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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0899231 | (X3) Date Survey Completed 03/26/2025 |
| Name of Provider or Supplier Beaumont Internal Medicine & Geriatric Associates | Street Address, City, State 755 N 11th St Suite P5200, Beaumont, 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 |
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| D0000 | The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on March 26, 2025. |
| D5411 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory instrument specifications, laboratory humidity records, and confirmed in interview, the laboratory failed to ensure the operating environment for the Roche Cobas Pure Chemistry Analyzer was within manufacturer specifications before patient testing for 15 of 40 days reviewed in January and February 2025. The findings included: 1. Review of the manufacturers "Cobas Pure" instructions for use, section "Specifications", subsection, "Environmental conditions during operation" included the following condition: "Ambient humidity: 30-85% (without condensation)" 2. Review of the laboratory temperature and humidity records included the following days in January and February 2025 where the humidity was below the operation specifications for the Roche Cobas Pure chemistry analyzer: January 2025: 13 Days 1/02/2025 - 27% 1/06/2025 - 25% 1/07/2025 - 25% 1/08/2025 - 'Lo' 1/09/2025 - 'Lo' 1/10/2025 - 'Lo' 1/14/2025 - 23 1/15/2025 - 23 1/16/2025 - 23 1/17/2025 - 'Lo' 1/20/2025 - 'Lo' 1/23/2025 - 'Lo' 1/24/2025 - 'Lo' February 2025: 2 days 2/20/2025 - 23% 2/21/2025 - 'Lo' Surveyor asked if laboratory operations were paused until the humidity could reach the appropriate operating specifications, and testing personnel (TP) 1 stated they did not. 3. In an interview on 3/26/2025 at 14:05, in the laboratory, TP1 confirmed that the humidity was out of the Roche Cobas Pure chemistry analyzer on the above days where patients were tested.</p> |

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

(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.

This STANDARD is not met as evidenced by:

Based on review of laboratory verification documents, laboratory data, and confirmed in interview, the laboratory failed to ensure that the normal reference intervals for 14 of 37 analytes, tested on the Roche Cobas Pure chemistry analyzer, were appropriate for the laboratory's patient population before it was put into use in December 2024. The findings included: 1. Review of the laboratory verification procedures for the Roche Cobas Pure chemistry analyzer, approved by the laboratory director on 12/20/2024, included the following instructions found on the "Verification of Reference Interval; Report Interpretation Guide": "A reference interval is typically established from a study which calculates the central 95% of results measured on specimens from healthy persons (minimum 120 persons). In contrast, the verification study hypothesizes that the proposed range is correct for the lab's population. It then test a much smaller number (minimum 20) of specimens to see if there is sufficient evidence to REFUTE the hypothesis. Specifically, the verification study tests whether more than 10% of the results are outside the proposed reference interval. If so, the verification fails. Otherwise it passes." 2. Review of the "Verification of Reference Interval Summary" included the following 14 chemistry analytes on the Cobas Pure that had greater than 10% of the results outside the proposed reference range, subsequently failing the verification of the proposed reference interval (ref int): Analyte [Ref Int] %outside: Passes Amy [23-85] 25%: No BUN [8-21] 20%: No Chol [50-200]30%: No CO2 [23-32] 30%: No Glu [70-105] 15%: No Iron [37-145] 15%: No Trig [35-160] 20%: No UIBC [111-343] 15%: No UA [3.4-7.0] 20%: No Ferritin [13-150] 25%: No FSH-Male [1.5-12.4] 20%: No Testost-F [8-48] 60%: No Vit B12 [232-1245] 15%: No Vit D [30-100] 50%: No Surveyor asked if any additional studies had been performed to verify the 14 that had failed and testing personnel (TP) 1 stated the laboratory had plans to submit additional patient information, but that they had not performed the additional studies yet. 3. In an interview on 3/26/2025 at 10:25 hours, in the conference room, testing personnel (TP)1 confirmed that the 14 analytes above failed to verify the proposed reference intervals by the manufacturer before the Cobas Pure was put into use for patient testing. Key: Amy - Amylase BUN - Blood Urea Nitrogen Chol - Cholesterol CO2 - carbon dioxide Glu - glucose Trig - triglycerides UIBC - Unsaturated Iron Binding Capacity UA - uric acid FSH-Male - follicle stimulating hormone - Male Testost-F - Testosterone - Female Vit B12 - Vitamin B12 Vit D - Vitamin D