external controls monthly or new lot# shipment; need to be within 2 SD [standard deviation] to pass quality review." 2. Review of laboratory records from July 2022 to February 2023 confirmed the laboratory used two Piccolo analyzers (Serial Number 000P05834 and 0000P05853) that performed the MetLac panel (Glucose, BUN (blood urea nitrogen), Creatinine, Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Phosphorus, Magnesium, Albumin, Lactate). 3. The laboratory performed one level of quality control for each Piccolo for five of six months reviewed of the MetLac Piccolo quality control from July 2022 to December 2022. No documentation of the other level were available for review. Piccolo (SN 000P05834) July 2022 - Level 1 August 2022 - Level 1 September 2022 - Level 1 November 2022 - Level 1 December 2022 - Level 1 Piccolo (SN 0000P05853) July 2022 - Level 2 August 2022 - Level 2 September 2022 - Level 2 November 2022 - Level 2 December 2022 - Level 2 4. Random review of laboratory patient test records from July 2022 to December 2022 confirmed the laboratory performed 16 MetLac testing on the following Piccolo analyzers with only one documented level of quality control for the corresponding month. Piccolo (SN 000P05834) 08/03/2022: Patient ID155441 11/04/2022: Patient ID157663 11/10 /2022: Patient ID 157859 12/05/2022: Patient ID 158457 12/17/2022: Patient ID 158768 01/01/2023: Patient ID159112 01/07/2023: Patient ID 159279 Piccolo (SN 0000P05853) 07/04/2022: Patient ID 154637 07/06/2022: Patient ID 154683 08/30 /2022: Patient ID 156052 09/10/2022: Patient ID 156272 09/13/2022: Patient ID 156372 11/11/2022: Patient ID 157880 11/13/2022: Patient ID 157909 12/01/2022: Patient ID 158393 12/04/2022: Patient ID 158429 5. An interview with the technical consultant #2 on 05/02/2023 at 1400 hours in the break room confirmed the above findings. She stated that she were unaware the testing personnel were using both piccolos for Metlac testing. II. Based on review of the laboratory INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) and confirmed in interview, the laboratory failed to document a complete quality control study to support the monthly frequency of the Quality Control Plan (QCP) for two of two analyzers: the Metlac panel on the Piccolo and CKMB, Troponin, and DDimer on the Biosite Triage analyzers. Findings |

| | |
|---|---|
| | included: 1. Review of the laboratory Qualiy Control Plan for the IQCP for the Piccolo analyzer stated "external controls monthly or new lot# shipment; need to be within 2 SD [standard deviation] to pass quality review." 2. Review of the laboratory records available revealed no documentation of the quality control study to confirm the modification of the QCP for both the Metlac on the Piccolo and CKMB, Troponin, and DDimer on the Biosite Triage analyzers. 3. An interview with the technical consultant #2 on 05/02/2023 at 1420 hours in the break room confirmed the above findings. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies, a review of the laboratory's quality control records from September to October 2022, and staff interview, it was revealed that the laboratory failed to ensure all three levels of quality control material were acceptable prior to reporting patient test results for three of sixty one days reviewed from September to October 2022 for Complete Blood Count (CBC) testing on the Beckman Coulter Act Diff2 hematology analyzer. Findings include: 1. A review of the laboratory's policy titled 'Quality Assurance Plan' revealed the following: "Beckman Coulter Act Diff2 - Hematology controls shall be run every 24 hours of patient testing - These laboratories will use the following QC material 4C-ES Cell Control It is the policy of this Laboratory to: - Review all QC ensure all QC is within acceptable range." 2. A review of the laboratory's quality control records for the Beckman Coulter Act Diff 2 analyzer revealed the laboratory used the 4C-ES Cell Control consisting of three levels of quality control material (low, normal, and high). 3. A review of the laboratory's quality control records from September to October 2022 revealed the following 3 days where only two levels of quality control material were acceptable and patient's CBC results were reported: - Date: 9/12/22 High Level QC failed Patients reported: 156692, 152994, 156700, 156703 - Date: 9/24/22 Low Level QC failed Patients reported: 111116 - Date: 10/21/22 Normal Level QC failed Patients reported: 76428, 157091, 125683, 157402, 74222 4. An interview with the facility administrator on 5/2/23 at 12:00 p.m. in the conference room, after review of the records, confirmed the above findings. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's instructions, random review of patient test records from July 2022 to January 2023, and confirmed in interview, the laboratory failed to document the corrective actions for one of ten patients reviewed for MetLac (Glucose, BUN (blood urea nitrogen), Creatinine (CRE), Sodium, Potassium (K), Chloride, Carbon Dioxide, Calcium, Phosphorus, Magnesium (MG), Albumin, Lactate (LAC) testing on the Piccolo chemistry analyzer. Findings included: 1. Review of the Piccolo Xpress Chemistry Analyzer Operator's Manual (PN: 1100-7108-1 Manual Text, Rev.E) under Interpreting Results stated "the effects of endogenous substances have been characterized for each of the Abaxis analytes test methods and cut-off levels have been set for each. The result will be automatically suppressed, and in its place HEM [hemolysis], ICT [icteric], or LIP [lipemic] will be indicated if the test results will be negatively affected. If the sample is identified as hemolytic, collect a new sample and run another reagent disc." 2. Random review of patient test records from July 2022 to December 2022 confirmed one of ten patients with results suppressed with 'HEM' that were repeated with no documentation of the corrective action. Patient Accession #159112, 01/01/2023 CRE: HEM K: HEM PHOS: HEM MG: HEM LAC: HEM 3. An interview with the technical consultant #3 on 05/02/2023 in the break room confirmed the above findings. She stated that the testing person did repeat the above sample with a new specimen but no documentation was available for review. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory records, patient test records from July 2022 to January 2023 and confirmed in interview, the laboratory failed to document the correct units of measurement for ten of ten patients reviewed for MetLac testing on the Piccolo chemistry analyzer. Findings included: 1. Review of the laboratory test records from the Piccolo chemistry analyzer indicated the units of measurement verified for the following four analytes were mmol/L. Potassium (K) Sodium (NA) Chloride (CL) Carbon Dioxide (CO2) 2. Random review of final patient test records from July 2022 to January 2023 confirmed the above analytes had incorrect units of measurement: mg/dL for five of five patients reviewed. Patient 159112 K: 4.8 mg/dL NA: 137 mg/dL CL: 101 mg/dL CO2: 16.0 mg/dL Patient 156372 K: 4.1 mg/dL NA: 142 mg/dL CL: 107 mg/dL CO2: 26.0 mg/dL Patient 154637 K: 4.3 mg/dL NA: 141 mg/dL CL: 105 mg/dL CO2: 25.0 mg/dL Patient 158457 K: 3.9 mg/dL NA: 143 mg /dL CL: 99 mg/dL CO2: 30.0 mg/dL Patient 157663 K: 4.4 mg/dL NA: 135 mg/dL CL: 99 mg/dL CO2: 30.0 mg/dL 3. An interview with the technical consultant #3 on 05/02/2023 at 1335 hours in the break room confirmed the above findings. |