| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 19D2319877 | 07/21/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Aesthetic And Breast Restorative Center, Llc | 6330 Mourning Dove Dr, Baton Rouge, LA | |

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 |
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| **D0000** | An Initial certification survey was performed at Aesthetic and Breast Restorative Center, LLC, CLIA ID 19D2319877, on July 21, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| **D5305** | TEST REQUEST<br>CFR(s): 493.1241(c)<br><br>(c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's patient test records and interview with personnel, the laboratory failed to document the specimen collection date and time for eight (8) of thirty-four (34) patient test records reviewed. Findings: 1. Review of a random selection of patient test records revealed the following patients did not have a date and /or time of specimen collection: a) Patient 11024 - No specimen collection date and time documented - Cotinine, blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit. b) Patient |

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| | 11124 - No specimen collection date and time documented - Cotinine, blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit. c) Patient 11144 - No specimen collection time documented - Blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit. d) Patient 11263 - No specimen collection time documented - Blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit. e) Patient 10870 - No specimen collection date and time documented - Cotinine, blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit. f) Patient 10705 - No specimen collection date and time documented - Cotinine, blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit tested. g) Patient 10204 - No specimen collection date and time documented - Blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit. i) Patient 10904 - No specimen collection date and time documented - Cotinine, blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit. 2. In interview on July 21, 2026 at 1:08 p.m., the Technical Consultant confirmed the collection date and/or time was not documented for the patient specimens as identified above. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of the manufacturer's package insert and the laboratory's patient test records, and interview with personnel, the laboratory failed to analyze patient samples for ionized calcium and TCO2 testing within ten (10) minutes of collection as required by the manufacturer for three (3) of twenty-six (26) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 21, 2026 at 10:29 a.m. revealed the laboratory utilized the i-STAT CHEM8 cartridge for ionized calcium and TCO2 testing. 2. Review of the manufacturer's package insert "i-STAT CHEM8 Cartridge" section "Blood Collection Options and Test Timing (time from collection to cartridge fill)" revealed the following: Ionized Calcium and TCO2 - Collection in evacuated tubes "with lithium heparin anticoagulant (tubes must be filled per manufacturer's recommendation)" must be tested within "10 minutes." 3. Review of the laboratory's patient test records for ionized calcium and TCO2 from March 17, 2026 to July 21, 2026 revealed the following three (3) patient samples exceeded the manufacturer's sample stability limits: a) MRN 11222: Collected 3/25 /2026 at 10:20 a.m. and analyzed 3/25/2026 at 10:34 a.m. (exceeded stability by four (4) minutes). b) MRN 12289: Collected 4/9/2026 at 7:10 a.m. and analyzed 4/9/2026 at 7:38 a.m. (exceeded stability by eighteen (18) minutes). c) MRN 11245: Collected 4 /29/2026 at 5 a.m. and analyzed 4/29/2026 at 5:18 a.m. (exceeded stability by eight (8) minutes). 4. In interview on July 21, 2026 at 12:45 p.m., the Technical Consultant confirmed the specimens identified above exceeded the manufacturer's sample stability as identified above. |
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| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation, review of the manufacturer's instructions, and interview with personnel, the laboratory failed to document the receipt temperature of i-STAT cartridges as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on July 21, 2026 at 10:29 a.m. revealed the laboratory utilized the i-STAT CHEM8 cartridge for testing the following analytes: Blood urea nitrogen (BUN), ionized calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, and hematocrit. 2. Review of the manufacturer's instructions revealed "Fill out record of receipt and forward with materials to refrigeration. Read the temperature strip without delay since it will change with exposure to room temperature." 3. In interview on July 21, 2026 at 10:40 a.m., Testing Personnel 1 stated they check the temperature of the cartridges upon receipt to ensure it is acceptable, but they do not document the temperature of the strip and/or retain the forms. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of the laboratory's performance specification studies, and interview with personnel, the laboratory failed to verify performance specifications for cotinine testing. Findings: 1. Observation by surveyor during the laboratory tour on July 21, 2026 at 10:29 a.m. revealed the laboratory utilized the COT One Step Cotinine Test Device (Urine) for cotinine testing. 2. Review of the FDA CLIA categorization database revealed the COT One Step Cotinine Test Device (Urine) was not categorized by FDA for test complexity. 3. Review of the laboratory's COT One Step Cotinine records revealed the laboratory did not verify the following performance specifications: a) Accuracy b) Precision to include day-to-day, run-to-run, within run, and operator variance c) Reference range 4. In interview on July 21, |

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| | 2026 at 3:06 p.m., the Technical Consultant stated the laboratory thought the COT testing kit was waived and confirmed the laboratory did not perform performance specification testing as identified above. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation; review of the laboratory's quality control records, patient test records, and the laboratory's test menu; as well as interview with personnel, the laboratory failed to perform positive and negative controls for cotinine testing for five (5) of five (5) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 21, 2026 at 10:29 a.m. revealed the laboratory utilized the COT One Step Cotinine Test Device (Urine) for cotinine testing. 2. Review of the FDA categorization website revealed the COT One Step Cotinine Test Device (Urine) was uncategorized. 3. Review of the laboratory's quality control (QC) and patient test records for a random selection of patients in 2026 revealed the following five (5) of five (5) patients did not have quality control testing performed prior to patient testing: a) MRN 11124 - Tested 3/23/2026 b) MRN 11024 - Tested 3/24/2026 c) MRN 10705 - Tested 5/6/2026 d) MRN 10904 - Tested 7/9/2026 e) MRN 10870 - Test date not included on instrument printout 4. In interview on July 21, 2026 at 3:06 p.m., Testing Personnel 1 stated the laboratory utilized the cotinine testing kit as waived testing and did not perform daily negative and/or positive controls. She confirmed the laboratory did not perform QC for cotinine testing as identified above. 5. Review of the laboratory's test menu revealed the laboratory performs three hundred (300) cotinine tests annually. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of records, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to analyze patient samples for ionized calcium and TCO2 testing within ten (10) minutes of collection as required by the manufacturer for three (3) of twenty-six (26) patients reviewed. Refer to D5411. 2. The laboratory failed to document the receipt temperature of i-STAT cartridges as required by the manufacturer. Refer to D5413. 3. The laboratory failed to verify performance specifications for cotinine testing. Refer to D5421. 4. The laboratory failed to perform positive and negative controls for cotinine testing for five (5) of five (5) patients reviewed. Refer to D5449. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c) |

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| | (c) 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 observation; review of the manufacturer's instructions, the laboratory's patient test records, and the laboratory's test menu; as well as interview with personnel, the laboratory failed to report cotinine results as required by the manufacturer for five (5) of five (5) final patient test reports reviewed. Findings: 1. Observation by surveyor on July 21, 2026 at 10:29 a.m. during the laboratory your revealed the laboratory utilized the COT One Step Cotinine Test Device (Urine) for cotinine testing. 2. Review of the "COT One Step Cotinine Test Device Package Insert" section "Intended Use" revealed "This assay provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography and mass spectrometry (GC /MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results used." 3. Review of the following five (5) random patient test reports revealed the laboratory did not identify results as preliminary as defined by the manufacturer: a) MRN 11124 - Tested 3/23/2026 b) MRN 11024 - Tested 3/24 /2026 c) MRN 10705 - Tested 5/6/2026 d) MRN 10904 - Tested 7/9/2026 e) MRN 10870 - Test date not included on instrument printout 4. In interview on July 21, 2026 at 3:06 p.m., the Testing Technical Consultant confirmed the laboratory did not report cotinine results as preliminary on the final patient test reports for cotinine. 5. Review of the laboratory's test menu revealed the laboratory performs three hundred (300) cotinine tests annually. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to analyze patient samples for ionized calcium and TCO2 testing within ten (10) minutes of collection as required by the manufacturer for three (3) of twenty-six (26) patients reviewed. Refer to D5411. 2. The laboratory failed to document the receipt temperature of i-STAT cartridges as required by the manufacturer. Refer to D5413. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established |

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| | and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Refer to D5791. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of the Clinical Consultant to one (1) of one (1) personnel serving in the role. 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed Personnel 5 serving as Clinical Consultant. 2. Review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Clinical Consultant to Personnel 2. 3. In interview on July 21, 2026 at 11:02 a.m., the Technical Consultant confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities to Personnel 2 as identified above. |
| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to analyze patient samples for ionized calcium and TCO2 testing within ten (10) minutes of collection as required by the manufacturer for three (3) of twenty-six (26) patients reviewed. Refer to D5411. 2. The laboratory failed to document the receipt temperature of i-STAT cartridges as required by the manufacturer. Refer to D5413. |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b) |

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| | 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D5305. |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5421. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the quality assessment programs were established to assure the quality of laboratory testing. 1. The laboratory failed to perform positive and negative controls for cotinine testing for five (5) of five (5) patients reviewed. Refer to D5449. 2. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. |
| **D6098** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(8)<br><br>(e)(8) Ensure that reports of test results include pertinent information required for interpretation;<br><br>This STANDARD is not met as evidenced by: |

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| | Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805. |
| **D6139** | CLINICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1457(c)<br><br>(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Clinical Consultant failed to ensure patient final reports included required pertinent information. Refer to D5805. |