Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0671060	**(X3) Date Survey Completed** 04/07/2026
Name of Provider or Supplier Primary Care Internists Of Montgomery	**Street Address, City, State** 1722 Pine Street Suite 309, Montgomery, AL	
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 on-site validation survey was conducted on April 07, 2026 with the following standard level deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: I. Based on direct observation, review of the laboratory's humidity records, and interview with the Testing Personnel (TP) #1 according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to define humidity ranges in accordance with manufacturer instructions for two of two instruments (Sysmex XN-430 and Ortho Vitros 5600). Findings Included: 1) During a tour of the laboratory at 1:20 PM on 4/07/2026, the following analyzers were observed in use within the laboratory: a) 1 Sysmex XN-430, Manufacturer Humidity Requirements 20 to 85% non-condensing b) 1 Ortho Vitros 5600, Serial Number 56005005, Manufacturer Humidity Requirements 15 to 75% non-condensing 2) Review of the laboratory's humidity records revealed an acceptable range of 10 to 80%. 3) In an interview at 1:25 PM on 4/07/2026, TP#1 confirmed the humidity range was not defined in accordance with manufacturer instructions for the two instruments. II. Based on direct observation, review of the laboratory's room temperature records, and interview with Testing Personnel (TP) #1 according to the Centers for Medicare and

	Medicaid Services (CMS) Form 209, the laboratory failed to define, monitor and document room temperature for the reagent and supply storage room for 2 of 2 years (2024 and 2025). Findings Included: 1) During a tour of the laboratory at 1:25 PM on 4/07/2026, the following temperature-dependent supplies were observed in storage available for use: a. 700 Becton Dickinson (BD) Vacutainer Gold-Top Serum Separator Tubes (SST), Lot Number 5324071, Manufacturer storage temperature requirements 4 to 25 degrees Celsius b. 1000 BD Vacutainer Tiger-Top SST Tubes, Lot Number 367988, Manufacturer storage temperature requirements 4 to 25 degrees Celsius c. 200 BD Vacutainer Purple-Top K2E Tubes, Lot Number 5317214, Manufacturer storage temperature requirements 4 to 25 degrees Celsius 2) Review of the laboratory's room temperature records revealed no monitoring and documentation of room temperature in the reagent and supply storage room for 2024 and 2025. 3) In an interview at 1:26 PM on 4/07/2026, TP#1 confirmed the laboratory did not monitor and document laboratory temperatures in the reagent and supply storage room.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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: Based on direct observation, review of the laboratory's Quality Control (QC) records, policies and procedures, and confirmed in an interview with Testing Personnel (TP) #1 according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to document corrective actions taken when Quality Control (QC) failures, repeat QC failures requiring recalibration, and equipment malfunctions leading to QC failures occurred on the Ortho Vitros 5600 for 2 of 2 years (2024 and 2025). Findings Included: 1) During a tour of the laboratory at 1:20 PM on 4/07/2026, one Ortho Vitros 5600 analyzer (Serial Number 56005005) was observed in operation within the laboratory. 2) Review of the laboratory's Quality Control (QC) records on QuidelOrtho online Quality Assurance (QA) software for the Ortho Vitros 5600 analyzer revealed duplicate QC failures requiring recalibration on the following dates (random review): 1/5/2026, 1/6/2026, 1/12/2026, 1/16/2026, 1/19/2026, 1/20/2026, with no documentation or comments of corrective actions taken. 3) Review of the laboratory's policies and procedures revealed the following: a. Policy titled 'Failure Policy - Primary Care Internists of Montgomery' stated "Policy: If any instrument in the Primary Care Internists of Montgomery the instruments used to run patients tests are found to have the following: Control runs outside of two SD (standard deviations from the mean) for two sets of controls ...Cannot pass startup maintenance ...All specimens to be run on that day must be referred to a CLIA certified reference laboratory for testing ..." b. Policy titled 'Quality Control Plan' stated "IV. Assessment and Documentation: All quality assurance actions are documented. When documenting a quality assurance situation, some information to be included in the report are Date of occurrence, Incident, Research/Findings, Solution, Review of

	laboratory and lab director (both signatures)." 4) In an interview at 1:22 PM on 4/07 /2026, TP #1 confirmed the laboratory did not put comments in the QuidelOrtho online QA software for both single and duplicate QC failures requiring recalibration as well as mechanical failures, and did not document the corrective actions anywhere.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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 direct observation, review of quality control (QC) records, laboratory test records, and confirmed in an interview with the Testing Personnel (TP) #1 according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to take corrective action(s) necessary to ensure the evaluation of all patient test results obtained since the last acceptable test run after QC failures requiring recalibration on the Ortho Vitros 5600 analyzer for 7 of 31 days (Random review January 2026). Findings Included: 1) During a tour of the laboratory at 1:20 PM on 4/07/2026, one Ortho Vitros 5600 analyzer (Serial Number 56005005) was observed in operation within the laboratory. 2) Review of the laboratory's QC records between January 1, 2026 and January 31, 2026 (random review) revealed the following QC failures, with subsequent recalibration, where evaluation of patient test results since the last acceptable test run was not performed: a) Total Bilirubin (TBIL) QC Failures requiring recalibration 1/5/2026, 1/6/2026, 1/7/2026, 1/16/2026; patients tested for TBIL in last acceptable test run (12/31/2025) - 9, (1/5/2026) - 47 tests, (1/6/2026) - 33 tests, (1/16/2026) - 34 tests b) Alanine Transaminase (ALT) QC Failures requiring recalibration 1/20/2026; patients tested for ALT in last acceptable test run (1/19/2026) - 6 tests c) Cholesterol (CHOL) QC Failures requiring recalibration 1/20/2026, 1/21 /2026; patients tested for CHOL in last acceptable test run (1/19/2026) - 42 tests, (1/20 /2026) - 43 tests d) Total Protein (TP) QC Failures requiring recalibration 1/13/2026; patients tested for TP in last acceptable test run (1/12/2026) - 52 tests 3) Review of the laboratory's chemistry test volume on the Ortho Vitros 5600 revealed an annual test volume of 40,800. 4) In an interview at 1:21 PM on 4/07/2026, TP#1 confirmed the QC failures with subsequent recalibrations performed and lack of patient evaluations to the last acceptable test run.